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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 April 2013 (25.04.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/059202 A1

(51) International Patent Classification:
A61M 25/10 (2013.01) *A61F 2/966* (2013.01)
A61B 17/3207 (2006.01) *A61F 2/958* (2013.01)

(21) International Application Number:
PCT/US2012/060436

(22) International Filing Date:
16 October 2012 (16.10.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/548,629 18 October 2011 (18.10.2011) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available):* AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available):* ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

(54) Title: INTEGRATED CROSSING BALLOON CATHETER

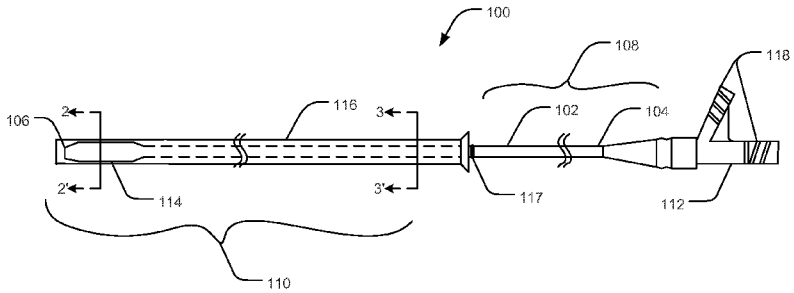

FIG. 1A

(57) Abstract: An integrated crossing balloon catheter (100). The catheter includes a hub assembly (112) secured to the proximal end of (104) the catheter shaft (102), an inflatable balloon (114) secured to the distal end of (106) the catheter shaft, and a stiffening tube (116) positioned over the inflatable balloon and a distal end portion of the catheter shaft. The stiffening tube is configured to be advanced through a vasculature with the catheter shaft as a unit. The stiffening tube is translatable along the catheter shaft from a first position in which the inflatable balloon is within the stiffening tube to a second position in which the inflatable balloon is exposed from the stiffening tube.

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INTEGRATED CROSSING BALLOON CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. §119 to U.S. Provisional Application Serial No. 61/548,629, filed October 18, 2011, the entirety of which is incorporated herein by reference.

TECHNICAL FIELD

This disclosure relates generally to catheters and more particularly to integrated intravascular catheters for crossing chronic total occlusions.

BACKGROUND

The use of intravascular catheters is an effective method for treating many types of vascular disease. In general, an intravascular catheter is inserted into the vascular system of a patient and navigated through the vasculature to a desired target site. Using this method, virtually any target site in the patient's vascular system may be accessed, including the coronary, cerebral, and peripheral vasculature. Example therapeutic applications of intravascular catheters include percutaneous transluminal angioplasty (PTA), and percutaneous transluminal coronary angioplasty (PTCA).

Intravascular catheters are commonly used in conjunction with a guidewire. A guidewire may be advanced through the patient's vasculature until it reaches a target location. Once in place, the catheter may be threaded onto the guidewire and urged distally until the distal end of the catheter reaches the target location.

Typically, the guidewire is inserted into the patient's vasculature from a convenient percutaneous location and then advanced to a target region. The path traversed by the catheter through the vascular system is often tortuous, requiring the guidewire to change direction frequently. To conform to a patient's circuitous vascular system, the guidewire is preferably flexible, particularly near the distal end.

During its course through the vasculature, the guidewire may confront a stenosis, lesion, or clot. Sometimes, the stenosis completely blocks the vessel, as is the case with a chronic total occlusion (CTO). In these cases, the guidewire may not be able to penetrate the occlusion, owing to its flexibility. To overcome this

difficulty, a catheter can be inserted over the guidewire to increase rigidity, or a more rigid guidewire may replace the existing guidewire.

If the occlusion is hard plaque, even the catheter and guidewire combination may not be able to cross it. In these cases, the intravascular catheter may be replaced by a crossing catheter. A crossing catheter may be configured to advance through the occlusion. For example, the crossing catheter may include a vibrating distal portion, a smaller profile than the intravascular catheter, a rigid distal portion, and/or a tapered distal tip enabling it to penetrate through hard plaques relatively easily. Once the plaque is crossed, the crossing catheter is removed and replaced by a balloon catheter to enlarge the pathway through the occlusion and/or positions a stent across the occlusion.

In this described arrangement, once the occlusion is crossed, the crossing catheter is retracted, and the balloon catheter is inserted in its place. Retraction and replacement, however, increases operation time and cost. Moreover, sometimes, the pathway formed through the plaque may not be sufficient to insert the flexible balloon catheter, increasing placement complexity.

Therefore, there exists a need for an integrated medical device that can penetrate the occlusion and without complete retraction provide interventional treatment (for example, but not limited to, dilating the occlusion or placing a stent) at the target location.

SUMMARY

Some embodiments of the present disclosure pertain to integrated crossing and balloon catheters, as well as related components, systems and methods. Some embodiments provide for alternative structures, methods of making, and methods of using the integrated crossing and balloon catheter. In many instances, it may be desirable to penetrate and remove chronic total occlusions in a patient's vasculature. Stents, dilatation balloons, or atherectomy devices may be inserted in the occlusion to alleviate stenosis. Some embodiments of the present disclosure introduce a novel catheter that integrates the features of a crossing, scoring and/or balloon catheter in one medical device.

In one embodiment, the integrated catheter includes a catheter shaft having a proximal end, a distal end, a proximal end portion proximate the proximal end and a distal end portion proximate the distal end. The catheter further includes a hub assembly secured to the proximal end of the catheter shaft, and an inflatable balloon

secured to the distal end of the catheter shaft. Further, a stiffening tube may be positioned over the inflatable balloon and the distal end portion of the catheter shaft. The stiffening tube may be configured to advance through a vasculature with the catheter shaft as a unit. Moreover, the stiffening tube may be translatable along the catheter shaft from a first position in which the inflatable balloon is within the stiffening tube to a second position in which the inflatable balloon is exposed from the stiffening tube.

In other embodiments, the length of the stiffening tube may be less than the length of the catheter shaft. For example, the stiffening tube may extend along approximately 70% or more of the catheter shaft length. Further, the stiffening tube may be translatable relative to the catheter shaft over a distance at least as long as the length of the inflatable balloon, so that in one position it covers the balloon and in another position it exposes the balloon.

In another embodiment, the stiffening tube may be dimensioned such that its proximal portion remains exterior of a patient while the balloon is positioned proximate a target site within a vessel lumen. Moreover, in some embodiments the proximal end of the stiffening tube may flare outwards allowing a physician to grasp the tube and manipulate it.

In other embodiments, the stiffening tube may frictionally engage the catheter shaft when the stiffening tube is translated along the catheter shaft.

The present disclosure further describes a crossing catheter system including a catheter having an elongate shaft extending from a hub assembly at a proximal end of the catheter to an inflatable balloon at a distal end of the catheter. The catheter further includes an inflation lumen extending through the elongate shaft from the hub assembly to the inflatable balloon for delivering inflation fluid to the inflatable balloon. The system further includes a stiffening tube having a proximal end, a distal end, and a length measured from the proximal end to the distal end. The stiffening tube surrounds the elongate shaft and is in intimate contact with an outer surface of the elongate shaft along a majority of the length of the elongate shaft. Further, the stiffening tube may be configured to advance through a vasculature with the catheter as a unit. In addition, the stiffening tube may be translatable along the elongate shaft from a first position in which a distal end of the stiffening tube is positioned distal of the inflatable balloon to a second position in which the distal end of the stiffening tube is positioned proximal of the inflatable balloon.

In other embodiments, the stiffening tube may have a tapered distal tip configured to expand from a first configuration to a second configuration. The first configuration is a low profile configuration for traversing an occlusion and the second configuration is sized to allow the inflatable balloon to be deployed through the tapered distal tip. Further, the stiffening tube may include an expandable region surrounding the inflatable balloon. The expandable region may include a distensible material configured to expand radially outward when the inflatable balloon is inflated within the expandable region. In some embodiments, the expandable region may include a plurality of slots.

The present disclosure further describes methods for crossing an occlusion in a vessel lumen. In some embodiments, the method includes advancing a crossing balloon catheter over a guidewire intravascularly to a location proximal of an occlusion in the vessel lumen. The crossing balloon catheter may include an elongate shaft extending between an inflatable balloon and a hub assembly, and a stiffening tube surrounding the balloon and extending proximal of the balloon over a majority of a length of the elongate shaft. The method further includes positioning the balloon across the occlusion, and retracting the stiffening tube from the balloon by translating the tube proximally relative to the elongate shaft. Further, the method includes inflating the balloon within the occlusion to expand the occlusion by delivering inflation fluid through an inflation lumen of the elongate shaft from the hub assembly to the balloon.

In some embodiments, the balloon may be positioned across the occlusion with the stiffening tube surrounding the inflatable balloon. Further, the balloon may be at least partially inflated within the stiffening tube while positioning the balloon across the occlusion.

The foregoing and other objects, aspects, features, and advantages of the present disclosure will become apparent from the following description, the drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate exemplary embodiments of the present disclosure and together with the description, serve to explain the principles of the disclosure.

FIG. 1A is an illustrative diagram of a crossing balloon catheter in a first position according to one embodiment of the present disclosure.

FIG. 1B is an illustrative diagram of the crossing balloon catheter of FIG. 1A in a second position according to one embodiment of the present disclosure.

FIG. 2 is a cut-away sectional view of the crossing balloon catheter of FIG. 1 taken along line 2-2'.

FIG. 3 is a cut-away sectional view of the crossing balloon catheter of FIG. 1 taken along line 3-3'.

FIGS. 4A and 4B are illustrative diagrams of an alternative embodiment of the crossing balloon catheter with the balloon in a deflated and inflated position, respectively.

FIGS. 5A and 5B are illustrative diagrams of an alternative embodiment of the crossing balloon catheter with the balloon in a deflated and inflated position, respectively.

FIGS. 6A and 6B are illustrative diagrams of an alternative embodiment of the crossing balloon catheter with the balloon in a deflated and inflated position, respectively.

FIGS. 7A and 7B are illustrative diagrams of an exemplary distal portion of an alternative embodiment of the crossing balloon catheter in a first position and second position, respectively.

FIGS. 8A-8H illustrate various aspects for crossing an occlusion using the crossing balloon catheter of FIG. 1.

DETAILED DESCRIPTION

Reference will now be made in detail to some example embodiments of the present disclosure, an example of which is illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

Overview

Some embodiments of the present disclosure introduce an integrated crossing intravascular catheter to cross an occlusion in a patient's vasculature, dilate the occlusion, and/or provide therapeutic treatment at the occlusion site without exchanging medical devices. This integrated catheter performs the functions of both a

crossing catheter and an intravascular catheter, such as a balloon catheter. To this end, a stiffening tube may cover and be integrated with the intravascular catheter, such that the stiffening tube may be translatable along the length of the intravascular catheter. In one position, the stiffening tube may cover a distal portion of the intravascular catheter, providing stiffness and support to cross the occlusion, and in a second position, the stiffening tube may expose the distal portion of the intravascular catheter, to provide therapeutic treatment to the occlusion.

The intravascular catheter, in the following sections, is embodied as a balloon catheter. It will be understood that this choice is merely exemplary and any other intravascular catheter may replace the balloon catheter without departing from the scope of the present disclosure.

For purposes of this disclosure, "proximal" refers to the end closer to the device operator during use, and "distal" refers to the end further from the device operator during use.

Exemplary Device Embodiments

FIGS. 1-3 illustrate an exemplary integrated crossing balloon catheter 100. More particularly, FIG. 1A depicts the crossing balloon catheter 100 in a first position and FIG. IB depicts the crossing balloon catheter 100 in a second position, while FIGS. 2 and 3 are cross-sectional views of the catheter 100 taken along line 2-2' and line 3-3' in FIG. 1A, respectively. The catheter's structure and functioning is described with reference to these figures in the following section.

The crossing balloon catheter 100 may include a catheter shaft 102 having a proximal end 104, a distal end 106, a proximal end portion 108, and a distal end portion 110. The catheter 100 may further include a hub assembly 112 secured to the shaft's proximal end 104, an inflatable balloon 114 secured to the shaft's distal end 106, and a stiffening tube 116 positioned over the inflatable balloon 114 and the distal end portion 110 of the catheter shaft 102.

The catheter shaft 102 may include a central guidewire lumen 202 extending from its distal end 106 to its proximal end 104, or a portion thereof. A guidewire 204 may be inserted through this lumen 202 and thus the catheter 100 may be advanced over the guidewire 204 through a vasculature. The shaft 102 may have any cross-sectional shape, such as circular, rhombic, rectangular, oval, semicircular, or any other suitable shape. Moreover, the shaft's diameter may also depend on the

dimensions of the vasculature. For example, the diameter of the shaft 102 may be approximately equal to 3F or 4F in some embodiments, allowing the catheter 100 to easily glide in the vasculature without damaging the vessel walls. Further, the catheter shaft 102 may have a uniform cross-section or diameter from its distal end 106 to proximal end 104. Alternatively, the cross-section and diameter may vary through its length.

Because the catheter shaft 102 may remain within a patient's body for extended periods, the device may be made of non-allergic or biocompatible material. Such materials include polyamide, polyether block amide (PEBA), silicones, polyvinyl chloride (PVC), and nylon. It will be understood that any other suitable material may just as easily be used. In some instances, coatings useful to the function of the catheter, such as lubricious coatings, may be applied to the catheter shaft.

To allow easy insertion of the catheter shaft 102 in the vasculature, and the guidewire 204 in the lumen 202, the inner and outer surface of the catheter shaft 102 may include a lubricious coating or lining such as high-density polyethylene (HDPE) or polytetrafluoroethylene (PTFE). Moreover, depending upon the particular implementation and intended use, the catheter shaft 102 can be rigid along its entire length, flexible along a portion of its length, or configured for flexure at only certain specified locations. For example, its distal end portion 110 may be more flexible that the rest of the shaft length as the distal end portion 110 of the catheter shaft 102 may need to guide the shaft through a tortuous path to the occlusion.

Moreover, certain radiopaque markers or bands may be placed along the length of the shaft. For example, one marker may be on the distal end 106 of the shaft, and/or one or more marker bands may be placed equidistant from each other along the length of the shaft, or otherwise arranged along the catheter shaft 102. Additionally or alternatively, the catheter shaft, or portions thereof, may be made of a radiopaque material. Using a suitable imaging device, such as a fluoroscope, operators may know the exact position of the catheter 100 with respect to the patient's vasculature. Moreover, visual indicia such as a marker 117 may be placed just proximal of the stiffening tube 116 when the stiffening tube is in the first position (i.e., positioned across the balloon 114). Observing this marker, operators may know whether the catheter 100 is in the first position or the second position during the medical procedure.

The catheter shaft 102 may include an expandable member, such as an inflatable balloon 114, disposed at the distal end of the catheter shaft 102. The inflatable balloon 114 may be coupled to the distal end portion 110 of the elongate shaft 102 proximate the distal end 106. The balloon 114 may be made from typical angioplasty balloon materials including polymers such as polyethylene terephthalate (PET), polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), polybutylene terephthalate (PBT), polyurethane, polyvinylchloride (PVC), polyether-ester, polyester, polyamide, elastomeric polyamides, polyether block amide (PEBA), as well as other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like.

In other embodiments, the expandable member may be an expandable basket, cage, scaffold, or other mechanically expandable structure. In some embodiments, the expandable member may be formed of a shape memory alloy such as nitinol, stainless steel, or other metal alloy, or a polymeric material, if desired. In these instances, the expandable member may be a collapsible or self-expandable basket having several legs longitudinally extending along the length of the distal end portion. On actuation, the central portion of each leg may spring radially into an expanded configuration. Suitable actuation mechanisms such as levers, electronic switches, or wires may be introduced in the hub assembly 112 to actuate the expandable member, when desired, or the expandable member may be automatically expandable once unconstrained. Other collapsible or self-expandable structures formed of shape memory alloys, shape memory polymers, or other materials may also be contemplated without departing from the scope of the present disclosure.

In the illustrated embodiment, the balloon 114 may be a membrane, which may switch between a deflated and inflated state using expansion agents such as fluids, having a particular density. In the deflated state, the balloon 114 may be folded and wrapped around the distal portion of the shaft, as shown in FIG. 2. Once the balloon 114 is positioned in the occlusion, the expansion agent may be introduced in the balloon through the inflation lumen 306, inflating it. The inflated balloon 114 may exert a radial force on the occlusion, increasing the vessel diameter at the occlusion site and allowing unrestricted passage of blood through the occlusion.

FIG. 2, which is a cross-section taken along line 2-2' of FIG. 1A, illustrates one such balloon 114 in the deflated state positioned in the stiffening tube 116. Here, the balloon 114 may be coupled to the distal portion of the shaft 102 by means of an

adhesive, or other bonding means such as RF signal, laser, or other thermal bonding. The interior of the balloon 114 may be in fluid communication with the inflation lumen 306 such that expansion agents may be introduced through the inflation lumen 306 of the catheter shaft 102 to inflate the balloon 114.

FIG. 3 is a cross-section taken along line 3-3' of FIG. 1A. Here, the shaft 102 may include an outer tubular member 302, which may be coaxially disposed about an inner tubular member 304 to define an annular inflation lumen 306 between the members over a substantial portion of the length of the shaft. The inflation lumen 306 may extend from a port in the hub assembly 112 to the balloon 114. In some embodiments, the outer tubular member 302 may have an outer diameter ranging from about 0.030 inches to about 0.050 inches with a wall thickness ranging from about 0.0028 inches to about 0.006 inches in some instances. In one embodiment, the outer tubular member 302 may have an outer diameter of about 0.045 inches, an inner diameter of about 0.035 inches, and a wall thickness of about 0.005 inches. Materials used to form the outer tubular member 302 may vary to achieve the stiffness desired for the shaft 102. Nylon and polyamides are examples of suitable polymers for outer tubular members 302.

The inner tubular member 304 may define the guidewire lumen 202, which provides a passage for the guidewire 204 therethrough. Moreover, the inner tubular member 304 may be made of the same material as the outer tubular member 302, or a different material, and may be configured such that when placed within the outer tubular member 302, the gap left between the two tubular members defines the annular inflation lumen 306. The inner diameter of the inner tubular member 304 may be sized to allow a standard guidewire 204 to pass through as the catheter shaft 102 is advanced over the guidewire 204. Moreover, the wall thickness and/or diameters of the tubular members may depend on the required stiffness and on the ability of the members to resist kink formations along their lengths.

To couple the balloon 114 to this tubular configuration, a proximal portion of the balloon 114 may be fixed to the outer tubular member 302 and a distal portion may be fixed to the inner tubular member 304. This particular arrangement may allow the expandable balloon 114 to be in fluid communication with the annular inflation lumen 306. The inflatable balloon 114 and techniques of coupling the balloon 114 to a distal portion of the shaft 102 are commonly known in the art and will not be described here further.

Referring back to FIGS. 1A and IB, the hub assembly 112 connected to the shaft's proximal end 104 may include multiple ports 118 for inserting medical instruments such as guidewires in the guidewire lumen 202, or inflation agents such as fluids in the inflation lumen 306. The hub assembly 112 may be permanently or temporarily attached to the proximal end 104 of the catheter shaft 102. For permanent attachment, the hub 112 may be glued, welded, or molded with the catheter shaft 102. For temporary attachment, the hub 112 and the shaft's proximal end 104 may include engaging elements such as protrusions, screw threads, or luer-lock elements. These elements may engage each other to form a connection. In some embodiments, the hub assembly 112 may include actuation means to actuate the expandable member in instances where the expandable member is mechanically expandable, to guide or deflect the distal end portion 110 of the catheter 100, and/or guide the guidewire 204. Further, the hub assembly 112 may include features to allow an operator to grasp the catheter 100 comfortably. For example, the hub assembly 112 may include a handle portion, grooves adapted for an operator's fingers, etc.

The stiffening tube 116, as previously mentioned, may surround the catheter shaft 102, and be coupled to the shaft 102 such that it is translatable along the catheter shaft 102 from a first position (also referred to as a crossing position) to a second position (also referred to as a deployed position). FIG. 1A illustrates the stiffening tube 116 in the crossing position and FIG. IB illustrates the tube in the deployed position. In the crossing position, the inflatable balloon 114 may be within the stiffening tube 116; and in the deployed position, the inflatable balloon 114 may be exposed from the stiffening tube 116. The stiffening tube 116 may be placed in the crossing position to provide additional stiffness to the shaft's distal end portion 110 to cross an occlusion. Further, the stiffening tube 116 may be withdrawn to be placed in the deployed position once the occlusion is crossed and the operator is ready to inflate the balloon 114.

In some instances in which the inflatable balloon 114 may include a coating, such as a lubricious coating or a drug eluting coating, the stiffening tube 116 may provide a cover or protective barrier over the inflatable balloon 114. For instance, in instances in which the inflatable balloon 114 includes a lubricious coating, the stiffening tube 116, overlaying the balloon 114, may prevent "watermelon seeding" (i.e., slipping of the balloon 114 in a stenosis). In instances in which the inflatable balloon 114 includes a drug coating, the stiffening tube 116 may protect the coating

from inadvertent or premature exposure, and/or the stiffening tube 116 may prevent the drug from washing off of the inflatable balloon 114 or eluding from a polymer carrier before the balloon 114 reaches the site of the stenosis.

To translate the stiffening tube 116 between these two positions over the shaft 102, the length of the stiffening tube 116 may be shorter than the length of the shaft 102. In one embodiment, the stiffening tube 116 may extend along about 70% or more, about 80% or more, or about 90% or more of the length of the shaft 102. It will be understood, however, that the length of the stiffening tube 116 may also depend on the length of the inflatable balloon 114. For example, the stiffening tube 116 may be sized to be sufficiently shorter than the shaft 102 so that when the stiffening tube 116 is pulled proximally toward the proximal end 104 of the shaft, the balloon 114 may be fully exposed at the distal portion of the shaft. In other words, the stiffening tube 116 may be permitted to axially translate along the catheter shaft 102 a sufficient distance to fully expose the balloon 114.

Moreover, the stiffening tube 116 and the catheter shaft 102 may be dimensioned such that the proximal portion 108 of the catheter shaft 102 and the stiffening tube 116 may remain exterior to a patient's body, while the balloon 114 is placed in the occlusion. This way, an operator may hold the proximal end of the stiffening tube 116 to translate it between the crossing and deployed positions after navigating the distal end 106 to a location in the vasculature proximate an occlusion. To ease an operator's grasp of the proximal end of the stiffening tube 116, the proximal end may flare outwards. The flare also ensures that the stiffening tube 116 does not inadvertently slip inside a patient's vasculature during translation. In other embodiments, the proximal end of the stiffening tube 116 may include other grasping means, such as hooks, handles, or loops. Alternatively, other actuation means including electronic means such as switches or mechanical means such as levers, or wires may be present on the hub 112 to translate the stiffening tube 116.

In other instances, the stiffening tube 116 may include a hub at a proximal end of the stiffening tube 116 configured to engage the hub 112 at the proximal end of the catheter shaft 112. For example, the hub of the stiffening tube 116 may include a threaded connector for threadably engaging a threaded connector of the hub 112. Additionally or alternatively, the proximal end of the stiffening tube 116 may include a hermetic seal or hemostasis valve to prevent blood from leaking between the stiffening tube 116 and the catheter shaft 102.

In some embodiments, the stiffening tube 116 may be configured to be removable from the catheter shaft 102 while the catheter shaft 102 remains in place in the vasculature. For example, in some instances, the stiffening tube 116 may include a preferential score line, weakened area, perforated line, or other feature along which portions of the stiffening tube 116 may be separated to permit the stiffening tube 116 to be completely removed from the catheter shaft 102 in situ.

To enable smooth translation, a lubricious coating may be applied to the inner surface of the stiffening tube 116. Other low friction translation means may also be considered. For example, in some embodiments, the inner surface may include guide rails and the outer surface of the shaft 102 may include longitudinal protrusions that slide into the guide rails for movement, or vise versa.

The wall thickness and/or diameter of the stiffening tube 116 may depend on the desired application. For example, the stiffening tube may be rigid enough to penetrate soft plague, hard plaque, or calcifications. In some embodiments, the wall thickness of the stiffening tube 116 may be approximately in the range of 0.004 inches to 0.008 inches, or about 0.006 inches. Moreover, the stiffening tube 116 may closely surround the catheter shaft 102 to stiffen the shaft 102 such that the stiffening tube 116 frictionally engages the catheter shaft 102 as the stiffening tube 116 is translated along the catheter shaft 102. For instance, in some embodiments, the inner diameter of the stiffening tube 116 may be about 0.04 inches, or about 0.05 inches and the outer diameter of the catheter shaft 102 may be about 0.05 inches or about 0.06 inches. The stiffening tube 116 may be dimensioned such that the difference in inner diameter of the stiffening tube 116 and the outer diameter of the catheter shaft 102 is less than 0.003 inches or less than 0.002 inches in some instances. Accordingly, the gap between the inner diameter of the stiffening tube 116 and the outer diameter of the catheter shaft 102 may be 0.0015 inches or less, or 0.001 inches or less. For instance, in one embodiment, the inner diameter of the stiffening tube 116 may be about 0.047 inches while the outer diameter of the catheter shaft 102 may be about 0.045 inches. The inner diameter of the stiffening tube 116 may be dimensioned to accommodate the folded balloon 114 therein.

Suitable materials to form the stiffening tube 116 may include Teflon, polyethylene, nylon, polyesters, polyoxymethylenes, or polyether ether ketones (PEEK). Other lubricious or biocompatible materials such as other known polymer

thermoplastics may also be considered without departing from the scope of the present disclosure.

In some instances, the integrated crossing balloon catheter 100 may be inserted in the vasculature of a patient and the distal portion of the catheter 100 urged distally until it reaches an impassable occlusion, such as a chronic total occlusion (CTO). In such an instance, the catheter 100 may be configured to penetrate or pass through the occlusion with the stiffening tube 116 in the crossing position (i.e., with the stiffening tube 116 extending over the balloon 114). Subsequently, when the crossing catheter 100 has crossed the occlusion or the balloon 114 is otherwise positioned across the occlusion, the stiffening tube 116 may be partially retracted such that the balloon 114 is exposed. In this manner, the occlusion may be crossed and the balloon 114 may be placed in the occlusion to dilate the occlusion without the need of exchanging any medical devices.

In some instances, in the crossing position, the balloon 114 may be partially inflated within the stiffening tube 116 to increase the rigidity of the catheter 100 while penetrating through a tough occlusion. In some instances, the stiffening tube 116 may be sufficiently rigid, and thus not radially expand when the balloon 114 is inflated therein.

In other instances, the stiffening tube 116 may be configured to include an expandable region surrounding the balloon 114, which may be readily expandable when subjected to a radially outward force generated by inflating the balloon 114 against the interior wall of the expandable portion of the stiffening tube 116. FIGS. 4A-4B illustrate one such embodiment. More particularly, FIG. 4A illustrates the catheter with a deflated balloon 114 positioned within an expandable portion 402 of the stiffening tube 116 and FIG. 4B illustrates the catheter with the balloon 114 inflated to radially expand the expandable portion 402. The expandable balloon 114 may be coupled between the distal end of the inner tubular member 304 and the distal end of the outer tubular member 302 with a well-defined inflation lumen 306 therebetween. In this embodiment, the distal portion of the stiffening tube 116 may include an expandable portion 402, which may be readily expanded when the balloon 114 is inflated therein. Particularly, a distal portion of the stiffening tube 116, which may or may not exclude the distal terminal end of the stiffening tube 116, may be expandable. Thus, when the balloon 114 is inflated, the expandable portion 402 may also expand. The expandable portion 402 may be formed of any desired material,

such as a distensible polymeric material, including elastomeric polymers, rubber, latex, etc. The degree of expansion may depend on the rigidity of the expandable portion 402, pressure applied by the balloon 114, and/or other such factors. In such embodiments, the balloon 114 may be inflated within the stiffening tube 116, even after the occlusion is crossed and the balloon 114 is positioned across the occlusion within the stiffening tube 116. Accordingly, the occlusion may be dilated or expanded by the combined force of the stiffening tube 116 and the inflated balloon 114 therein, expanding radially outward against the occlusion.

FIGS. 5A and 5B illustrate another exemplary embodiment of the crossing balloon catheter 100 in which the stiffening tube 116 includes an expandable region formed in the stiffening tube 116. For example, the stiffening tube 116 may include one or more, or a plurality of slots 502 formed through the wall of the stiffening tube 116. FIG. 5A illustrates the distal portion of the stiffening tube 116 with a deflated balloon 114 and FIG. 5B illustrates the stiffening tube 116 with the balloon 114 inflated therein. Here, the expandable portion 402 includes longitudinal slots 502 defining longitudinal struts 410 therebetween. When the balloon 114 is deflated, the diameter of this expandable portion 402 may be equal to the diameter of the remaining portion of the tube 116. When the balloon 114, however, is inflated, the force exerted by the balloon 114 may widen the longitudinal slots, expanding the longitudinal struts 410 radially outward, and thus enlarging the expandable portion 402. The degree of slot 502 expansion and strut 410 deflection may depend on the proximity of the stiffening tube 116 to the balloon 114, the degree of balloon 114 expansion, and/or the rigidity of the expandable material forming the struts 410.

In this embodiment, the stiffening tube 116 may function as a scoring catheter. When the balloon 114 inflates, the struts 410 may be expanded against the occlusion to score the plaque, dilating the occlusion further. Scoring may be helpful in lesions where catheter delivery may be difficult, balloon 114 slippage may occur, and/or very high pressures may be required to dilate the lesions.

FIGS. 6A and 6B also illustrate another embodiment of the expandable stiffening tube 116 including an expandable region. Here, the distal portion may include helical slots 602 that help the stiffening tube 116 to expand under pressure from an inflating balloon 114 within the expandable region. Thus, when the balloon 114 is inflated within the expandable portion 402, the expandable portion 402 may be radially expanded against an occlusion to score the plaque and/or dilate the occlusion.

Once the plaque is sufficiently scored and/or dilated, the balloon 114 may be deflated, the expandable portion 402 may return to its normal size. If desired, the stiffening tube 116 may then be retracted to deploy the balloon 114 without the stiffening tube 116, and further dilation may be performed with the exposed balloon 114.

In the expandable configurations described previously with reference to FIGS. 4A-4B, 5A-5B, and 6A-6B, in some instances the expandable portion 402 may be formed of a different material than the remaining portion of the stiffening tube 116. For example, the expandable portion 402 may be formed of shape-memory alloys such as nitinol, or shape memory polymers in some instances. In other embodiments, polymeric materials, such as elastomers, or synthetic elastics may be used. Further, any suitable biocompatible expandable materials widely known in the art may be used without departing from the scope of the present disclosure. In another embodiment, the complete stiffening tube 116 may be formed of an expandable material.

FIGS. 4A-4B, 5A-5B, and 6A-6B illustrate a few exemplary expandable configurations of the stiffening tube 116. It will be understood, however, that multiple other expandable configurations are possible. For example, the expandable portion 402 may include lateral slots or cutouts of any other shape without departing from the scope of the present disclosure.

FIGS. 7A and 7B illustrate another exemplary embodiment of the crossing balloon catheter 100. FIG. 7A illustrates the distal portion of the stiffening tube 116 in the crossing position and FIG. 7B illustrates the distal portion of the stiffening tube 116 as the balloon 114 is being deployed out of the distal end of the stiffening tube 116 toward the deployed position. Here, the distal end of the stiffening tube 116 may include a tapered portion 702 to facilitate passing the catheter 100 through an occlusion. For example, the tapered tip 702 may increase the ability of the stiffening tube 116 to pierce or penetrate through an occlusion. As the tapered portion 702 may narrow to a diameter as small as the shaft 102 or even smaller, the tapered portion 702 may extend beyond the distal end 106 of the shaft 102 and the inflatable balloon 114.

Once an occlusion is crossed with the crossing catheter 100, the stiffening tube 116 may be retracted to expose the balloon 114. To facilitate retracting the stiffening tube 116 proximally, the tapered portion 702 may include one or more slits or slots 704 that enable the tapered end to expand radially when the stiffening tube 116 is pulled proximally over the inflatable balloon 114 and/or when the balloon 114 is urged distally. FIGS. 7A and 7B illustrate one slot 704, it will be understood that the

tapered portion 702 may include multiple slots 704 circumferentially arranged around the tapered portion 702 in some instances.

Moreover, the tapered portion 702 may expand automatically as a result of the force exerted by the catheter shaft 102 on the tapered portion 702, or externally by an activation mechanism.

Exemplary Methods

FIGS. 8A-8H illustrate various aspects of crossing an occlusion in a vessel lumen using the crossing catheter 100. It will be understood that these aspects are merely exemplary and any of the described aspects may be modified, combined with one or more other aspects, or deleted without departing from the scope of the present disclosure. Moreover, any suitable steps to cross an occlusion may be added to any combination of aspects described herein.

As shown in FIG. 8A, during a medical procedure, such as an angioplasty procedure, a flexible guidewire 204 may be inserted in a patient's vasculature 802 from a percutaneous opening or incision. The guidewire 204 may be urged distally until it reaches an occlusion 804. In some instances, the guidewire 204 may be unable to cross the occlusion 804. For example, in some instances the guidewire 204 may lack sufficient stiffness/rigidity to advance unaided through the occlusion 804. Accordingly, aspects of the crossing catheter 100 may be utilized to facilitate crossing the occlusion 804. For example, as shown in FIG. 8B, the integrated crossing catheter 100 may be guided over the guidewire 204 to the occlusion 804.

When the crossing catheter 100 reaches the occlusion 804, in some instances the operator may try crossing the occlusion 804 with just the guidewire 204, as shown in FIG. 8C, using the crossing catheter 100 to support the guidewire 204 proximal of the occlusion 804. With the guidewire 204 now supported by the catheter 100, the guidewire 204 may be able to exert more force on the occlusion 804. In some instances, the guidewire 204 may be able to cross the occlusion 804 with this added support; for example, in cases where the occlusion is soft. In other cases, however, the guidewire 204, alone, may not be sufficient to cross the occlusion 804.

The operator may attempt to cross the occlusion 804 with the crossing catheter 100 in combination with the guidewire 204 previously positioned through the occlusion 804, or without the guidewire 204 previously positioned through the occlusion 804. For example, as shown in FIG. 8D, in some instances, the catheter

shaft 102 and balloon 114 may be advanced distally of the stiffening tube 116 to cross the occlusion 804 while the stiffening tube 116 may remain proximal of the occlusion 804.Thus, the deflated balloon 114 may be positioned across the occlusion 804 while uncovered by the stiffening tube 116. In other instances, the operator may attempt to cross the occlusion 804 with the stiffening tube 116 in the crossing position, as shown in FIG. 8E (i.e., with the stiffening tube 116 positioned over the balloon 114). This arrangement may be implemented, for example, to cross hard and calcified occlusions in some instances. In some instances, the balloon 114 may be inflated (at least partially inflated) within the stiffening tube 116 to provide further rigid support between the stiffening tube 116 and the catheter shaft 102 while crossing the occlusion 804.

Once the balloon 114 of the crossing catheter 100 has been advanced across the occlusion 804, the balloon 114 may be inflated to dilate the occlusion 804. For example, as shown in FIG. 8G, the balloon 114 may be inflated with the stiffening tube 116 retracted proximally to the deployed position. Thus, inflation of the balloon 114 may exert a radial force on the occlusion 804 to dilate the occlusion 804. In other instances, such as shown in FIG. 8F, the balloon 114 may be inflated within the stiffening tube 116 to dilate the occlusion 804, urging the expandable portion 402 of the stiffening tube against the occlusion 804 to exert a radial force on the occlusion 804 and/or score the occlusion 804.

As stated previously, it will be understood that additional or alternative steps may be implemented to cross the occlusion 804, as desired. For example, if the first guidewire 204 was unable to cross the occlusion 804, the operator may attempt to cross the occlusion 804 with a stiffer guidewire before attempting to cross the occlusion 804 with the catheter 100. For example, as shown in FIG. 8H, the first guidewire 204 may be withdrawn and a stiffer guidewire 810 may be advanced through the catheter 100 to cross the occlusion 804.

Some embodiments of the present disclosure may be used in any medical or non-medical procedure, including any medical procedure where draining visceral fluid is desired. In addition, at least certain aspects of the aforementioned embodiments may be combined with other aspects of the embodiments, or removed, without departing from the scope of the disclosure.

Other embodiments of the present disclosure will be apparent to those skilled in the art from consideration of the specification and practice of the embodiments

disclosed herein. It is intended that the specification and examples be considered as exemplary only, and departure in form and detail may be made without departing from the scope and spirit of the present disclosure as described in the following claims.

What is claimed is:

1. An integrated crossing balloon catheter comprising:

a catheter shaft having a proximal end, a distal end, a proximal end portion proximate the proximal end, and a distal end portion proximate the distal end;

a hub assembly secured to the proximal end of the catheter shaft;

an inflatable balloon secured to the distal end of the catheter shaft; and

a stiffening tube positioned over the inflatable balloon and the distal end portion of the catheter shaft, the stiffening tube configured to be advanced through a vasculature with the catheter shaft as a unit;

wherein the stiffening tube is translatable along the catheter shaft from a first position in which the inflatable balloon is within the stiffening tube to a second position in which the inflatable balloon is exposed from the stiffening tube.

2. The integrated crossing balloon catheter of claim 1, wherein the catheter shaft has a length measured from the inflatable balloon to the hub assembly, and the stiffening tube has a length measured from a distal end of the stiffening tube to a proximal end of the stiffening tube, wherein the length of the stiffening tube is less than the length of the catheter shaft.

3. The integrated crossing balloon catheter of claim 2, wherein the inflatable balloon has a length, and the stiffening tube is translatable relative to the catheter shaft over a distance at least as long as the length of the inflatable balloon.

4. The integrated crossing balloon catheter of claim 2 or 3, wherein in the first position a distal end of the stiffening tube is positioned distal of the inflatable balloon and in the second position the distal end of the stiffening tube is positioned proximal of the inflatable balloon.

5. The integrated crossing balloon catheter of any of claims 2-4, wherein the stiffening tube extends along 70% or more of the length of the catheter shaft.

6. The integrated crossing balloon catheter of any of claims 2-5, wherein the stiffening tube is dimensioned such that the proximal end of the stiffening tube

remains exterior of a patient while the balloon is positioned proximate a target site within a vessel lumen throughout a medical procedure.

7. The integrated crossing balloon catheter of any of claims 2-6, wherein the proximal end of the stiffening tube is flared outward to be grasped by a physician in order to manipulate the stiffening tube.

8. The integrated crossing balloon catheter of any of claims 2-7, wherein the stiffening tube surrounds the catheter shaft and is in intimate contact with an outer surface of the catheter shaft along a majority of the length of the catheter shaft.

9. The integrated crossing balloon catheter of any of claims 1-8, wherein the stiffening tube frictionally engages the catheter shaft as the stiffening tube is translated along the catheter shaft.

10. The integrated crossing balloon catheter of claim 9, wherein the catheter shaft has an outer diameter and the stiffening tube has an inner diameter, wherein the difference between the outer diameter of the catheter shaft and the inner diameter of the stiffening tube is 0.002 inches or less.

11. The integrated crossing balloon catheter of any of claims 1-10, wherein the catheter shaft includes visual indicia located proximate a proximal end of the stiffening tube when the stiffening tube is at the first position to indicate the stiffening tube is positioned over the inflatable balloon.

12. The integrated crossing balloon catheter of any of claims 1-1 1, wherein the stiffening tube has a tapered distal tip configured to expand from a first configuration to a second configuration, the first configuration being a low profile configuration for traversing an occlusion and the second configuration being sized to allow the inflatable balloon to be deployed through the tapered distal tip.

13. The integrated crossing balloon catheter of any of claims 1-12, wherein the stiffening tube includes an expandable region surrounding the inflatable balloon.

14. The integrated crossing balloon catheter of claim 13, wherein the expandable region includes a distensible material configured to expand radially outward when the inflatable balloon is inflated within the expandable region.

15. The integrated crossing balloon catheter of claim 13, wherein the expandable region includes a plurality of slots.

16. A method of crossing an occlusion in a vessel lumen, the method comprising:

advancing a crossing balloon catheter over a guidewire intravascularly to a location proximal of the occlusion in a vessel lumen, the crossing balloon catheter including an elongate shaft extending between an inflatable balloon and a hub assembly, and a stiffening tube surrounding the balloon and extending proximal of the balloon over a majority of a length of the elongate shaft;

positioning the balloon across the occlusion;

retracting the stiffening tube from the balloon by translating the stiffening tube proximally relative to the elongate shaft; and

inflating the balloon within the occlusion to expand the occlusion by delivering inflation fluid through an inflation lumen of the elongate shaft from the hub assembly to the balloon.

17. The method of claim 16, wherein the balloon is positioned across the occlusion with the stiffening tube surrounding the balloon.

18. The method of claim 17, wherein the balloon is at least partially inflated within the stiffening tube while the balloon is positioned across the occlusion.

19. The method of claim 16, wherein the guidewire is advanced through the occlusion after the crossing balloon catheter has been advanced to the location proximal of the occlusion, yet before the balloon is positioned across the occlusion, the crossing balloon catheter acting to support the guidewire during advancement of the guidewire through the occlusion.

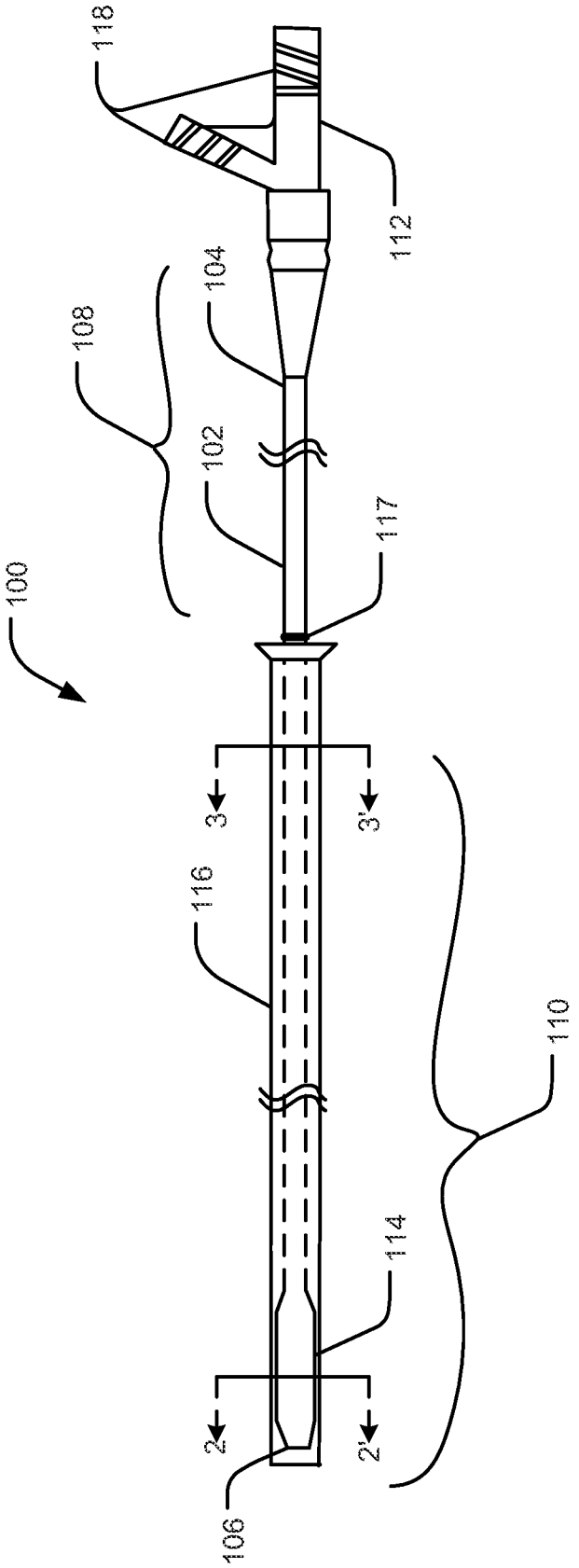

FIG. 1A

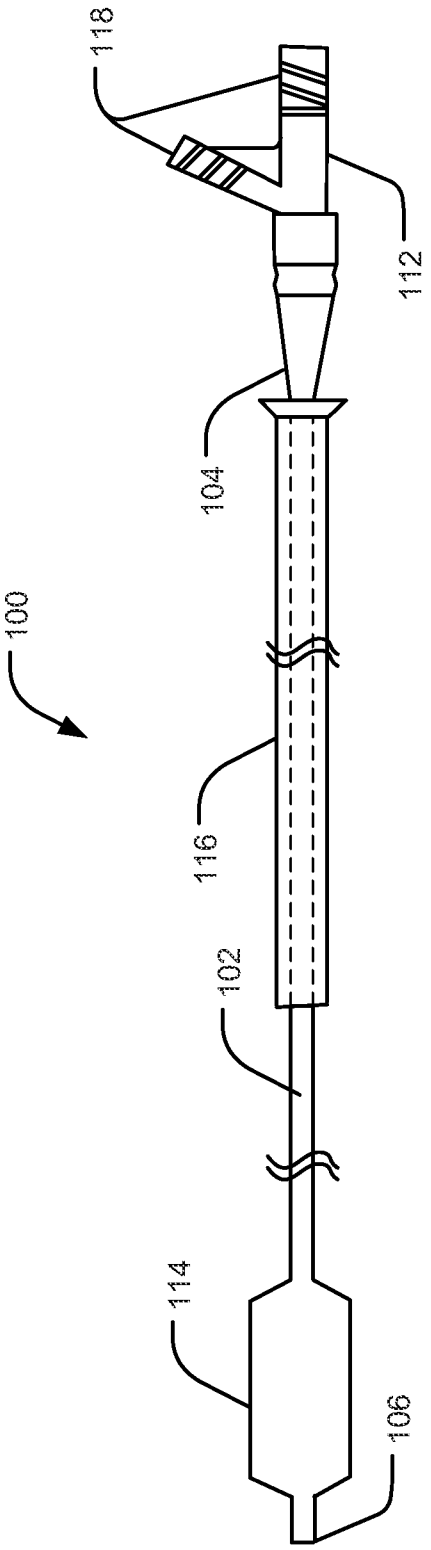

FIG. 1B

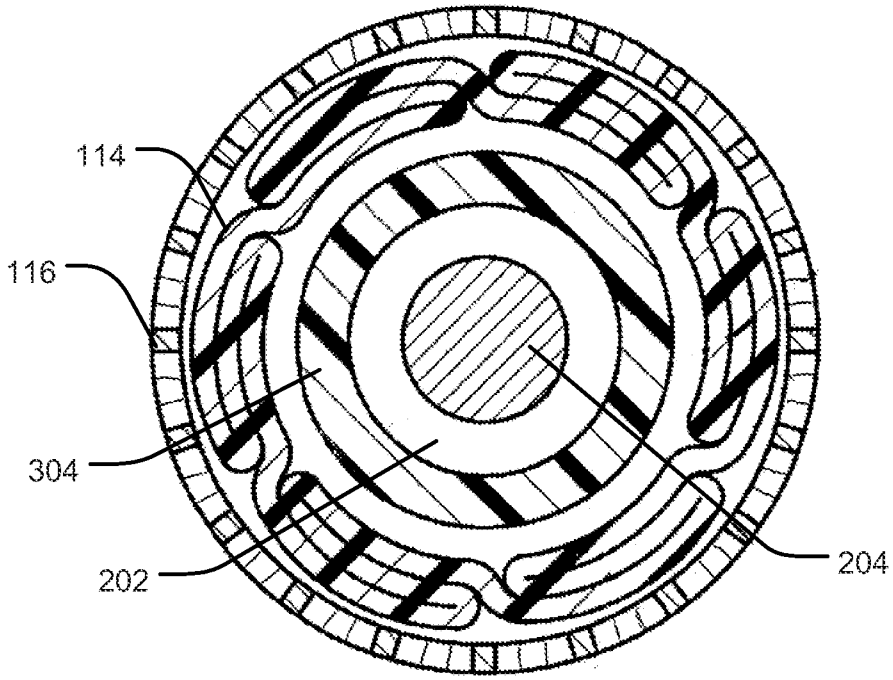

FIG. 2

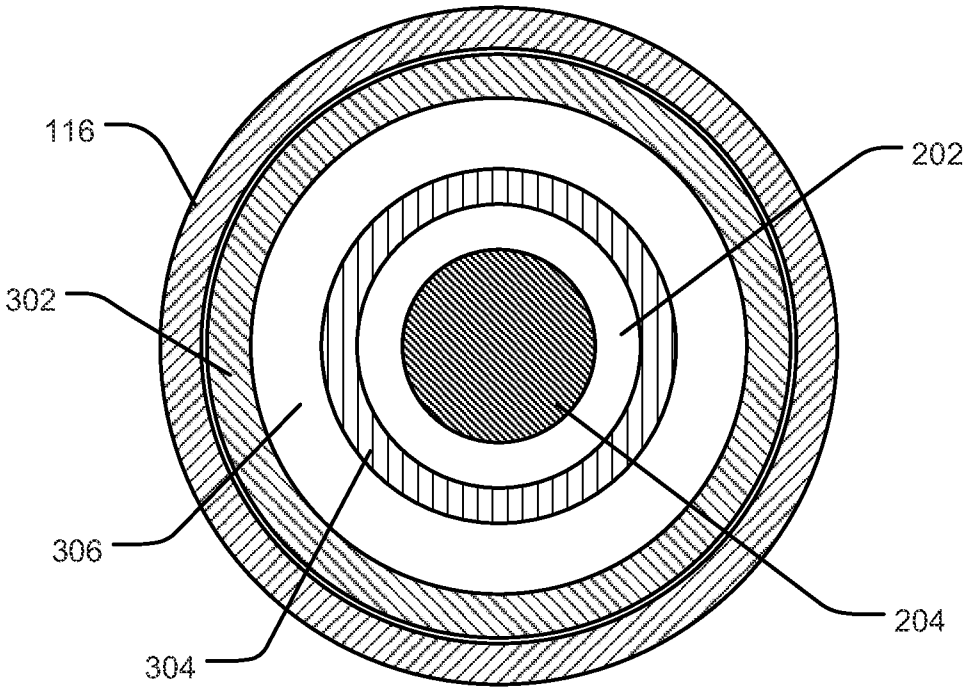

FIG. 3

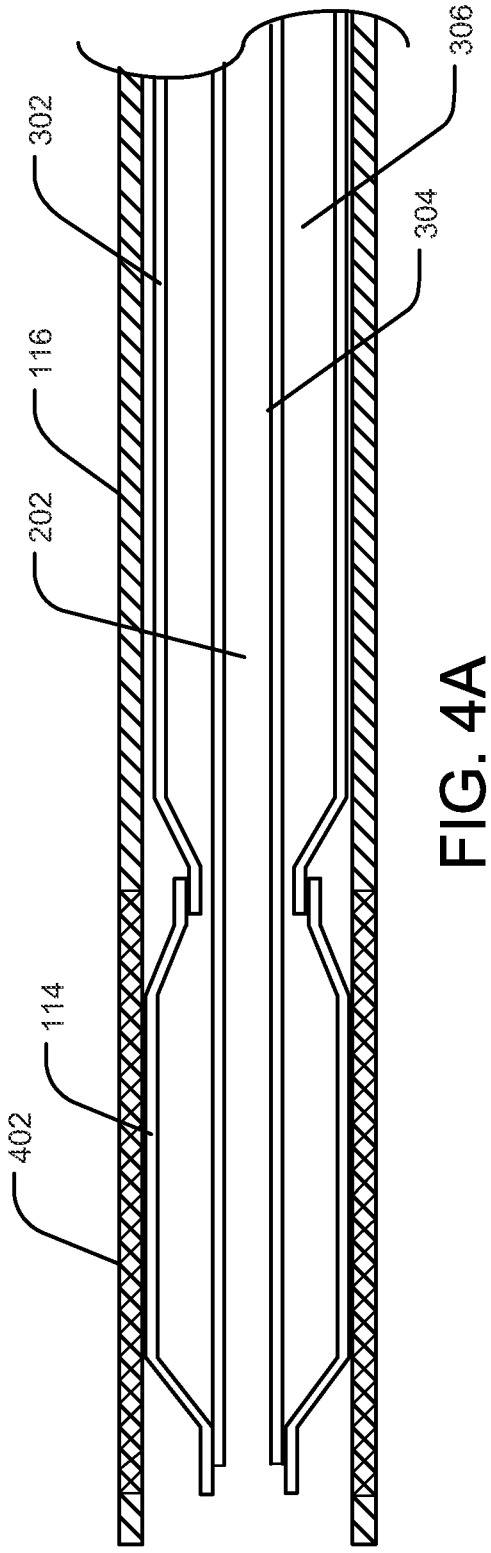

FIG. 4A

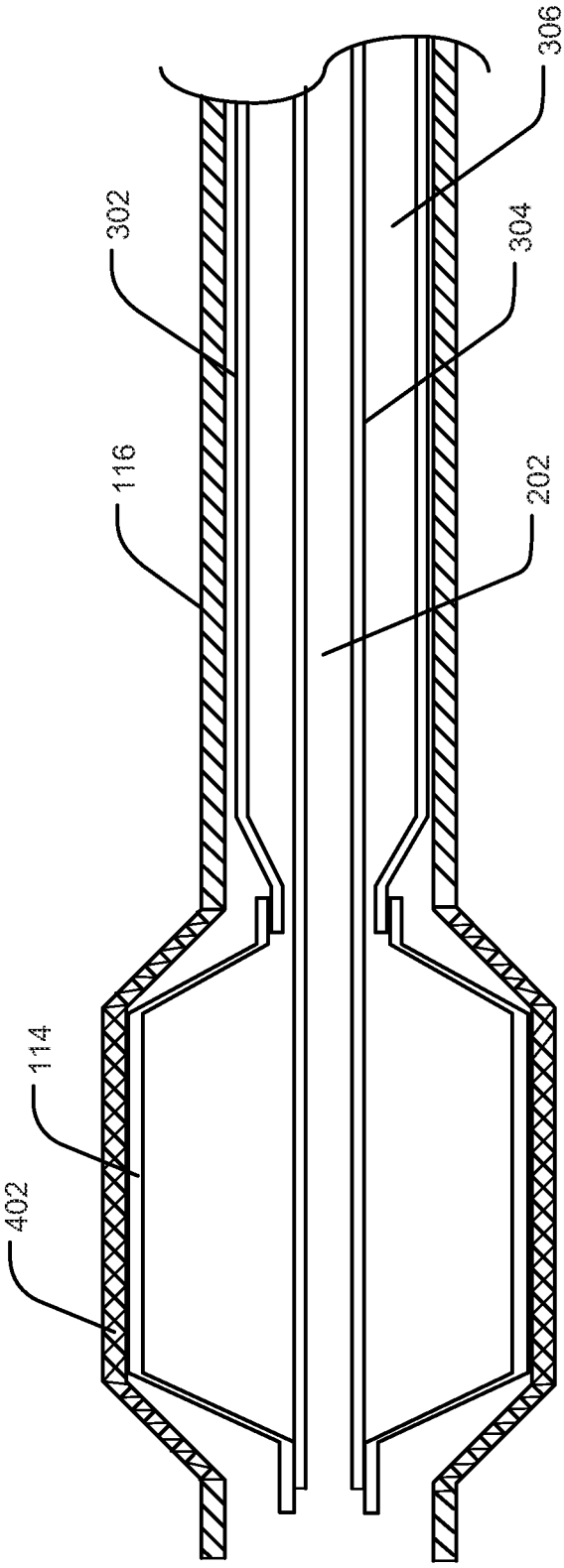

FIG. 4B

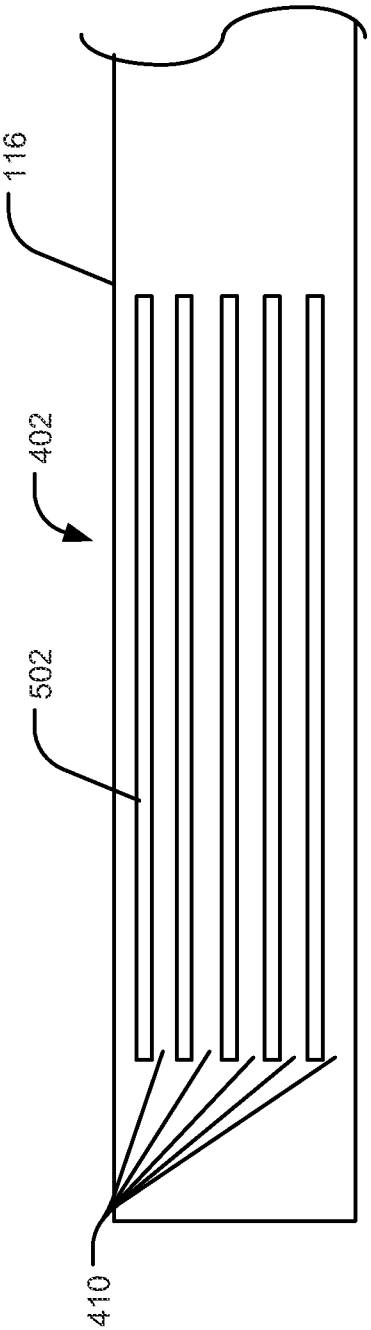

FIG. 5A

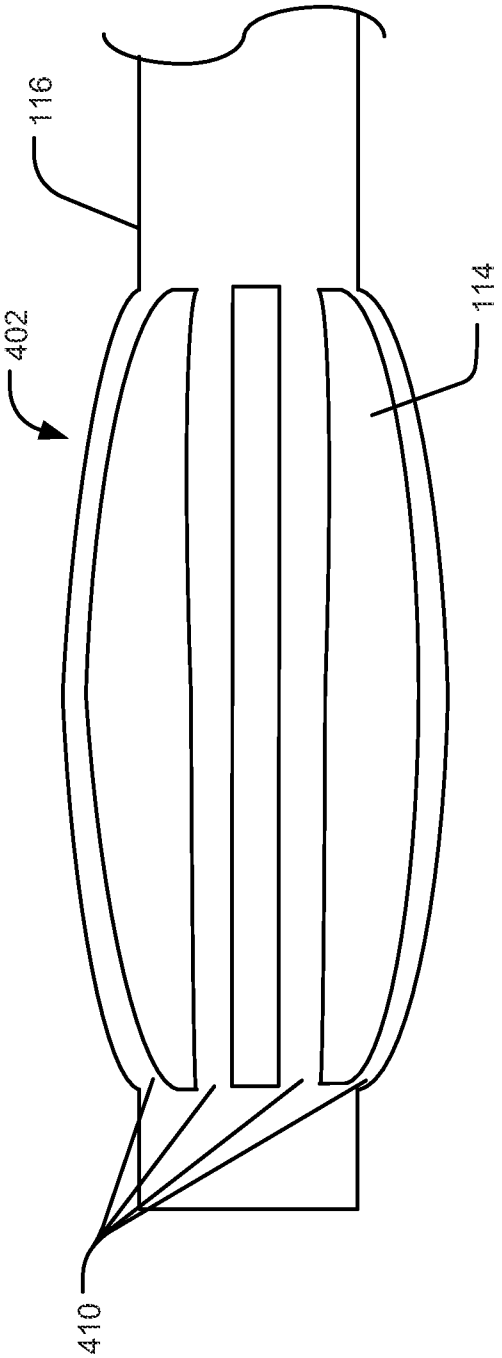

FIG. 5B

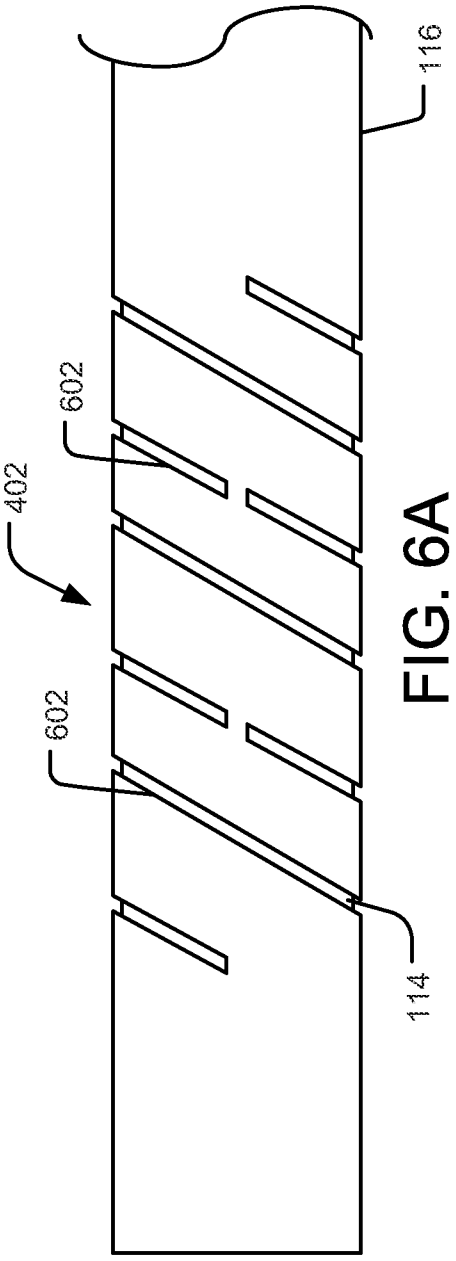

FIG. 6A

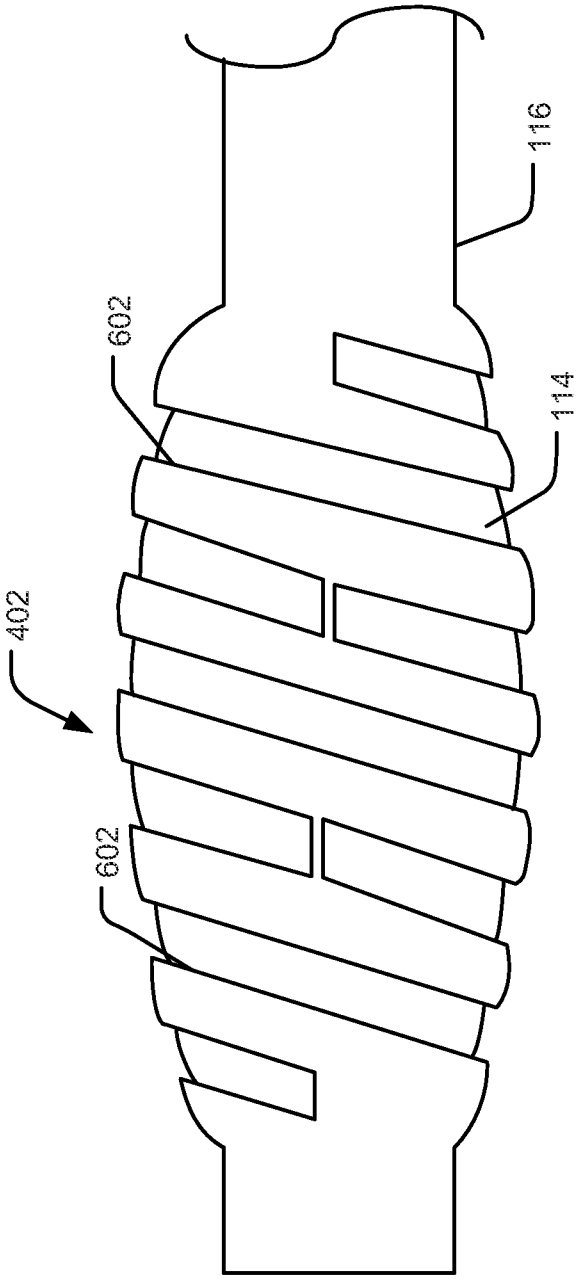

FIG. 6B

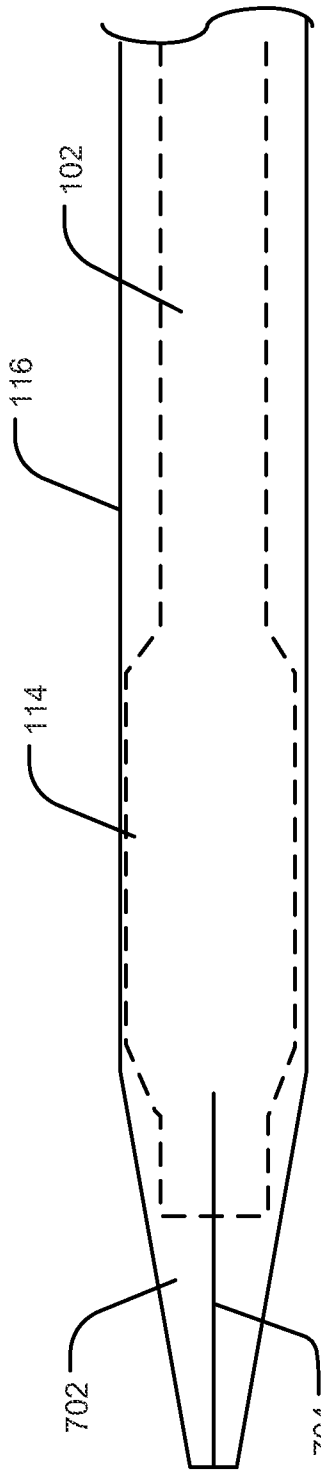

FIG. 7A

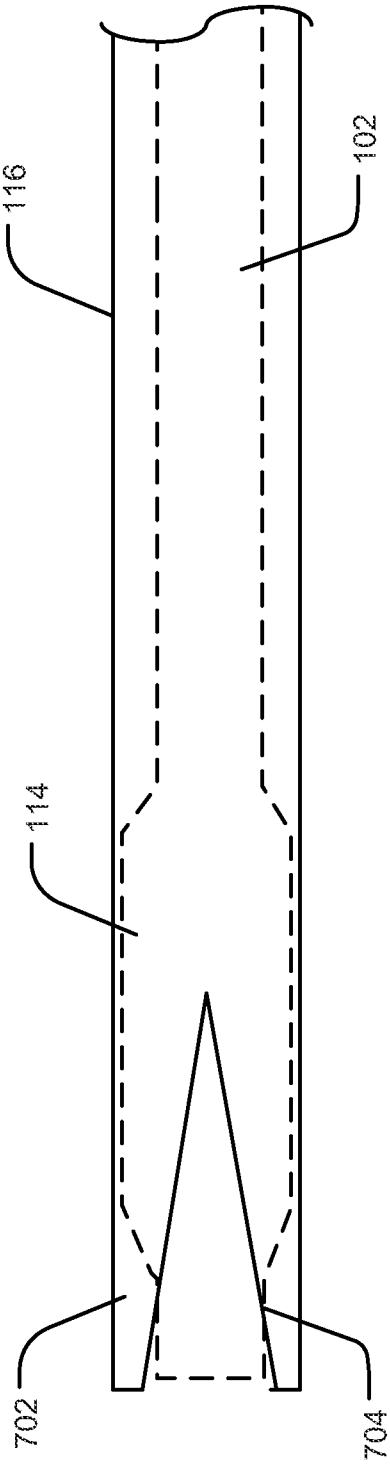

FIG. 7B

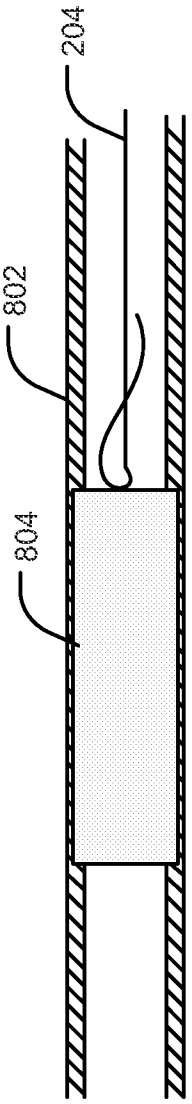

FIG. 8A

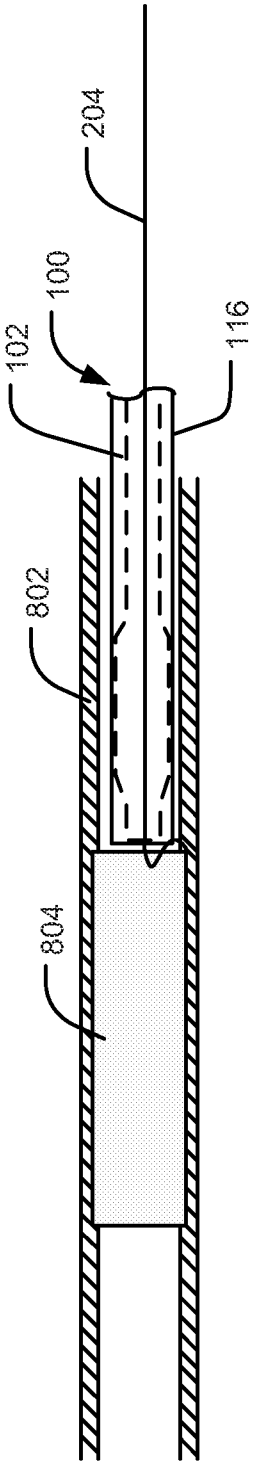

FIG. 8B

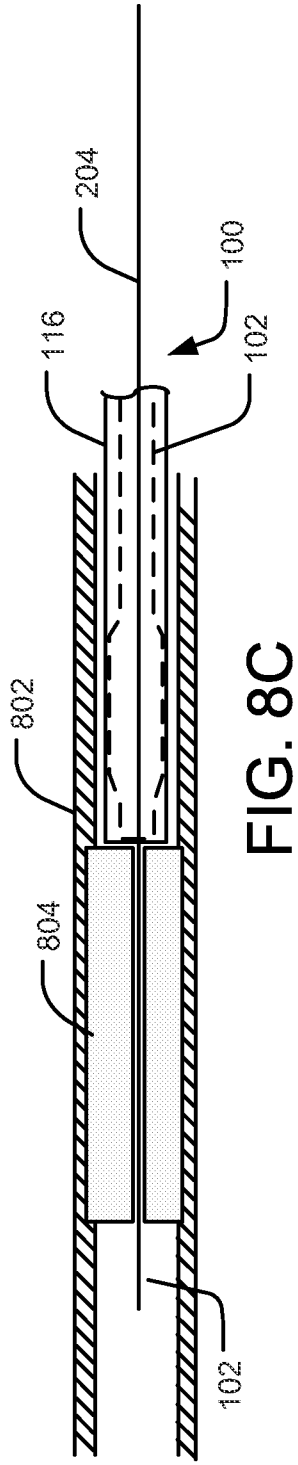

FIG. 8C

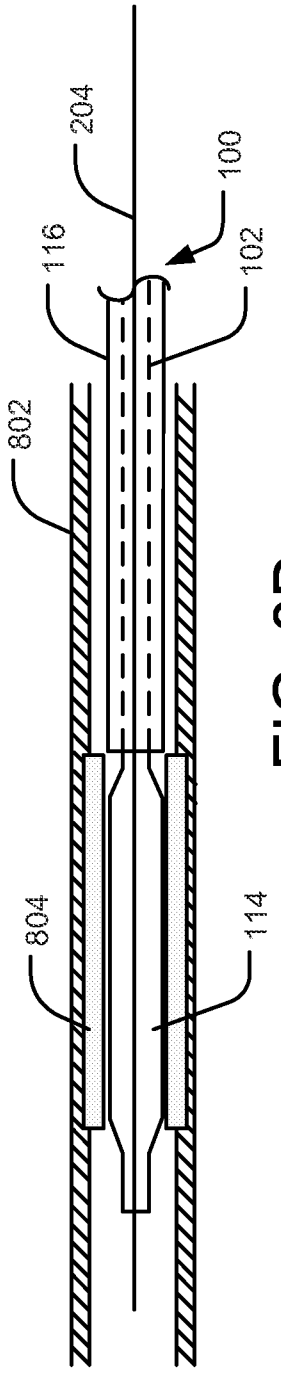

FIG. 8D

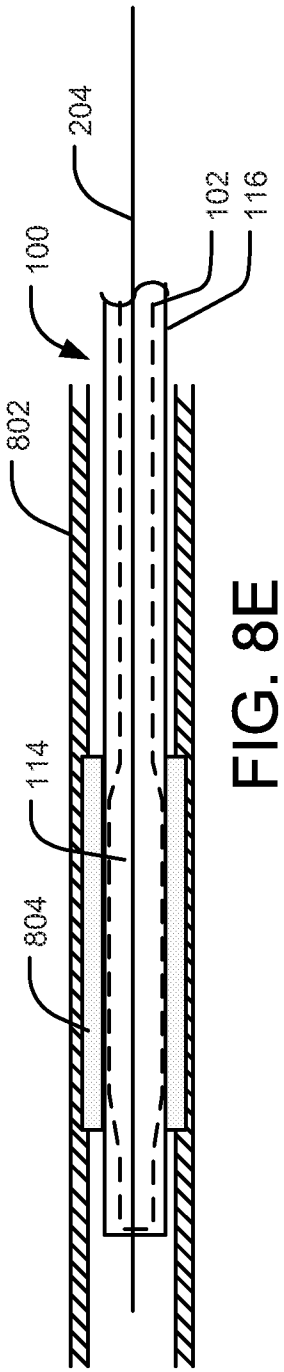

FIG. 8E

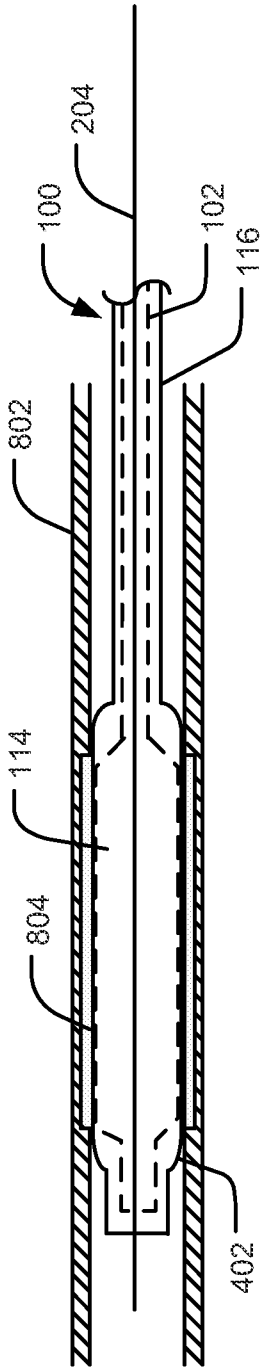

FIG. 8F

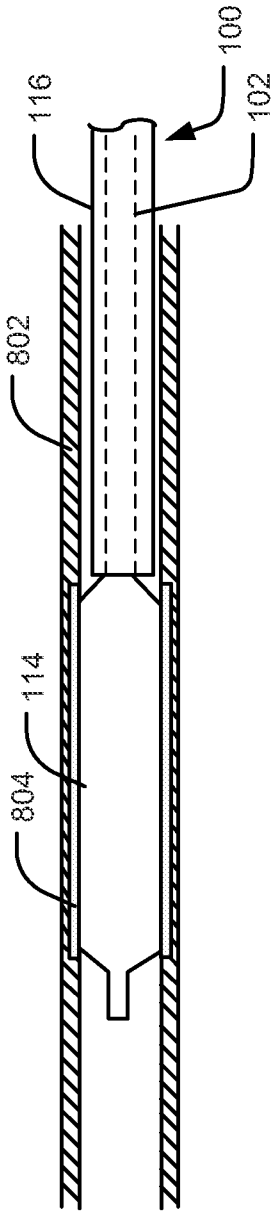

FIG. 8G

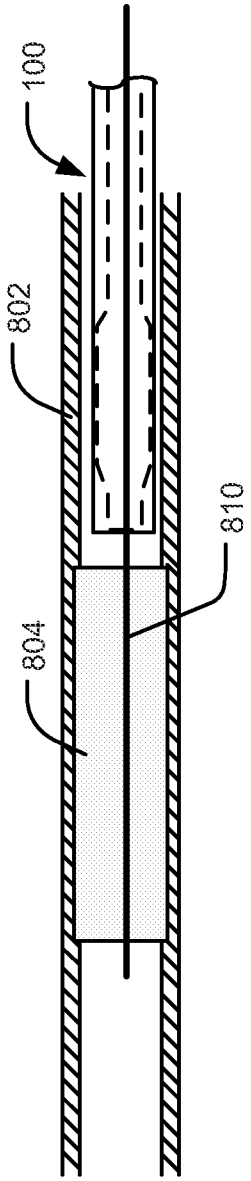

FIG. 8H

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/060436

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/10 A61B17/3207 A61F2/966 A61F2/958
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61B A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 344 045 Bl (LIM FLORENCIA [US] ET AL) 5 February 2002 (2002-02-05)	1-6,8-14
Y	columns 3-7 ; figures 1-5	7
X	WO 96/40349 Al (ADVANCED CARDIOVASCULAR SYSTEM [US]) 19 December 1996 (1996-12-19)	1-6,8-11
Y	pages 7-10; figures 1-3	7, 12, 13
X	US 2007/225659 Al (MELSHEIMER JEFFRY S [US]) 27 September 2007 (2007-09-27)	1-6, 8-13, 15
Y	paragraphs [0025] - [0030], [0036] - [0040] ; claims 17-20; figures 1,2,7,8,9	7
Y	WO 98/39056 A2 (SCIMED LIFE SYSTEMS INC [US]) 11 September 1998 (1998-09-11) pages 11-14, 2; figures 7-9i , 11, 26-31i	7, 13

-/- .

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 January 2013	24/01/2013

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/060436

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 290 295 A (QUERALS LUIS A [US] ET AL) 1 March 1994 (1994-03-01) columns 4,5,8,9; figures 2,3,10	12
X,P	EP 2 450 010 A1 (BIOTRONIK AG [CH]) 9 May 2012 (2012-05-09) the whole document	1-4,7-11

International application No.
PCT/US2012/060436

INTERNATIONAL SEARCH REPORT

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 16-19
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgeryThe methods for crossing an occlusion in a vessel lumen described in claims 16-19 comprise the step of advancing a crossing balloon catheter over a guidewire intravascularly. These methods are thus surgical methods.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos. :

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos. :

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/060436

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6344045 Bl	05-02-2002	NONE	
WO 9640349 Al	19-12-1996	US 6695863 Bl	24-02-2004
		WO 9640349 Al	19-12-1996
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W0 9839056 A2	11-09-1998	AT 254488 T	15-12-2003
		DE 69819880 Dl	24-12-2003
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