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(54) **HYPOTUBE CATHETER**

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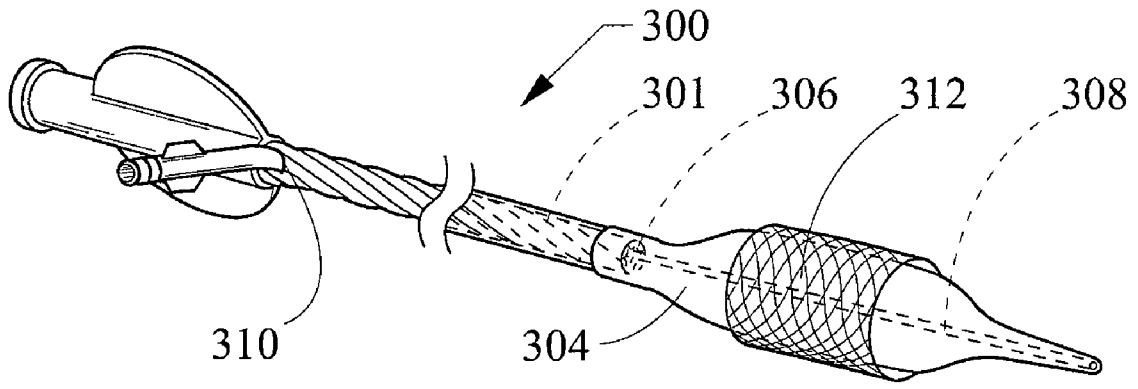
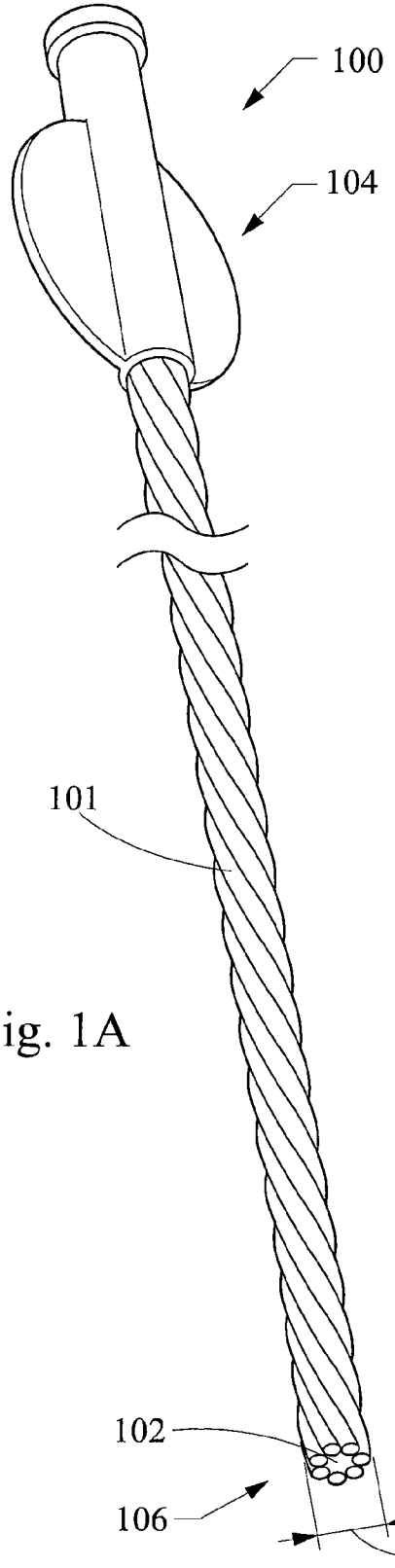
(57) **ABSTRACT**

A balloon catheter device (**300**) of the present invention includes an elongate catheter shaft (**301**) comprising a helically-cut hypotube having a proximal portion and a distal portion. The proximal portion includes a coating that allows the shaft to provide a patent fluid passage, and a part of the distal portion inside a balloon (**304**) may be uncoated or otherwise open to the balloon lumen, allowing for passage of fluid through the shaft into the balloon lumen.





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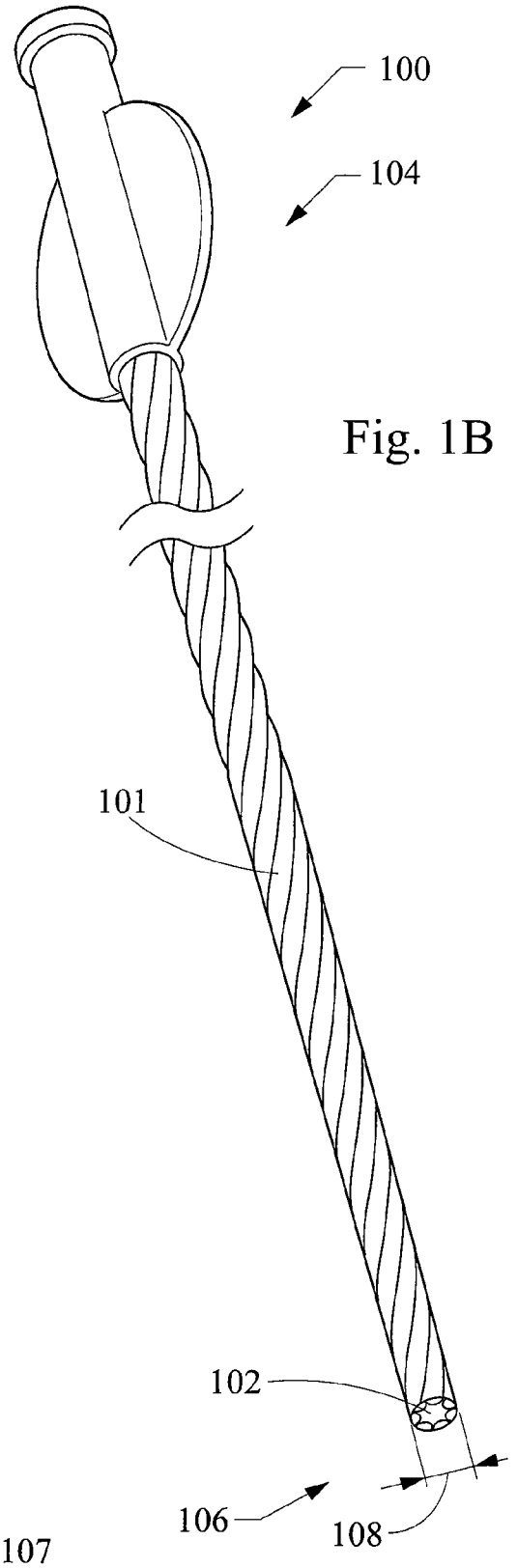
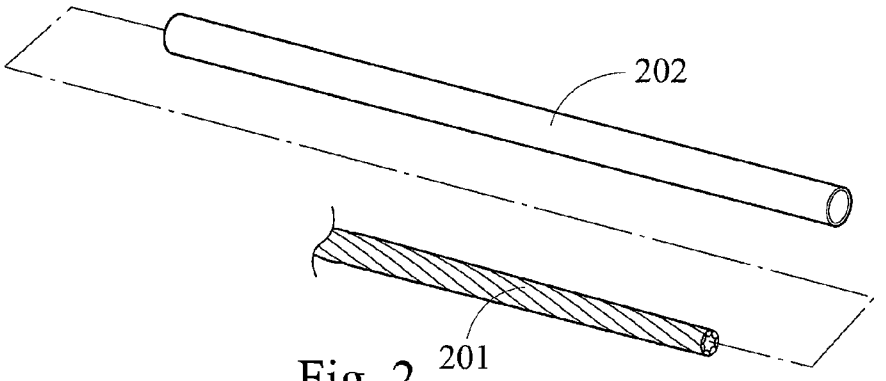


Fig. 1B



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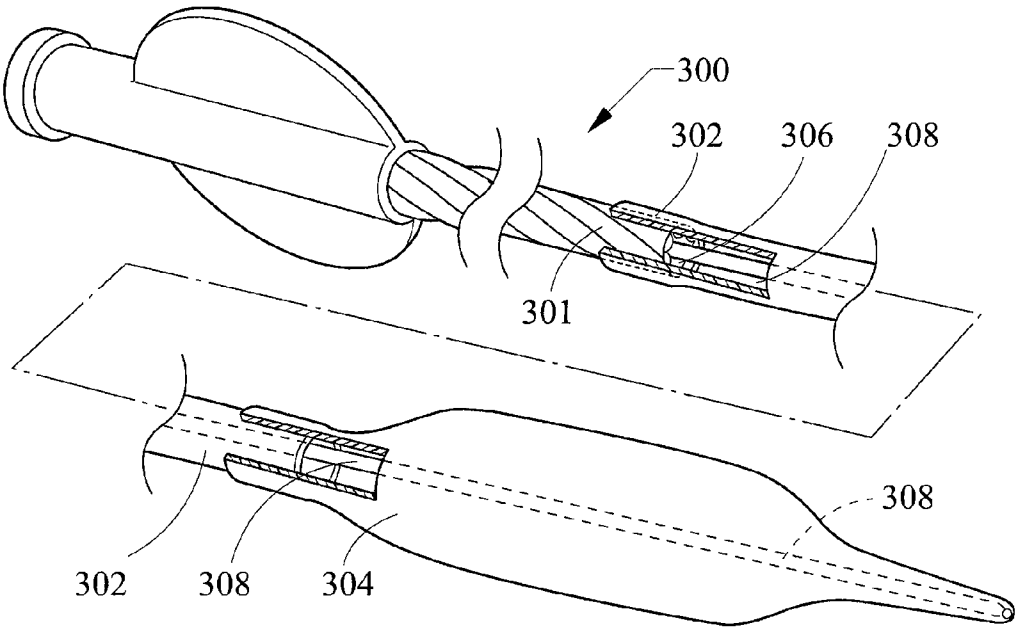
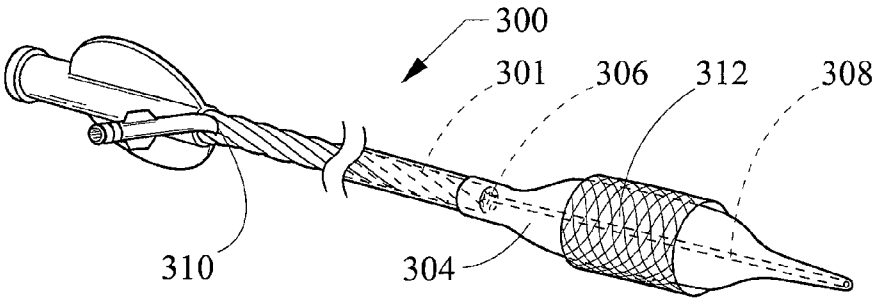


Fig. 3A



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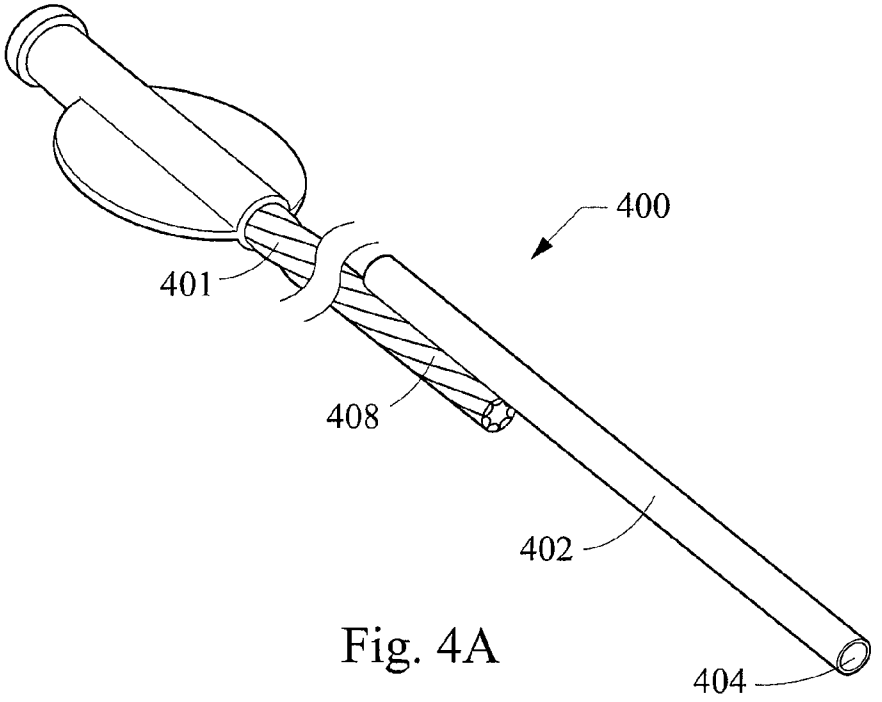

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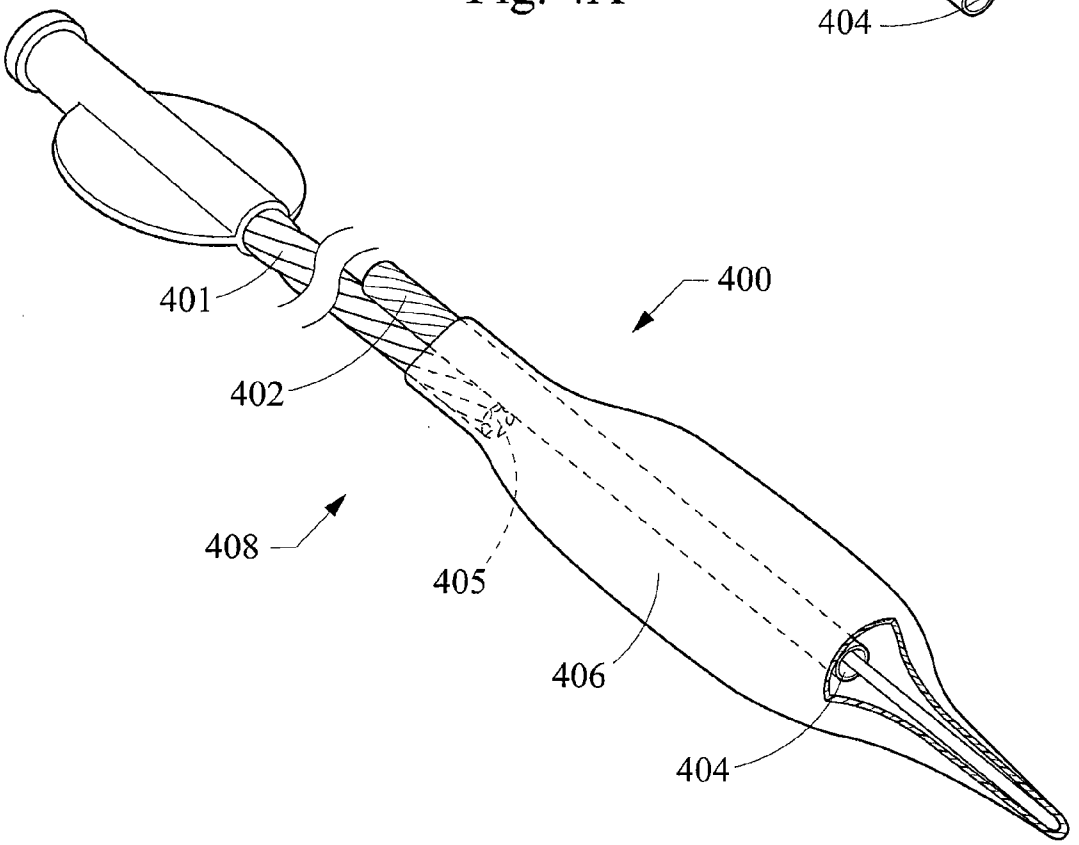

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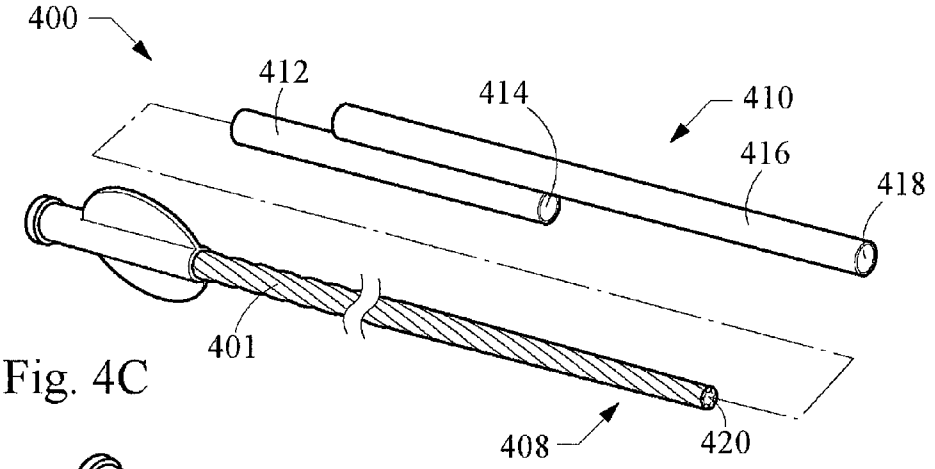
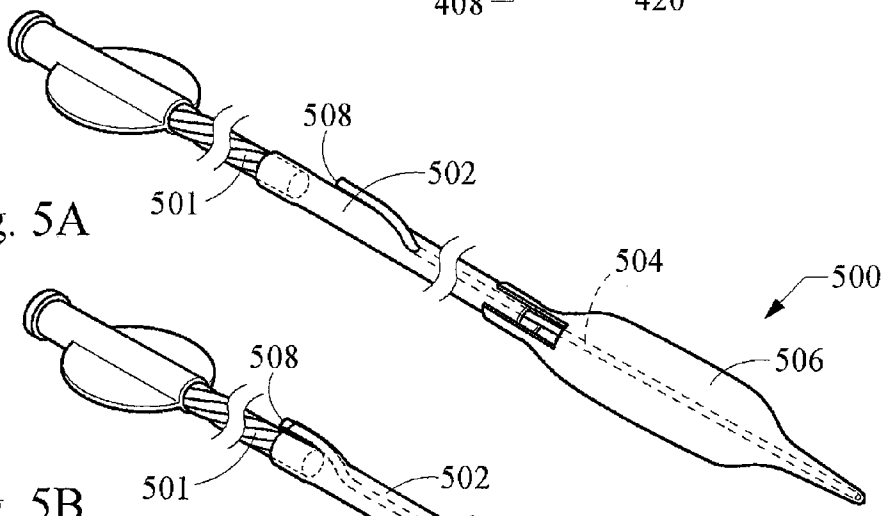


Fig. 4C



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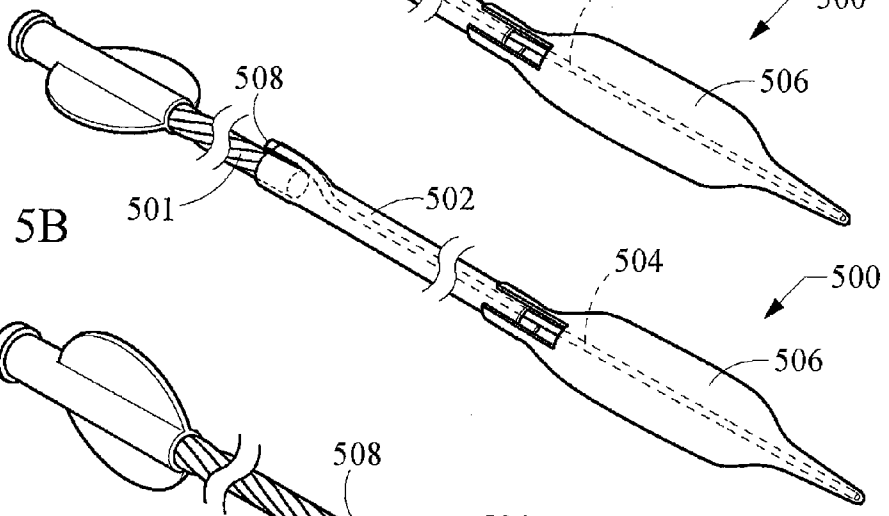

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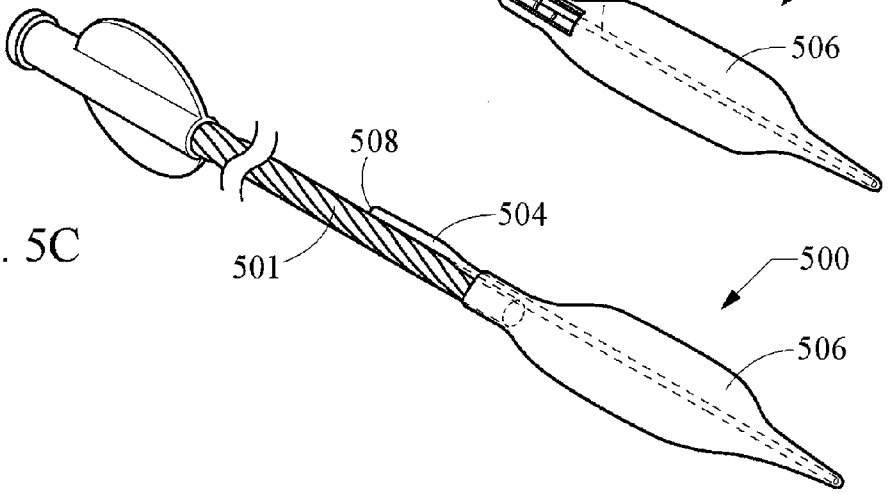

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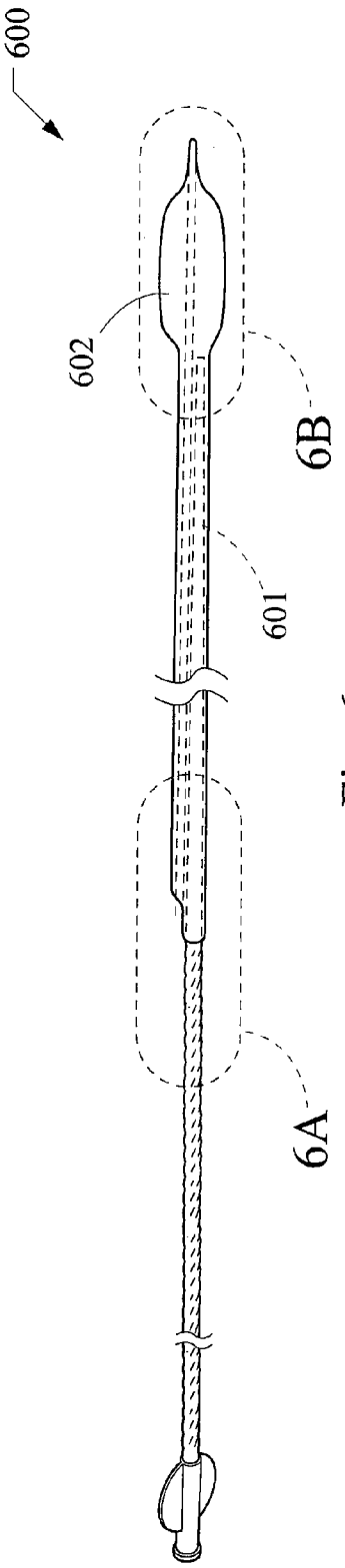

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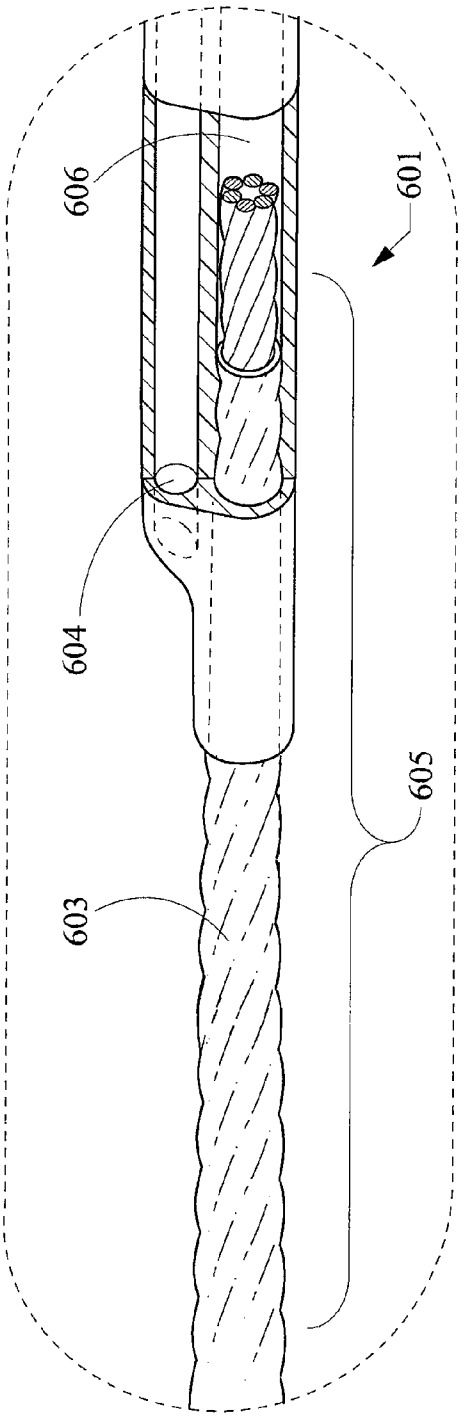

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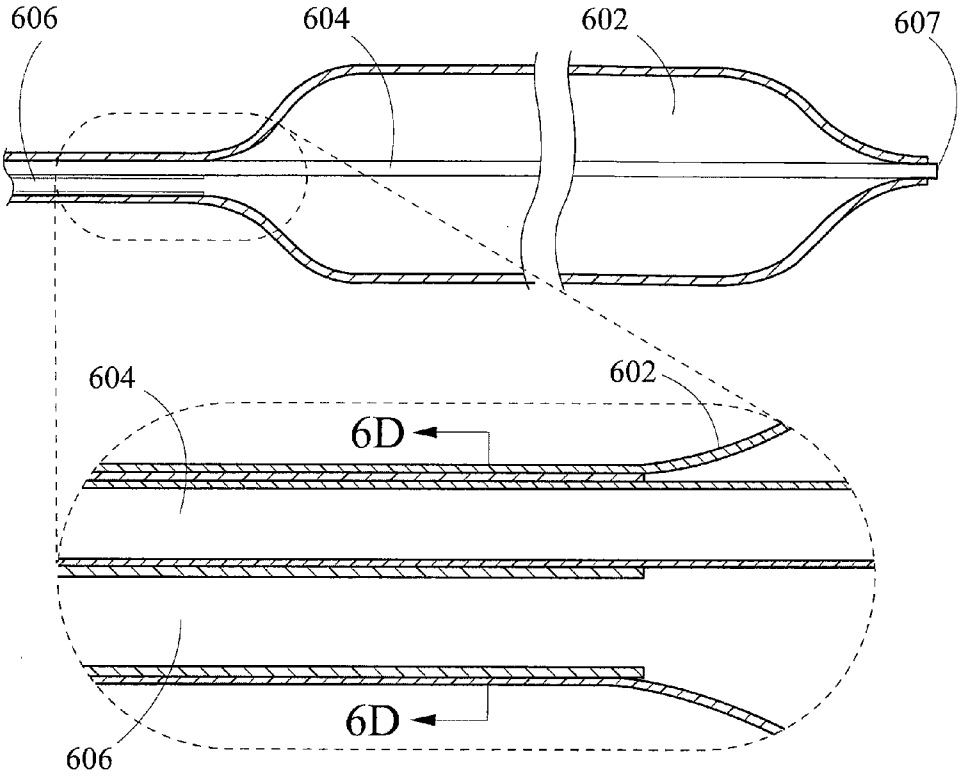

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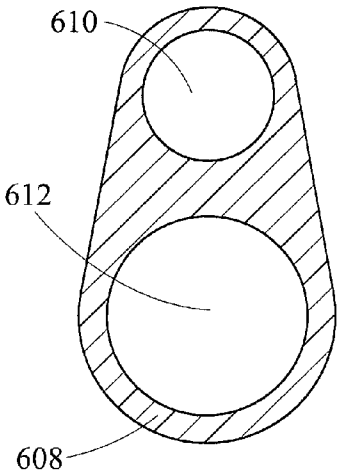

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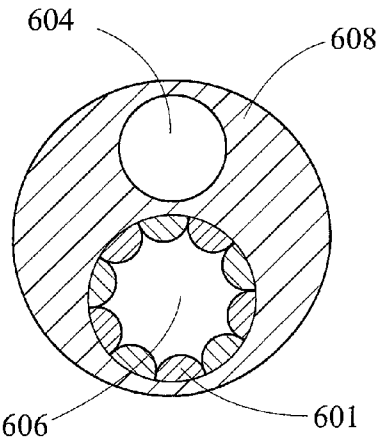

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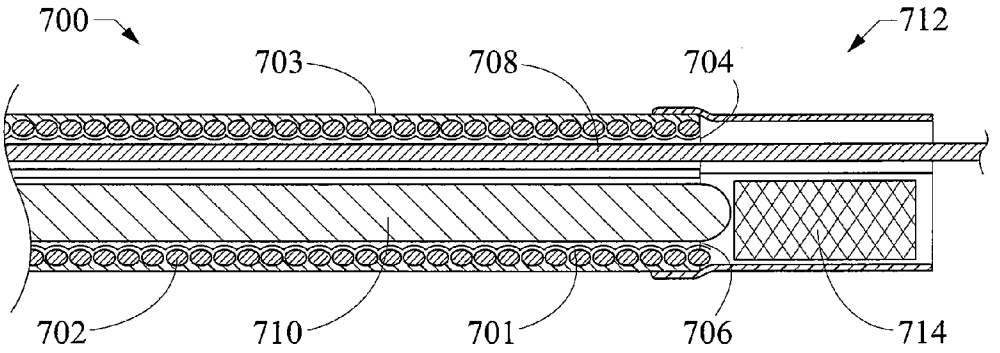

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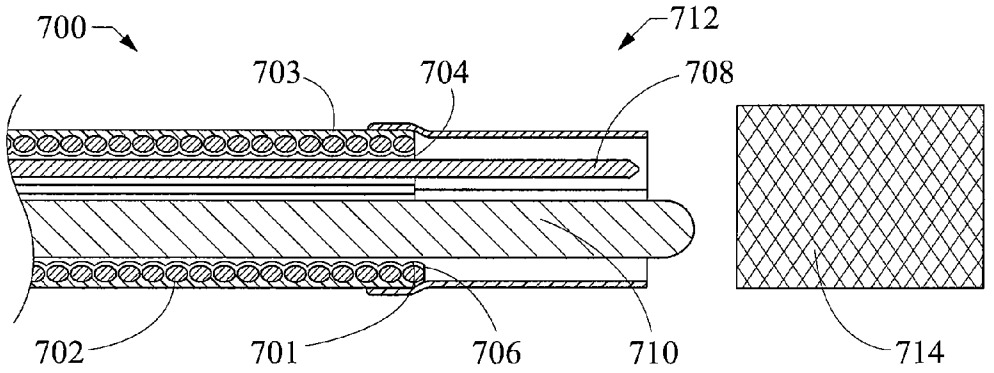

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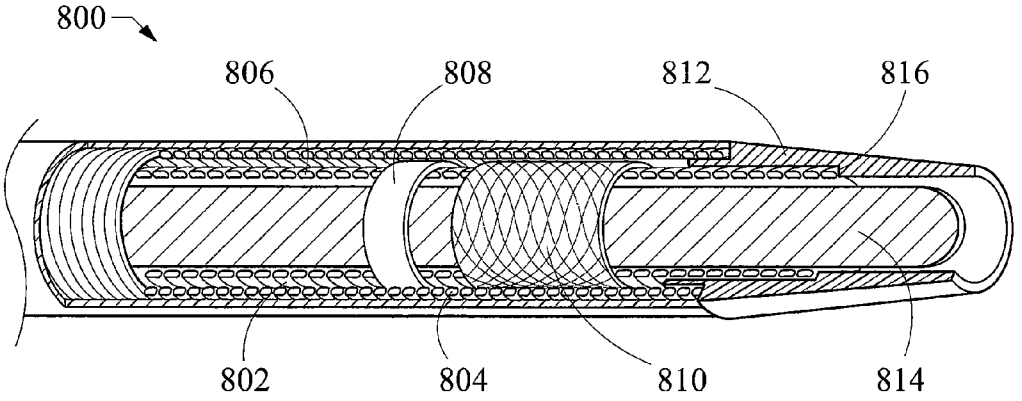

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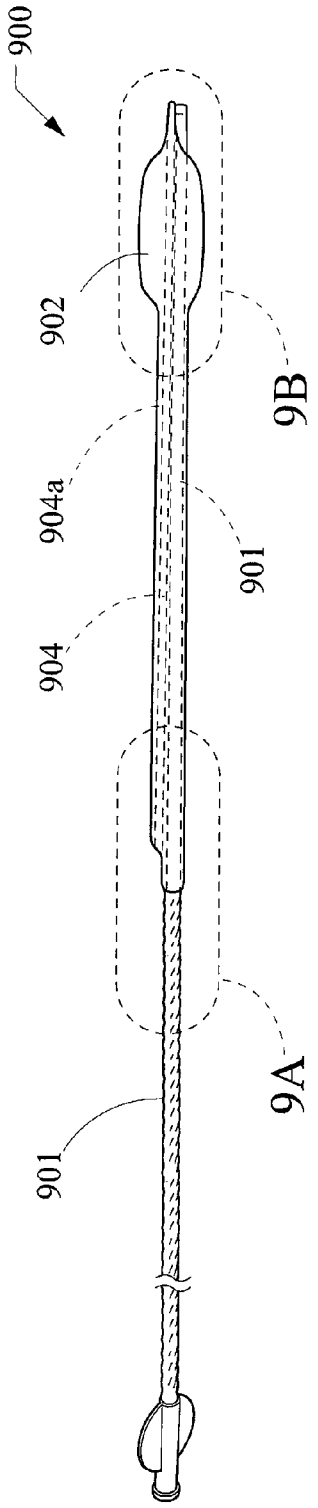

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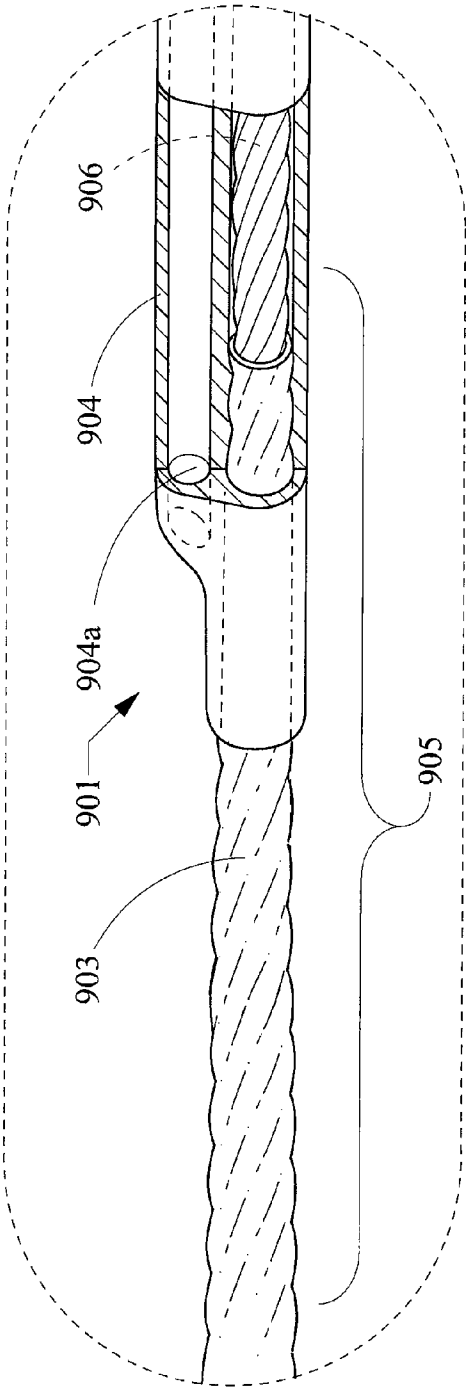

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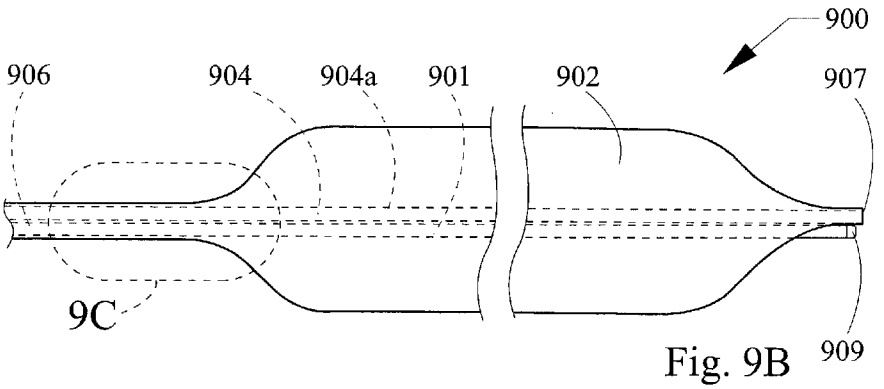

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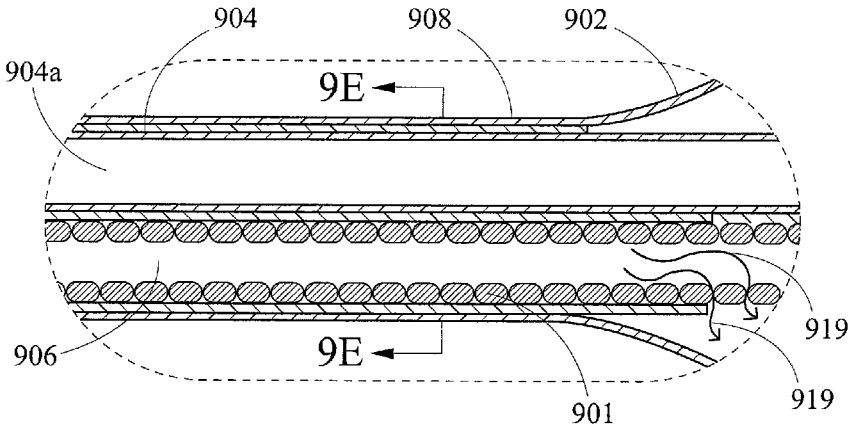

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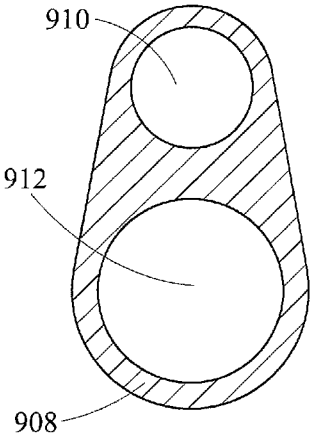

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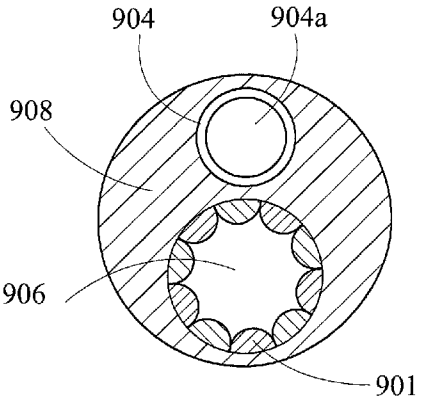

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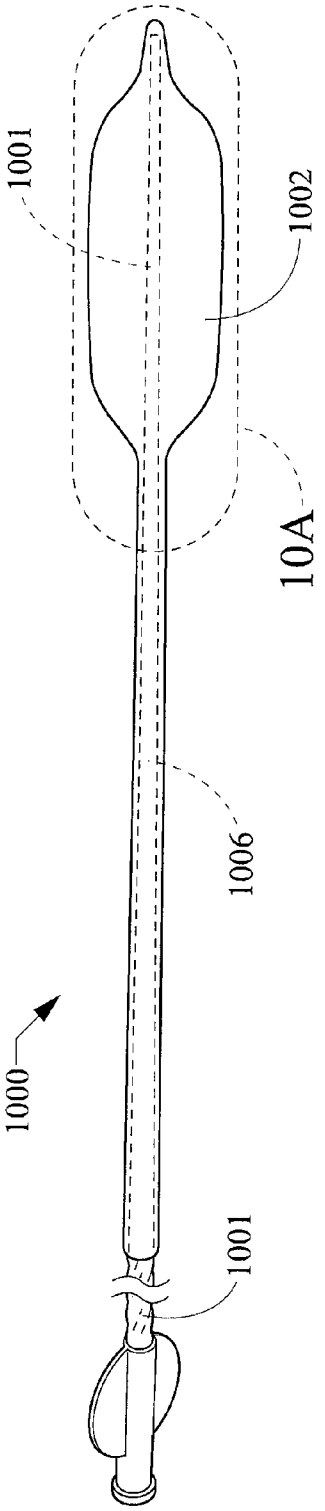

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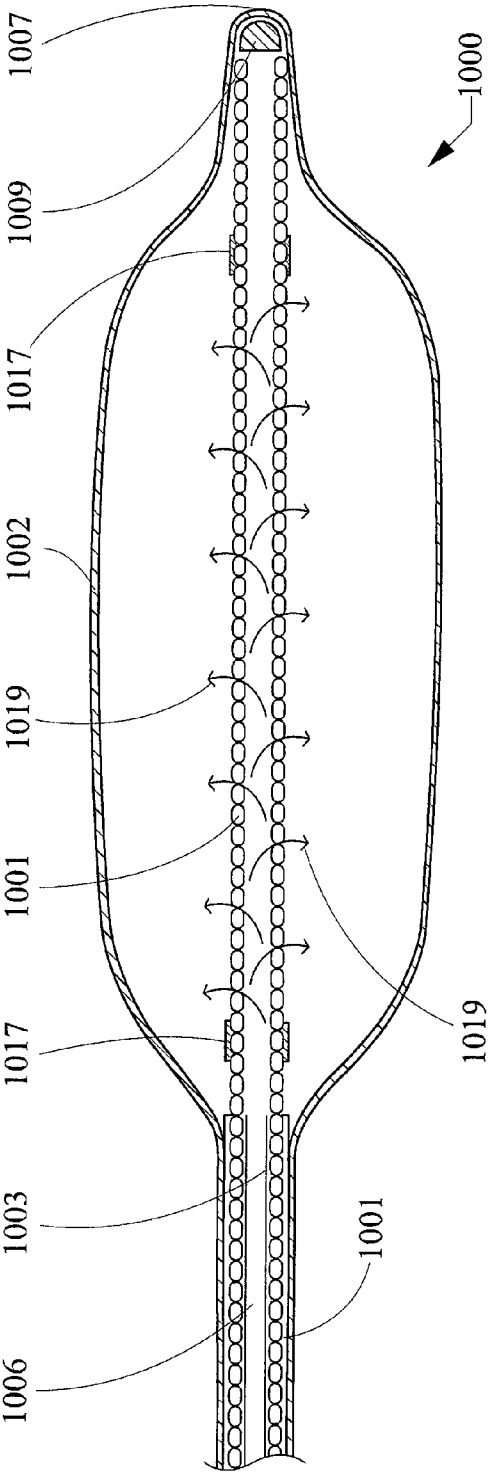

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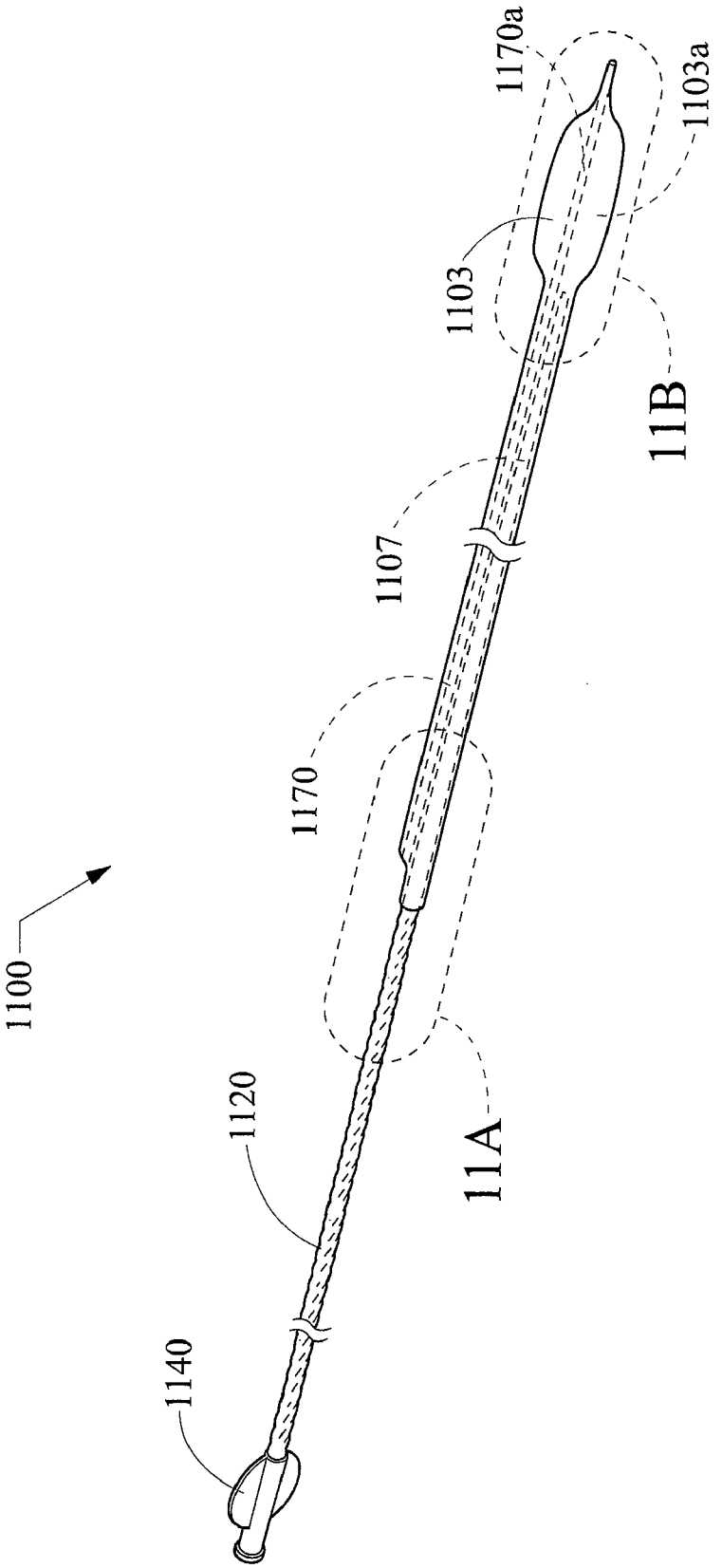

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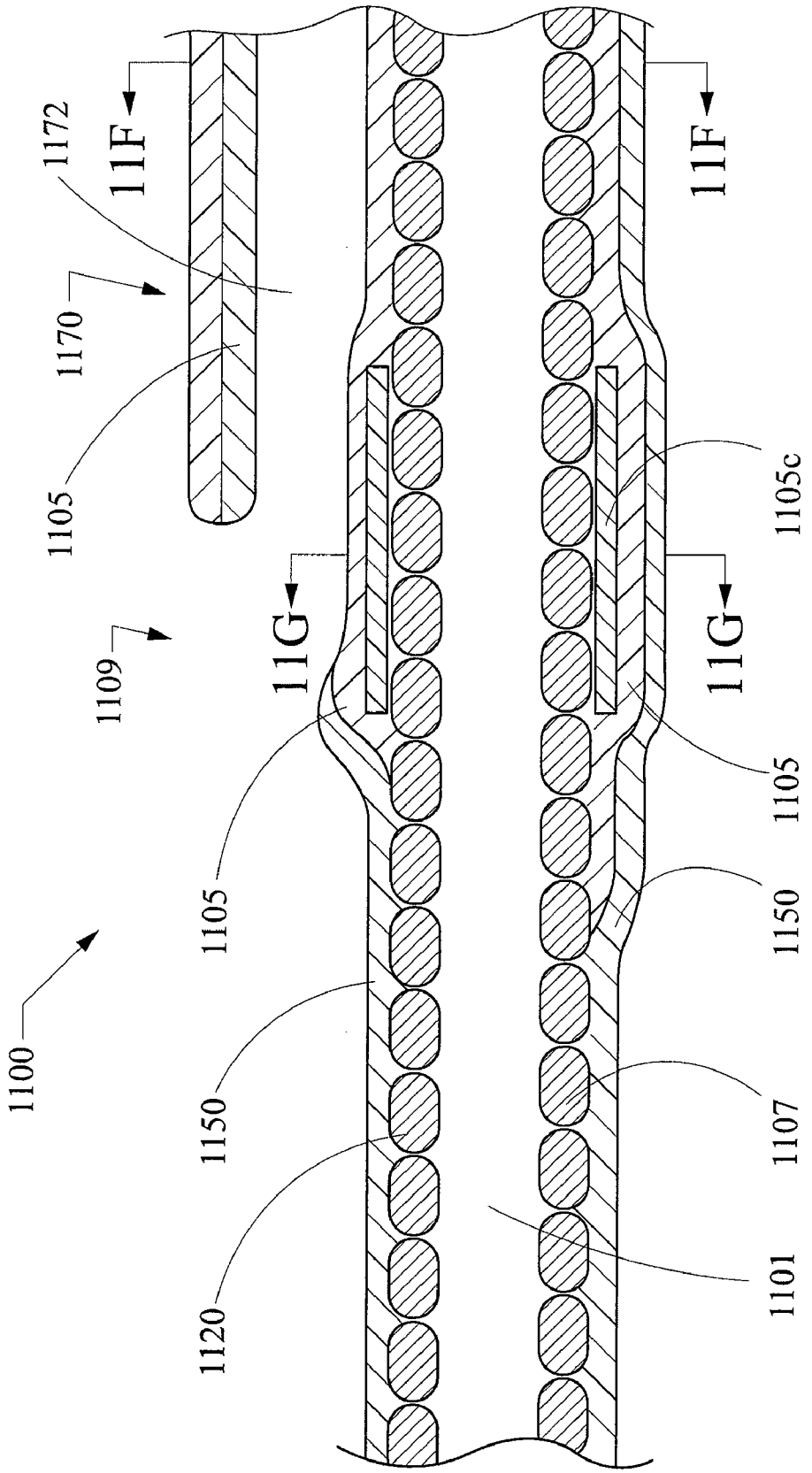
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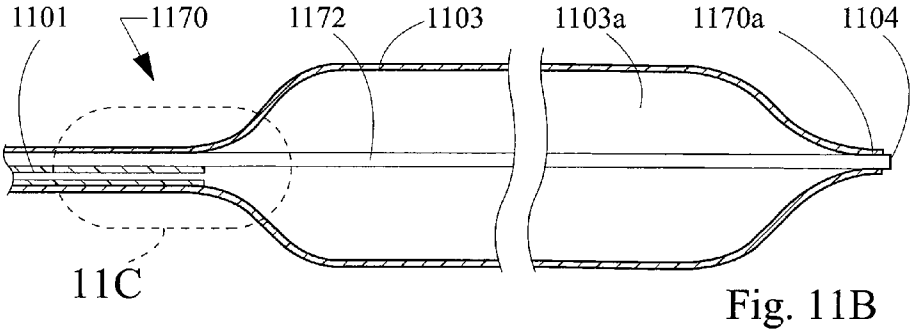
Fig. 11A



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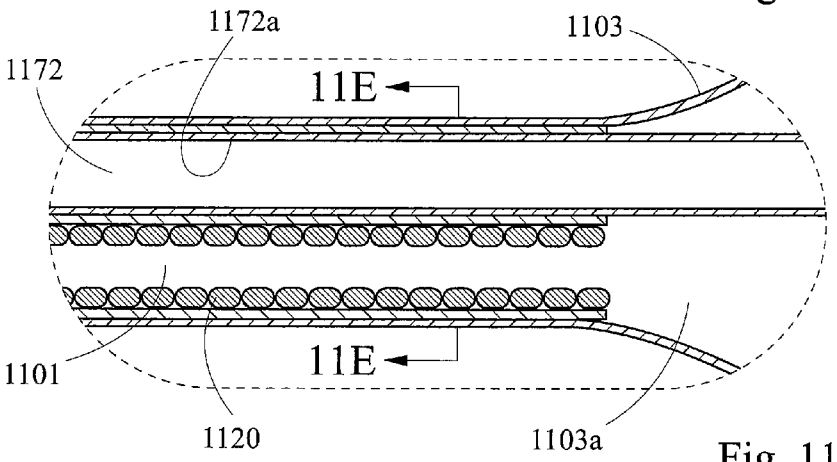

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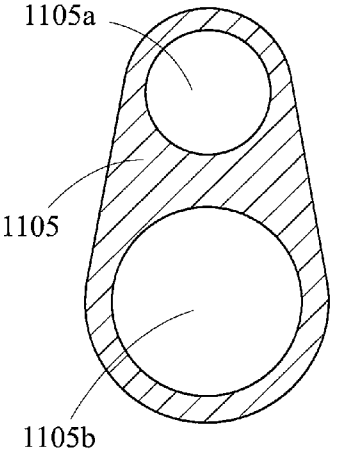

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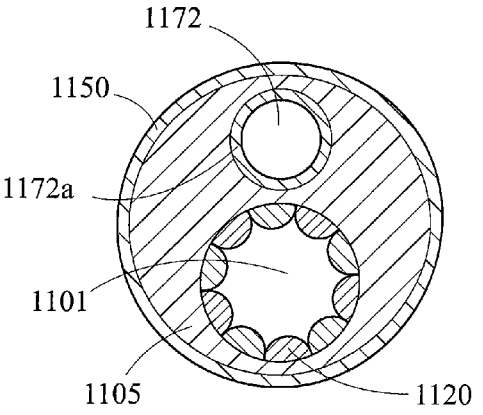

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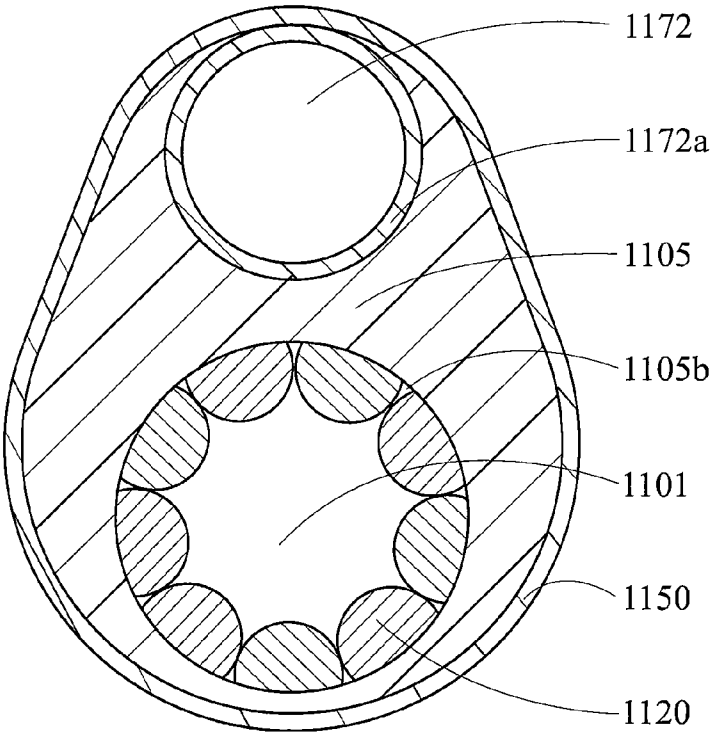

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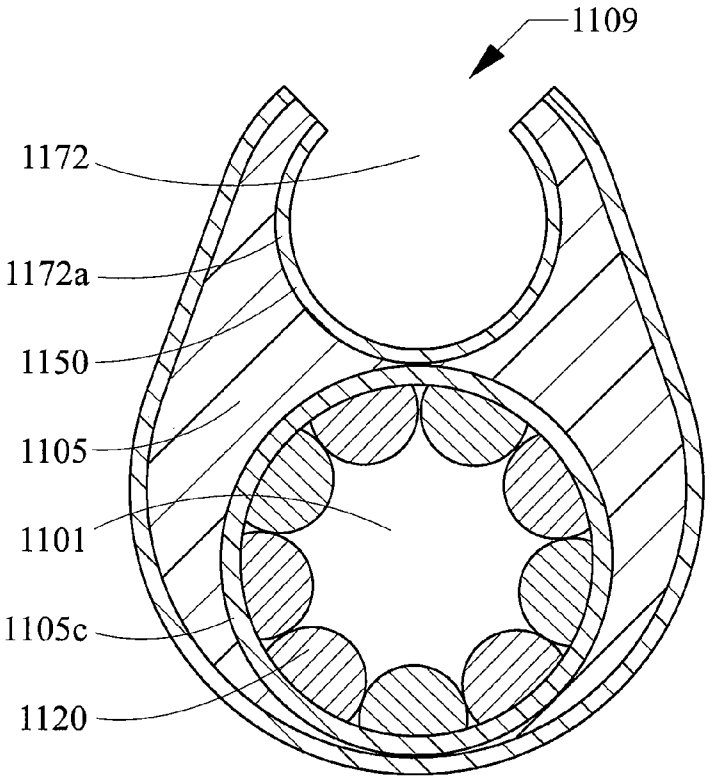

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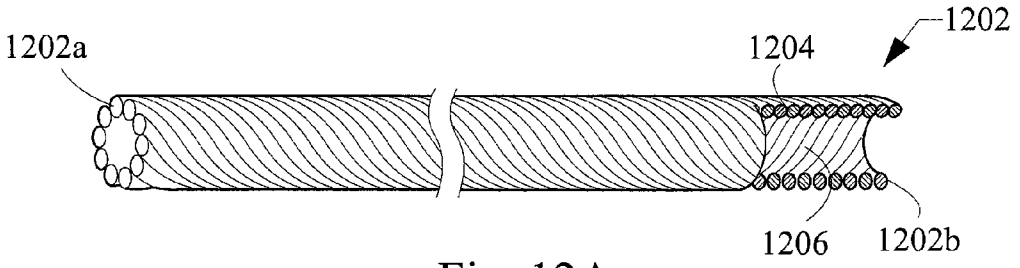

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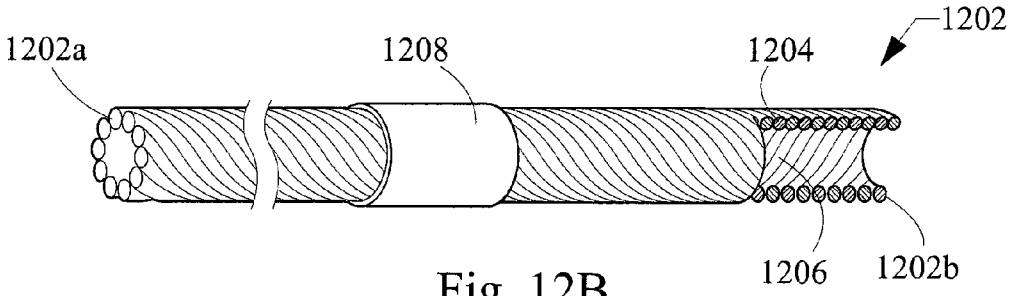

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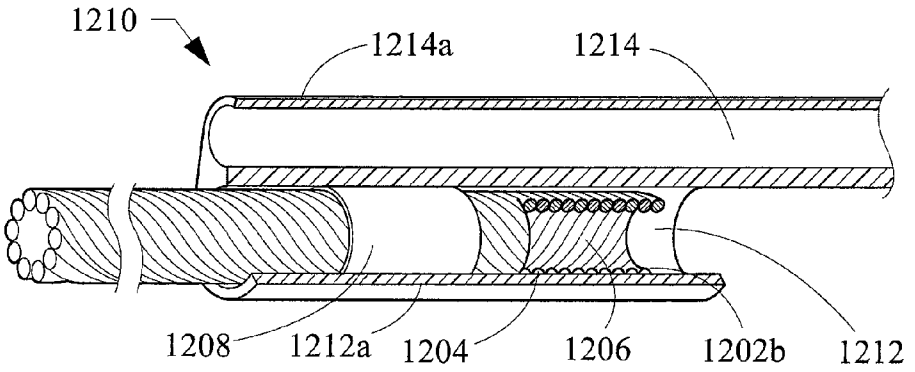

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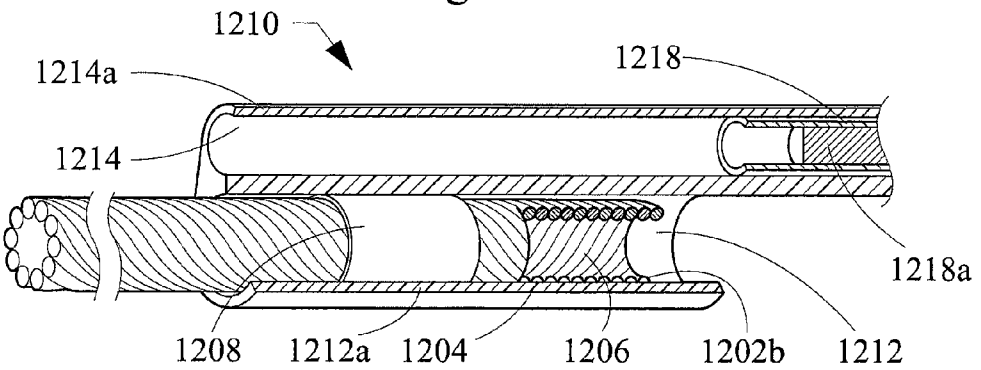

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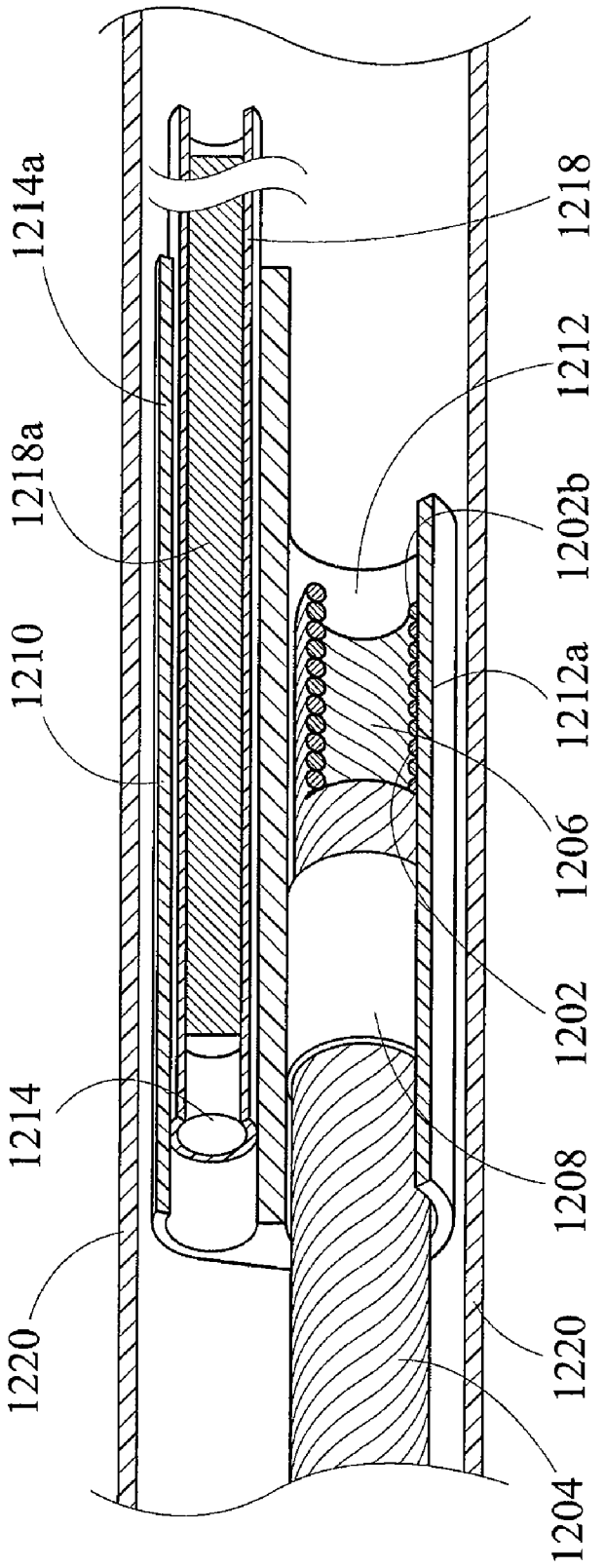
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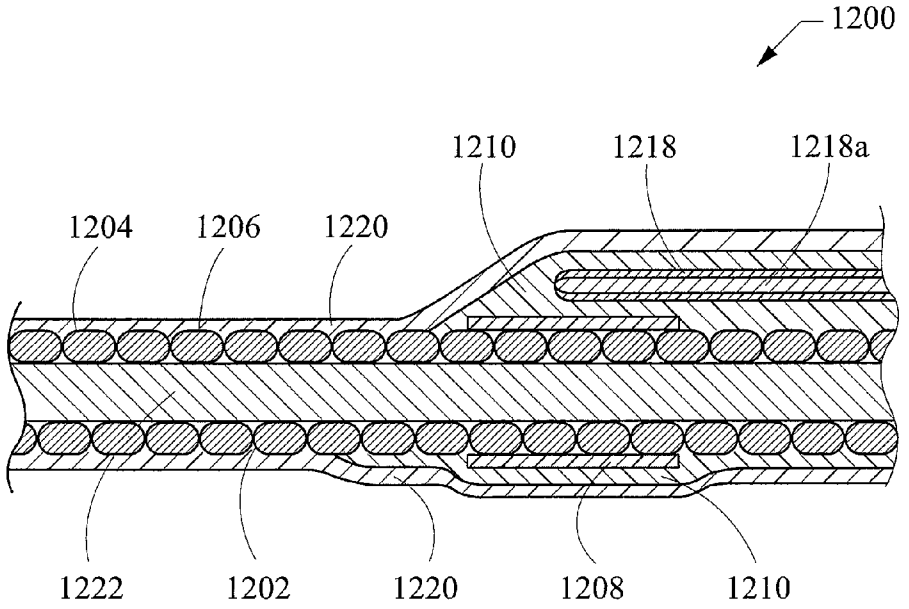
Fig. 12E



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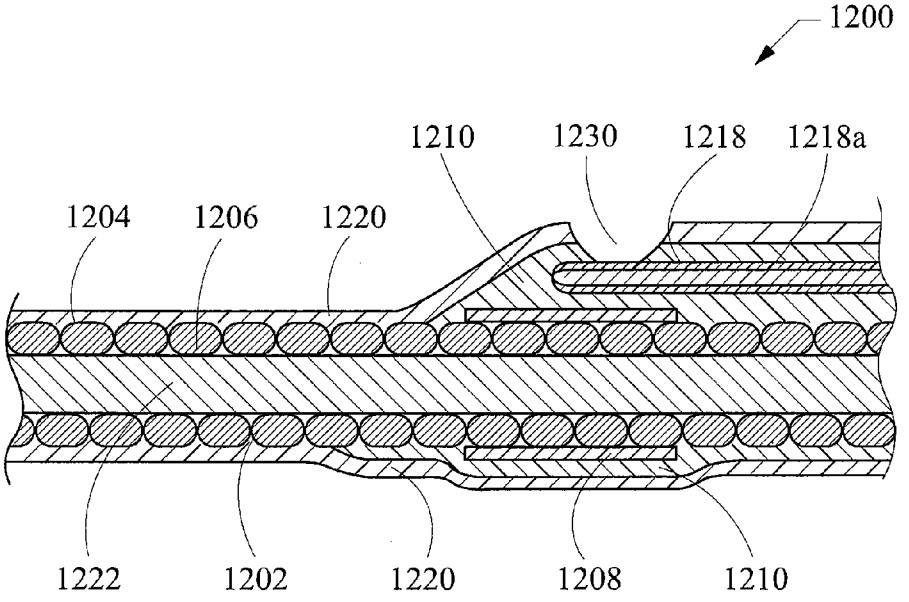

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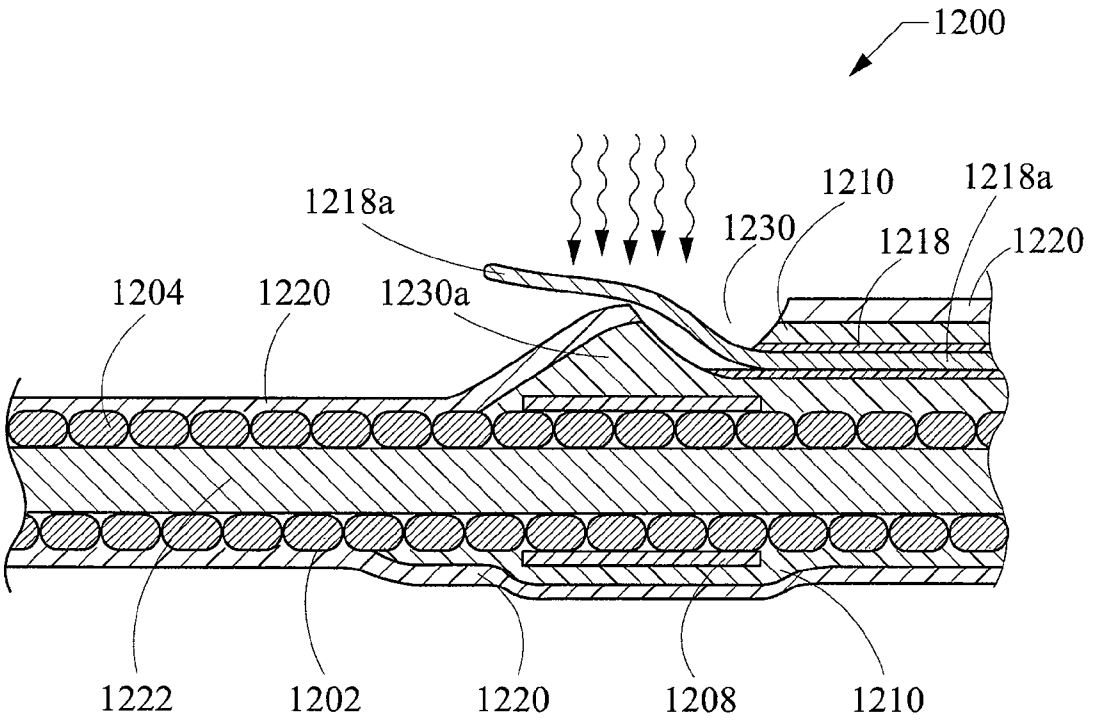
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Fig. 12H

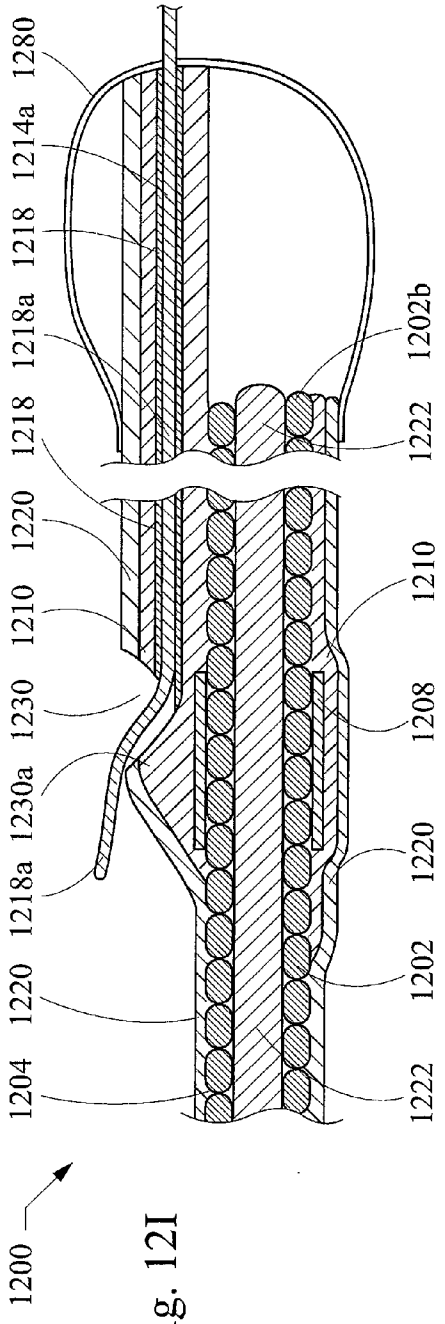
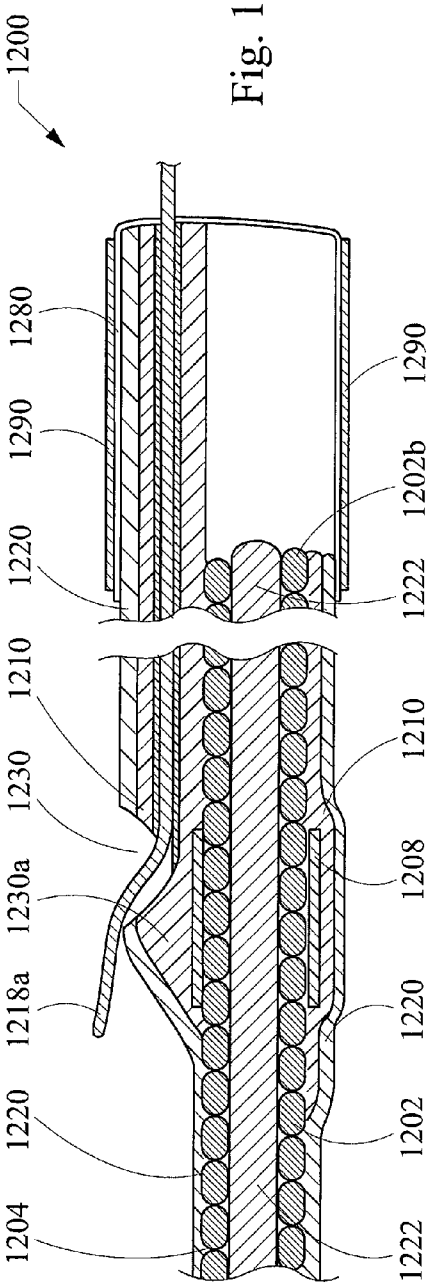


Fig. 12I



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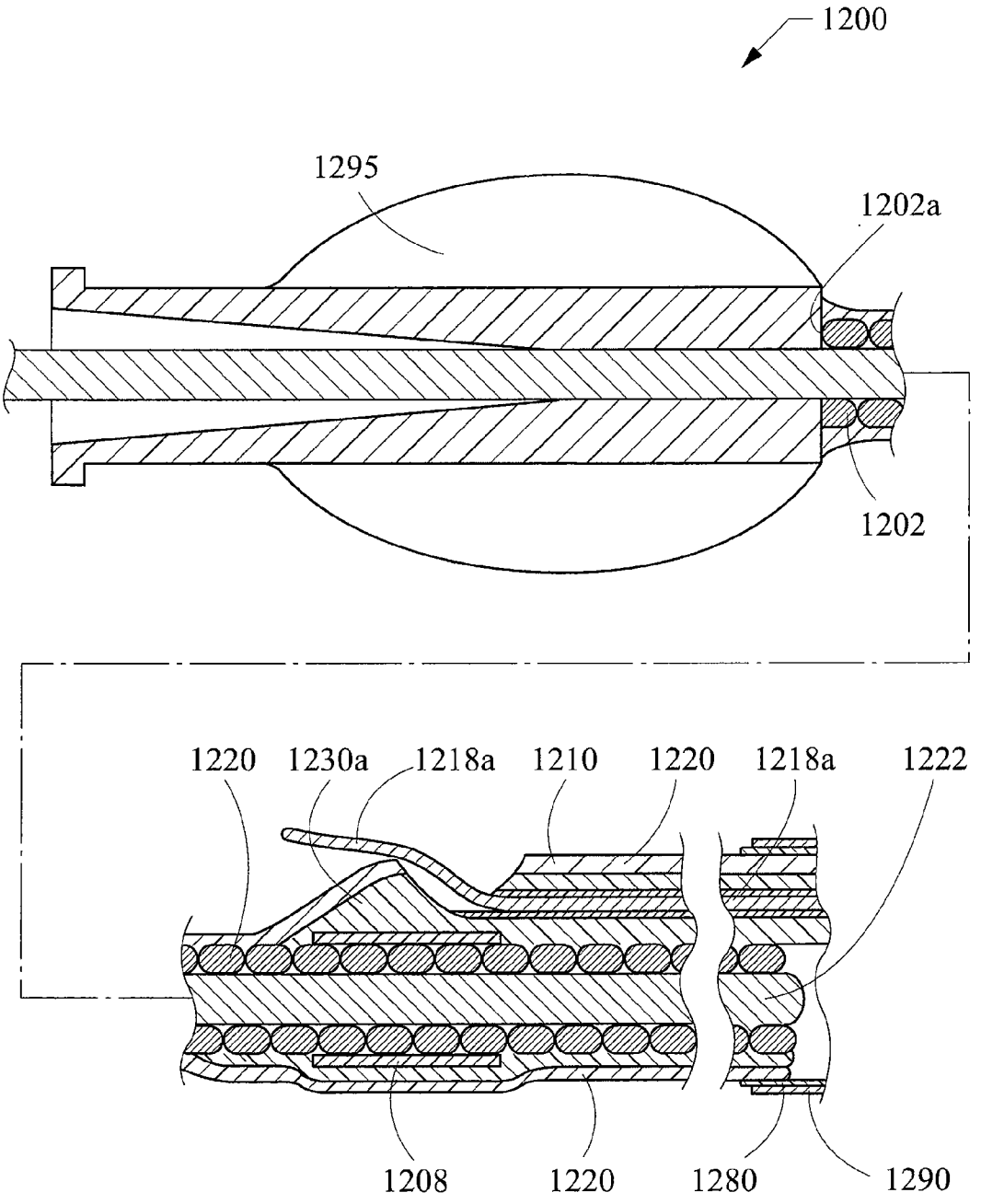
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Fig. 12K

HYPOTUBE CATHETER

TECHNICAL FIELD

[0001] The present application relates to medical catheters, and more specifically to medical catheters useful in endovascular and other body lumens.

BACKGROUND

[0002] Medical delivery catheters are well known in the art of minimally invasive surgery for introduction of fluids and devices to sites inside a patient's body. For example, balloon dilation of luminal stenoses (e.g., in procedures such as angioplasty or balloon dilation of a bile duct), stent placement, and introduction of radio-opaque contrast fluids are common uses of catheters.

[0003] The most widely used form of angioplasty makes use of a dilation catheter having an inflatable balloon at its distal end. In coronary procedures, a hollow guide catheter or wire guide typically is used for guiding the dilation catheter through the vascular system to a position near the stenosis (e.g., to a coronary arterial lumen occluded by plaque). Using fluoroscopy, the physician guides the dilation catheter the remaining distance through the vascular system until a balloon is positioned to cross the stenosis. The balloon is then inflated by supplying pressurized fluid, through an inflation lumen in the catheter, to the balloon. Inflation of the balloon causes a widening of the lumen of the artery to reestablish acceptable blood flow through the artery. In some cases, a stent may be deployed with or instead of the balloon to widen and hold open the occluded arterial lumen.

[0004] Preferably a catheter used in endovascular lumens will have several physical characteristics. The profile and shaft size of the dilation catheter should be such that the catheter can reach and cross a very tight stenosis. Portions of the dilation catheter must also be sufficiently flexible to pass through a tight curvature or tortuous passageway, especially in a catheter adapted for use in the coronary arteries. The ability of a catheter to bend and advance effectively through the endovascular or other lumens is commonly referred to as the "trackability of the catheter." Another important feature of a dilation catheter is its "pushability." Pushability involves the transmission of longitudinal forces along the catheter from its proximal end to its distal end so that a physician can push the catheter through the vascular or other lumenal system and the stenoses. Effective catheters should be both trackable and pushable.

[0005] Two commonly used types of dilation catheters are referred to as "long-wire" catheters and "short-wire" catheters. A long-wire catheter is one in which a wire guide lumen is provided through the length of the catheter that is adapted for use with a wire guide that can first be used to establish the path to and through a stenosis to be dilated. The dilation catheter can then be advanced over the wire guide until the balloon on the catheter is positioned within the stenosis.

[0006] In short-wire catheters, the wire guide lumen may not extend the entire length of the catheter. In this type of catheter, the wire guide lumen may extend only from the distal end of the balloon to a point intermediate the distal and proximal ends of the catheter. This shorter lumen is the only portion of the catheter contacting the wire guide. It is sometimes desirable to exchange this first catheter and/or balloon for a second catheter (e.g., to "exchange out" a balloon catheter, and then "exchange in" a stent-deployment catheter). The exchange is preferably executed by leaving the wire guide in place during removal of the first catheter and using it as a guide for the second catheter. The first catheter is withdrawn or otherwise removed over the wire guide, and then a second catheter is introduced over the wire guide.

[0007] Short-wire catheters are often easier to exchange than catheters having the wire guide lumen extending the entire length of the catheter. This is because the wire guide need not be as long as a "long wire" configuration, which requires that a length of the wire guide extending outside the patient's body be longer than the portion of the catheter extending over the long wire guide in order for a doctor or assistant to maintain a grasp on the wire guide (to avoid undesired movement or displacement thereof). The short wire guide configuration catheters also create less friction during mounting and exchange operations due to the shorter wire guide lumen, leading to a reduced likelihood of displacing the wire guide.

[0008] Catheters for use in endovascular lumens typically require a variation in physical properties along different portions thereof. For example, a certain degree of stiffness is required for pushability and trackability near the proximal end while distal end requires a great deal of flexibility. A catheter having uniform properties throughout its length poses disadvantages in that it is likely to be too proximally flexible or too distally stiff. As a result, most catheter shafts (especially endovascular catheters) are made from multiple materials along the shaft length. For example, a catheter shaft may have a stiff proximal portion made of metal hypotube, a middle portion made of a stiff plastic, and a distal portion made of a more flexible plastic. This combination of materials poses problems of cost and efficiency in construction, and the junctions provide problematic possibilities for structural failure (such as binding, kinking, or even separation) as well as requiring specialized connection means. In another example, a catheter shaft may be made of plastic for a major part of its length, but have a stiffening wire disposed through a significant portion of that length to enhance stiffness. Some long wire catheters rely almost wholly on placement of a wire guide therethrough to retain the needed stiffness, which presents the problems of length and unwieldiness discussed above. In contrast, the proximal sections of short wire catheters must have adequate stiffness independent of the wire guide.

[0009] Several different structures for shortened guide wire lumen dilation catheters have been proposed and used to obtain the desired physical properties described above, but each of these structures tends to suffer from several disadvantages. For example, in a short wire catheter having a relatively flexible one-piece plastic design, because only a small portion of the wire guide extends through the catheter body near the distal end of the catheter shaft, the wire guide portion does not contribute to the pushability of the rest of the catheter shaft. As a result, the proximal shaft portion of such a catheter has low column strength. With such a configuration, the shafts and guide wire may tend to develop undesirable flexure (e.g., scissoring, bowing, buckling, kinking) when the balloon is being manipulated in a lumen. This undesired flexure may cause an irregular exterior surface such as a sharp edge which can in turn cause injurious abrasions to the inner lining of the artery or other lumen (e.g. other body lumen or a working lumen of an endoscope). This undesired flexure also leads to poor pushability and trackability of the catheter. To counteract this deficiency, some known designs have extended the

length of the wire guide lumen and/or provided additional stiffener elements in the shaft.

BRIEF SUMMARY

[0010] In one aspect the present invention provides a catheter device, adaptable for use in endovascular lumens or other body lumens, that has a construction of helically-scored hypotube for a substantial portion of its length and that is adaptable for use in a short-wire or long-wire configuration. The embodiments described and claimed herein provide a catheter shaft having good pushability and trackability. Embodiments of the present invention may be adaptable for a variety of applications (e.g., placement of expandable stents, balloon dilation of stenoses) and use in a variety of surgical locations (e.g., vascular, gastroenterological).

[0011] The embodiments herein may be adaptable for use in a variety of minimally invasive surgical treatments (including, e.g., angioplasty or bile duct dilation).

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. **1**A is a perspective view of a catheter, with an enlarged detail view of the catheter's distal end;

[0013] FIG. **1**B is a perspective view of a tapered catheter device, with an enlarged detail view of the catheter's distal end;

[0014] FIG. **2** is a perspective view of a catheter shaft with a sleeve;

[0015] FIG. **3**A is a perspective view of a catheter device having a distal extension and an inflation balloon, with an enlarged detail view of the features at the catheter's distal end;

[0016] FIG. **3**B is a perspective view of a catheter device with an inflation balloon;

[0017] FIG. **4**A is a perspective view of a catheter device having an external distal wire guide lumen structure, with an enlarged detail view of the features at the catheter's distal end;

[0018] FIG. **4**B is a perspective view of a catheter device having an external distal wire guide lumen structure and an inflation balloon, with an enlarged detail view of the features at the catheter's distal end;

[0019] FIG. **4**C is a perspective view of a catheter device with a distal dual lumen structure having a wire guide lumen structure and a mounting portion;

[0020] FIGS. **5**A-**5**B show a side view of catheter devices having a distal extension and a wire guide lumen structure;

[0021] FIG. **5**C is a side view of a catheter device having an external distal wire guide lumen structure and an inflation balloon;

[0022] FIG. **6** is a side view of a tapered catheter device having an external distal wire guide lumen structure and an inflation balloon;

[0023] FIG. **6**A is a detail of FIG. **6** and shows a longitudinal cross-sectional view of the tapering portion and external wire guide lumen of a catheter device;

[0024] FIG. **6**B is a detail of FIG. **6** and shows a longitudinal cross-sectional view of the distal portion of the catheter device, with an enlarged detail view of features where the catheter shaft meets the balloon;

[0025] FIG. **6**C is a transverse cross-sectional view of a dual-lumen mounting sleeve;

[0026] FIG. **6**D is a transverse cross-sectional view along line **6**D-**6**D of FIG. **6**B showing two lumens of the catheter device surrounded by a mounting sleeve;

[0027] FIGS. **7**A and **7**B illustrate a cross-sectional view of another embodiment of a catheter device;

[0028] FIG. **8** illustrates a partial cross-sectional view of yet another embodiment of a catheter device;

[0029] FIGS. **9**-**9**E depict still another catheter device embodiment, including a wire guide lumen tube; and

[0030] FIGS. **10**-**10**A show yet another catheter device embodiment.

[0031] FIG. **11** is a side view of a catheter device having a distal wire guide lumen structure and an inflation balloon;

[0032] FIGS. **11**A-**11**B are detail views of FIG. **11**;

[0033] FIG. **11**C is a transverse cross-sectional view of a dual-lumen mounting sleeve;

[0034] FIGS. **11**D-**11**F show transverse cross-sectional views of the catheter device of FIG. **11**; and

[0035] FIGS. **12**A-**12**K show one method of making a catheter of the present invention.

DETAILED DESCRIPTION

[0036] In one aspect, presently described embodiments of a tube catheter shaft may be adaptable for use in a variety of minimally invasive surgical applications (e.g. endoscopic procedures, central or peripheral cardiovascular intervention procedures such as, for example, angioplasty).

[0037] FIGS. **1**A-**1**B illustrate an embodiment of a catheter device **100** with a shaft **101** constructed of a helically-cut or helically-scored hypotube (such as, for example, stainless steel or nitinol hypotube), collectively referred to herein as helically-scored hypotube. Helically-scored hypotube is well known in the catheter art. The preferred helically-scored hypotube provides very desirable pushability and trackability with virtually no probability of kinking. The helically-scored hypotube may include interior or exterior coatings.

[0038] In FIG. **1**A, the exterior diameter **107** is approximately the same along the length of the shaft **101**. In the embodiment shown in FIG. **1**B, the proximal end **104** has a greater exterior diameter than the distal end **106**. The catheter shaft **101** tapers toward a smaller exterior diameter **108** at the distal end **106**. Tapering can enhance flexibility of the shaft **101** in several ways. For example, flexibility is enhanced by decreasing the outside diameter of the catheter shaft **101**. The portion of the catheter shaft **101** having a smaller diameter is more flexible than the portion having a larger diameter. Such tapering also decreases the thickness of the wall of the catheter shaft **101**. Alternatively, tapering may be used within the internal diameter of a catheter, enhancing flexibility by decreasing wall thickness without altering the exterior diameter of the shaft **101**. The steepness and location of the tapering is determined by the desired application for the catheter shaft **101**. For example, in alternative embodiments, there may be multiple stepwise or gradual differences in diameter to confer different degrees of flexibility throughout the length of the catheter. For example, catheter shaft **101** for use in coronary arteries will typically benefit from a smaller diameter than a catheter shaft **101** for use in a bile duct, both for gross size and flexibility. A grinding process or other suitable process may be used to reduce the exterior diameter as appropriate for the desired application. Reducing the exterior diameter provides an added benefit by reducing the profile of the device. The flexibility of the catheter shaft **101** or a portion thereof may also be altered by increasing or decreasing the number of filars. In one aspect, the embodiments described herein also provide a catheter shaft having consistent construction material throughout most of the length of the cath-

eter shaft, with gradual transition from a stiffer proximal end to a more flexible distal end and lacking sharp transitions that undermine structural integrity.

[0039] A further embodiment of the catheter shaft **101** includes a coating on internal and/or external surfaces for at least a portion of the catheter shaft **101**. The coating is selected to confer or improve one or more properties of reduced friction, flexibility, and sealing a lumen **102** of the catheter. Sealing the lumen **102** allows the lumen to be used, for example, for introduction of inflation fluid to a dilation balloon or introduction of a medicative substance or radio-opaque contrast fluid.

[0040] The coating may be, for example, a sheath or sleeve **202** as illustrated in FIG. **2**. In various alternative embodiments, the sheath **202** may comprise an extruded sleeve, shrink tube, extruded over-jacket, or dip coat. The sheath **202** is preferably a thermoset material or a thermoplastic material and may comprise, for example, HDPE, PTFE, PET, polyester or polyether block amide (PEBA), polyurethane, polyimide, polyolefin, nylon, or any combination thereof. The coating may be applied by, for example, over-extrusion, dip-coating, melt fusion, or heat shrinking. For example, PET shrink tube **202** has the advantage of providing an increased stiffness to a small diameter catheter shaft **201**. On the other hand, a PEBA shrink tube **202** can be used with a larger diameter catheter shaft **201** where greater flexibility is desired. The type of sleeve **202** material may also be selected to complement other catheter components; for example, a nylon sleeve **202** may bond and interact better with a nylon expandable member such as a balloon or basket and/or a nylon wire guide lumen. Selection of coating materials, filar size and number, and diameter allow manipulation of the catheter shaft's **201** shore hardness to offer the desired functional properties.

[0041] FIGS. **3**A-**3**B illustrate embodiments of balloon catheters **300** comprising a helically-scored hypotube **301**. In the embodiment of FIG. **3**A, the catheter shaft **301** has a distal extension **302**, upon which is mounted an inflation balloon **304**. The distal extension **302** can be formed of the same group of materials used in the coating (HDPE, PTFE, PEBA, PET, polyurethane, polyimide, polyolefin, nylon, or any combination thereof) and provides a shaft portion that may be more flexible than the shaft **301**. As can clearly be seen in the detail illustration portion of FIG. **3**A, the extension **302** encloses an inflation lumen **306** which continues from an inflation lumen **306** of the catheter shaft **301**. The extension **302** also encloses a wire guide lumen **308**. In the illustrated long wire configuration catheter **300**, the wire guide lumen extends from the proximal end of the catheter shaft **301** and extends through the inflation balloon **304** at the distal end.

[0042] The embodiment illustrated in FIG. **3**B has an inflation balloon **304** disposed directly on the distal end of the catheter shaft **301**. An inflation lumen **306** of the catheter shaft **301** opens into the inflation balloon **304**. A wire guide lumen **308** traverses the interior of the balloon **304**, continuing the wire guide lumen **308** of the catheter shaft **301** to a point distal of the inflation balloon **304**. As illustrated an expandable stent **312** may be positioned about the balloon **304**. In an alternative embodiment, an expandable member other than a balloon (e.g., a basket) may be disposed near the distal end of the catheter shaft **301**. Such an embodiment optionally may have a wire guide through the expandable member. At its proximal end the catheter **300** has a port **310** in fluid communication with the inflation lumen **306**. In an alternative embodiment, the port **310** offers access to the guide wire lumen **308**. The port **310** may be included in other embodiments, and in other positions on the catheter **300**. In another alternative embodiment, the catheter shaft **301** has two ports **310**, offering separate access to each of the inflation lumen **306** and the wire guide lumen **308**. In other alternative embodiments, the port **310** may be useful for introducing another fluid such as a contrast fluid.

[0043] FIGS. **4**A-**4**B illustrate embodiments of a helically-scored hypotube balloon catheter device **400** comprising a catheter shaft **401** and further comprising an external, distally disposed short wire guide lumen structure in the form of a cannula **402** having a wire guide lumen **404** disposed therethrough. In FIG. **4**A, the cannula **402** is attached on the distal end **408** of the catheter shaft **401** using an adhesive. Alternative means of attachment include, for example, forced convection heating, radio frequency heating, ultrasonic welding, and laser bonding. Alternatively, shrink tubing may be used as a manufacturing aid to help compress and fuse the cannula **402** to the catheter shaft **401**. The shrink tubing may be removed and disposed of after the cannula **402** is connected to the catheter shaft **401**, or may remain on as part of the connected structure. If the catheter shaft **401** has a coating, the cannula **402** may be bonded to the coating or directly to the catheter shaft **401**. A heat shrink tubing, for example PEBA, may be applied over the entire assembly, which increases the strength of the assembly. In the embodiment shown in FIG. **4**B, the cannula **402** is constructed of helically-scored hypotube. An inflation balloon **406** is mounted on the distal end **408** of the catheter shaft **401**. An inflation lumen **405** of the catheter shaft **401** is open to the interior of the inflation balloon **406**. The cannula **402** extends through the inflation balloon **406** and has an extension **407** on its distal end. A wire guide lumen **404** runs through the length of the cannula **402** and its extension **407**. Although not shown, it should be appreciated that an expandable stent can be disposed about the balloon **406**. The cannula **402** providing a wire guide lumen structure can be formed of HDPE, PTFE, PEBA, PET, polyurethane, polyimide, polyolefin, nylon, or any combination thereof. In one embodiment, the cannula **402** comprises a PTFE inner liner and a PEBA outer cover. Other materials may be used as an inner liner such as, for example, HDPE, PET, and polyimide.

[0044] In FIG. **4**C, a dual lumen structure **410** is disposed on the distal end **408** of the catheter shaft **401**. A portion of the length of dual lumen structure **410** has a "FIG. **8**" cross section. A mounting portion **412** of the dual lumen structure **410** has a lumen **414**. The distal end **408** of the catheter shaft **401** fits into the lumen **414**. The lumen **414** may be completely occupied by the distal end **408** of the catheter shaft **401**, or may continue coaxially beyond the distal end **408** so as to form an extension. If the mounting portion **412** is placed as an extension, the lumen **414** is in fluid communication with a lumen **420** of the shaft **401**. A wire guide portion **416** of the dual lumen structure **410** has a wire guide lumen **418** running therethrough. The dual lumen structure **410** is attached on the distal end **408** of the catheter shaft **401** using one of the attachment methods described for the embodiment shown in FIG. **4**A. In this embodiment, the lumen **414** of the dual lumen structure is in fluid communication with a lumen **405** of the catheter shaft **401**. In an alternative embodiment, a part of the mounting portion **412** is mounted inside the lumen **420** of the catheter shaft **401**.

[0045] FIGS. **5**A-**5**C illustrate embodiments of a balloon catheter **500** incorporating a helically-scored hypotube shaft **501** and having a short wire guide configuration. The embodiments shown in FIGS. **5**A-**5**B each have a coaxial extension **502** of the shaft **501**, a short wire guide lumen structure in the form of a tube **504**, and an inflation balloon **506**. The coaxial extension **502** may have the same or a different flexibility than the shaft **501**. In the embodiment illustrated in FIG. **5**A, the proximal end **508** of the tube **504** is disposed distal of the juncture of the extension **502** with the shaft **501**. The tube **504** enters the extension **502** and extends through the distal end of the balloon **506**. Thus, this embodiment comprises a distal extension of the shaft (in this case the coaxial extension **502**) and the wire guide lumen structure **504**, a portion of the wire guide lumen structure **504** being coaxial within the distal extension, another portion of the wire guide lumen structure **504** being outside the distal extension adjacent thereto.

[0046] In the embodiment illustrated in FIG. **5**B, the proximal end **508** of the tube **504** is disposed proximal of the juncture of the extension **502** with the shaft **501**. The tube **504** enters the extension **502** and proceeds through the distal end of the balloon **506**. Thus, this embodiment comprises a distal extension of the shaft (in this case the coaxial extension **502**) and the wire guide lumen structure **504**, a portion of the wire guide lumen structure being coaxial within the distal extension, another portion of the wire guide lumen structure **504** being outside the shaft adjacent thereto. The embodiment illustrated in FIG. **5**C does not have an extension. The balloon **506** is disposed on the distal end of the shaft **501**. The proximal end **508** of the tube **504** is disposed proximal of the juncture of the extension **502** with the shaft **501** and is affixed to the exterior of the shaft **501**. The tube **504** passes through the middle of the balloon **506** and proceeds through the distal end of the balloon **506**. In each of the embodiments shown in FIGS. **5**A-**5**C, the placement of the proximal end **508** of the tube **504** along the shaft **501** affects the flexibility of the shaft **501**. Therefore, variation in the placement is useful in increasing or reducing flexibility as desired in other embodiments.

[0047] FIG. **6** illustrates one embodiment of a balloon catheter **600** having an elongate shaft **601** comprising a helically-scored hypotube. An inflation balloon **602** is disposed near the distal end. FIG. **6**A is an enlarged detail illustration of a middle section of the catheter **600**. As can be clearly seen in FIG. **6**A, the shaft **601** includes an external wire guide lumen **604** and an internal inflation lumen **606**. As shown in FIG. **6**A, this embodiment the catheter shaft **601** is coated with a PEBA coating **603**. The coating **603** serves to reduce friction during introduction of the catheter shaft **601** and provides a seal to prevent leakage of inflation fluid from the inflation lumen **606** through the walls of the shaft **601**. As can also be seen in FIG. **6**A, the catheter shaft **601** tapers distally to a smaller diameter along the region **605**.

[0048] FIG. **6**B is an enlarged detail illustration of a distal section of the balloon catheter **600**. As shown in FIG. **6**B, the inflation lumen **606** opens into the inflation balloon **602**, and the wire guide lumen **604** extends through the balloon **602** to the distal end **607**. FIG. **6**B includes an enlarged detail portion more clearly illustrating the relationship between the balloon **602** and the two lumens (**604** and **606**). In this embodiment, the balloon **602** and wire guide lumen **604** are mounted to the shaft **601** with a PEBA shrink sleeve **608**. As shown in FIG. **6**C, a cross-sectional view of the sleeve **608** has approximately a figure-eight shape before mounting. The sleeve **608** has two central apertures (**610** and **612**) to allow mounting the sleeve **608** over the wire guide lumen **604** and the shaft. In this embodiment, after the balloon **602** and wire guide **604** are assembled to the shaft **601** together with the sleeve **608**, the sleeve **608** is heated to shrink and form to the assembly of shaft **601**, balloon **602**, and wire guide **604**. FIG. **6**D is a transverse cross section along line **6**D-**6**D of FIG. **6**B, and shows the finished configuration. The sleeve **608** forms to the shaft **601** and leaves open the inflation lumen **606** and the wire guide lumen **604**.

[0049] Cross-lumen communication may be prevented. For example, the walls of the helically-scored hypotube of the elongate shaft **601** may be porous, and pressure exerted on an inflation fluid in the inflation lumen **606** may urge inflation fluid into the wire guide lumen **604**. According to one aspect, this may be prevented by lining the wire guide lumen **604** with a liner such as, for example, PTFE, although other materials may be used. Furthermore, an inner coating segment may be placed over the elongate shaft **601** beneath the proximal breach or side opening of the wire guide lumen **604**. The inner coating segment may be, for example, PEBA. The inner coating segment may be implemented to alter flexibility in the area of the segment, for example to avoid abrupt changes in flexibility. In one embodiment, the proximal end of the segment terminates at about halfway through the taper and the distal end of the segment terminates just distal of the proximal breach or side opening of the wire guide lumen **604**. According to another aspect, cross-lumen communication may be prevented by placing the coating **603** over essentially the entire length of the elongate shaft **601**, and the sleeve **608** may subsequently be placed over the coating **603** and elongate shaft **601**. According to yet another aspect, cross-lumen communication may be prevented by simply making the walls of the sleeve **608** thicker. A 0.001 inch (0.025 mm) wall thickness of the coating **603** or sleeve **608**, for example, may be sufficient. As mentioned previously, the coating **603** and sleeve **608** may be PEBA or another suitable material. These principles may be implemented in other embodiments of the invention as may be desirable due to fluid being passed through or injected into one of the lumens.

[0050] FIGS. **7**A-**7**B illustrate a cross-sectional view of a portion of a catheter device **700** according to one aspect of the present invention. A shaft wall comprising multiple filars **702** includes an inner coating **701** and an outer coating **703**, and surrounds a first lumen **704** and a second lumen **706**. A wire guide **708** extends through the first lumen **702**, and a stent-deployment shaft **710** extends through the second lumen **706**. As shown in FIG. **7**A, the catheter device **700** includes a distal extension **712** that houses a self-expandable stent **714**. FIG. **7**B illustrates the stent **714** having been pushed out of the second lumen **706** by the stent-deployment shaft **710** such that the stent **714** is deployed. Prior to deployment of the stent **714**, the wire guide **708** is typically retracted into the shaft wall or lumen **704** so as not to interfere with deployment of the stent **714**.

[0051] FIG. **8** illustrates a partial cross-sectional view of another embodiment of a catheter device **800**, including a self-expanding stent **810**. The catheter device **800** has a central lumen **802** surrounded by a first, outer tubular helically-scored hypotube body **804**. A second, inner helically-scored hypotube is coaxially disposed in the central lumen **802** for use as a pusher **806**. The pusher **806** has a protruding engagement surface **808** for pushing the self-expanding stent **810** out of the central lumen **802** or for holding the stent **810** as the outer tubular body **804** is being pulled in a proximal direction.

A tapered tip **12** is mounted on the distal end of the pusher **806**, and provides a minimally traumatic leading surface for the catheter device **800**. A wire guide **814** extends through a central wire guide lumen **816** of the pusher **806**. Optionally, apertures (not shown) may be provided through the side of the outer tubular body **804** and the pusher **806** to permit the wire guide **814** to exit the central lumen **802** and the wire guide lumen **816** at an intermediate location. The self-expanding stent **810** is adapted to be deployed when a user retracts the outer tubular body **804** proximally while holding the pusher **806** substantially in place. The protruding engagement surface **808** of the pusher **806** holds the self-expanding stent **810** substantially in place while the outer tubular body **804** is withdrawn from around it. Once the stent **810** is deployed, the pusher **806** and wire guide **814** are withdrawn, leaving the stent **810** in the position where it was deployed.

[0052] FIGS. **9-9**E illustrate one embodiment of a balloon catheter device **900** having an elongate helically-scored hypotube shaft **901** and being configured for use in a short-wire application using a wire guide. An inflation balloon **902** is disposed near the distal end of the device **900** and is sealed thereto. FIG. **9**A is an enlarged detail illustration of an intermediate section of the catheter **900**. As shown in FIGS. **9** and **9**A, the catheter **900** includes an internal shaft lumen **906** and an external wire guide lumen **904***a* that is housed by a wire guide tube **904**. As shown in FIG. **9**A, the shaft **901** may be coated with a PEBA or other coating **903**. In one aspect, the coating **903** may help to reduce friction during introduction of the catheter shaft **901** and provide a seal that prevents leakage of inflation fluid from the shaft lumen **906** through the wall of the shaft **901**. Those of skill in the art will appreciate that a coating **903** may be disposed on the exterior of the shaft **901**, or it may be disposed as a lining/coating on the interior/lumenal surface of the shaft lumen **906**, or both. As is also depicted in FIG. **9**A, the catheter shaft **901** tapers distally to a smaller diameter along a narrowing transitional region **905**, which provides for a distal shaft portion that is more flexible than the proximal shaft portion. An increased distal flexibility may allow the catheter device **900** to be more readily navigated through tortuous passages.

[0053] FIG. **9**B is an enlarged detail illustration of a distal section of the balloon catheter **900**. As shown in FIG. **9**B, both the shaft **901** and the wire guide lumen tube **904** extend through the balloon **902** to the distal end **907**. The distal end of the shaft **901** may be provided with a sealing tip **909**, which preferably has an atraumatic distal profile. FIG. **9**C shows an enlarged detail portion of FIG. **9**B to illustrate the relationship between the balloon **902** and the wire guide and shaft lumens (**904***a* and **906**). The portion of the shaft **901** inside the balloon **902** does not include the coating **903**, and the filars forming the wall of the shaft **901** do not form a fluid-tight barrier. As a result, and as indicated by arrows **919**, the shaft lumen **906** may be used effectively as an inflation lumen because inflation fluid introduced therethrough can pass through an intralumenal portion the wall of the shaft **901** (inside the lumen of the balloon **902**) to inflate the balloon **902**. However, the wire guide lumen tube **904** most preferably is configured not to allow fluid communication from the shaft lumen **906** or the lumen of the balloon **902**. Specifically, the wire guide lumen tube **904** is configured such that inflation fluid passing through the wall of the shaft **901** into the lumen of the balloon **902** will not escape through the wire guide lumen **904***a*. As is also shown in this embodiment, the shaft **901** extending through the length of the balloon **902** may provide longitudinal support for the balloon **902**.

[0054] As is also shown in this embodiment, the balloon **902** and wire guide lumen tube **904** may be mounted to the shaft **901** with a shrink sleeve **908**. As shown in FIG. **9**D, the sleeve **908** has approximately a figure-eight shape before mounting. The sleeve **908** includes two central apertures (**910** and **912**) to allow for mounting the sleeve **908** over the wire guide lumen tube **904** and the shaft **901**. In this embodiment, after the balloon **902** and wire guide tube **904** are assembled to the shaft **901** together with the sleeve **908**, the sleeve **908** may be heated to shrink and form to the assembly of the shaft **901**, balloon **902**, and wire guide tube **904**. FIG. **9**E is a transverse cross section view along line **9**E-**9**E of FIG. **9**C that shows the finished configuration. The sleeve **908** forms to the exterior surface of the shaft **901** and leaves open the shaft lumen **906** and the wire guide lumen **904***a*. As is shown in FIG. **9**A, the sleeve **908** may extend over and proximally beyond the wire guide tube **904**. Accordingly, a wire guide aperture **914** may be skived out or otherwise created to provide access to the wire guide lumen **904***a*. Those of skill in the art will appreciate that, in lieu of using a sleeve, the coating **903** may be extended to contact the wire guide tube **904** and/or the balloon **902** to provide a seal of the coating **903** with the wire guide tube **904** and/or the balloon **902**, or that other means for securing the wire guide tube **904** and balloon **902** to the shaft **901** may be used within the scope of the present invention.

[0055] FIGS. **10-10**A illustrate an embodiment of a balloon catheter device **1000** having an elongate helically-scored hypotube shaft **1001** and being configured for use without a wire guide. In one aspect, the embodiment of FIG. **10** may be configured such that it may be manipulated during navigation in the same manner as a wire guide. An inflation balloon **1002** is disposed near the distal end of the device **1000** and is sealed thereto in a manner that forms a continuously sealed length of the shaft lumen **1006** proximal of the balloon **1002** in cooperation with an internal shaft lumen coating **1003**. In one aspect, the coating **1003** may help to provide a seal that prevents leakage of inflation fluid from the shaft lumen **1006** through the wall of the shaft **1001**. The catheter shaft **1001** may include a tapering diameter that is smaller distally than proximally and provides for a distal shaft portion that is more flexible than the proximal shaft portion while maintaining desirable pushability and trackability.

[0056] FIG. **10**A is an enlarged detail illustration of a distal section of the balloon catheter **1000**. As shown in FIG. **10**A, the shaft **1001** extends through the balloon **1002** to the distal end **1007**. The shaft can thus extend over the entire length of the catheter avoiding—particularly around the balloon location—any disjuncture that might promote kinking. The distal end of the shaft **1001** may be provided with a sealing tip **1009**, which preferably has an atraumatic distal profile. The coating **1003** substantially covers the surface of the shaft lumen **1006** through the proximal length of the shaft **1001** and terminates near the proximal end of the balloon **1002** such that an intralumenal portion of the shaft **1001** (inside the interior space of the balloon, at least part of which forms a lumen of the balloon **1002**) does not include the coating **1003**, and the filars forming at least that portion of the wall of the shaft **1001** do not form a fluid-tight barrier. As a result, and as indicated by arrows **1019**, the shaft lumen **1006** may be used effectively as an inflation lumen because inflation fluid introduced therethrough can pass through the wall of the shaft **1001** to inflate

the balloon **1002**. Those of skill in the art will appreciate that a coating may be used on the shaft exterior in addition to or instead of the lumenal shaft coating **1003**, and that, if a coatings are present on both the interior and exterior shaft surfaces, each coating may include the same or different materials as the other coating. Also, it is not necessary for the entire length of the distal portion within the balloon to be uncoated; provided that there is sufficient leakage of inflation fluid through this distal portion of the tube to permit inflation of the balloon. In this embodiment, the shaft **1001** also provides longitudinal support for the balloon **1002**. It will be seen that the shaft extends through the entire longitudinal extent of the balloon. The shaft portion disposed within the balloon **1002** may include a pair of radio-opaque markers **1017** configured to allow a user to fluoroscopically visualize the position of the balloon **1002**. Suitable radio-opaque markers may include swaged metal (such as, for example, stainless steel, platinum, gold) or an polymer infused with barium or another radio-opaque material.

[0057] In one preferred embodiment, a balloon catheter device such as the balloon catheter **1000** lacking an external wire guide structure may be constructed such that it may function similar to a wire guide. Specifically, the catheter **1000** may be configured such that it has a small outer diameter, is sufficiently flexible to pass through a tight curvature or tortuous passageway, and has pushability and trackability sufficient to be navigated through such tightly curved and/or tortuous pathways in the same manner as a wire guide, thereby obviating the need for a separate wire guide. Those of skill in the art will appreciate that a preferred outer diameter will be different for different applications, but the outer diameter a catheter embodiment configured for use in peripheral blood vessels may be in the range of about 0.040-0.055 inches, and that the outer diameter may differ along the length of the catheter embodiment.

[0058] In some embodiments, the shaft coating (if any) may be a material other than PEBA, and may include the same material or different material than the material in a mounting sleeve used to mount a balloon (for example, HDPE, PTFE, PET, polyurethane, polyimide, polyolefin, nylon, or any combination thereof). The balloon catheters of the present invention may be adaptable for use with expandable stents as is illustrated, for example, in FIG. **3**B. In the embodiments described above, a flexible stylet (not shown) may be inserted through the inflation lumen for use during advancement/navigation of the catheter device to a desired location. Such a stylet may be used to increase stiffness and pushability in a circumstance where that is desirable (such as, for example, if the catheter is being used to cannulate a lesion). Use of a stylet that is shaped (such as, for example, with a curve of up to about 70°) may also allow a user to reshape the distal end of the catheter shaft in a manner that may, for example, allow easier indication and navigation of branch vessels. A preferred stylet will not extend beyond the distal end of the catheter device.

[0059] Another balloon catheter device embodiment **1100** is shown with reference to FIGS. **11**-**11**G. The catheter device **1100** includes an elongate shaft **1107** including a helically cut hypotube **1120**. An inflation balloon **1103** is disposed near the distal end of the device. A hub **1140** is disposed adjacent the proximal end of the device. FIG. **11**A is an enlarged detail illustration of a distal-middle portion of the device **1100**, showing a magnified longitudinal section view that includes a proximal portion of a wire guide lumen structure **1170** configured for use of the device in a short wire guide configuration. The wire guide lumen structure **1170** includes a wire guide lumen **1172** that extends substantially parallel with an inflation lumen **1101** of the shaft **1107**.

[0060] In the illustrated embodiment, substantially the entire length of the shaft **1107** may include an outer layer **1150** as a coating. A preferred coating is a thermoplastic polymer such as, for example, a polyester or polyether block amide (e.g., PEBAX®). A preferred coating will provide a desirable lubricity profile that exhibits low friction during introduction of the device through, for example, a blood vessel. A preferred coating will also provide a fluid-tight seal configured to prevent leakage of pressurized inflation fluid (for example, at pressures in a normal operating range up to about 8-14 atm, and preferably configured to prevent leakage at pressures exceeding normal ranges, for example, up to or exceeding about 27 atm).

[0061] A preferred catheter shaft **1107** tapers from a greater proximal outer diameter (such as, for example, about 0.048 to about 0.052 inches) to a lesser distal diameter (such as, for example, about 0.044 to about 0.040 inches). Those of skill in the art will appreciate that the lesser distal diameter may present improved trackability for navigation of tortuous passages.

[0062] As is shown in FIGS. **11**B and **11**C (which is an enlarged detail view of FIG. **11**B), the inflation lumen **1101** of the catheter device **1100** is open to and provides fluid communication with the balloon lumen **1103***a* of the balloon **1103**. A distal portion **1170***a* of the wire guide lumen structure **1170** including the wire guide lumen **1172** also extends through the balloon lumen **1103***a* and through the distal end of the balloon **1103** to a distal tip **1104**. The distal end portion **1170***a* of the wire guide lumen structure **1170** preferably is very flexible (high trackability), and it may provide an advantage in directing the device **1100** along a wire guide (not shown) through particularly tortuous passages. FIG. **11**B also shows the attachment of the balloon **1103** to the device **1100**. Those of skill in the art will appreciate that, in another embodiment within the scope of the present invention, the balloon **1103** may be attached to the tube **1120** and configured such that the distal wire guide lumen structure portion **1170***a* extends exterior (of the balloon lumen **1103***a*) and adjacent the balloon **1103**.

[0063] FIG. **11**D shows a transverse cross-section of a dual-lumen thermoset sleeve **1105**, which has a generally figure-8 cross-section and includes an upper lumen **1105***a* and a lower lumen **1105***b*. The sleeve **1105** preferably is constructed of a thermoplastic binder material such as, for example, a polyolefin, polyester or polyether block amide (PEBA), or other appropriate polymeric material having thermoplastic materials suitable for helping to form the wire guide lumen structure **1170** and to attach it to the tube **1120**. As depicted in FIGS. **11**E-**11**F (each of which represents a transverse cross-sectional view along line **11**E-**11**E of FIG. **11**A), the upper lumen **1105***a* of the sleeve **1105** defines the wire guide lumen **1172**. The wire guide lumen **1172** may include a wire guide lumen liner **1172***a*, which preferably is made of a lubricious polymer that can form a thin wall with high strength such as, for example, PTFE, polyethylene, polyimide, or a similar material. In one aspect, the liner **1172***a* may help prevent fluid from leaking from the inflation lumen **1101** through pores of the tube **1120** into the wire guide lumen **1172**. Preventing inflation fluid from leaking out of the inflation lumen is preferable for at least the reason that a substantially patent fluid lumen is

required to allow passage of inflation fluid at a pressure and rate desired for proper inflation and deflation of the balloon. In another aspect, the portion of the sleeve **1105** between the sleeve lumens **1105***a* and **1105***b* may be provided with a desired thickness such as, for example, about 0.001 inches to minimize the likelihood of cross-lumen communication between the inflation lumen **1101** and wire guide lumen **1172**.

[0064] The lower lumen **1105***b* surrounds the tube **1120**. The outer layer coating **1150** of the device may extend over and surround the exterior of the sleeve **1105**. As shown in FIGS. **11**E-**11**F, the thermoset sleeve **1105** has been heated to conform around the wire guide lumen **1172** and tube **1120**. FIG. **11**E shows the sleeve **1105** as having been formed with a round cross-section, and FIG. **11**F shows the sleeve **1105** as having been formed with an out-of-round cross-section. The latter configuration is preferred when the device **1100** is to be used in conjunction with a guide sleeve (not shown) through which contrast fluid may be injected, because the out-of-round profile will more readily permit contrast fluid to flow through a circular-cross-section guide sheath lumen and around the sleeve **1105**. However, it is preferable that the cross-sectional height not be greatly different than the cross-sectional width.

[0065] A wire guide aperture **1109** is described with reference to FIGS. **11**A and **11**G (which is a transverse cross-sectional view of FIG. **11**A along line **11**G-**11**G). In order to facilitate use of the catheter device **1100** in a short wire configuration, a wire guide aperture **1109** is provided near the proximal end of the wire guide lumen structure **1170**. The wire guide aperture **1109** may be formed by skiving an opening through the outer layer **1150**, upper surface of sleeve **1105**, and (if present) wire guide lumen liner **1172***a*. This aperture **1109** will, for example, allow a wire guide (not shown) directed from the distal end **1104** through the wire guide lumen **1172** to exit. As described above, mounting the device **1100** onto a wire guide in this manner may facilitate rapid introduction and/or exchange of the device **1100** along the wire guide. In order to provide additional protection against cross-lumen leakage in the aperture region, an additional barrier **1105***c* may be provided around the circumference of the shaft **1107** along a shaft region adjacent the aperture **1109**. The barrier **1105***c* preferably will be formed of a high-strength polymer that preferably is impermeable to inflation fluid such as, for example, a polyether block amide or similar material.

Example 1

[0066] An exemplary method of making a wire-guided balloon catheter **1200** is described with reference to FIGS. **12**A-**12**K. Those of skill will appreciate that this and other embodiments may be constructed using alternative methods within the scope of the present invention. As shown in FIG. **12**A, a tubular shaft **1202** is provided, including a monolayer tubular shaft of ten filars coiled together to form a shaft wall **1204** defining a shaft lumen **1206**. The shaft **1202** includes a proximal end **1202***a* and a distal end **1202***b*, and it has desirable pushability and trackability characteristics, with a structure that tapers from a proximal outer diameter of about 0.05 inches to a distal diameter of about 0.04 inches. (NOTE: FIGS. **12**A-**12**K, along with all other figures of the present application, may not be drawn to scale). Next, as shown in FIG. **12**B, a PEBA barrier sleeve **1208** is placed around a distal region of the shaft wall **1204** and heated to sealingly shrink around it (**1204**).

[0067] Then, as depicted in FIG. **12**C, an elongate dual-lumen sleeve **1210** is provided. The dual-lumen sleeve **1210** includes a lower lumen **1212** and an upper (wire guide) lumen **1214**. An upper lumen portion **1214***a* of the sleeve **1210** extends distally beyond a lower lumen portion **1212***a* of the sleeve **1210**. FIG. **12**C shows the dual-lumen sleeve **1210** as having been mounted onto the shaft wall **1204** of the shaft **1202** by sliding a distal portion of the shaft **1202** into the lower lumen **1212** until the distal shaft end **1202***b* is near the distal end of the lower lumen portion **1212***a*.

[0068] FIG. **12**D shows a PTFE wire guide lumen liner **1218** provided on a first mandrel **1218***a*. The liner **1218** will be directed into the upper (wire guide) lumen **1214** until its (**1218**) proximal end is adjacent the proximal end of the upper (wire guide) lumen **1214**. Next, as shown in FIG. **12**E, a tubular PEBA thermoplastic sheath **1220** is directed over the entire length of the shaft **1202** such that it also encircles that portion of the dual-lumen sleeve **1210** around the distal region of the shaft **1202**. Then, as illustrated in FIG. **12**F, after the assembly is heated, the sheath **1220** shrinks around the shaft length to form a sealing coating **1220** along the length of the shaft **1202** and fusing the dual lumen sleeve **1210** to the shaft wall **1204** and the liner **1218**. During the heat-shrink step, a second mandrel **1222** is provided through the shaft lumen **1206** to prevent it from becoming occluded by any coating material that may seep through the shaft wall.

[0069] Next, as depicted in FIG. **12**G, a wire guide aperture **1230** is skived near the proximal end of the upper (wire guide) lumen **1214** by cutting or otherwise incising through the sheath **1220**, the sleeve **1210**, and the liner **1218**. FIG. **12**H shows that the first mandrel **1218***a* (or a different mandrel, not shown) is directed through the wire guide aperture **1230** in a manner that compresses a portion of the dual lumen sleeve **1210** immediately proximal of the wire guide aperture **1230**. The compressed region is heated and, as shown in FIG. **12**J, substantially fuses to form a proximal ramped surface **1230***a* as a proximal portion of the wire guide aperture **1230**.

[0070] As illustrated in FIG. **12**I, the proximal end of a balloon **1280** is attached (preferably by a heat seal or equivalent means) to the assembly adjacent the distal shaft end **1202***b* such that the upper lumen portion **1214***a* of the sleeve **1210** extends through the lumen **1282** and distal end of the balloon **1280**. The distal end of the balloon **1280** is sealed (also preferably by a heat seal or equivalent means) to the upper lumen portion **1214***a* of the sleeve **1210**, which houses the wire guide lumen **1214**. The PTFE wire guide liner **1218** does not need to extend completely to the distal end of the upper lumen portion **1214***a* of the dual-lumen sleeve **1210**. The balloon **1280** can be compressed and folded, and—if desired—a stent **1290** mounted thereto as shown in FIG. **12**J. And, as shown in FIG. **12**K, a hub **1295** may be mounted to the proximal shaft end **1202***a*. In another embodiment of this method, the longitudinal shape of that upper lumen portion that is distal of the shaft may be modified to align generally with a longitudinal axis of that shaft or of the combined shaft and outer sleeve **1210** in a manner similar to that shown in FIG. **5**C.

[0071] Those of skill in the art will appreciate that other embodiments and variants of the structures and methods described above may be practiced within the scope of the present invention. It will also be recognized that features described in particular combinations may be also be useful in combinations of features other than those specifically described or referred to. It is therefore intended that the fore-

going detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, that are intended to define the scope of this invention.

1. A medical balloon catheter, comprising:
an elongate helically-scored hypotube comprising a longitudinal tube lumen therethrough, a coated proximal portion, and an uncoated distal portion;
an inflatable balloon disposed about the uncoated distal portion such that a lumen of the balloon substantially comprises the uncoated distal portion;
wherein the tube is configured such that the coated proximal portion provides a substantially patent path of fluid communication with the uncoated distal portion and the uncoated distal portion permits fluid communication between the tube lumen and the balloon lumen.

2. The medical balloon catheter of claim **1**, wherein the coated proximal portion comprises a coating on an exterior surface of the tube.

3. The medical balloon catheter of claim **1**, wherein the coated proximal portion comprises a first coating on a surface of the tube lumen and a second coating on an exterior surface of the tube.

4. The medical catheter of claim **3**, wherein the first coating comprises a material different that the second coating.

5. The medical balloon catheter of claim **4**, further comprising a wire guide tube,
wherein the wire guide tube is connected to the hypotube and extends substantially longitudinally parallel with the hypotube from a location proximal of the balloon to a location near the distal end of the balloon; and
wherein the wire guide tube comprises a wire guide lumen.

6. The medical balloon catheter of claim **4**, further comprising a sleeve connecting the wire guide tube to the hypotube.

7. The medical balloon catheter of claim **1**, further comprising a balloon-deployable stent configured to be deployed from the balloon.

8. A catheter device, comprising:
an elongate helically-scored hypotube shaft comprising a shaft lumen extending longitudinally therethrough;
a balloon disposed upon a distal end portion of the shaft such that a intralumenal shaft portion is disposed substantially longitudinally through an interior space of the balloon; and
a coating disposed upon at least one of an exterior shaft surface portion and an interior shaft lumen surface portion,
wherein the coated surface portion provides a fluid-tight seal of the shaft, and
wherein the coating does not extend substantially onto the intralumenal shaft portion so as to permit fluid communication between the shaft lumen and the interior space of the balloon.

9. A medical balloon catheter device configured for use with a wire guide, the catheter comprising:
an elongate helically-scored hypotube, said tube comprising a proximal tube end, a distal tube end, and a longitudinal tube lumen extending therebetween;
a wire guide lumen structure disposed adjacent the distal tube end and extending distally beyond the distal tube end, said structure comprising a wire guide lumen;
an inflatable balloon disposed adjacent the wire guide lumen structure and attached near the distal tube end such that a lumen of the balloon is in fluid communication with the tube lumen;
wherein the tube is configured such that a coated proximal tube portion provides a substantially patent path of fluid communication between the proximal tube end and the balloon lumen.

10. The catheter device of claim **9**, wherein the wire guide lumen structure extends through a portion of the balloon lumen.

11. The catheter device of claim **9**, wherein a coating of the coated proximal tube portion comprises a material selected from HDPE, PTFE, PET, polyester block amide, polyether block amide, polyurethane, polyimide, polyolefin, nylon, and any combination thereof.

12. The catheter device of claim **11**, further comprising means for preventing fluid communication between the tube lumen and the wire guide lumen.

13. The catheter device of claim **12**, wherein the means for preventing fluid communication comprises a polymer sheath disposed around a distal portion of the tube.

14. The catheter device of claim **12**, wherein the means for preventing fluid communication comprises a dual-lumen sleeve, a part of which is disposed around a distal portion of the tube.

15. The catheter device of claim **9**, wherein the wire guide lumen structure comprises a dual-lumen sleeve, the sleeve comprising the wire guide lumen and a tube-surrounding lumen substantially parallel thereto, said tube-surrounding lumen substantially encompassing a circumferential distal portion of the tube.

16. The catheter device of claim **15**, wherein the wire guide lumen structure further comprises a wire guide aperture near a proximal end of the wire guide lumen structure, said aperture configured to allow passage of a wire guide therethrough.

17. The catheter device of claim **15**, wherein the tube-surrounding lumen is bonded to an exterior distal portion of the tube.

18. The catheter device of claim **15**, wherein a distal end portion of the balloon is sealed to the wire guide lumen structure to form a fluid-tight seal.

19. The catheter device of claim **15**, wherein the wire guide lumen further comprises a lining layer coaxially disposed against a surface of the wire guide lumen.

20. The catheter device of claim **19**, wherein the lining layer comprises PTFE.

21. The medical balloon catheter of claim **9**, further comprising a balloon-deployable stent configured to be deployed from the balloon.

22. A medical balloon catheter device configured for use with a wire guide, the catheter comprising:
an elongate tube formed of a helically-scored hypotube, said tube comprising a proximal tube end, a distal tube end, and a longitudinal tube lumen extending therebetween;
a dual-lumen sleeve structure disposed adjacent the distal tube end, said dual-lumen sleeve structure comprising a first sleeve lumen and a second sleeve lumen; and
an inflatable balloon comprising a balloon lumen, said balloon lumen being in fluid communication with the tube lumen;
wherein the first sleeve lumen comprises a wire guide lumen and extends distally beyond the distal tube end;

wherein the second sleeve lumen comprises a tube-bonding lumen through which is disposed a tube portion adjacent the distal tube end;

wherein a coating covers substantially the exterior surfaces of the tube and the sleeve structure, and provides a patent fluid communication path along the tube lumen between the proximal tube end and the balloon lumen;

wherein a proximal portion of the balloon is connected to the tube and the sleeve structure, and is connected distally to the sleeve structure such that at least a portion of the sleeve structure extends through the balloon lumen;

wherein the first sleeve lumen extends distally beyond a distal end of the balloon; and

wherein a wire guide aperture is disposed on a proximal portion of the wire guide lumen and is configured to provide passage therethrough for a wire guide.

23. The catheter device of claim **22**, wherein a coating comprises a material selected from HDPE, PTFE, PET, polyester block amide, polyether block amide, polyurethane, polyimide, polyolefin, nylon, and any combination thereof.

24. The catheter device of claim **22**, wherein the wire guide lumen further comprises a lining layer coaxially disposed against a surface of the wire guide lumen.

25. The catheter device of claim **22**, further comprising a balloon-deployable stent configured to be deployed from the balloon.

26. The catheter device of claim **22**, wherein the helically-scored hypotube comprises a helically-cut hypotube.

27. A method of making a balloon catheter device comprising

the steps of:

providing an elongate tube in the form of a helically-scored hypotube having a proximal tube end and a distal tube end with a tube lumen therebetween;

providing a dual-lumen sleeve having an upper sleeve lumen and a lower sleeve lumen, wherein said upper lumen includes a greater distal length than said lower lumen;

directing the distal tube end into the lower lumen until the distal tube end is near a distal end of the lower lumen;

directing a tubular sheath over the tube and the sleeve such that at least a substantial longitudinal portion of the tube and of the sleeve both extend through a sheath lumen of the tubular sheath;

shrinking the sheath around the tube and sleeve such that the sheath forms a coating thereabout;

skiving a wire guide aperture into a proximal portion of the upper lumen;

providing a balloon having a balloon lumen; and

attaching the balloon to the tube such that the tube lumen is in fluid communication with the tube lumen.

28. The method of claim **27**, further comprising a step before providing the dual-lumen sleeve, said step comprising providing a barrier sleeve disposed around a distal region of the tube.

29. The method of claim **27**,

further comprising a step of providing a tubular liner in the upper lumen of the dual-lumen sleeve.

30. The method of claim **27**, further comprising a step of providing a mandrel directed through the wire guide aperture and compressing a region immediately proximal thereof to form a ramped surface.

31. The method of claim **27**, wherein a portion of the upper lumen that includes the greater distal length than the lower lumen extends through a portion of the balloon lumen.

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