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(54) **MULTIFILAR CABLE CATHETER**

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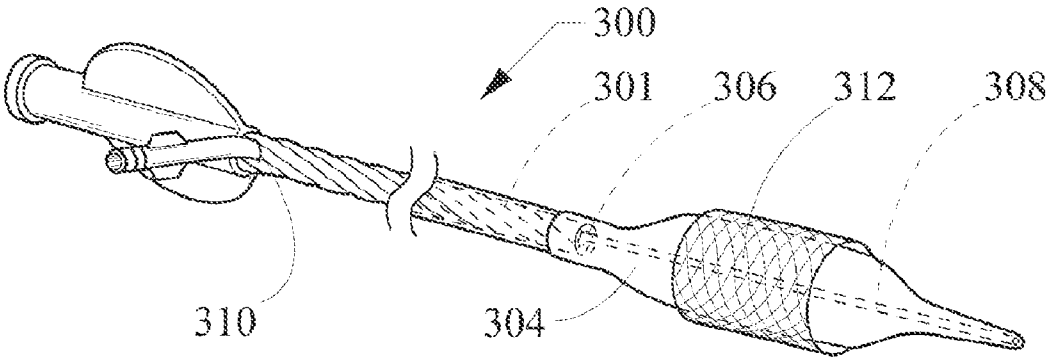
(57) **ABSTRACT**

A catheter device including an elongate catheter shaft comprising a multifilar cable tubing having a proximal portion and a distal portion. At least a part of the distal portion is more flexible than the proximal portion. The shaft includes two lumens, one of which houses a stent deployment shaft configured to deploy a self-expanding stent disposed in a distal extension of the shaft.



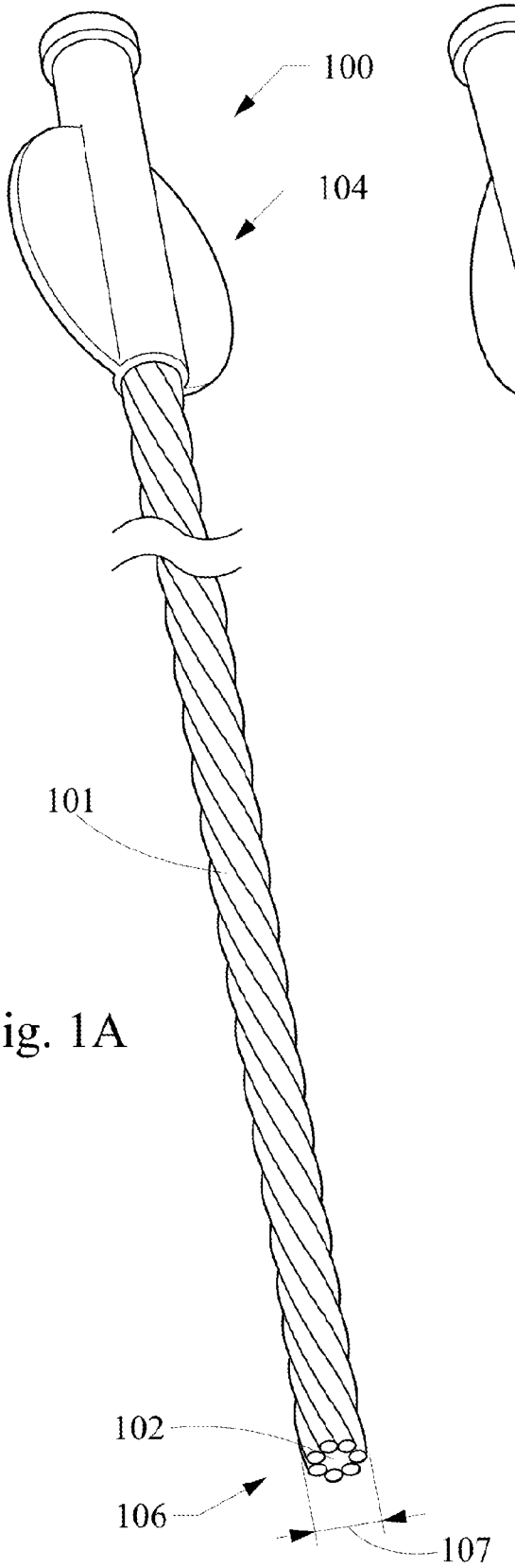


Fig. 1A

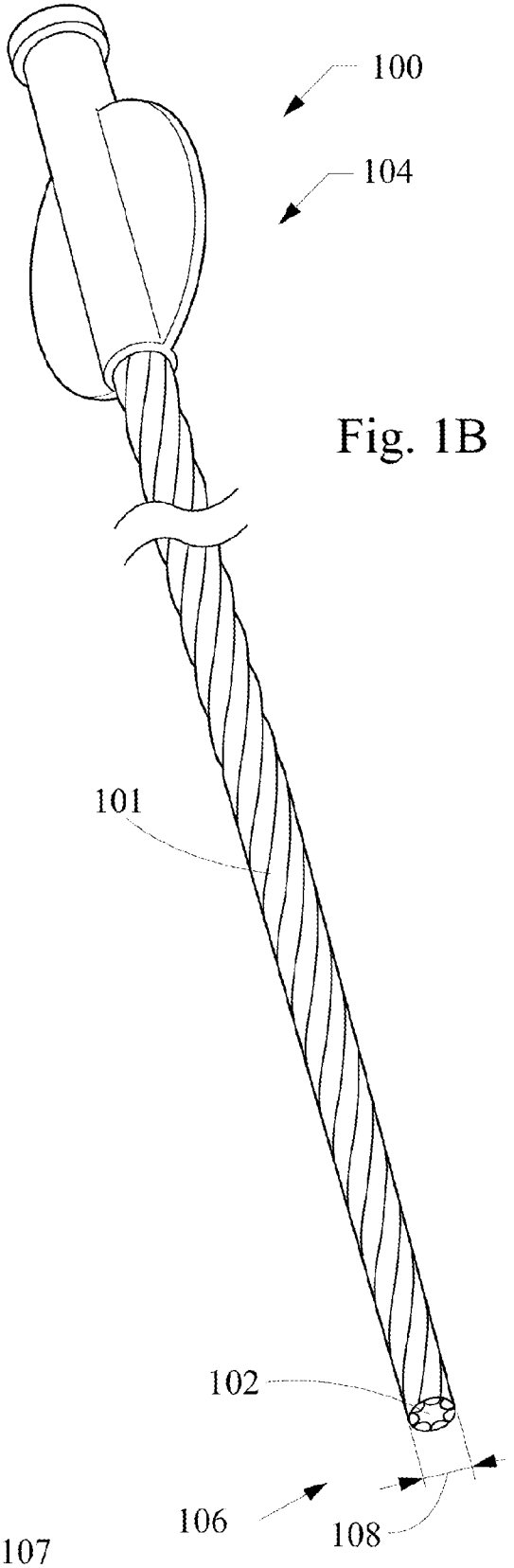


Fig. 1B

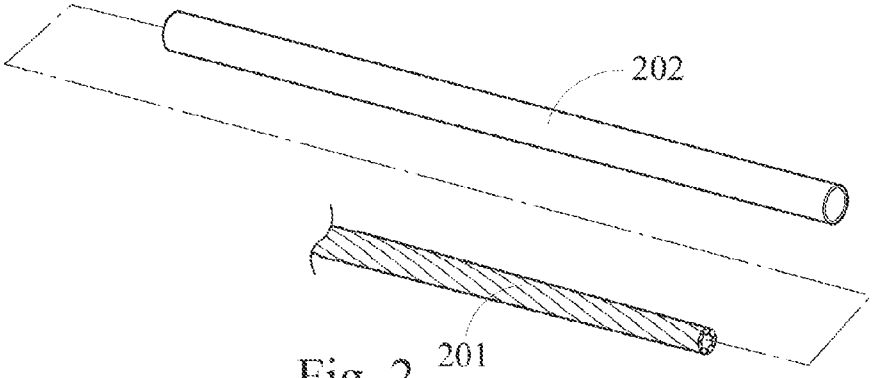


Fig. 2

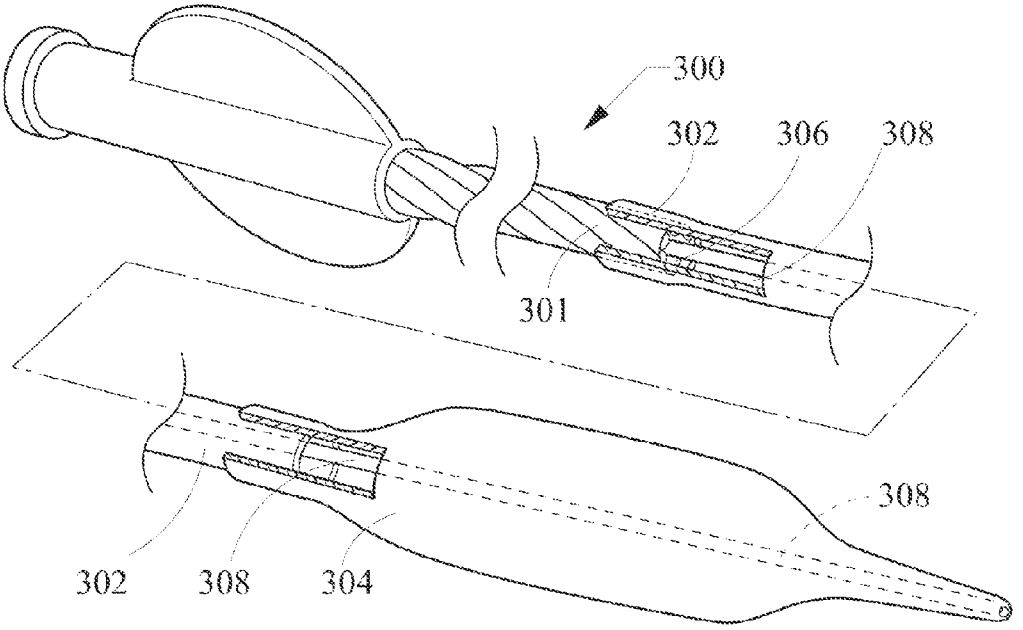


Fig. 3A

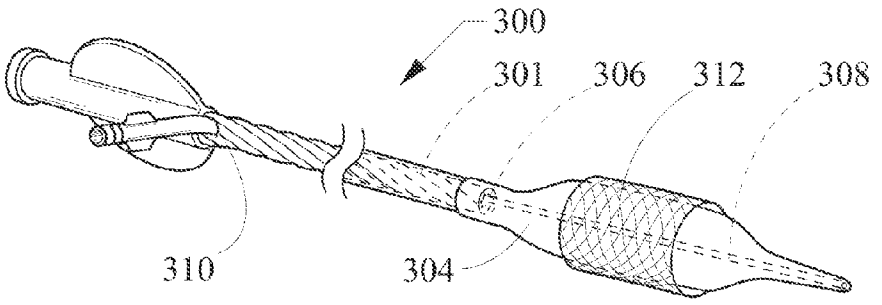


Fig. 3B

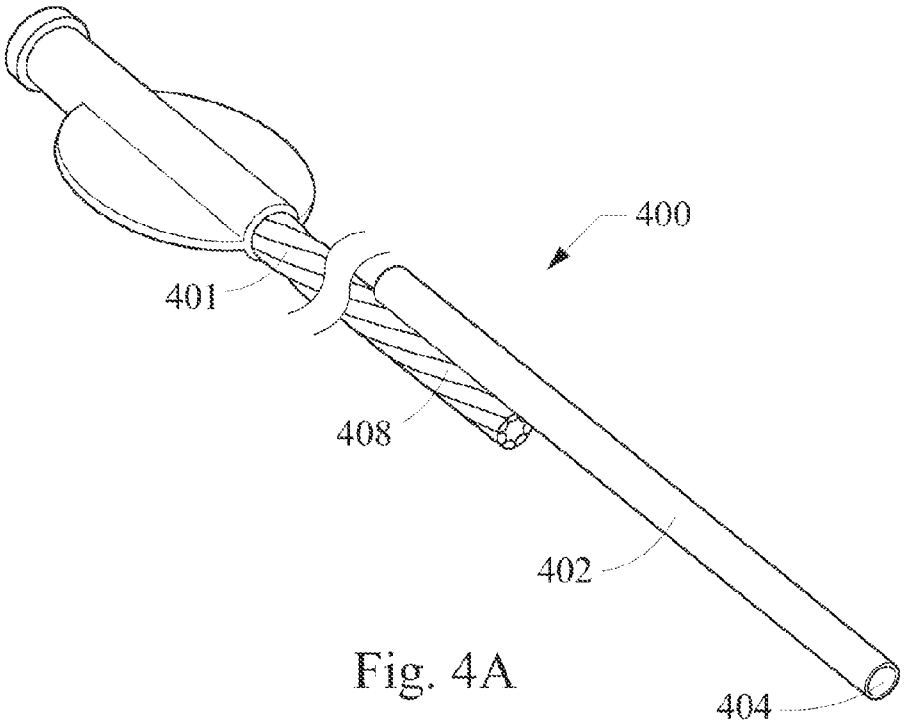


Fig. 4A

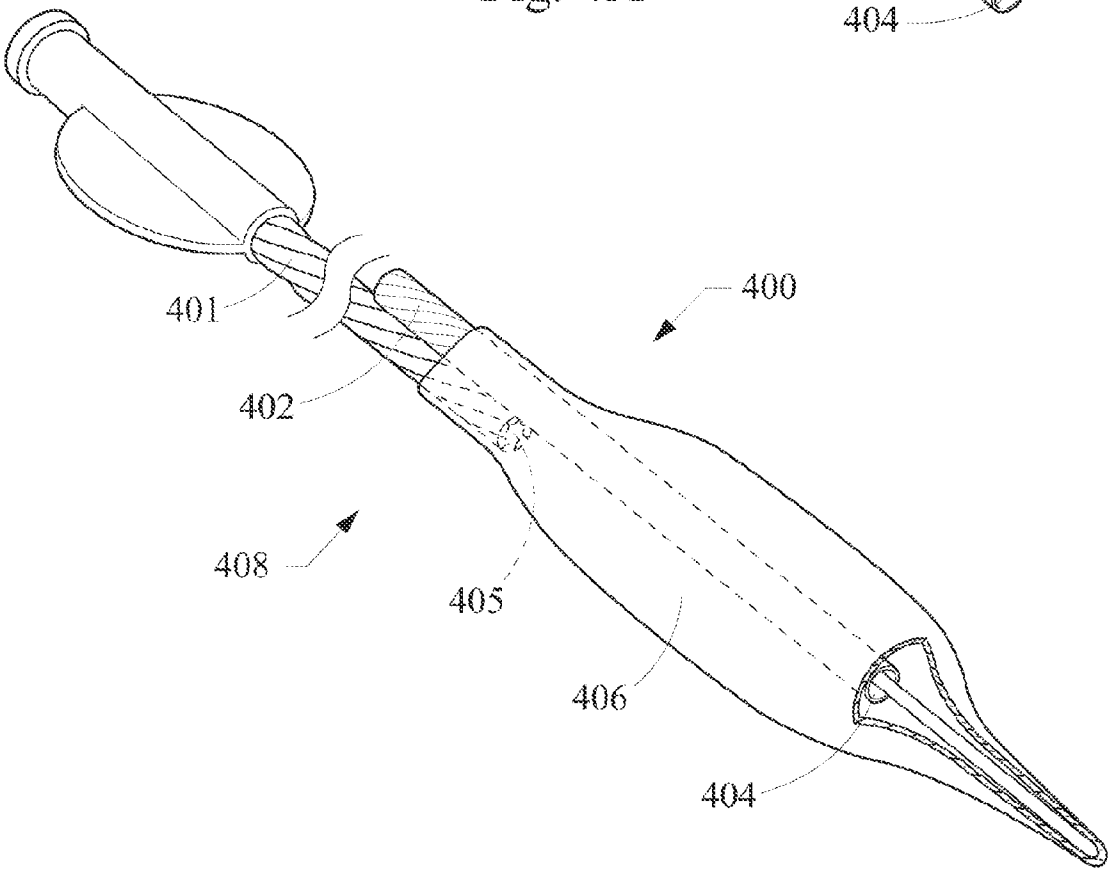


Fig. 4B

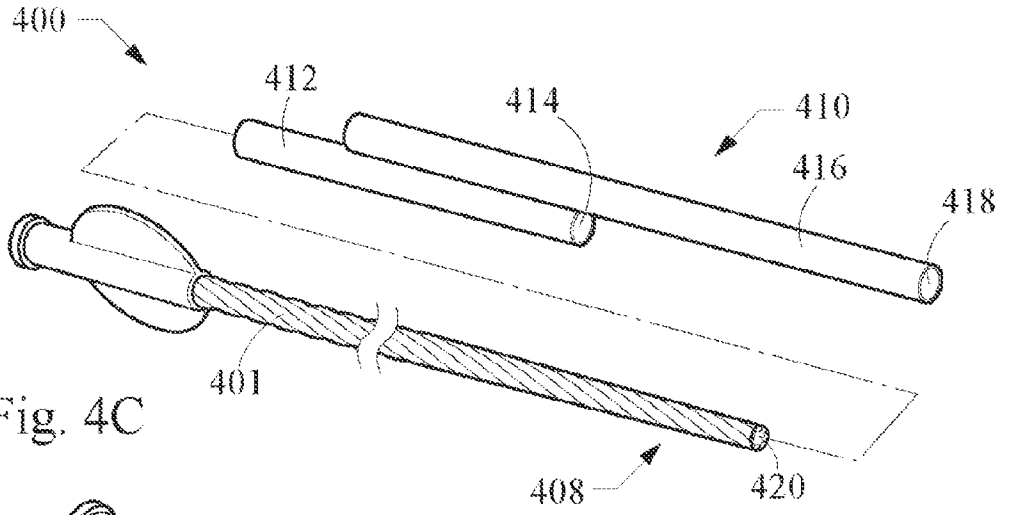


Fig. 4C

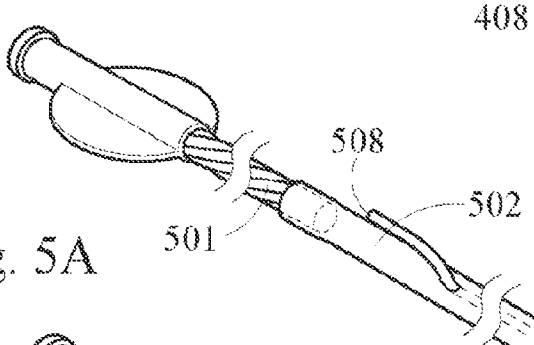


Fig. 5A

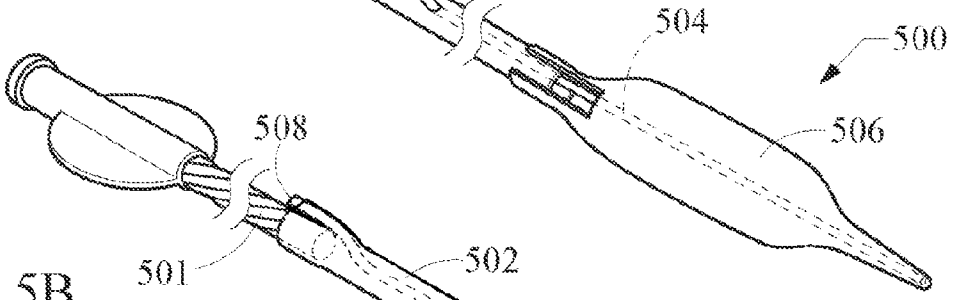


Fig. 5B

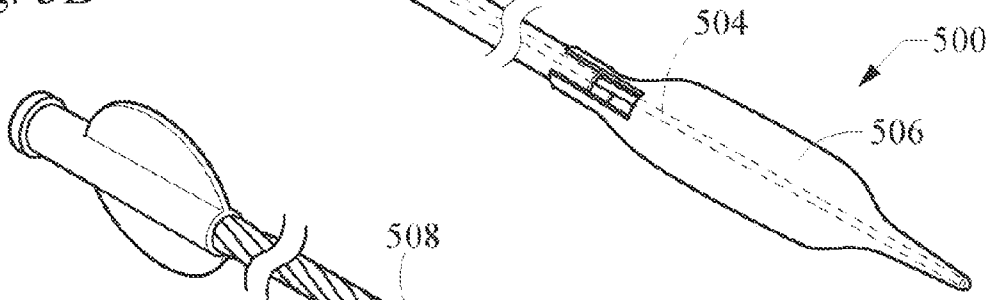


Fig. 5C

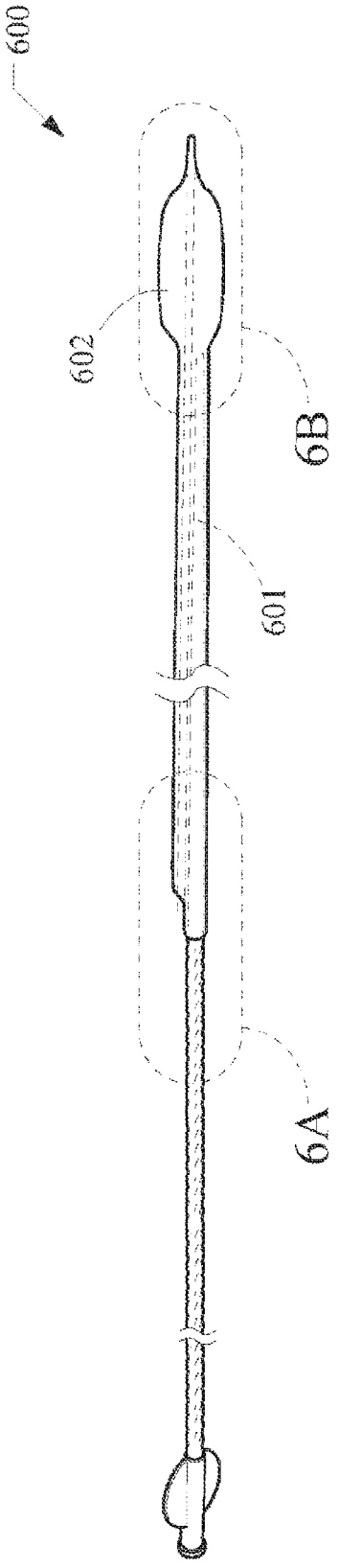


Fig. 6

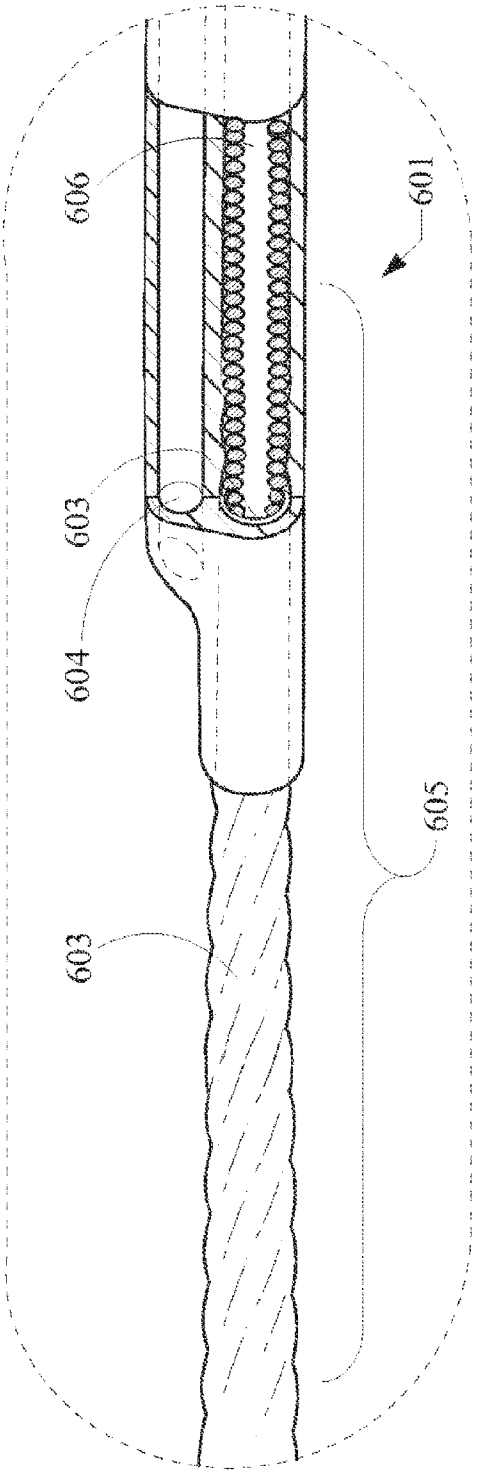


Fig. 6A

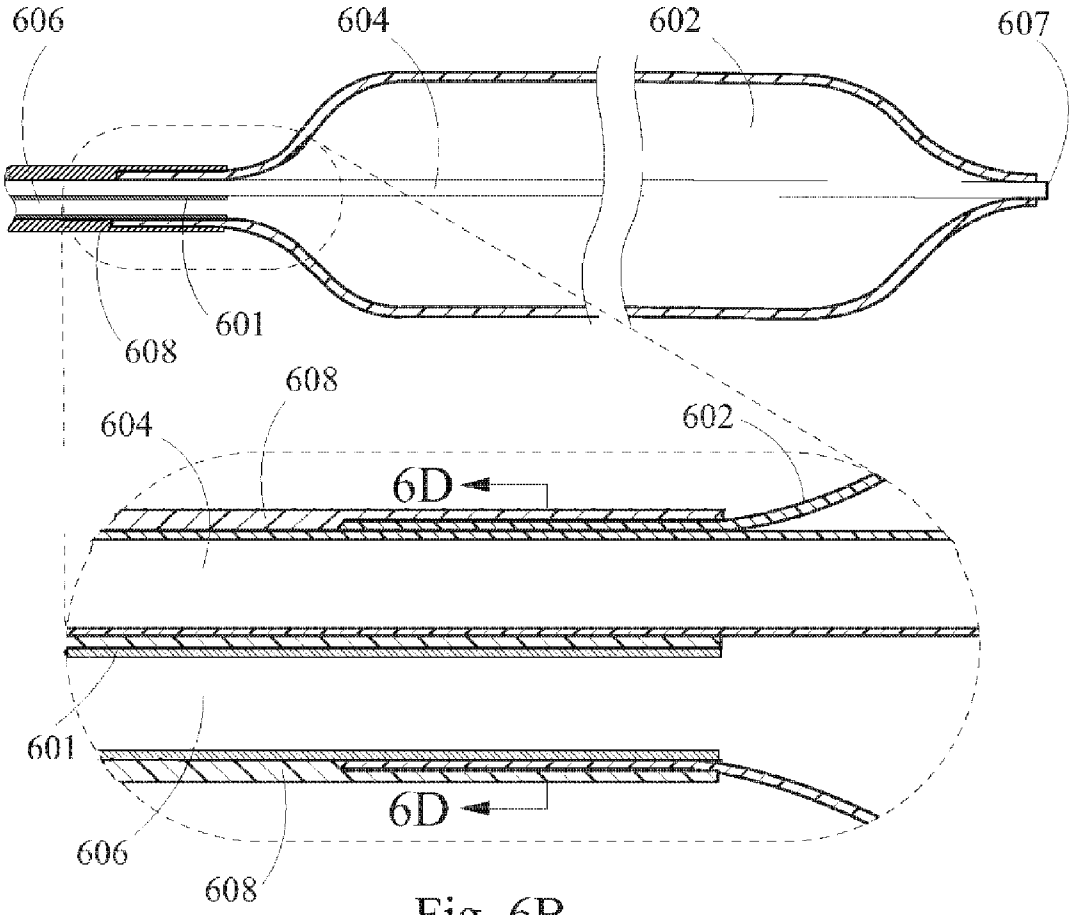


Fig. 6B

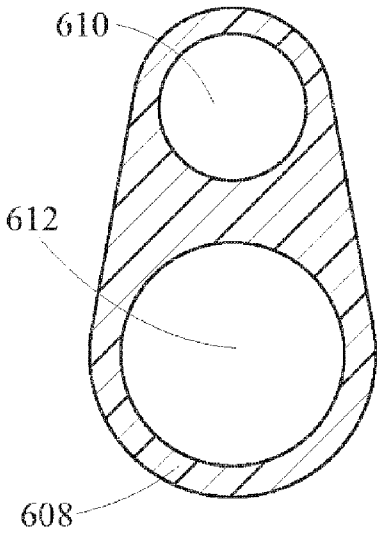


Fig. 6C

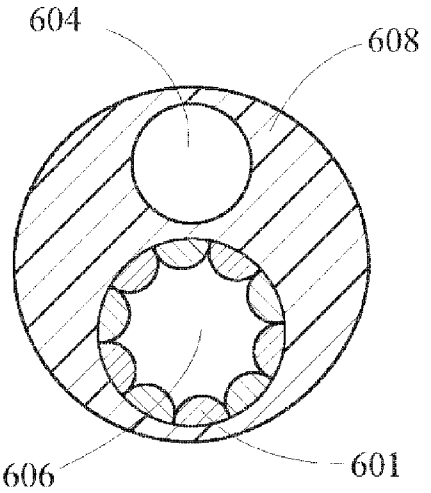


Fig. 6D

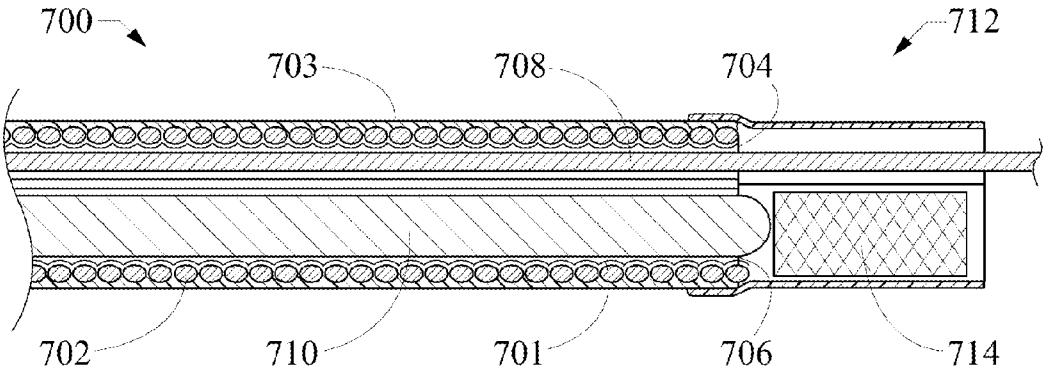


Fig. 7A

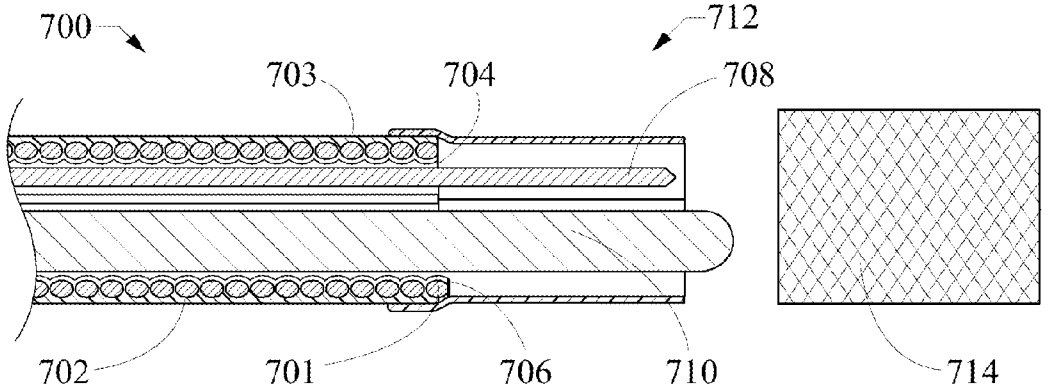


Fig. 7B

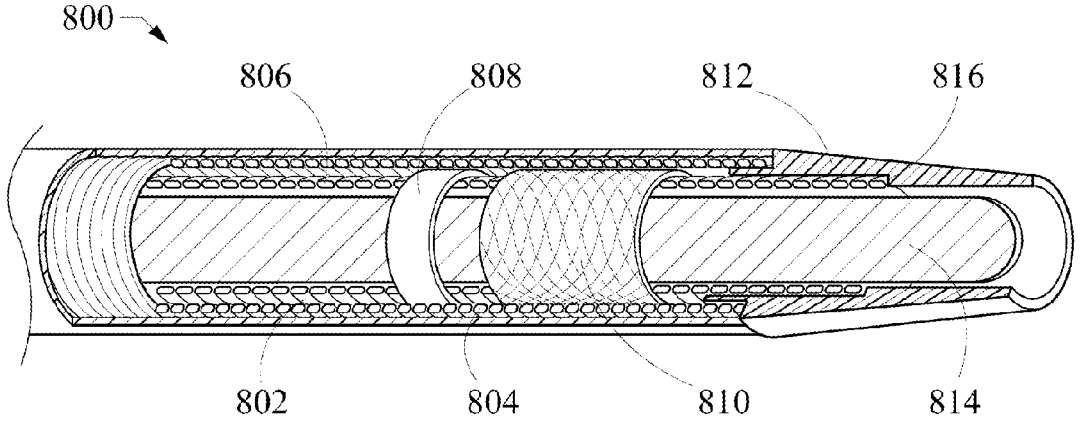


Fig. 8

MULTIFILAR CABLE CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 11/300,635, filed Dec. 14, 2005, and claims priority thereby to U.S. Provisional Application Ser. No. 60/636,192, filed Dec. 15, 2004, each of which is incorporated herein in its entirety.

TECHNICAL FIELD

[0002] The present application relates to medical catheters, and more specifically to medical catheters useful in endovascular and other body lumens.

BACKGROUND

[0003] 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.

[0004] 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.

[0005] 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.

[0006] 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.

[0007] 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.

[0008] 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.

[0009] 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.

[0010] 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.

[0011] In one design, a significant proximal portion of the catheter shaft is made of a metallic tubing (commonly referred to as a hypotube), which provides the desired pushability while maintaining a relatively small outer diameter. The distal portion of the catheter shaft is a second, more flexible (commonly plastic) tubing. In short-wire catheters using the hypotube design, a first aperture for introduction of a wire guide to the wire guide lumen is usually placed in the hypotube near to the distal end thereof. Alternatively, this first aperture is placed in the second tubing, or near the juncture between the hypotube and second tubing. These types of catheters, however, present certain disadvantages. Having the first aperture in the hypotube mitigates the advantages of a short-wire catheter: the wire guide must be longer, and advantages conferred by reduced friction are lessened. Having the first aperture at the aforementioned junction or in the second tubing creates a likelihood of undesired flexure (e.g., kinking or bunching) as there will be at least some portion of the more flexible second tubing unsupported by a wire guide, and therefore lacking column strength. Not only may such undesired flexure injure an endovascular or other lumen housing the catheter, but it may close off an inflation lumen or other lumen of the catheter, which is undesirable. The problems of increased cost of assembly and various mechanical problems presented by constructing and using a catheter having both semi-flexible hypotube and more flexible second tubing portions of the same catheter are addressed in the present invention.

BRIEF SUMMARY

[0012] The present invention provides a catheter device, adaptable for use in endovascular lumens or other body lumens, that has a construction of multifilar cable tubing 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 are 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).

[0013] The embodiments herein are adaptable for use in a variety of minimally invasive surgical treatments (including, e.g., angioplasty or bile duct dilation).

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. **1**A is a perspective view of a catheter, with an enlarged detail view of the catheter's distal end;

[0015] FIG. **1**B is a perspective view of a tapered catheter device, with an enlarged detail view of the catheter's distal end;

[0016] FIG. **2** is a perspective view of a catheter shaft with a sleeve;

[0017] 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;

[0018] FIG. **3**B is a perspective view of a catheter device with an inflation balloon;

[0019] 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;

[0020] 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;

[0021] 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;

[0022] FIGS. **5**A-**5**B show a side view of catheter devices having a distal extension and a wire guide lumen structure;

[0023] FIG. **5**C is a side view of a catheter device having an external distal wire guide lumen structure and an inflation balloon;

[0024] FIG. **6** is a side view of a tapered catheter device having an external distal wire guide lumen structure and an inflation balloon;

[0025] 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;

[0026] 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;

[0027] FIG. **6**C is a transverse cross-sectional view of a dual-lumen mounting sleeve;

[0028] 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;

[0029] FIGS. **7**A and **7**B illustrate a cross-sectional view of another embodiment of a catheter device

[0030] FIG. **8** illustrates a partial cross-sectional view of yet another embodiment of a catheter device.

DETAILED DESCRIPTION

[0031] The presently described embodiments of a multifilar tube catheter shaft are adaptable for use in a variety of minimally invasive surgical applications (e.g. endoscopic procedures, angioplasty).

[0032] FIGS. **1**A-**1**B illustrate an embodiment of a catheter device **100** with a shaft **101** constructed of a multifilar material and having an internal lumen **102**. The multifilar tubing described is made of a plurality of wires twisted together and leaving a central lumen. Such multifilar tubing may be obtained, for example, from Asahi-Intecc (Newport Beach, Calif.). Materials and methods of manufacturing a suitable multifilar tubing are described in Published U.S. Pat. App. 2004/0116833 (Koto et al.), the contents of which are incorporated herein by reference. Use of multifilar tubing in a vascular catheter device is described in U.S. Pat. No. 6,589,227 (Sonderskov Klint, et al.; Assigned to Cook Inc. of Bloomington, Ind. and William Cook Europe of Bjaeverskov, Denmark), which is also incorporated herein by reference.

[0033] 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 catheter shaft, with gradual transition from a stiffer proximal end to a more flexible distal end and lacking sharp transitions that undermine structural integrity.

[0034] 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.

[0035] 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, PEBA, PET, 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 (Polyether Block Amide) 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.

[0036] FIGS. **3**A-**3**B illustrate embodiments of balloon catheters **300** comprising a multifilar shaft **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 multifilar 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 multifilar catheter shaft **301** and extends through the inflation balloon **304** at the distal end.

[0037] 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 multifilar 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**. An expandable stent **312** is positioned about the balloon **304**. In an alternative embodiment, an expandable member other than a balloon (e.g., a basket) is 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** is useful for introducing another fluid such as a contrast fluid.

[0038] FIGS. **4**A-**4**B illustrate embodiments of a multifilar tube balloon catheter device **400** comprising a multifilar 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 multifilar 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 multifilar 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 multifilar 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 multifilar tubing. 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 dis-

posed 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.

[0039] In FIG. **4**C, a dual lumen structure **410** is disposed on the distal end **408** of the multifilar catheter shaft **401**. A portion of the length of dual lumen structure **410** has a "figure 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 **404** 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**.

[0040] FIGS. **5**A-**5**C illustrate embodiments of a balloon catheter **500** incorporating a multifilar 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 multifilar 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 multifilar 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 multifilar 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.

[0041] 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 multifilar 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 multifilar shaft **501**. The proximal end **508** of the tube **504** is disposed proximal of the juncture of the extension **502** with the multifilar shaft **501** and is affixed to the exterior of the multifilar 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 multifilar 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.

[0042] FIG. **6** illustrates one embodiment of a balloon catheter **600** having an elongate shaft **601** comprising a multifilar tube. 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**.

[0043] 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**.

[0044] Cross-lumen communication may be prevented. For example, the walls of the multifilar tube 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. 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.

[0045] 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** may be retracted into the shaft wall or lumen **704** so as not to interfere with deployment of the stent **714**.

[0046] 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 multifilar body **804**. A second, inner multifilar cable tube 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 multifilar 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.

[0047] In alternative embodiments, the shaft coating (if any) may be a material other than PEBA, and may be the same or different 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). In other alternative embodiments, the multifilar catheter shaft need not have a lumen running through its length, but may be relatively solid (e.g., for use as a pushing tool, or for use in a configuration not requiring a lumen through the catheter shaft). The balloon catheters of the present invention are adaptable for use with expandable stents as is illustrated, for example, in FIG. **3**B.

[0048] It is therefore intended that the foregoing 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 spirit and scope of this invention.

We claim:

1. A catheter device, comprising:

an elongate catheter shaft comprising a multifilar tubing having a proximal portion and a distal portion wherein at least a part of the distal portion is more flexible than the proximal portion, the multifilar tubing defining a first lumen, and further comprising:

a self-expanding stent;

a second lumen;

and a stent deployment shaft disposed in the second lumen.

2. The catheter device of claim **1**, further comprising a distal extension disposed on a distal end of the multifilar tubing, where the self-expanding stent is deployably disposed in the distal extension.

3. The catheter device of claim **1**, wherein the first lumen is configured for passage of a wire guide.

4. The catheter device of claim **1**, further comprising a wire guide disposed through the first lumen.

5. The catheter device of claim **1**, further comprising a polymeric coating, said coating covering an inner region of the multifilar tubing.

6. The catheter device of claim **1**, further comprising a polymeric coating, said coating covering an outer region of the multifilar tubing.

7. The catheter device of claim **1**, where the stent deployment shaft is configured as a second multifilar cable tube.

8. A catheter device, comprising:

an elongate catheter shaft comprising multifilar tubing having a proximal portion and a distal portion, the multifilar tubing comprising:

a first lumen configured for passage therethrough of a wire guide;

a second lumen, through which a stent-deployment shaft is disposed; and

a distal extension disposed on a distal end of the tubing, wherein the distal extension deployably houses a self-expanding stent.

9. The catheter device of claim **8**, further comprising a distal extension disposed on a distal end of the multifilar tubing, where the self-expanding stent is deployably disposed in the distal extension.

10. The catheter device of claim **8**, wherein at least one of the first lumen is configured for passage of a wire guide.

11. The catheter device of claim **8**, further comprising a wire guide disposed through the first lumen.

12. The catheter device of claim **8**, further comprising a polymeric coating, said coating covering an inner region of the multifilar tubing.

13. The catheter device of claim **8**, further comprising a polymeric coating, said coating covering an outer region of the multifilar tubing.

14. The catheter device of claim **8**, where the stent deployment shaft is configured as a second multifilar cable tube.

15. A method of using the catheter device of claim **8**, said method comprising a step of directing the stent deployment shaft distally against the stent, pushing the stent out of the distal extension.

16. The method of claim **15**, further comprising a step of providing a wire guide disposed through the second lumen.

17. The method of claim **16**, further comprising a step of retracting the wire guide into the second lumen.

18. The method of claim **17**, wherein the step of retracting the wire guide is executed prior to the step of directing the stent deployment shaft distally.

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