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(71) Applicant *(for all designated States except US)*: **SCIMED LIFE SYSTEMS, INC.** [US/US]; ONE SCIMED PLACE, MAPLE GROVE, MN 55311 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **WU, Show-Mean** [US/US]; 12464 Ragweed Street, San Diego, CA 92129 (US).

(74) Agent: **CROMPTON, David M.**; CROMPTON, SEAGER & TUFTE, LLC, 1221 Nicollet Avenue, Suite 800, Minneapolis, Minnesota 55403 (US).

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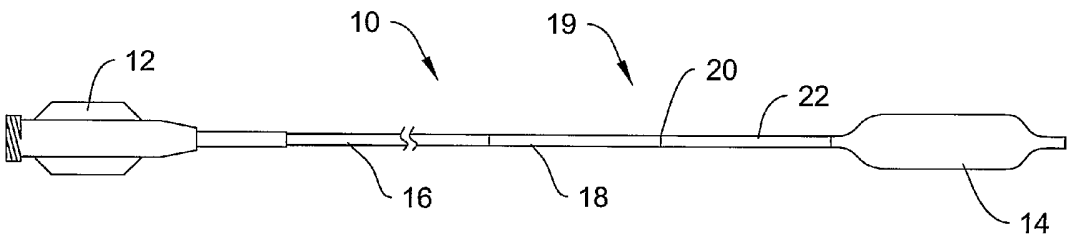
(54) Title: CUTTING BALLOON CATHETER WITH IMPROVED PUSHABILITY



(57) Abstract: Rapid exchange angioplasty catheters and methods of constructing rapid exchange angioplasty catheters including features that provide good pushability and kink resistance. In an illustrative embodiment, a catheter is provided, the illustrative catheter including a proximal hypotube section, which connects to a more distal braided catheter section. The braided catheter section connects to a midshaft portion that includes a guidewire entry port. Distal of the midshaft portion is a distal section having a cutting balloon disposed thereon. An inflation lumen extends the length of the catheter, while a guidewire lumen extends only from the guidewire entry port to the distal end of the catheter. Optionally, a core wire may extend across the joint from the hypotube, to the braided catheter section, and past the guidewire entry port.

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CUTTING BALLOON CATHETER WITH IMPROVED PUSHABILITY

Field of the Invention

The present invention pertains to angioplasty and angioplasty balloon catheters. More particularly, the present invention pertains to angioplasty cutting balloon catheters that include improved pushability

Background of the Invention

Heart and vascular disease are major problems in the United States and throughout the world. Conditions such as atherosclerosis result in blood vessels becoming blocked or narrowed. This blockage can result in lack of oxygenation of the heart, which has significant consequences since the heart muscle must be well oxygenated in order to maintain its blood pumping action.

Occluded, stenotic, or narrowed blood vessels may be treated with a number of relatively non-invasive medical procedures including percutaneous transluminal angioplasty (PTA), percutaneous transluminal coronary angioplasty (PTCA), and atherectomy. Angioplasty techniques typically involve the use of a balloon catheter. The balloon catheter is advanced over a guidewire so that the balloon is positioned adjacent a stenotic lesion. The balloon is then inflated, and the restriction of the vessel is opened. It is typically considered desirable to have a catheter which varies in flexibility along its length, from a stiffer proximal section to a more flexible distal section.

One of the major obstacles in treating coronary artery disease and/or treating blocked blood vessels is restenosis. Evidence has shown that cutting the stenosis, for example with an angioplasty balloon equipped with a cutting blade, during treatment can reduce incidence of re-stenosis in certain applications. Additionally, cutting the stenosis may reduce trauma at the treatment site and/or may reduce the trauma to adjacent healthy tissue. Cutting blades may also be beneficial additions to angioplasty procedures when the targeted occlusion is hardened or calcified. Thus, angioplasty balloons equipped with cutting edges have been developed to attempt to enhance angioplasty treatments.

Summary of the Invention

The present invention includes catheters adapted for use as rapid exchange angioplasty catheters including features which provide good pushability and kink

resistance. In a first embodiment, a rapid exchange cutting balloon angioplasty catheter is provided, the illustrative catheter including a proximal hypotube section which connects to a more distal braided catheter section. The braided catheter section connects to a midshaft portion that includes a guidewire entry port. Each of the hypotube, braided catheter section, and midshaft portion includes at least one inflation lumen for providing fluid communication from a proximal end of the catheter to a distally disposed cutting balloon. Distal of the midshaft portion is a distal section having an inflation lumen and a guidewire lumen, and a cutting balloon is disposed on the distal section in fluid communication with the inflation lumen. In a further illustrative embodiment, a core wire extends across the joint from the hypotube to the braided catheter section and may even extend past the guidewire entry port. The use of a braided catheter section just distal of the hypotube not only allows for a kink-resistant transition but also provides additional pushability for that portion of the shaft, while still adding to the flexibility and softness of the catheter shaft distal of the hypotube.

Brief Description of the Drawings

Figure 1 is a schematic view of a balloon angioplasty catheter;

Figure 2 is a cross-sectional side view of an illustrative guidewire entry port;

Figure 3 is a cross-sectional view taken along line 3-3 in Figure 2;

Figure 4 is a cross-sectional side view of an illustrative cutting balloon;

Figure 5 is a cross-sectional view taken along line 5-5 in Figure 4;

Figure 6 is a cross-sectional view taken along line 6-6 in Figure 4;

Figure 7 is a top view of an illustrative slit and flared member;

Figure 8 is a side view showing a step of forming an illustrative port joint;

Figure 8A is a cross-sectional view taken along line A-A in Figure 8;

Figure 9 is a side view showing another step in forming an illustrative port joint;

Figure 10 is a side view showing yet another step in forming an illustrative port joint; and

Figure 10A is a cross-sectional view taken along line A-A in Figure 10.

Detailed Description of the Preferred Embodiments

The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Figure 1 is a schematic view of a balloon angioplasty catheter. The catheter 10 includes a proximal hub assembly 12 and a distal balloon 14 (which may include cutting elements as further illustrated below) with an elongated shaft therebetween. The catheter 10 includes a hypotube 16, a braided member 18 attached to the hypotube 16, a port joint 20, and a distal section 22. The port joint 20 may be considered either a part of the distal section 22 or may be a part of a midshaft 19 that runs between the distal section 22 and the braided member 18, or may be an integral part of the catheter 10.

The hypotube 16 is a thin walled metallic tubular element that is preferably made of stainless steel, though a variety of other materials may also be used, as desired. The hypotube 16 may include a lubricious coating such as a polytetrafluoroethylene coating to reduce frictional resistance. The braided member 18 is attached to the hypotube 16 in a lap joint created by passing the distal end of the hypotube 16 into the braided member 18 by some distance, with an adhesive applied to one, the other, or both of the hypotube 16 and braided member 18. Alternatively, an adhesive may be added after placing the distal end of the hypotube 16 into the braided member 18 by taking advantage of capillary action occurring in the small space therebetween. In other embodiments, heating, welding, or mechanical attachment may also be used to couple the hypotube 16 to the braided member 18. An inflation lumen extends from the hub 12 through the hypotube 16 and into the braided member 18, with the joint between the hypotube 16 and the braided member 18 constructed to maintain the integrity of the inflation lumen.

The braided member 18 may take on a number of forms. Typically the braided member 18 will include a lubricious inner layer and a polymeric outer layer, with a braid composed of a number of filaments or strands braided between the inner and outer layers. A helical, double helical, coiled, or woven member may be used in place of the braid. In one illustrative example, the braid is formed of a flat stainless steel wire of a size 0.00075 inches by 0.003 inches, and is placed between an inner polyimide inner layer having a thickness of about 0.00075 inches and a polyether

block amide (PEBAX) outer layer having a thickness of about 0.0015 inches. In this illustrative example, the overall braided member 18 has an inner diameter of about 0.028 inches and an outer diameter of about 0.0355 inches (note that these illustrative values are considered from a point where two strands of the braid cross). The braid may be annealed or soft and in the illustrative example, has a pick count of about 55 using a 16-strand construction. Typically, the braid is wound or formed on a mandrel, slid over the inner layer, and then tightened onto the inner layer, and the outer layer is added over the top. The braid may also be wound directly on the inner layer. Coextrusion of the braid and the inner and outer layers may also be done. The above sizes and materials are merely illustrative of one particular embodiment and are not meant to be limiting.

Other embodiments may use a number of alternative braid materials including, for example, tungsten, Ni-Ti alloys, hardened steel, liquid crystal polymers and other metallic or synthetic materials. Additionally, the pick count and number of strands used may be varied widely depending on the desired final characteristics. It should be noted that there is a trade off where, as pick count increases, pushability also increases but kink-resistance tends to decrease. The braided member 18 provides a transition in flexibility as well as extra kink resistance and pushability from the distal end of the hypotube 16 to more distal portions of the catheter.

Distal of the braided member 18 is a port joint 20 in the midshaft 19. The port joint 20 allows a guidewire to be inserted and carried within the catheter 10 distally from the port joint 20 to at least the balloon 14. In a preferred embodiment, the braided member 18 is used to form a part of the port joint 20. Distal of the port joint 20 is a distal member 22 which includes an inflation lumen as well as a guidewire lumen. It should be noted that proximal of the port joint 20, in a preferred embodiment, the guidewire lumen is not included. There is one more lumen distal of the port joint 20 than there is proximal of the port joint 20.

A balloon 14 is then attached to the distal member 22. In a preferred embodiment the balloon includes a number of cutting members 36, as further illustrated in Figure 4. The cutting members or cutting blades can include any type of protrusion extending radially from at least a portion of the balloon. Radially projecting longitudinal blades are depicted in Figure 4. However, cutting blades can be stiffening members, elongated ridges, molded or attached polymeric ridges, polymeric protrusions and combinations thereof.

The use of the braided member 18 may allow several advantages. In one aspect, the catheter pushability is most greatly affected by its weakest member. Distal of the port joint 20, the catheter 10 passes over a guidewire in use, and with a guidewire through the guidewire lumen, the pushability of that section tends to be relatively good. The hypotube 16 is highly pushable. Without the braided member 18, either the hypotube 16 must be longer or a non-braided polymeric member can be used. The length of the hypotube 16, however, is somewhat limited by anatomy of the patient, since the hypotube 16 is ill suited to traverse the more tortuous vasculature nearer the heart. By providing the braided member 18, the hypotube 16 may make up only a more proximal portion of the catheter 10 that does not traverse particularly difficult areas of the vasculature.

Figure 2 is a cross-sectional side view of an illustrative guidewire entry port. The braided member 18 is illustrated coupled with the distal member 22, which includes both an outer member 22a and an inner member 22b. The braided member 18 is shown having a triple layer configuration, with an outer polymeric layer 18a that is preferably a relatively soft polymer which may include a hydrophilic coating, a braided middle layer 18b having a metallic or non-metallic filament/strand braid, and a lubricious inner layer 18c. In a preferred embodiment, the distal member 22 is made of two integral pieces, an outer member which is a PEBA element and an inner tri-layer member having an inner lubricious layer, a tie layer, and an outer polymer layer. In one embodiment, the inner member 22b is a tri-layer construction including an inner layer of high density polyethylene, an outer layer of PEBA and a tie-layer of a modified low density polyethylene. The port joint 20 allows entry of a guidewire to the inner member 22b at the proximal end of the inner member 22b. An optional core wire 24 is illustrated as crossing the port joint 20 to improve kink resistance across the port joint 20.

The core wire 24 may be provided as a full length core wire extending from the proximal hub (Figure 1), or may be attached to the proximal hypotube (Figure 1) section by a suitable method such as brazing or welding. The core wire 24 may attach to the hypotube 16 by crimping the hypotube 16 to surround and attach to the core wire 24 or the proximal end of the core wire 24 may extend into this distal end of the hypotube 16 lumen and be affixed therein.

It should be noted that while the members 18, 22a, 22a are illustrated as separate pieces, in some embodiments a port joint 20 may be constructed using a

heating process (such as that discussed with reference to Figures 7-10A below and as shown in cross section in Figure 3) that causes reflow of various elements such that sharp distinction of the several members 18, 22a, 22b no longer exists in an actual fabricated catheter. The port joint 20 may be constructed by any suitable fashion, and that discussed below is only provided for illustrative purposes.

Figure 3 is a cross-sectional view taken along like 3-3 in Figure 2. A guidewire lumen 30 is provided through the portion distal of the port joint 20 (Figure 1). The core wire 24 is seen to sit within an inflation lumen 28. The shape of the inflation lumen 28 near the port joint 20 is illustrated in accordance with the illustrative port joint discussed in Figures 7-11. Lumens having other shapes may also be used, as desired. As noted above, the illustrative port joint of Figure 3 has been constructed so that the several elements used in making the port joint are no longer clearly discerned. The cross section includes areas of double cross hatching 18b to indicate that a portion of the braided member 18b stands out from what is otherwise a melted-together blend of polymers.

Figure 4 is a cross-sectional side view of an illustrative cutting balloon shown in an inflated configuration. The cutting balloon 14 is attached at its distal end 32 to the inner member 22b, and at its proximal end 34 to the outer member 22a. This leaves the interior of the cutting balloon 14 in fluid communication with a generally annular inflation lumen 40 defined between the outer member 22a and the inner member 22b. The balloon 14 may be attached using heat welding processes, adhesives, or a heat shrink wrapping, for example. Two marker bands 38 are included on the inner member 22b to aid in visualizing the location of the balloon 14 in the vasculature. The balloon 14 may be made from typical angioplasty balloon materials including, for example, polymers or blends of polymers such as polyethylene terephthalate (PET), polyetherimid (PEI), and/or polyethylene (PE).

On the surface of the balloon 14 are a number of cutting elements 36. The cutting elements 36 may be disposed in any configuration including, for example, two, four or six equally spaced cutting elements 36. The cutting elements 36 may be blades or other structures configured for cutting into plaque or tissue such as a lesion. While the cutting elements 36 may be made of metal, the exact composition of the cutting elements 36 may vary and may include, for example, hard, flexible plastics. In use, when the balloon 14 is inflated, the cutting elements 36 create cuts in

surrounding tissue, lesions, or plaque. These cuts are believed to create scoring that improves removal of a blockage and also reduces the occurrence of re-stenosis.

The inner member 22b extends through the balloon 14 to the distal tip of the catheter. A guidewire lumen 42 through the inner member 22b allows the balloon 14 and catheter to be advanced over a guidewire which passes through guidewire lumen 42 of the inner member 22b.

Figure 5 is a cross-sectional view taken along line 5-5 in Figure 4. As shown in Figure 5, the outer member 22a surrounds the inner member 22b such that a generally annular inflation lumen 40 is defined therebetween. This inflation lumen 40 is in fluid communication with the balloon as well as the proximal end of the catheter, and is used for allowing an inflation fluid to be passed into the catheter, through several proximal elements, through the annular lumen, and into a balloon at the distal end. The inner member 22b defines a guidewire lumen 42.

Figure 6 is a cross-sectional view taken along line 6-6 in Figure 4. It can be seen that the cutting elements 36 extend out from the outer surface of the balloon 14. It should be noted that the several Figures are not necessarily to scale. The guidewire lumen 42 is separated from the interior of the balloon by the inner member 22b.

Figures 7-10 are provided to show an illustrative "slit and flare" method for forming a port joint in a catheter such as the port joint 20 illustrated in Figure 2. This illustrative method is provided merely to allow one skilled in the art to practice the invention. However, other methods for producing a port joint may also be used. Instead of a slit and flare method, for example, a proximal member may be crimped to create a guidewire entry location, and a guidewire receiving tubular element provided distal of the crimp.

Figure 7 is a top view of an illustrative slit and flared midshaft member. The midshaft member 60 is preferably a multilayer shaft with a braid or other support structure. In Figure 7, the braid is not shown to aid in depicting the joint. As can be seen, one end of the midshaft member 60 has been slit and flared to create a flared portion 62 and a tab 64. The midshaft member 60 is used as noted below with respect to Figure 10. A mandrel (not shown) having a crescent shaped end is loaded through the midshaft member 60 with the crescent end passing out through the slit and flared end of the midshaft member 60.

Figure 8 is a side view showing a step of forming an illustrative port joint. An inner member 66 has been skived at one end at an angle of about 60 degrees. For the

illustrative port joint, the inner member is a tri-layer design having a lubricious inner polymer layer (preferably a high density polyethylene), a tie layer, and a poly-ether block amide (PEBA) outer layer, where the tie layer is used in the conventional manner to allow the lubricious inner layer to adhere to the PEBA outer layer. Other lubricious materials, tie layers, and outer layers may be used as desired. The skive 68 is shaped to enable ready fabrication of a guidewire entry port, with the guidewire entering through the skive 68. The inner member 66 is shown with an inner mandrel 70 extending through the skive 68. The inner member 66 is loaded through an outer member 72 until the skive 68 passes out of the outer member 72.

A crescent mandrel 74 is illustrated as passing into the outer member 72. The crescent mandrel 74 includes a curved "bed" which allows it to pass between the inner member 66 and the outer member 72, with one side of the curved area of the crescent mandrel 74 generally matching the inner wall of the outer member 72. The other side of the curved area is shaped to match the outer wall of the inner member 66. The skive 68 is aligned to open facing away from the crescent mandrel 74.

Figure 8A is a cross sectional view taken along line A-A in Figure 8. As can be seen from Figure 8A, the curved portion of the crescent mandrel 74 is shaped to slide in between the inner member 66 and the outer member 72. There is some amount of extra space allowed, which is used to receive the tab 64 (Figure 7) of the midshaft member 60 (Figure 7), as further illustrated below in Figures 10-10A. The other mandrel 70 is illustrated in place for maintaining the shape and position of the inner member 66 during subsequent placement, shrink wrapping, and laser welding processes.

Figure 9 is a side view showing another step in forming an illustrative port joint. With the crescent mandrel 74 placed as illustrated in Figure 8, the midshaft member 60 is slid toward the distal inner member 66 and distal outer member 72. The tab 64 is placed between the distal inner member 66 and the crescent mandrel 74. For the illustrative method, the tab is only about 1.25 millimeters long, while the crescent mandrel 74 extends about 8 millimeters into the distal outer member 72, so the crescent mandrel 74 prevents the tab 64 from touching the distal outer member 72. The short side of the distal inner member 66 extends about 1 millimeter past the end of the distal outer member.

Figure 10 is a side view showing yet another step in forming an illustrative port joint. After the configuration of Figure 9 is achieved, with the tab 64 (not shown)

properly placed as explained, the midshaft member 60 is slid over the crescent mandrel 74 until the slits that define the tab 64 (not shown) bottom out against the outer member 72. The flared portion 62 is placed to partially surround the distal outer member 72.

Figure 10A is a cross-sectional view taken along line A-A in Figure 10. As illustrated, the crescent mandrel 74 sits between the outer member 72 and the tab 64 of the midshaft member 60. The tab 64 sits against the inner member 66, while the inner member sits against the outer member 72 on its other side.

Once in the configuration of Figures 10-10A, a heat shrink member is placed over the port joint to secure the various elements in place. Then a laser heating process is used to cause reflow and fusion between the several pieces. The heat shrink member and mandrels are then removed, and the finished port joint subassembly is used as a component of a catheter such as the catheter 10 of Figure 1. The finished port joint subassembly may be treated to trim any residual pieces from the heating process. Also, in some methods, the port joint is skived or trimmed so that a part of the inner member 66 is removed to create a smooth, well controlled and well defined guidewire entry location.

It should be noted that in an alternative embodiment, an additional polymeric member may be used. For example, referring to Figure 1, a polymeric member lacking an inner braid may be provided between the port joint 20 and the braided member 18, with the polymeric member included to make the fabrication of a slit and flared member for use in the port joint 20 easier. In another embodiment, the port joint 20 may be provided as a discrete component having a polymeric member, which may include a simple single layer construction or may be more complicated and include a braid or special tri-layer design. The polymeric member may extend proximally and connect to the braided member 18.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

What is Claimed Is:

1. A rapid exchange catheter comprising:

an elongated shaft having proximal and distal ends, the elongated shaft including:

a hypotube having a proximal end and a distal end;

a first midshaft portion including a braided member having a proximal end and a distal end, the first midshaft portion being attached near its proximal end to a location near the distal end of the hypotube;

a second midshaft portion having a proximal end, a distal end, and a guidewire entry port, the second midshaft portion being attached near its proximal end to a location near the distal end of the first midshaft portion; and

a distal portion defining a short guidewire lumen and an inflation lumen, the distal portion being attached to the second midshaft portion and extending distally therefrom; and

a balloon disposed near the distal end of the elongated shaft, the balloon including one or more cutting blades adapted for cutting an occlusion.

2. The rapid exchange catheter of claim 1, further comprising:

a core wire attached to the hypotube and extending distally of the distal end of the hypotube and across the location at which the proximal end of the first midshaft portion is attached to the distal end of the hypotube.

3. The rapid exchange catheter of claim 2, wherein the core wire is tapered.

4. The rapid exchange catheter of claim 3, wherein the core wire extends distally beyond the guidewire entry port.

5. The rapid exchange catheter of claim 3, wherein the core wire extends past the proximal end of the guide wire lumen.

6. The rapid exchange catheter of claim 1, wherein the first midshaft portion includes a lubricious inner layer, a braid disposed about the lubricious inner layer, and a polymeric outer layer placed over the braid.

7. The rapid exchange catheter of claim 6, wherein the outer layer is comprised of a polyether block amide.

8. The rapid exchange catheter of claim 6 wherein the first midshaft portion further includes a hydrophilic coating disposed on the outside of the polymeric layer.

9. The rapid exchange catheter of claim 6, wherein the lubricious inner layer includes polyimide.

10. The rapid exchange catheter of claim 6, wherein the braid comprises a number of stainless steel strands.

11. The rapid exchange catheter of claim 1, wherein the first midshaft portion is tapered from its proximal end to its distal end.

12. The rapid exchange catheter of claim 1, wherein the distal end of the hypotube is crimped, and wherein the catheter further comprises a core wire attached to the hypotube, the core wire being placed into the crimp and then secured to the hypotube.

13. The rapid exchange catheter of claim 1, wherein the elongated shaft defines an inflation lumen extending from near the proximal end of the elongated shaft to the balloon and a guidewire lumen extending from the guidewire entry port to the distal end of the elongated shaft.

14. The rapid exchange catheter of claim 1, wherein first midshaft portion includes a polyimide inner layer, a braided steel member disposed about the polyimide inner layer, and a polyether block amide layer disposed about the braided steel member, and a hydrophilic coating disposed on the outside of the polyether block amide layer.

15. The rapid exchange catheter of claim 1, wherein the elongate shaft has an overall length sufficient to reach coronary blood vessels when inserted to a human patient via the femoral artery.

16. A rapid exchange catheter comprising:

an elongated shaft having proximal and distal ends, the elongated shaft including:

a hypotube having a proximal end and a distal end;

a first midshaft member having a braided construction with a proximal end and a distal end, the first midshaft member being attached near its proximal end to a location near the distal end of the hypotube, the first midshaft member including a lubricious inner layer, a braided member disposed about the lubricious inner layer, and a polymeric outer layer placed over the braided member;

a second midshaft portion having a proximal end, a distal end, and a guidewire entry port, the second midshaft portion being attached near its proximal end to a location near the distal end of the first midshaft portion;

a distal portion defining a short guidewire lumen and an inflation lumen, the distal portion being attached to the second midshaft portion and extending distally therefrom; and

a tapered core wire attached to the hypotube and extending distally of the distal end of the hypotube, across the location at which the proximal end of the first midshaft portion is attached to the distal end of the hypotube, and past the guidewire entry port; and

a balloon disposed near the distal end of the elongated shaft, the balloon including one or more cutting blades adapted for cutting an occlusion.

17. The rapid exchange catheter of claim 16, wherein the lubricious inner layer includes polyimide, the braided member is made of steel, and the polymeric outer layer includes polyether block amide.

18. The rapid exchange catheter of claim 16 wherein the elongate shaft has an overall length sufficient to reach coronary blood vessels when inserted to a human patient via the femoral artery.

19. A method of manufacturing a rapid exchange catheter having a proximal end and a distal end, a proximal hypotube section, and a distal guidewire port a substantial distance from the proximal end of the catheter, the method comprising:

providing a core wire inside the catheter and crossing the distal guidewire port for providing support across the distal guidewire port; and

attaching a braided catheter section having a proximal end and a distal end to the distal end of the hypotube to provide kink resistance and pushability distal of the hypotube;

wherein the braided catheter section is provided proximally of the distal guidewire port.

20. The method of claim 19, wherein the guidewire port is constructed using the distal end of the braided catheter section.

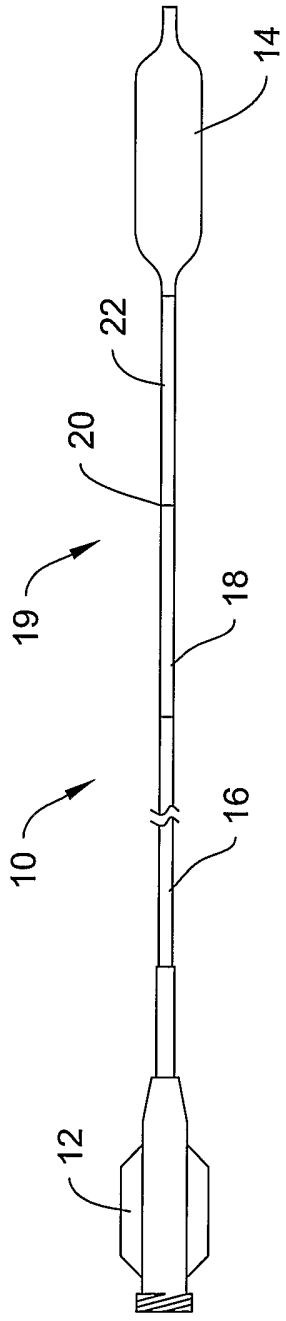


Fig.1

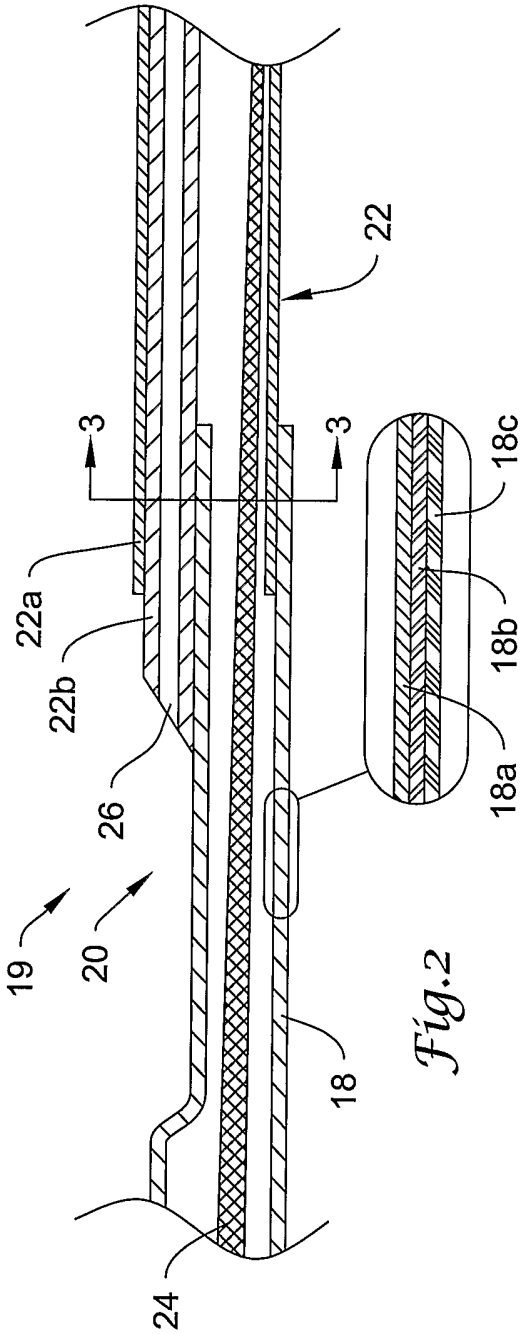


Fig.2

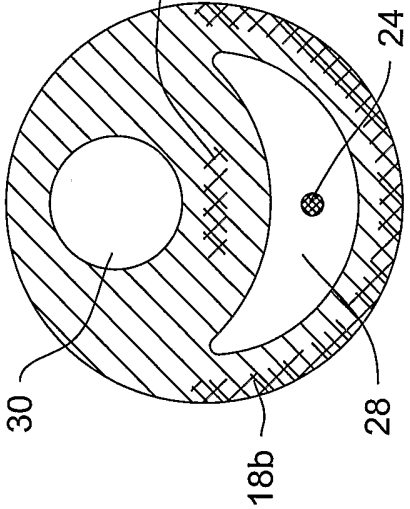


Fig.3

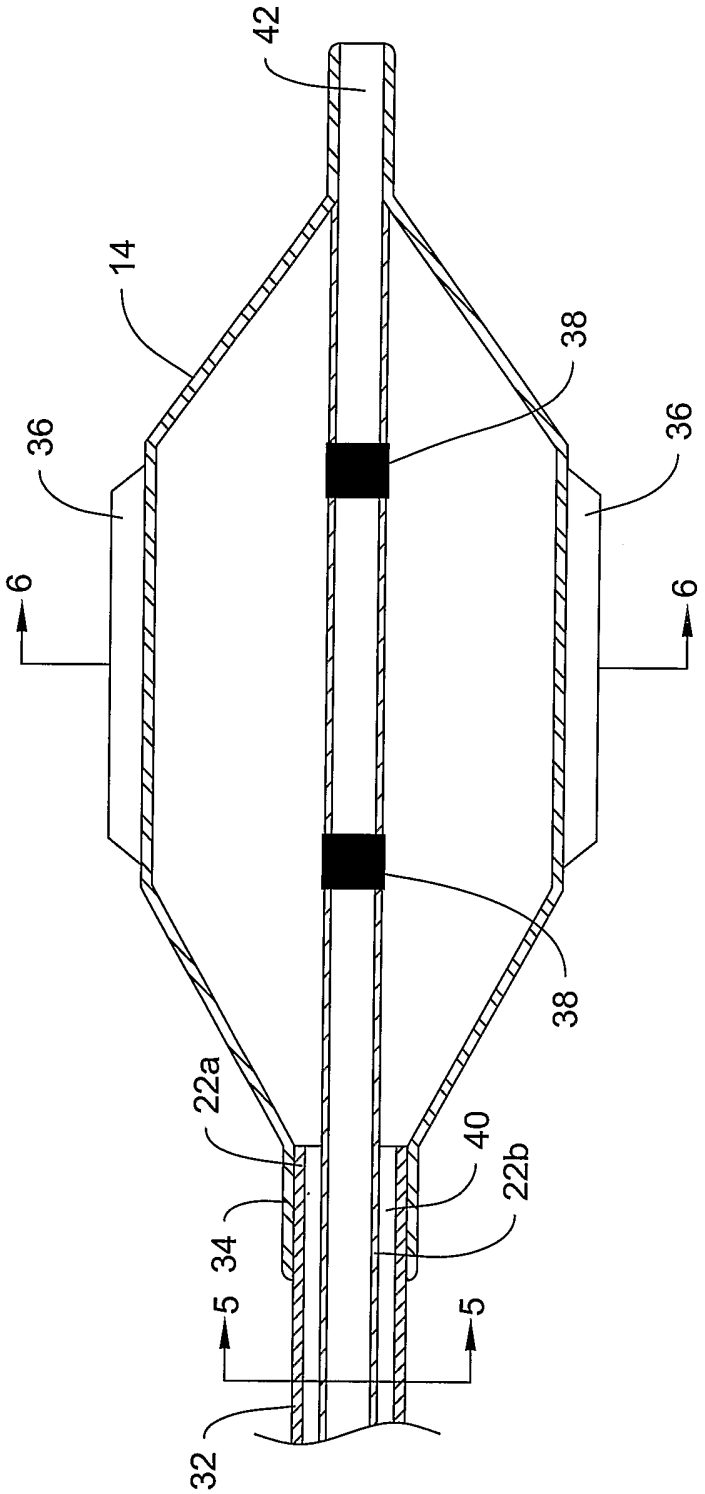


Fig.4

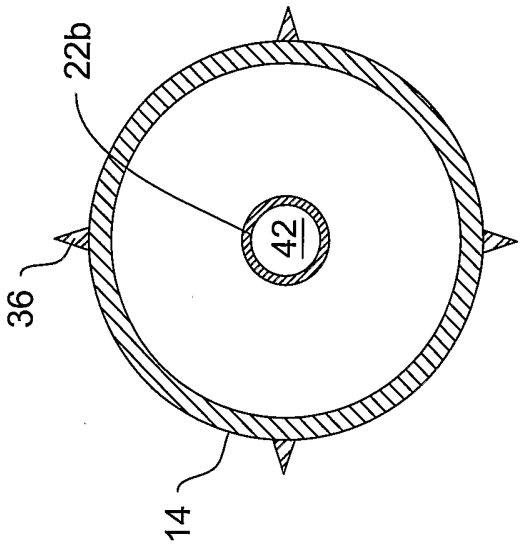


Fig.6

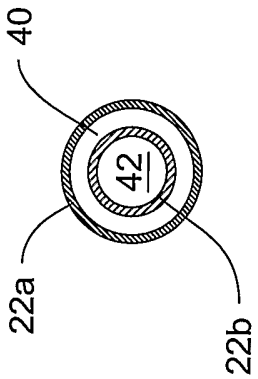


Fig.5

Fig.7

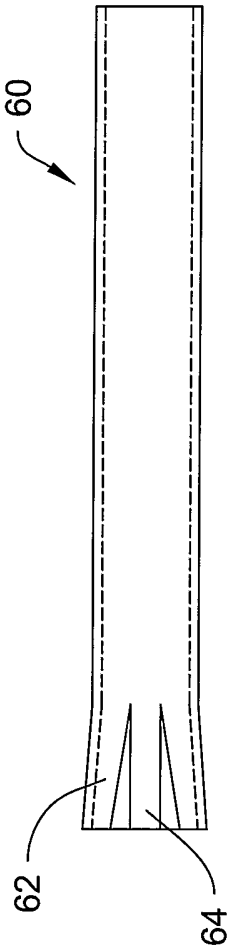
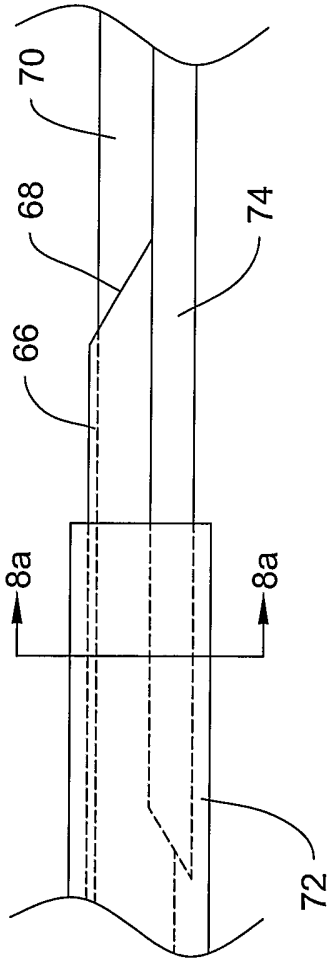


Fig.8



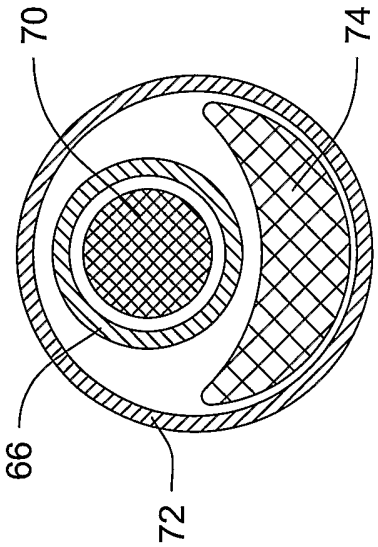


Fig.8A

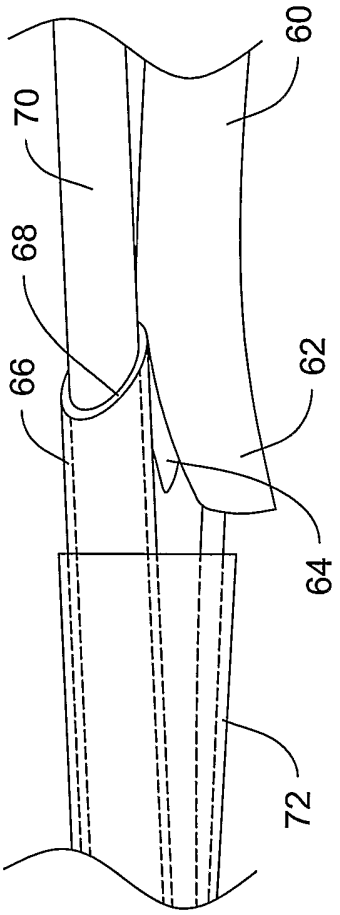


Fig.9

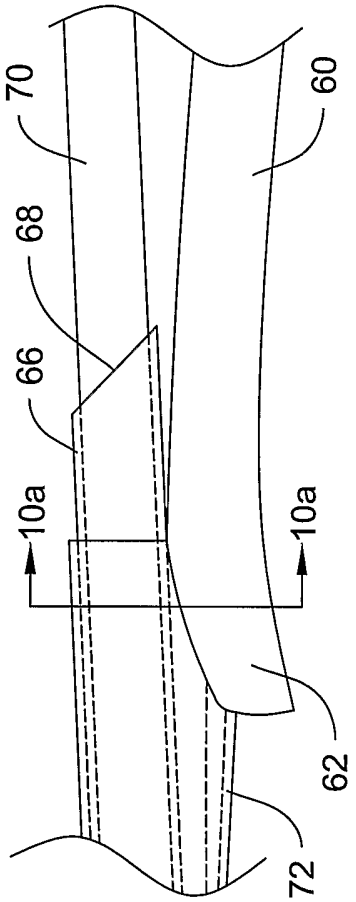


Fig.10

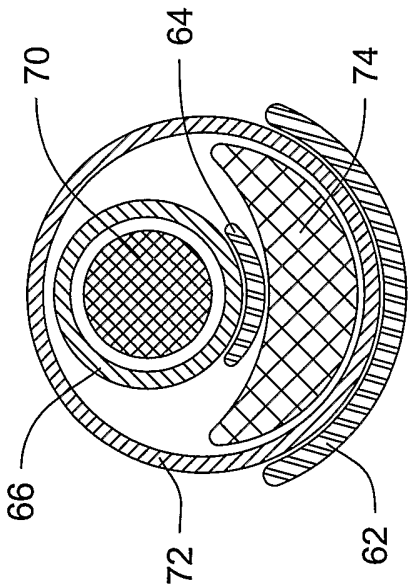


Fig.10A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/014323

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/10

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 6 165 167 A (DELALOYE STEPHANE) 26 December 2000 (2000-12-26) the whole document	19,20 1-5
Y	US 5 320 634 A (BARATH PETER ET AL) 14 June 1994 (1994-06-14) abstract; figures 1,4	1-5
A	US 5 196 024 A (BARATH PETER I) 23 March 1993 (1993-03-23) abstract; figures 1-3	1-20
A	EP 0 792 656 A (TARGET THERAPEUTICS INC) 3 September 1997 (1997-09-03) the whole document	6-10, 16-20

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 September 2004	08/10/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Mausser, T

INTERNATIONAL SEARCH REPORT

Information on patent family members

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