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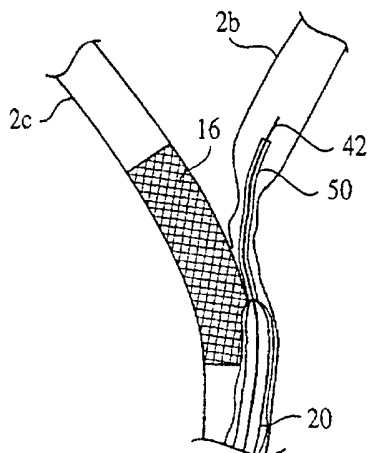
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(54) Title: STENT INTRODUCER SYSTEM



(57) Abstract: A stent delivery system for positioning a first and second stent the first and second branch lumens of a bifurcation. The stent delivery system includes stent introducers (10,20) and a sheath or catheter (50) having a frangible wall. A method of delivering stents to anatomies such as bifurcated ducts or vessels.

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STENT INTRODUCER SYSTEM

RELATED APPLICATIONS

[0001] This claims the benefit of U.S. Provisional Application Serial No. 60/558,721, filed March 31, 2004, entitled "Stent Introducer System," which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] This invention generally relates to medical devices, and more particularly to devices for delivering stents to a target anatomy.

BACKGROUND

[0003] Stents are elongate tubes that are used to prop open occluded or narrowed vessels or body lumens. Among other things, stents are often used to maintain the patency of the biliary tree, or common bile duct. Figure 1 is a partial, cross-sectional view of a biliary system **2** showing the common bile duct **2a**, the left hepatic duct **2b**, the right hepatic duct **2c**, the gall bladder **2d**, the pancreas **2e** and the duodenum **2f**.

[0004] Strictures or occlusions that develop in the upper common bile duct and/or the left and right hepatic ducts can interfere with the proper drainage of those ducts. Figure 2 illustrates a partial cross-sectional view of the biliary system **2** having strictures **3** within the common bile duct **2a**, the left hepatic duct **2b** and the right hepatic duct **2c**. One method of establishing proper drainage through the diseased ducts is to prop open the ducts by placing stents, such as self-expanding biliary stents, within the diseased ducts. Because of the branched configuration of the duct anatomy it is often necessary to place two or more stents in an overlying or side-by-side configuration.

[0005] However, currently available stent and introducer geometries are such that placement of a first stent often impedes placement of a second stent. Figure 3 illustrates the problems associated with the prior art method of placing stents in the common bile duct **2a** and the left and right hepatic ducts **2b**, **2c**. That is, placing stent **16** within the common bile duct **2a** and the left hepatic duct **2b**

impedes subsequent access to the stricture in the right hepatic duct **2c**. This prevents placement of a stent in the right hepatic duct **2c**.

[0006] Figure 3A illustrates one problem encountered in the prior art by placing two stents sequentially. That is, once the first stent is deployed, it impedes insertion of the second introducer **20** used to deploy the second stent. An alternative to sequential deployment of the stents is simultaneous deployment. Simultaneous deployment, however, requires the side-by-side arrangement of two stent introducers within the working channel of an endoscope. Depending on the size of the stents to be placed and the limited size of the working channel of the endoscope, this option may be unworkable.

[0007] Consequently, there is a need for a self-expanding stent delivery system which overcomes the problems associated with prior art delivery systems. Specifically, there is a need for a self-expanding stent delivery system which allows the physician to sequentially place a first and second stent in the side branches and main lumen of a bifurcation.

SUMMARY OF THE INVENTION

[0008] Accordingly, it is an object of the present invention to provide a medical device, method, and kit having features that resolve or improve on one or more of the above-described drawbacks.

[0009] The foregoing object is obtained by providing a stent delivery system having a first introducer used to deploy a first stent, and a sheath or catheter used to receive a second introducer, which in turn is used to deploy a second stent. The first introducer and the catheter can be simultaneously deployed, for example, in a staggered configuration, through the working channel of an endoscope. Once the first stent is deployed, the catheter facilitates delivery of the second introducer to the target anatomy. The catheter or sheath can be splittable.

[0010] In another aspect, wire guides are used to guide the placement of the first introducer, the catheter, and the second introducer.

[0011] In yet another aspect, the foregoing object is obtained by providing a method of placing at stents in the branches of a bifurcated target anatomy. The

method includes placing a first and a second wire guide in a working channel of an endoscope. The first wire guide is inserted into the first branch lumen of the bifurcation. The second wire guide is inserted into the second branch lumen of the bifurcation. A first introducer and splittable catheter can then be advanced over the respective wire guides to the respective target anatomies. Once in place, the first stent can be deployed. A second introducer can then be introduced over the second guide wire, through the splittable catheter and to the proper target anatomy. Once the second introducer is in place, the second stent can be deployed.

[0012] The method of the invention may further include any of the following steps: disposing the first introducer and the splittable catheter within the working channel of the endoscope such that the first introducer proximal portion is disposed adjacent to the splittable catheter and the first introducer distal portion is disposed distal to the splittable catheter while inside the working channel of the endoscope; deploying the first stent within the first branch lumen and the main lumen of the bifurcation and withdrawing the first introducer from the bifurcation; and/or splitting the splittable catheter and withdrawing the splittable catheter from the bifurcation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Figure 1 is a partial, cross-sectional view of a biliary system showing the common bile duct, the left hepatic duct, the right hepatic duct, the gall bladder, the pancreas and the duodenum.

[0014] Figure 2 is a partial, cross-sectional view of the biliary system of Figure 1 showing strictures within the common bile duct, the left hepatic duct and the right hepatic duct.

[0015] Figure 3 is a partial, cross-sectional view of the biliary system of Figure 2 illustrating a stent that has been placed in the common bile duct and the left hepatic duct.

[0016] Figure 3A is a partial, cross-sectional view of the biliary system of Figure 1 illustrating a first stent previously placed by a first introducer in the right hepatic duct and the common bile duct that obscures the access of a second

introducer attempting to place a second stent in the left hepatic duct and common bile duct.

[0017] Figure 4 is a partial, cross-sectional view of the biliary system of Figure 2 illustrating the placement of first and second stents in the left and right hepatic ducts, respectively, and the common bile duct according to a preferred method of the present invention.

[0018] Figure 5 is a partial, cross-sectional view of a preferred embodiment of the stent delivery system of the present invention illustrating a first introducer placed within the right hepatic duct and the common bile duct and a splittable catheter placed in the right hepatic duct and the common bile duct.

[0019] Figure 6 is a partial, cross-sectional view of the preferred embodiment of the stent delivery system of Figure 5 illustrating a first stent deployed in the right hepatic duct and common bile duct after the first introducer has been removed and the splittable catheter placed in the right hepatic duct and the common bile duct.

[0020] Figure 7 is a partial, cross-sectional view of the preferred embodiment of the stent delivery system of Figure 6 illustrating a first stent deployed in the right hepatic duct and common bile duct and the splittable catheter shielding a second introducer as the second introducer is advanced over a second wire guide into the common bile duct and the left hepatic duct.

[0021] Figure 8 is a cross-sectional, end view of the stent delivery system of the present invention showing the first introducer and the splittable catheter within the working channel of an endoscope.

[0022] Figure 9 is a partial, cross sectional, side-view of a preferred embodiment of the stent delivery system of the present invention showing the first introducer and the splittable catheter within the working channel of an endoscope.

[0023] Figure 10 is a cross-sectional view of an embodiment of the first introducer of the stent delivery system of the present invention.

[0024] Figure 11 is a partial, cross-sectional view of a distal portion of the first introducer of Figure 5.

[0025] Figure 12 is a partial, cross-sectional view of an alternate embodiment of the distal portion of the first introducer of Figure 5.

[0026] Figure 13 is a partial, cross-sectional view of the distal portion of the first introducer of Figure 5 showing the wire guide and wire guide lumen.

[0027] Figure 14 is a partial, cross-sectional view of the distal portion of the first introducer of Figure 5 showing an alternate embodiment of the wire guide and the wire guide lumen.

[0028] Figure 15 is a partial, cross-sectional view of the distal portion of the first introducer of Figure 5 showing an alternate embodiment of the wire guide and the wire guide lumen.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0029] Referring now to the Figures wherein like numerals indicate the same element throughout the views, there is shown in Figures 1-2 and 4 a bifurcation having a main lumen, a first branch lumen and a second branch lumen. In particular, these figures illustrate a bifurcation in the biliary system, wherein the main lumen comprises the common bile duct **2a** and the first and second branch lumens comprise the left and right hepatic ducts **2b**, **2c** respectively. Figure 1 shows a normal, or healthy, biliary system without strictures. Figure 2 shows the biliary system with strictures **3** residing in the main lumen and in both branch lumens of the bifurcation. Figure 4 shows a pair of stents placed in the left and right hepatic ducts **2b**, **2c**, respectively, and the common bile duct **2a** according to a method of the present invention.

[0030] Referring now to Figures 5-9, a stent delivery system 1 made in accordance with the present invention is shown. Stent delivery system 1 includes a first introducer **10** having a first stent **16**, a second introducer **20** comprising a second stent **26** and a splittable catheter **50**. The first introducer **10** and the splittable catheter **50** are adapted to be disposed within the working channel **8a** of an endoscope **8** as shown in Figures 5, 8 and 9. Figure 7 illustrates, the splittable catheter **50** comprises an inner diameter through which the second introducer is

advanced. The stent delivery system 1 may also include first and second wire guides **32**, **42** as illustrated in Figure 5.

[0031] The splittable catheter **50** comprises an inner diameter and an outer diameter. The splittable catheter **50** inner diameter is adapted to receive the second introducer **20** as best seen in Figure 7. Splittable catheter **50** can be made from any suitable material known in the art including, but not limited to, PTFE, polyamide, polyurethane, polyethylene and nylon including multi-layer or single layer structures. Alternatively, the splittable catheter **50** can be constructed of a splittable material, i.e. a material that readily tears in a longitudinal direction along the length of the sheath. A non-limiting example of a splittable material is a molecularly oriented (non-isotropic) polytetrafluoroethylene (PTFE) such as that used in the PEEL-AWAY™ Sheath (Cook Incorporated, Bloomington, Ind.). Optionally, the splittable catheter **50** comprises a groove, pre-score, a weakened area or a pre-slit end to facilitate splitting. Typically, splittable catheter **50** ranges in size from about 5 Fr. to about 9 Fr. These sizes are provided for illustrative purposes only and are not intended to be construed as a limitation of the present invention. As one of ordinary skill in the art would appreciate, the size of the splittable catheter **50** is related to the size of the second introducer **20** that is advanced through it, which in turn is related to the size of the second stent **26** in its compressed or unexpanded configuration. Thus, splittable catheters smaller than about 5 Fr. that may become available in the future are contemplated as being within the scope of the claims of the invention.

[0032] With respect to the first and second introducers **10**, **20** of the stent delivery system of the present invention, any introducer capable of introducing and deploying stents is contemplated. Non-limiting examples include biliary stent deployment delivery systems as well as the introducers described in co-pending provisional application number 10/728,589 (Attorney docket number 10000/218), which is incorporated by reference in its entirety. The first and second introducers **10**, **20** may be of the same or different type and size. Thus, with respect to the exemplary introducers described herein, reference will be made to only the first introducer **10**.

[0033] Figures 10-15 illustrate several, non-limiting, exemplary embodiments of introducer **10**. In one exemplary embodiment, illustrated in Figure 10, introducer **10** has a proximal end and a distal end and comprises inner and outer coaxial tubes. The outer coaxial tube forms an outer catheter, or sheath, **11**. The inner coaxial tube forms a shaft **13**.

[0034] Shaft **13** has a proximal end **13a**, a distal end **13b** and a stent retaining area **15**. Optionally, shaft **13** may include a pusher band **17** attached to the stent retaining area **15**, a distal tip **18** attached to the shaft distal end **13b** and a wire guide lumen **19**. Shaft **13** can be made from any suitable material known in the art including, but not limited to, polyethylene ether ketone (PEEK), polytetrafluoroethylene (PTFE), polyamide, polyurethane, polyethylene and nylon, including multi-layer or single layer structures and may also include reinforcement wires, braid wires, coils and or filaments. Preferably, shaft **13** comprises a proximal portion made of a relatively rigid material such as stainless steel or any other suitable material known in the art.

[0035] Stent retaining area **15** is preferably located on a distal portion of the shaft **13**. The stent retaining area **15** retains a stent **16** to be deployed in the bifurcation. Optionally, stent **16** is a self-expanding stent.

[0036] Pusher band **17** helps to prevent the stent from proximally migrating as the outer catheter **11** is withdrawn proximally to deploy the stent. The pusher band **17** is located proximal to the stent **16** such that the proximal end of the stent **16** abuts the pusher band **17** as shown in Figures 10-15.

[0037] Distal tip **18** helps prevent fluids from entering the outer catheter **11** as the introducer **10** is navigated through the body lumens. As shown in Figures 10-15, distal tip **18** has a proximal end **18a** and a distal end **18b**. The distal tip proximal end **18a** has a diameter that is less than the diameter of the distal outer catheter distal end **14b** and is received therein. Optionally, the distal tip **18** tapers to a smaller diameter towards its distal end **18b** as shown in Figure 12. Distal tip **18** can be made from any suitable material known in the art including, but not limited to, PEEK, PTFE, polyamide, polyurethane, polyethylene and nylon, including multi-layer or single layer structures.

[0038] In the embodiment shown in Figures 10 and 13, wire guide lumen **19** extends through the shaft **13**, from the shaft distal end **13b** to the shaft proximal end **13a**. In this embodiment, the shaft proximal end **13a** optionally includes a luer-lock fitting **31** for releaseably fixing a wire guide **32** relative to shaft **13** as shown in Figure 10. In the embodiments shown in Figures 10 and 13, the stent delivery system **1** of the present invention includes an over-the-wire type wire guide. Such wire guides are known in the art.

[0039] Alternatively, the wire guide lumen **19** may extend through the shaft **13** from the shaft distal end **13b** to the shaft proximal end **13a** but the wire guide **32** exits through an aperture positioned along the length of the introducer **10**. For example, as shown in Figure 14, the wire guide **32** extends through a portion of the distal tip **18** and exits through an aperture **30** positioned along the length of the distal tip **18**. In this embodiment, the wire guide **32** extends through the distal tip **18** and exits the introducer **10** without passing through stent **16**. For example, wire guide **32** may extend proximally through distal tip **18** for a distance of about 1 cm.

[0040] In the alternate embodiment shown in Figure 15, the wire guide lumen **19** extends through the length of the shaft **13** but the wire guide **32** extends through a portion of the shaft **13** and exits through an aperture **30** positioned along the length of outer catheter **11**. In this embodiment, wire guide **32** extends through the distal tip **18**, through a portion of the shaft **13** and passes through stent **16** before exiting introducer **10**. For example, wire guide **32** may extend through the distal tip **18** and through the stent retaining area **15** for a distance of about 20 cm.

[0041] In yet other alternative embodiments, the wire guide lumen **19** may extend through a portion of shaft **13** and may exit through an aperture **30** positioned along the length of the introducer **10**. Any number of apertures **30** positioned at any location along the length of the introducer **10** is contemplated. In addition, the wire guide lumen **19** may also comprise a channel or split.

[0042] Aperture **30** provides the stent delivery system of the present invention with rapid-exchange capabilities. In particular, by extending the wire guide **32** through only a distal portion of the wire guide lumen **19**, the delivery system can

be removed from a wire guide **32** having a length substantially shorter than the length necessary if the wire guide **32** were extended through the entire length of the wire guide lumen **19**.

[0043] Referring to Figure 10, the sheath, or outer catheter **11** has a proximal end **11a** and a distal end **11b**. Preferably, at least the distal portion of outer catheter **11** is made of any optically clear or imageable material so that the stent **16** mounted on the stent retaining area **15** of the shaft **13** can be viewed. The outer catheter **11** further includes a proximal outer catheter **12** having proximal and distal ends, **12a** and **12b**, respectively, and a distal outer catheter **14** having proximal and distal ends, **14a** and **14b**, respectively. The distal end **12b** of the proximal outer catheter **12** is attached to the proximal end **14a** of the distal outer catheter **14** to form outer catheter **11**. The distal end **12b** of proximal outer catheter **12** can be attached to the proximal end **14a** of distal outer catheter **14** by any method known in the art including, but not limited to, heat fusing, adhesive bonding, chemical bonding or mechanical fitting. Alternatively, the proximal outer catheter **12**, and the distal outer catheter **14** can be formed from of a single catheter or sheath. The first introducer proximal outer diameter is about 5 Fr. to about 6 Fr. and the first introducer distal outer diameter is about 6 Fr. to about 6.5 Fr. to place a first stent **16** having a compressed diameter of about 0.077 inches to about 0.78 inches. These sizes are provided for illustrative purposes only and are not intended to be construed as a limitation of the present invention. As one of ordinary skill in the art would appreciate, the size of the introducer required to place a stent is related to the size of the stent to be placed, and more particularly, to the size of the compressed configuration of the stent. Thus, introducers having distal outer diameters less than about 6 Fr. used to place stents having compressed configurations less than about 0.078 inches that may become available in the future are contemplated as being within the scope of the claims of the invention.

[0044] The first introducer **10** and the splittable catheter **50** are sized to be disposed next to each other in the working channel **8a** of an endoscope **8**. More particularly, the sum of the first introducer **10** outer diameter (i.e. either the proximal outer diameter or the distal outer diameter) and the splittable catheter

outer diameter is less than the inner diameter of the working channel **8a** of the endoscope **8**.

[0045] Referring to the embodiment shown in Figure 9, the first introducer **10** and the splittable catheter **50** are disposed next to each other in a staggered configuration within the working channel **8a** of an endoscope **8**. That is, the introducer has an increased diameter portion (the stent retaining area) and a decreased diameter portion (the proximal outer catheter). Likewise, the splittable catheter has an increased diameter portion (the stent retaining area) and a decreased diameter portion (the proximal outer catheter). When the introducer catheter are positioned in an endoscope adjacent to one another, and staggered, the respective increased and decreased diameter portions are nested together. As can be seen in Figure 9, the sum of the first introducer proximal outer diameter and the splittable catheter **50** is less than the inner diameter of the working channel **8a** of the endoscope **8**.

[0046] In yet another alternate embodiment of the stent delivery system **1** of the present invention, the first introducer **10** and the splittable catheter **50** are sized to also accommodate at least one wire guide **32**, **42** within the working channel **8a** of the endoscope **8**. For this embodiment, the sum of the first introducer proximal outer diameter, the splittable catheter outer diameter and at least one of the first and second wire guides **32**, **42** is less than the inner diameter of the working channel **8a** of the endoscope **8**.

[0047] The stent delivery system **1** of the present invention is used to place first and second stents **16**, **26** into a bifurcation having strictures **3** in the main lumen **2a** and the first and second branch lumens **2b**, **2c** as follows. Using an endoscope, a distal end of a first wire guide is advanced into the first branch lumen of the bifurcation and a distal end of a second wire guide is advanced into the second branch lumen of the bifurcation. The first introducer **10** and the splittable catheter **50** are inserted over the guide wire into the working channel **8a** of the endoscope **8**. As a result, the first introducer **10** is positioned within the first branch of the bifurcation and the splittable catheter **50** is positioned within the second branch lumen of the bifurcation, as shown in Figure 5. The first introducer

10 and splittable catheter **50** may be positioned sequentially or simultaneously. The first introducer **10** is positioned such that the first stent **16** is at least partially aligned within any occlusion or narrowing of the first branch of the bifurcation. Once aligned, the first stent is deployed within the first branch of the bifurcation and the first introducer is withdrawn as shown in Figure 6. After the first introducer **10** is removed, a second introducer **20** is passed through the working channel **8a** of the endoscope **8** and advanced over the second wire guide **42** through the splittable catheter **50**. Figure 7 shows that the splittable catheter **50** acts as a shield to protect the second introducer **20** from being snagged, or otherwise blocked, by the deployed first stent **16**. Figure 7 also shows the splittable catheter **50** splitting, or peeling away, as the second introducer **20** is advanced through it and into the second branch lumen **26**. Once the second introducer **20** is positioned in the second branch lumen **2b**, the splittable catheter **50** is removed and the second stent **26** is deployed within the second branch lumen **2b** and the main lumen **2a**. The resulting configuration is shown at Figure 4.

[0048] The above Figures and disclosure are intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in the art. All such variations and alternatives are intended to be encompassed within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the attached claims. For example, the invention has been described in the context of the biliary system for illustrative purposes only. Application of the principles of the invention to any other bifurcated lumens or vessels within the body of a patient, including areas within the digestive tract such as the pancreatic system, as well as areas outside the digestive tract such as other vascular systems, by way of non-limiting examples, are within the ordinary skill in the art and are intended to be encompassed within the scope of the attached claims.

CLAIMS

1. A kit for delivering first and second stents to a branched target anatomy, the kit comprising:

a first introducer comprising:

a tubular body having a proximal end, a distal end, and a stent carrying portion therebetween;

a second introducer comprising:

a tubular body having a proximal end, a distal end, and a stent carrying portion therebetween;

a catheter adapted to receive the second introducer, the catheter having a frangible wall; and

a sterile package adapted to receive the first introducer, the second introducer and the catheter.

2. The kit of claim 1, further comprising:

a first stent positioned within the stent carrying portion of the first introducer; and

a second stent positioned within the stent carrying portion of the second introducer.

3. The kit of claim 1 or 2, further comprising:

a first wire guide wherein the first wire guide is configured to receive the first introducer; and

a second wire guide wherein the second wire guide is configured to receive the second introducer, wherein the sterile package is adapted to receive the first and second wire guides.

4. The kit of claim 1 or 2, wherein the first introducer further comprises:

a passageway extending between the distal end and a port positioned proximal to the stent carrying portion, wherein the port is adapted to receive a wire guide.

5. The kit of claim 1 or 2, wherein the second introducer further comprises:

a passageway extending between the distal end and a port positioned proximal to the stent carrying portion, wherein the port is adapted to receive a wire guide.

6. The kit of claim 1 or 2, wherein the first introducer further comprises:

a passageway extending between the distal end and a port positioned distal to the stent carrying portion, wherein the port is adapted to receive a wire guide.

7. The kit of claim 1 or 2, wherein the second introducer further comprises:

a passageway extending between the distal end and a port positioned distal to the stent carrying portion, wherein the port is adapted to receive a wire guide.

8. The kit of claim 1, 2, or 4-7 wherein the first introducer and the catheter are adapted to be disposed in a partly staggered configuration within the working channel of an endoscope.

9. The kit of claim 2 wherein the stent is self-expanding.

10. The kit of any preceding claim wherein the frangible wall comprises a structural weakness.
11. The kit of claim 10 wherein the structural weakness is a score.
12. The kit of claim 10 wherein the structural weakness comprises a longitudinal slit.
13. The kit of claim 10 wherein the structural weakness comprises an interrupted longitudinal slit.
14. The kit of claim 10 wherein a first longitudinal portion of the frangible wall has a thickness less than the thickness of an adjacent portion of the longitudinal wall.

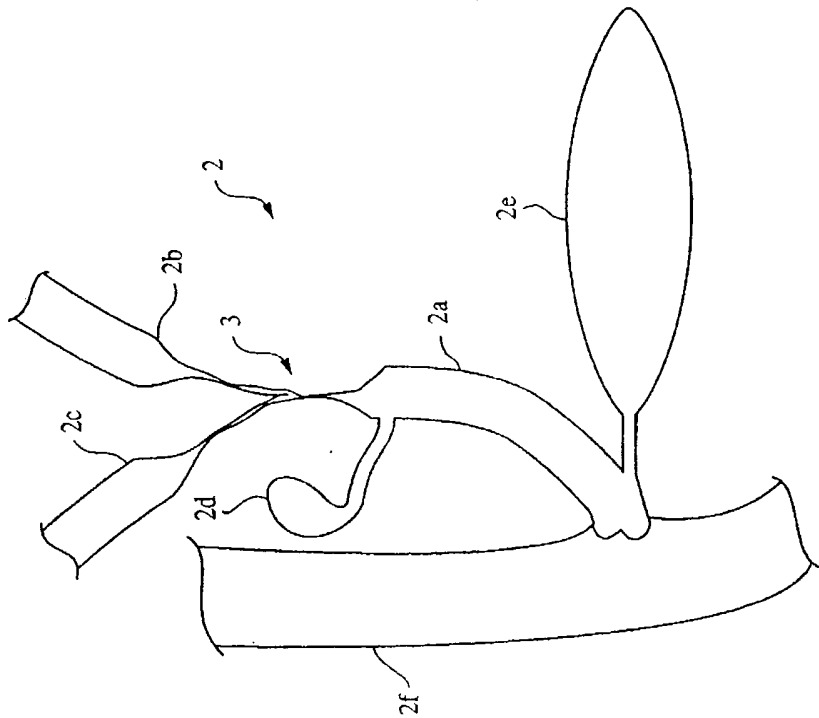


FIG. 2

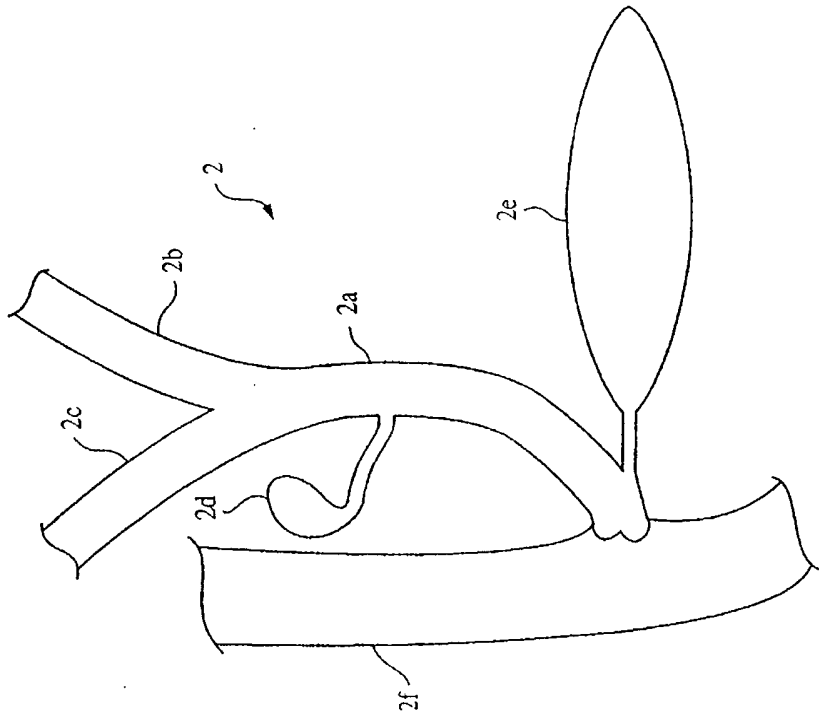


FIG. 1

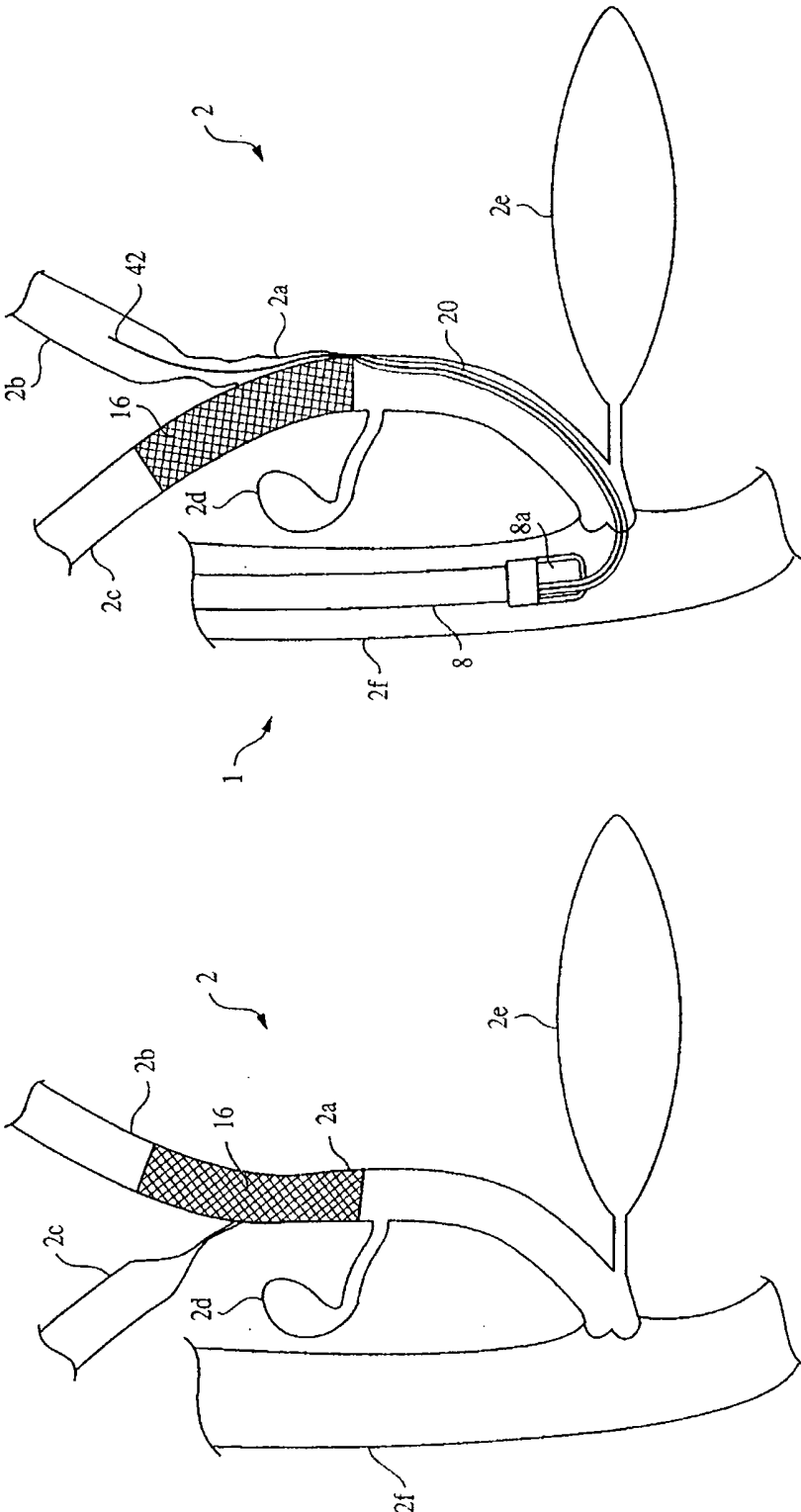


FIG. 3A

FIG. 3
PRIOR ART

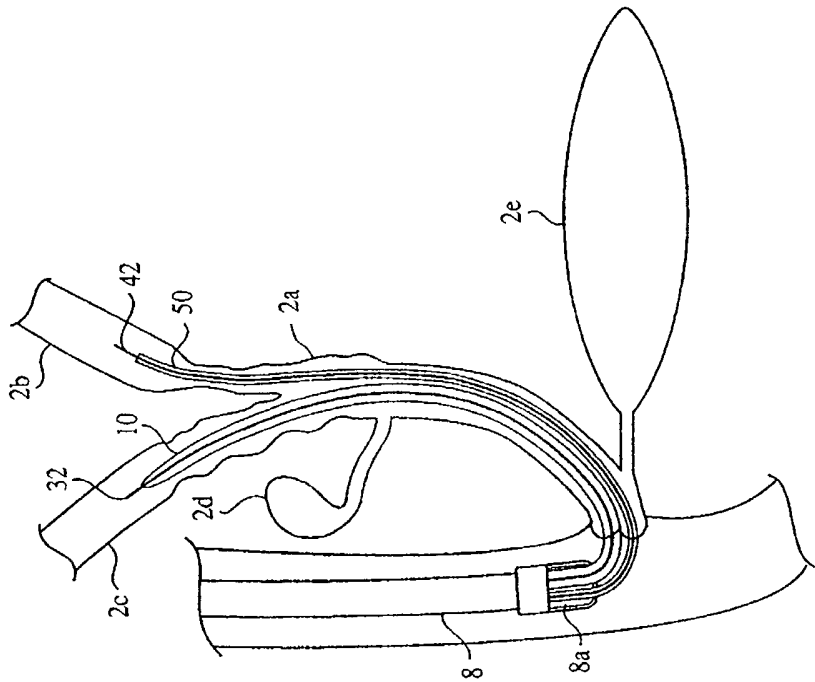


FIG. 5

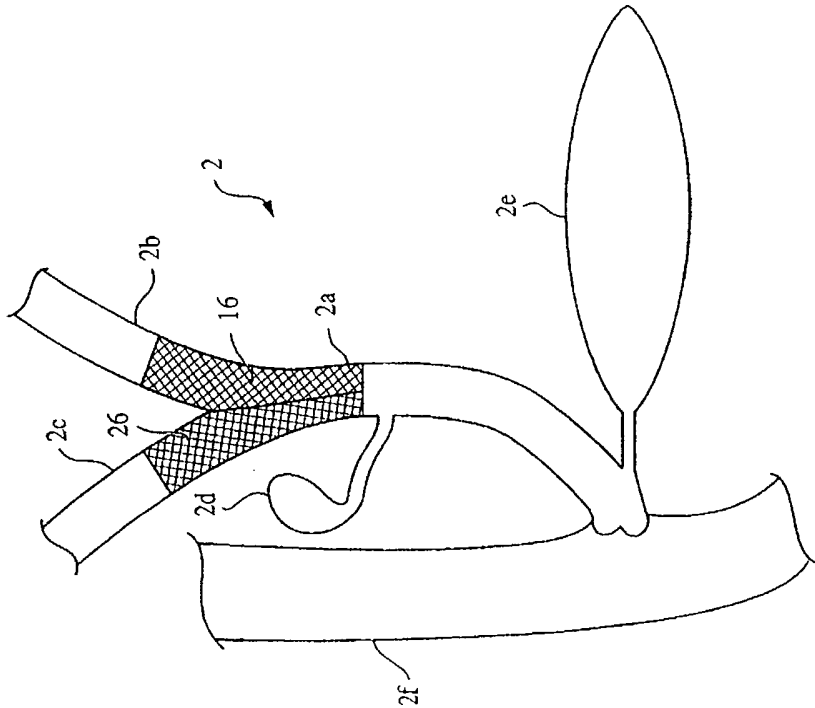


FIG. 4

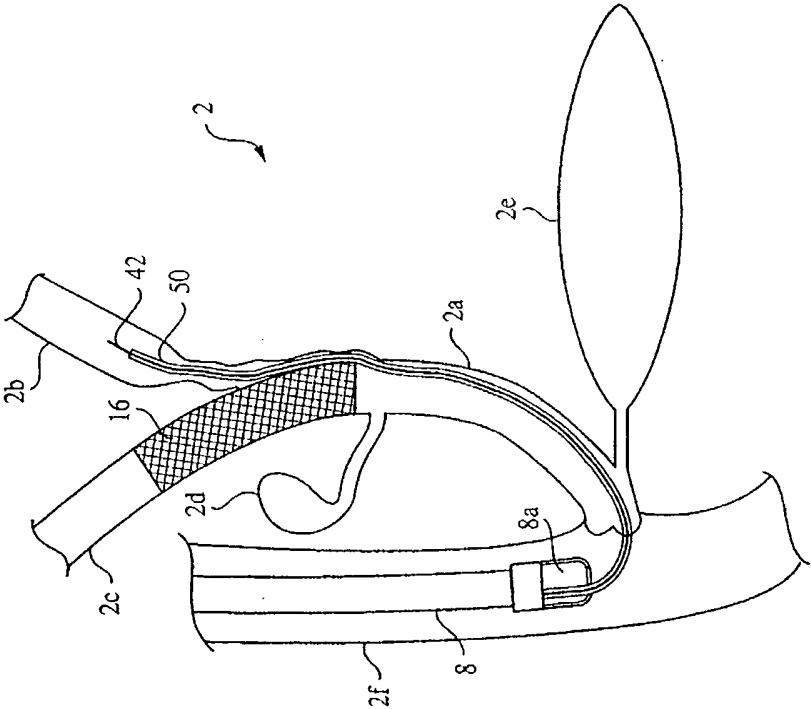


FIG. 6

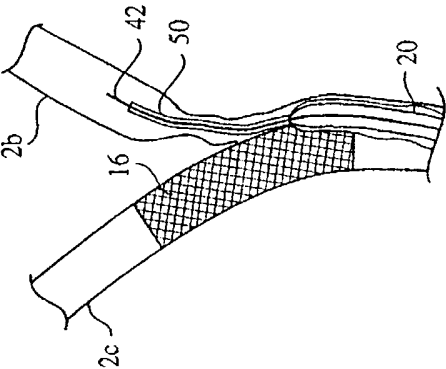


FIG. 7

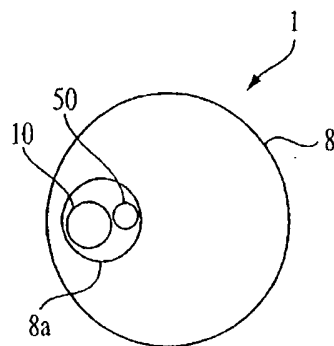


FIG. 8

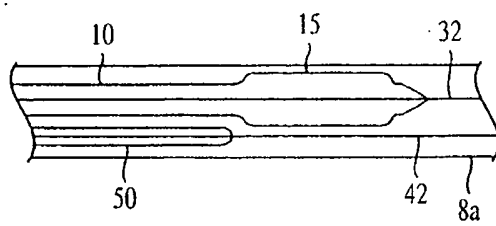


FIG. 9

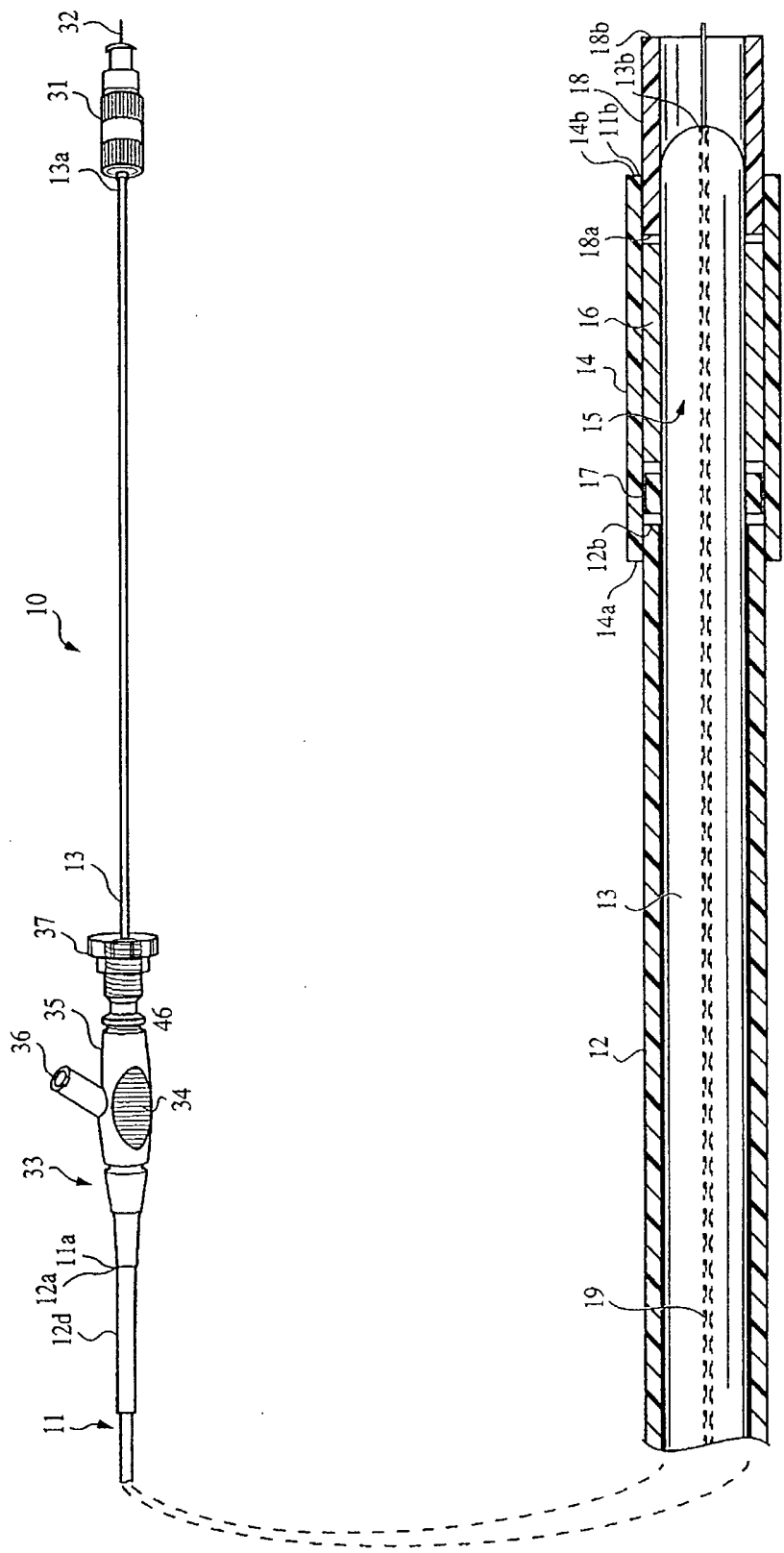


FIG. 10

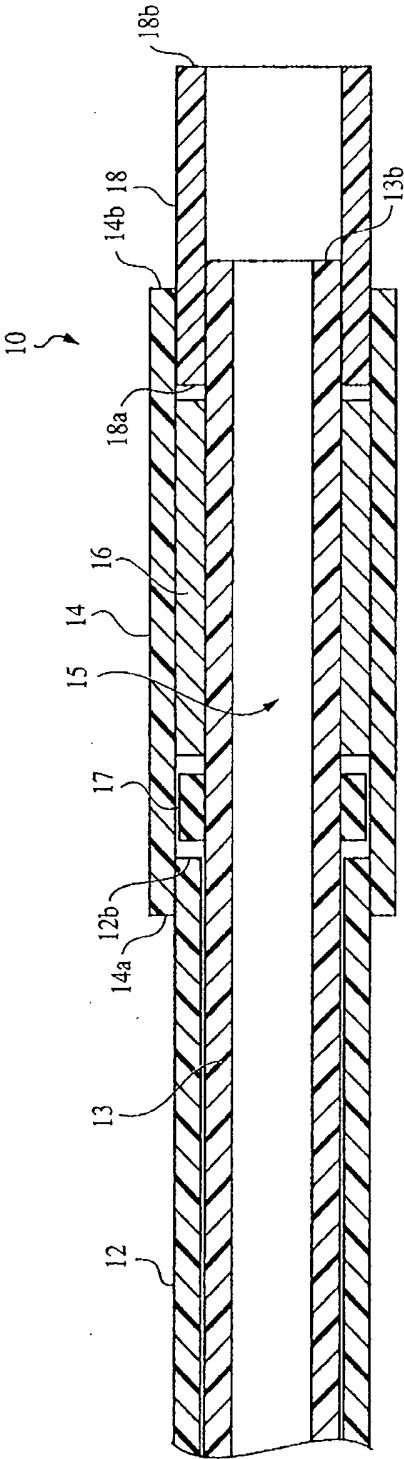


FIG. 11

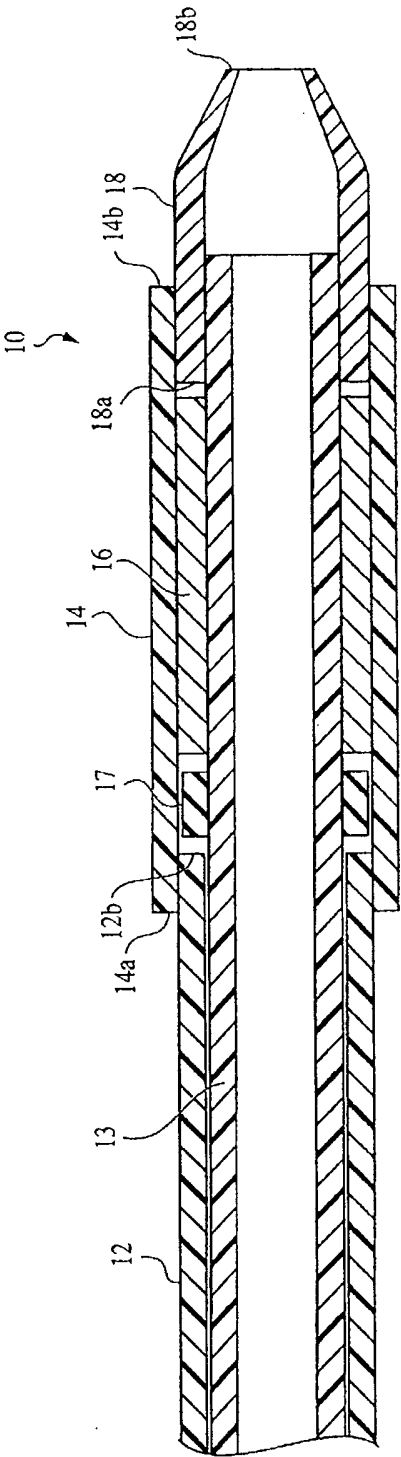


FIG. 12

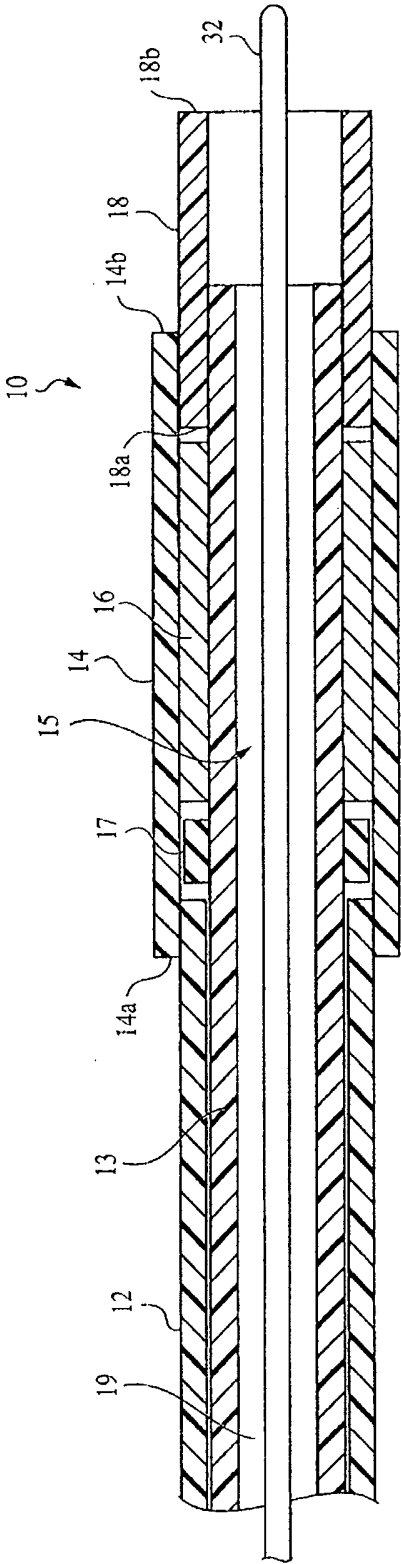


FIG. 13

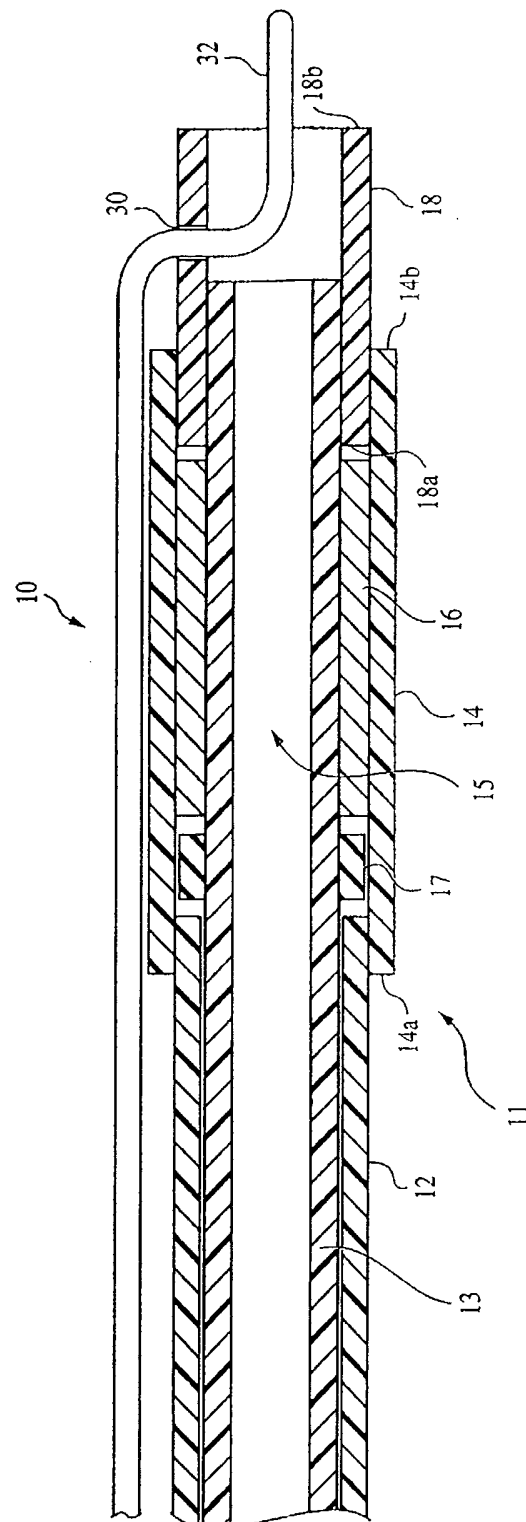


FIG. 14

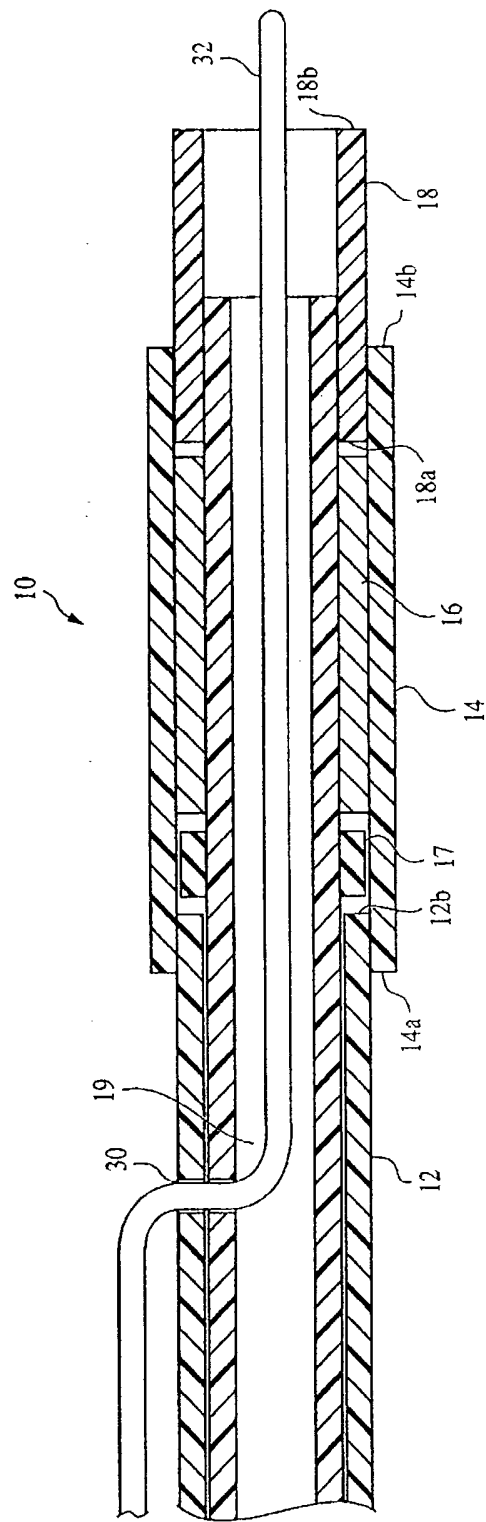


FIG. 15

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/010904

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/06 A61M25/06

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 A61F 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)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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Patent family members are listed in annex.

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Date of the actual completion of the international search

29 July 2005

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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