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(54) Title: METHOD AND APPARATUS FOR DIVERTING A GUIDEWIRE THROUGH A BIFURCATED PASSAGEWAY

(57) Abstract: The present invention is directed to a method and apparatus for diverting a guidewire and/or catheter through a bifurcated passageway (e.g., blood vessel). The apparatus comprises an elongated tube having an inner lumen being accessible via a proximal end opening, a distal end opening, and a first and second side openings provided on a distal section of said elongated tube, wherein the lumen comprises a partitioning element located in the distal section such that it partitions the lumen into a first and second separate lumens such that the first lumen is accessible via said first side opening and via said proximal end opening and the second lumen is accessible via the second side opening and via the distal end opening. A method for diverting a guidewire and/or catheter along a desired pathway through a bifurcated passageway by using this apparatus is also described.

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**METHOD AND APPARATUS FOR DIVERTING A GUIDEWIRE THROUGH A  
BIFURCATED PASSAGEWAY**

**Field of the Invention**

The present invention relates to a method and apparatus for diverting a guidewire through a bifurcated passageway. More particularly, the invention relates to a method and apparatus for maneuvering a guidewire or catheter towards a destined treatment site through a bifurcated body vessel or cavity such as blood vessels, respiratory airways, etc.

**Background of the Invention**

Passing guidewires through a bifurcated body passageway (e.g., blood vessel) is an initial mandatory step in many percutaneous therapeutic intervention. For example, in the coronary tree, multiple anatomical and post surgical variations create a tremendous challenge for the physician to direct and propagate wires into angulations of the vascular bifurcations of about 90°. Such bifurcations include T-type bifurcations and multiple tortuosities, including retrograde navigation into a native vessel through a bypass graft.

Directing guidewires and/or catheters through such branching passageways lead to prolonged procedure times, thereby exposing the patient to different maneuvers, multiple guidewires and balloons, etc., and leading to increased risk for procedure-related complications.

For example, when a treatment site is to be accessed via a bifurcated blood vessel a guidewire having a J-shaped tip is typically used. The J-shaped guidewire is inserted into a blood vessel through an incision and its location in the blood vessel is visualized using X-ray for instance. The physician

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maneuvers the J-shaped guidewire through turns and bifurcated vessels by rotating the guidewire about its axis.

US 6,231,563 (to *Geoffrey H. White et al*) describe an intraluminal catheter for directing a guidewire and/or catheter in a desired direction within a bodily vessel or cavity. This intraluminal catheter comprises a main elongate tube adapted to slide over a main guidewire positioned in the vessel, and a second elongated tube having an end portion that is deflectable relative to the locus of the main tube to direct a supplementary guidewire passing through an additional elongated tube into the bodily vessel in a direction transverse to the locus of the main guidewire.

US 2002/055732 (to *W. Stan Wilson*) describe a catheter assembly for advancing a pair of guidewires to a bifurcated vessel. This catheter assembly comprises two guidewire lumens which are substantially parallel to each other throughout their lengths, and it allows for the delivery of two wires to a bifurcation for carrying out an interventional procedure, such as implantation of a bifurcated stent.

US 2003/028233 (to *Gil M. Vardi et al*) describe a method for positioning a stent at a vessel bifurcation. A side opening is provided in the main stent that is positioned at the ostium of a branch vessel. A stent delivery system comprising a catheter with a flexible side sheath is advanced over a main guidewire passing in the main vessel such that its distal end extends past the bifurcation. The main stent is positioned over the catheter with the flexible side sheath positioned to pass through the interior of the main stent and out of the side opening in the main stent. A branch guidewire is advanced

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through the flexible side sheath attached to the catheter and into the branch vessel.

The methods described above have not yet provided satisfactory solutions for directing a guidewire and/or catheter through substantially narrow bifurcated passageways. Therefore there is a need for a method and apparatus for directing a guidewire and/or a catheter through a bifurcated body vessel or cavity.

It is therefore an object of the present invention to provide a method and apparatus for advancing a guidewire and/or catheter through relatively narrow bifurcated body vessel or cavity, such as in the coronary tree.

It is another object of the present invention to provide a relatively slender navigation catheter suitable for advancing a guidewire and/or catheter through relatively narrow bifurcated body vessel or cavity by using a single guidewire.

It is a further object of the present invention to provide a method for directing a guidewire and/or catheter through a relatively narrow and complicated, bifurcated passageway by using a single guidewire.

It is yet another object of the present invention to provide a catheter suitable for advancing a guidewire and/or catheter through a bifurcated passageway where the angle between the passageway and its branching passageway is greater than or equal to  $90^\circ$ .

Other objects and advantages of the invention will become apparent as the description proceeds.

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**Summary of the Invention**

The present invention provides a method and apparatus for diverting a guidewire and/or catheter through a bifurcated passageway such as blood vessels, respiratory airways, and body cavities.

The present invention is primarily directed to an apparatus for diverting a guidewire and/or catheter through a bifurcated passageway (e.g., blood vessels). The apparatus preferably comprise an elongated tube having an inner lumen being accessible via a proximal end opening, a distal end opening, and a first and second side openings provided on a distal section of the elongated tube, wherein the lumen comprises a partitioning element located in said distal section such that it partitions the lumen into a first and second separate lumens such that the first lumen is accessible via the first side opening and via the proximal end opening and the second opening is accessible via the second side opening and via the distal end opening.

The partitioning element is preferably adapted to force a guidewire advanced along the first lumen to exit the first lumen in a predetermined exit angle relative to the axis of the elongated tube.

Conveniently, the first and second side openings are located on opposing vertical sides of the elongated tube.

The elongated tube may further comprise a score between its proximal end opening and a point between the proximal end opening and its proximal side opening from which a guidewire may be removed from, or introduced into, the proximal lumen.

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According to another preferred embodiment of the invention the apparatus for diverting a guidewire and/or catheter through a bifurcated passageway is comprised of a main elongated tube having an inner lumen being accessible via a proximal end opening and a distal exit opening thereof and a supplementary tube having an inner lumen being accessible via a proximal entrance opening and a distal end opening thereof, wherein a distal end section of the main elongated tube is attached to the supplementary tube along a corresponding proximal end section thereof.

Preferably, the distal exit opening of the main elongated tube is designed to provide a desired exit angle of a guidewire passing therethrough relative to the main elongated tube.

The present invention is also directed to a method for diverting a guidewire and/or catheter along a desired pathway through a bifurcated passageway, comprising:

- providing a navigation catheter having separated proximal and distal lumens, wherein the proximal lumen is accessible from its distal side via a first side opening of the navigation catheter, and from its proximal side via a proximal end opening of the navigation catheter, and wherein the distal lumen is accessible from its proximal side via a second side opening of the navigation catheter, and from its distal side via a distal end opening of the navigation catheter;
- inserting a guidewire capable of being advanced through the first and second lumens into a bifurcated passageway until a distal tip thereof passes a bifurcation to be passed along the desired pathway;
- advancing the navigation catheter over the guidewire by threading its distal lumen thereon and placing the

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navigation catheter therein such that its first side opening is positioned in the vicinity of the bifurcation;

- retracting the guidewire proximally; and
- advancing the guidewire and/or a catheter device through the proximal lumen and adjusting the orientation of the navigation catheter such that the first opening faces the bifurcation and a distal portion of the advanced guidewire and/or catheter device exits the proximal lumen through the first side opening into a branching passageway at the bifurcation.

The method may further comprise retracting the navigation catheter proximally over the guidewire and/or catheter device.

#### **Brief Description of the Drawings**

The present invention is illustrated by way of example in the accompanying drawings, in which similar references consistently indicate similar elements and in which:

- Fig. 1A shows a longitudinal-section side view of a navigation catheter constructed from a single tube according to a preferred embodiment of the invention;
- Fig. 1B shows a longitudinal-section top view of a the navigation catheter of the invention;
- Fig. 2 schematically illustrates advancing the navigation catheter of the invention over a guidewire towards a bifurcation;
- Fig. 3 schematically illustrates advancing the guidewire into a bifurcated passage; and
- Fig. 4 is a longitudinal-section of a navigation catheter constructed from a main longitudinal tube attached at its distal end to a supplementary tube according to another preferred embodiment of the invention.

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**Detailed Description of Preferred Embodiments**

The present invention is directed to a navigation catheter, and to a procedure used therewith, for directing and navigating guidewires through branching body passageways. The present invention also aims to substantially simplify and shorten the intervention time required in such procedures.

The navigation catheter **10** of the present invention, as shown in Fig. 1A, may be constructed from an elongated flexible tube **17** comprising a single lumen **2**. Navigation catheter **10** comprise two end openings, a distal end opening **1** and a proximal end opening **6**, and two side openings, proximal side opening **3b** and distal side opening **3a**, located on a distal portion of elongated tube **17**.

Navigation catheter **10** further comprises a partition **5**, disposed in a distal portion of the lumen of elongated tube **17** between proximal side opening **3b** and distal side opening **3a**. Partition **5** preferably has either straight, diagonal, or curved inner walls, **5a** and **5b**. Distal inner wall **5a** is located proximally adjacent to distal side opening **3a**, such that distal lumen portion **2a** may be accessed via distal side opening **3a** and/or via distal end opening **1**. Similarly, proximal inner wall **5b** is located distally adjacent to proximal side opening **3b**, such that distal lumen portion **2b** may be accessed via proximal side opening **3b** and/or via proximal end opening **6**.

As will be explained herein below with reference to Figs. 2 and 3, partition **5** is utilized for diverting the path of a guidewire **15** introduced via proximal end opening **6** or via distal end opening **1**, from a straight (longitudinal) path into an angled path. Navigation catheter **10** is preferably designed



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to enable guidewire **15** inserted via one of its end openings (**1** and/or **6**) to exit lumen **2** via a corresponding side opening (**3a** and/or **3b**) at a desired angle  $\theta$ , relative to the longitudinal axis of elongated tube **17**. A desired exit angle  $\theta$  of guidewire **15** can be obtained by properly positioning partition **5** between the side openings and by a suitable design of its inner walls, **5a** and **5b**.

Navigation catheter **10** of the invention is preferably longitudinally scored along its outer surface, as shown in Fig. 1B. Longitudinal score **8** is preferably introduced along the wall of elongated tube **17** between proximal end opening **6** and to a point between proximal end opening **6** and proximal side opening **3b**, thereby allowing "peel-away" technique to be used during the procedure. Longitudinal score **8** allows the removal of guidewire **15** from the side of catheter **10** via longitudinal score **8**, or alternatively, allows introducing guidewire **15** into proximal lumen **2b** via longitudinal score **8**, thus allowing the use of a relatively short guidewire in the procedures performed therewith.

The catheter insertion procedure of the invention is preferably performed under X-ray visioning (Image Guided Surgery), and is initiated by inserting the guidewire **15** into body passageway **11** (e.g., blood vessel) until its distal tip passes bifurcation **12** into which it should be inserted. The navigation catheter is then threaded over guidewire **15** via its distal lumen **2a**, such that it is guided over its distal end opening **1** and its distal side opening **3a**, until its distal end portion reaches bifurcation **12**, as shown in Fig. 2.

Guidewire **15** is then retracted outwardly via side opening **3a** and removed outside passageway **11**. Thereafter, guidewire **15** is

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inserted into proximal lumen **2b** through proximal end opening **6** (or via longitudinal score **8**) of the navigation catheter **10**. Guidewire **15** is then advanced through proximal lumen **2b** and the navigation catheter **10** is manipulated simultaneously such that its proximal side opening **3b** is properly positioned alongside (facing) the entrance to passageway **11a** branching at bifurcation **12**. Guidewire **15** is then advanced in proximal lumen **2b** until it exits elongated tube **17** via proximal side opening **3b** and enters the branching passageway **11a**, as shown in Fig. 3. If the destined treatment site is located in branching passageway **11a**, Navigation catheter **10** is then removed and the treatment catheter is inserted therein over the guidewire **15**.

Obviously, the above procedure can be repeated multiple times using the same guidewire and navigation catheter, for arrival at treatment locations that require passing more than one bifurcation.

Elongated tube **17** can be made of biocompatible polymers such as polyurethane, nylon, Teflon and metal that are routinely used in catheter production. Partition **5** can be made of biocompatible materials such as stainless steel or hard polymers and it may be integrated into elongated tube **17** during its manufacture, or adhered or welded in lumen **2**. The length of partition **5** is generally in the range of 3 mm to 10 mm, preferably about 4 mm. The length of distal lumen **2a** is generally in the range of 10 to 100 mm, preferably about 20 mm, and the length of proximal lumen **2b** is generally in the range of 500 to 1500 mm, preferably about 750 mm. Guidewire **15** may be any suitable guidewire as commonly used in percutaneous therapeutic intervention, such as manufactured by Guidant, Cordis etc.

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Fig. 4 shows a longitudinal-section view of a navigation catheter **40** according to another preferred embodiment of the invention. Navigation catheter **40** is constructed from a main longitudinal tube **45** which distal end portion is attached to a proximal end portion of a supplementary tube **47**. Main longitudinal tube **45** comprise a proximal end opening **46** and an exit opening **44**, and supplementary tube **47** comprise a distal end opening **41** and a proximal entrance opening **43**.

Navigation catheter **40** may be used in a similar fashion, as was described hereinabove with reference to Figs. 1A-1B, 2 and 3. Similarly, desired exit angle of guidewire introduced via proximal end opening **46** and advanced through proximal lumen **48** of main longitudinal tube **45**, can be obtained by a corresponding design of the location of exit opening **44**. Distal lumen **42** of supplementary tube **47** and its proximal opening **43** are preferably aligned to allow straight passage of guidewire through lumen **42** thereof.

Main longitudinal tube **45** and supplementary tube **47** can be made of biocompatible polymers such as polyurethane, nylon, Teflon and metal that are routinely used in catheter production. Said tubes can be attached by adhering (e.g., thermobonding, ultrasonic UV) or welding a distal end portion in the range of 5 mm to 50 mm of main longitudinal tube **45** to a proximal end portion of a corresponding length of supplementary tube **47**. The length of main longitudinal tube **45** is generally in the range of 500 mm to 1500 mm, preferably about 750 mm, and the length of supplementary tube **47** is generally in the range of 20 mm to 120 mm, preferably about 40 mm.

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The navigation catheter may be manufactured in any size suitable for its intended use. As a general guide, the navigation catheter will have a length of 100 to 200 cm and an external diameter in between 0.5 to 1.5 mm. The navigation catheter of the present invention can be manufactured by means of any of the standard techniques which are routinely used in the manufacture of catheters. For example: Extrusion, molding, tipping, hole punching, etc.

As was described and exemplified herein above the navigation catheter of the invention can be effectively used for advancing a guidewire and/or catheter through relatively narrow bifurcated body vessel or cavity, such as blood vessels (e.g., the coronary tree). It should be appreciated that the navigation catheter of the invention may be efficiently used for passing a guidewire, catheter, or other suitable accessories through bifurcated passageways where the angle between the passageway and the branching passageway is greater than or equal to 90°.

All of the abovementioned parameters are given by way of example only, and may be changed in accordance with the differing requirements of the various embodiments of the present invention. Thus, the abovementioned parameters should not be construed as limiting the scope of the present invention in any way. In addition, it is to be appreciated that the different tubes, openings, and other members, described hereinabove may be constructed in different shapes (e.g. having oval, square etc. form in plan view) and sizes from those exemplified in the preceding description.

The above examples and description have of course been provided only for the purpose of illustration, and are not

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intended to limit the invention in any way. As will be appreciated by the skilled person, the invention can be carried out in a great variety of ways, employing more than one technique from those described above, all without exceeding the scope of the invention.

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**CLAIMS**

1. An apparatus for diverting a guidewire and/or catheter through a bifurcated passageway, comprising an elongated tube having an inner lumen being accessible via a proximal end opening, a distal end opening, and a first and second side openings provided on a distal section of said elongated tube, wherein said lumen comprises a partitioning element located in said distal section such that it partitions said lumen into a first and second separate lumens such that said first lumen is accessible via said first side opening and via said proximal end opening and said second lumen is accessible via said second side opening and via said distal end opening.
2. The apparatus of claim 1, wherein the partitioning element is adapted to force a guidewire advanced along the first lumen to exit said first lumen in a predetermined angle relative to axis of the elongated tube.
3. The apparatus of claim 1, wherein the first and second side openings are located on opposing vertical sides of the elongated tube.
4. The apparatus of claim 1, wherein the elongated tube further comprises a score between its proximal end opening and a point between said proximal end opening and its proximal side opening from which a guidewire may be removed from, or introduced into, the proximal lumen.
5. The apparatus of claim 1, wherein the bifurcated passageway is a blood vessel.

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6. An apparatus for diverting a guidewire and/or catheter through a bifurcated passageway, comprising a main elongated tube having an inner lumen being accessible via a proximal end opening and a distal exit opening thereof and a supplementary tube having an inner lumen being accessible via a proximal entrance opening and a distal end opening thereof, wherein a distal end section of said main elongated tube is attached to said supplementary tube along a corresponding proximal end section thereof.
7. The apparatus of claim 6, wherein the distal exit opening of the main elongated tube is designed to provide a desired exit angle of a guidewire passing therethrough relative to said main elongated tube.
8. A method for diverting a guidewire and/or catheter along a desired pathway through a bifurcated passageway, comprising:
  - a) providing a navigation catheter having separated proximal and distal lumens, wherein said proximal lumen is accessible from its distal side via a first side opening of said navigation catheter, and from its proximal side via a proximal end opening of said navigation catheter, and wherein said distal lumen is accessible from its proximal side via a second side opening of said navigation catheter, and from its distal side via a distal end opening of said navigation catheter;
  - b) inserting a guidewire capable of being advanced through said first and second lumens into a bifurcated passageway until a distal tip thereof passes a bifurcation to be passed along said desired pathway;
  - c) advancing said navigation catheter over said guidewire by threading its distal lumen thereon and placing said

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navigation catheter therein such that its first side opening is positioned in the vicinity of said bifurcation;

- d) retracting said guidewire proximally; and
- e) advancing said guidewire and/or a catheter device through said proximal lumen and adjusting the orientation of said navigation catheter such that said first opening faces said bifurcation and a distal portion of the advanced guidewire and/or catheter device exits said proximal lumen through said first opening into a branching passageway at said bifurcation.

9. The method of claim 8, further comprising retracting said navigation catheter proximally over said guidewire and/or a catheter device.

10. The method of claim 8, wherein the bifurcated passageway is a blood vessel.



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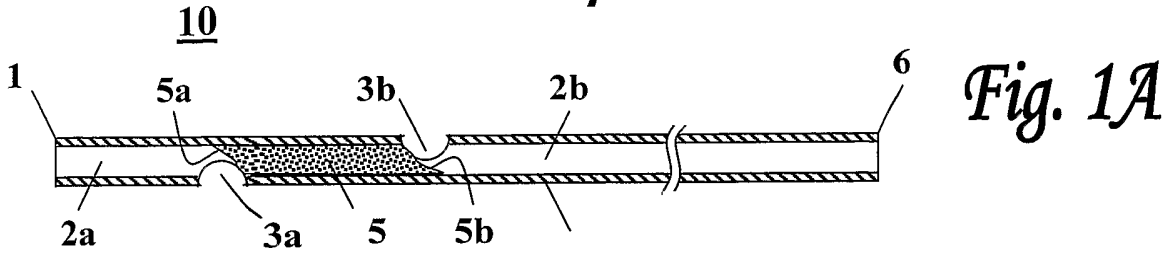


Fig. 1A

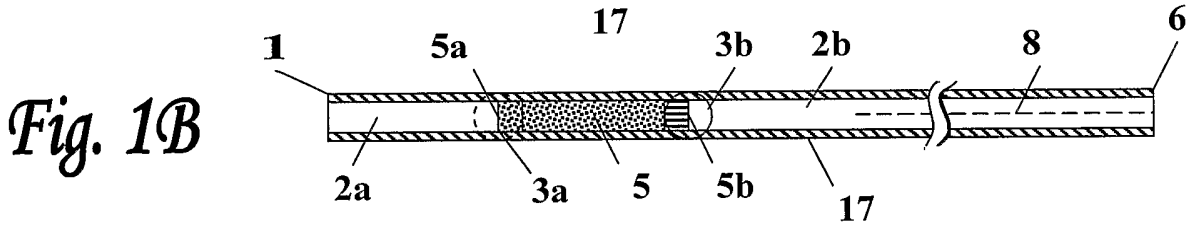


Fig. 1B

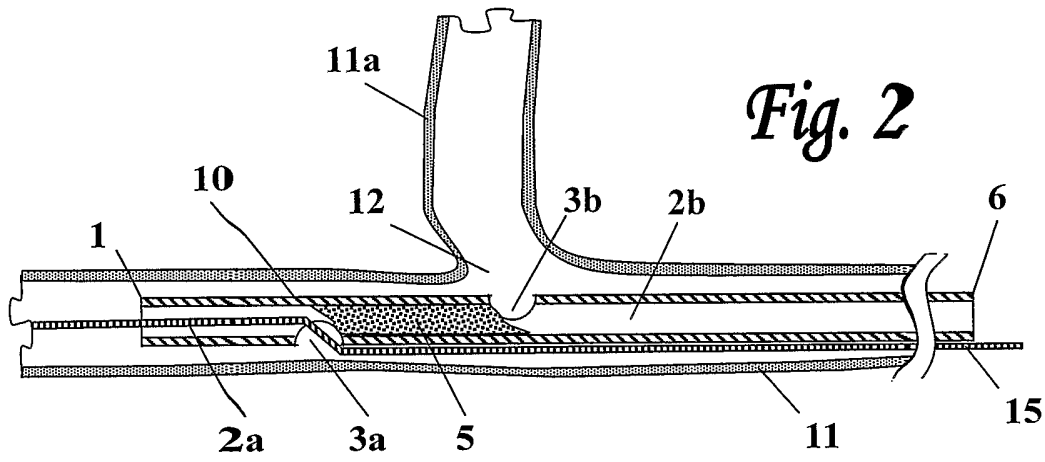


Fig. 2

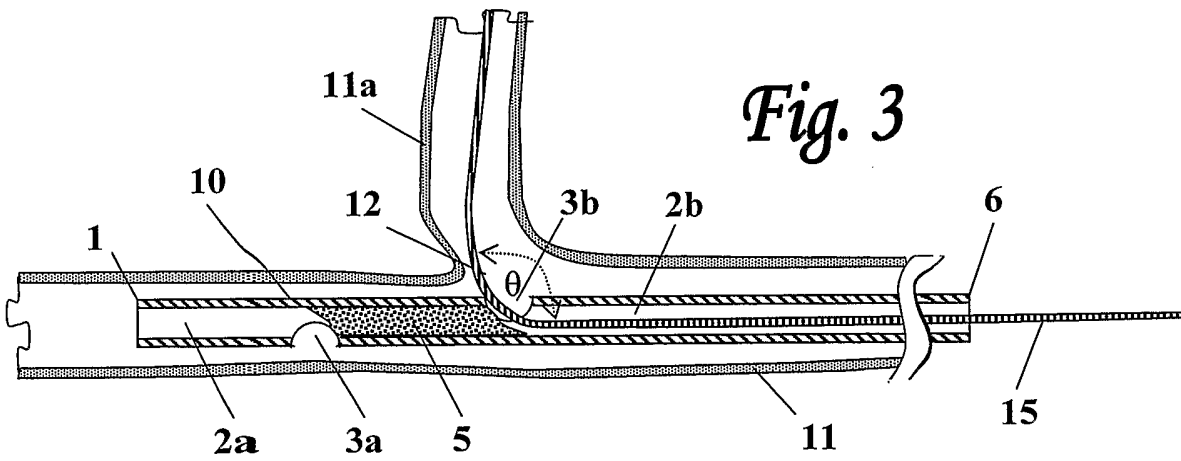


Fig. 3

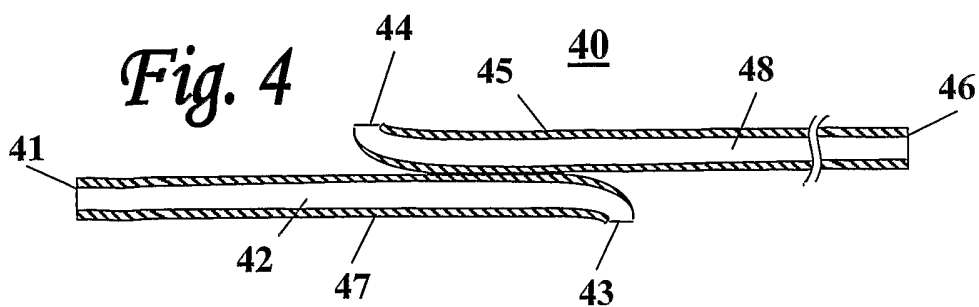


Fig. 4