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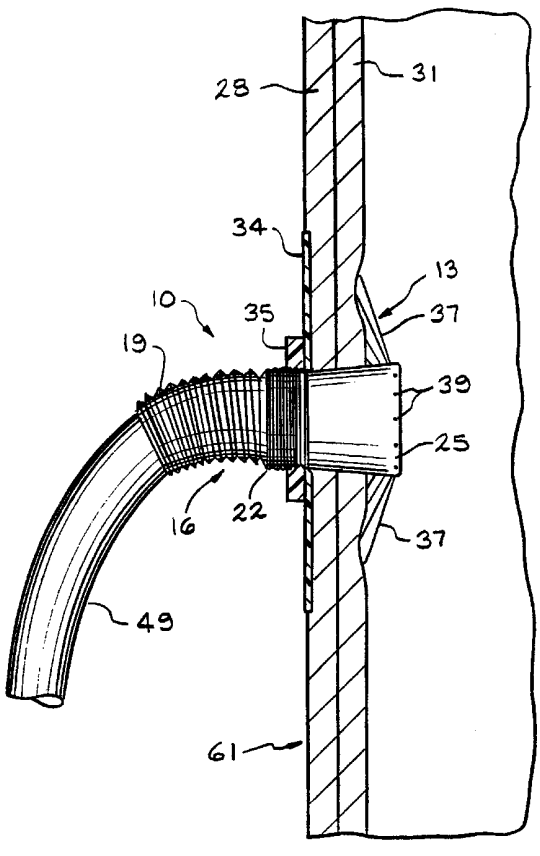
(54) Title: SELF-EXPANDABLE VASCULAR ANASTOMOTIC DEVICE AND METHOD OF COUPLING A CONDUIT TO AN AORTA OR OTHER SIMILAR VESSEL



(57) Abstract: A coupling device (10) and method. The device (10) includes a conduit (16) and a resilient filament (37) connected to the conduit (16). The filament (37) may be provided in the form of loops (103).

Published:
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Self-Expandable Vascular Anastomotic Device And Method Of Coupling A Conduit To An Aorta Or Other Similar Vessel

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to United States provisional patent application number 60/149,301, which was filed on August 17, 1999.

FIELD OF THE INVENTION

The present invention relates to a device and method of coupling a conduit to a larger arterial or venous conduit or inflow source.

SUMMARY OF THE INVENTION

The present invention provides a means for allowing rapid establishment of the inflow anastomosis for coronary artery bypass grafting (or other vascular procedures requiring aorta-conduit anastomosis) with minimal trauma to the aortic wall and no diversion of aortic blood stream. In order to attach a vein graft to the aorta, existing surgical procedures require that a clamp be placed on the aorta. In doing so, the clamp increases the risk of stroke. The present invention eliminates the need to clamp the aorta, and therefore reduces the risk of stroke.

A coupling device according to the present invention includes a conduit and a resilient filament joined to the conduit. The resilient filament may be provided in the form of loops extending from the conduit and remotely resembling the frame of an umbrella when expanded.

In a method according to the present invention, a coupling device having a conduit and a resilient filament is provided. The conduit is placed within a retaining sheath. Next, an incision is made in the

blood vessel, and a portion of the conduit and sheath are inserted into the blood vessel. The portion of the conduit inside the blood vessel is held within the blood vessel while the sheath is removed from the blood vessel and the filament is allowed to engage the blood vessel. Then the conduit is secured to the blood vessel, for example, by threading a nut onto the conduit.

BRIEF DESCRIPTION OF THE DRAWINGS

For a full understanding of the nature and objects of the present invention, reference should be made to the following detailed description taken in conjunction with the accompanying drawings, in which:

Figure 1 is a partially cross-sectioned view of the device according to the present invention installed in an aorta;

Figure 2A is a perspective view of the conduit showing some of the filaments comprising the expandable umbrella-like device in the expanded position;

Figure 2B is an end view of the conduit showing filaments with enlarged heads;

Figure 2C is an end view of an alternative embodiment of the conduit showing filaments with enlarged heads;

Figure 3 is a perspective view of the connector;

Figure 4 is a perspective view of the connector attached to a vein;

Figure 5A is a cross-sectioned side view of the present invention inside a retaining sheath, wherein the sheath has a beveled end;

Figure 5B is a cross-sectioned side view of the present invention inside a retaining sheath, wherein the sheath does not have a beveled end;

Figure 6A is a perspective view of the retaining sheath shown in Figure 5A;

Figure 6B is a perspective view of the retaining sheath shown in Figure 5B;

Figure 7 is a perspective view of the threaded stylet that may be used with the present invention;

Figure 8A is a partially cross-sectioned side view of an embodiment of the present invention being inserted into an aorta wall using the sheath depicted in Figure 6A;

Figure 8B is a partially cross-sectioned side view of an embodiment of the present invention being inserted into an aorta wall using the sheath depicted in Figure 6B;

Figure 9 is an exploded perspective view of a portion of the present invention shown in Figures 8A and 8B;

Figure 10 is a non-exploded cross-sectioned perspective view of the embodiment shown in Figure 9;

Figure 11 is a cross-sectioned top view of a portion of the embodiment shown in Figure 10 taken along the line 11--11 in Figure 10;

Figure 12 is an alternative embodiment of a portion of the conduit 25;

Figure 13 is a side view of a sheath according to the present invention and a device for cutting the aorta in order to insert the sheath in the aorta;

Figure 14 is a partially cross-sectioned side view of an embodiment of the sheath shown in Figure 13;

Figure 15 is a cross-sectional side view of a holder, according to the present invention;

Figure 16 is a partially cross-sectioned side view of the holder installed on the conduit, according to the present invention; and

Figure 17 shows steps of a method according to the present invention.

BEST MODE FOR CARRYING OUT THE INVENTION

Figure 1 shows a coupling device 10 according to the present invention installed in the aorta wall. It should be noted the present invention may be used with other blood vessels, and the scope of the present invention is not to be limited merely to use on the aorta. The coupling device 10 includes an umbrella-like device 13 and a conduit 16. The conduit 16 has a flexible first end section 19, a threaded middle section 22, and a second end section 25. As shown in Figure 1, when the coupling device 10 is properly installed, the second end section 25 extends through the outer aorta wall 28 and the inner aorta wall 31. The coupling device 10 also includes a washer 34 and a nut 35. The threaded middle section 22, second end section 25, washer 34 and nut 35 may be made from stainless steel, titanium, or other inert non-flexible materials. The first end section 19 may be made from polytetrafluoroethylene and may be connected to the threaded middle section 22 by an adhesive, mechanical means or a friction fit. The first end section 19 shown in Figure 1 may be connected to the threaded middle section 22 by an adhesive or a friction fit.

Figures 2A, 2B and 2C show the umbrella-like device 13 and the conduit 16. The umbrella-like device 13 has resilient filaments 37. Each filament 37 has a first end 37A movably anchored to the second end section 25 of

the conduit 16, and has a second end 37B movably attached to an adjacent filament 37. The first end 37A may be movably anchored by providing an enlarged head 38 shown in Figure 2B which is larger than the holes 39. Alternatively, the first end 37A can be looped around the second end section 25 as shown in Figure 2A. As shown in Figures 2A and 2B, the second end 37B may be movably attached by forming a loop in the second end 37B which encircles the adjacent filament 37. By interlocking the filaments 37, the umbrella-like device 13 would be stronger and more stable. As shown in Figure 2C, both ends of a filament may be anchored to the conduit 25 by enlarged heads 38 on both ends of a filament 37. The filaments 37 may be titanium or an alloy such as nitinol.

When assembled as shown in Figure 1, a connector 40, shown in Figures 3 and 4, is inside the conduit 16. The connector 40 has a circumferential groove 43 and one or more sealing flanges 46. The connector 40 may be made from polyvinylchloride. A vein 49 is attached to the connector 40 by passing the connector 40 over the vein 49 and turning the vein 49 back on itself, as shown by arrows 52 in Figure 4. Then the vein 49 is secured to the connector 40 by wrapping a thread 55 around the vein 49, cinching the thread 55 so that at least part of the vein 49 resides in the groove 43, and then tying the thread 55 to form a knot 58. The thread 55 may be a non-absorbable suture material, such as 5-0 ethibond.

To prepare the coupling device 10 for attachment to an aorta 61, the connector 40, with vein 49 attached thereto, is inserted into the conduit 16 so that the vein 49 extends from the first end section 19 and so that the sealing flanges 46 seat against the conduit 16,

as shown in Figures 5A and 5B. Then, the threaded stylet 64 is threaded onto the threaded middle section 22 of the conduit 16. Next, the conduit 16, with threaded stylet 64 attached thereto, is placed in a sheath 67 so that the umbrella-like device 13 collapses and is held against the second end section 25, as shown in Figures 5A and 5B. Figures 6A and 6B show the sheath 67 with the conduit 16 and stylet 64 therein. The sheath 67 may be made from polyvinylchloride. As shown in Figures 5A, 6A and 8A, the sheath 67 may have a beveled and hardened end 70 that may be sharpened to easily enter the aorta 61. Figure 7 shows the stylet 64. The stylet 64 has internal threads 68 for threading onto the threaded middle section 22 of the conduit 16.

To insert the coupling device 10 into the aorta 61, an incision is made in the aorta 61 extending through both the outer aorta wall 28 and inner aorta wall 31. In one embodiment of a method according to the present invention, the sheath 67, with the coupling device 10 and stylet 64 therein, is inserted through the aorta 61. Next, the sheath 67 is withdrawn from the aorta 61 while the conduit 16 is held in place by a surgeon using the threaded stylet 64. Once the sheath 67 is removed, the umbrella-like device 13 expands within the aorta 61. Next, the washer 34 is placed around the conduit 16, and then the nut 35 is threaded onto the threaded middle section 22 so that the aorta 61 is compressed between the washer 34 and the umbrella 13, as shown in Figure 1.

As shown in Figure 1, the second end section 19 is preferably corrugated and thereby flexes to permit the vein 49 to curve away from the coupling device 10. The flexible second end section 19 provides support for the

vein 49 and prevents the vein 49 from tearing or kinking.

Figures 8A-11 depict an alternative embodiment of the present invention. In Figures 8A-11 there is shown an inner ring 73 for capturing the filaments 37 within the second end section 25 while permitting the filaments 37 to rotate in order to deploy the umbrella-like device 13. As shown in Figure 9, the filaments 37 each have a substantially perpendicularly extending first end 37C. Figure 9 depicts the position of the first end 37C in the non-deployed position (solid lines) as well as in the deployed position (dashed lines). As indicated in Figures 9 and 10, the first end 37C is permitted to move from the non-deployed position to the deployed position within a gap 75 between the inner ring 73 and second end section 25. The inner ring 73 may be attached to the second end section 25 by an adhesive, friction fit or mechanical means.

Figure 12 shows another embodiment of the present invention. Unlike the embodiment shown in Figures 10 and 11, the embodiment shown in Figure 12 does not have the inner ring 73. The second end 25 of the conduit 16 has holes 76 therethrough, each hole 76 having therein a portion of one of the filaments 37. To movably attach one of the filaments 37 to the second end 25 of the conduit 16, a portion of the filament 37 is inserted into a hole 76 until the filament 37 extends into the gap 75. Further pushing the filament 37 through the hole 76 will cause the filament 37 to bend as it contacts lower surface 77. The lower surface 77 may be angled to facilitate bending of the filament 37. The filament 37 extending into the gap 75 is then forced to reside in the gap 75 by bending the filament 37 to

permanently deform the filament 37 so that the filament 37 can not be pulled back through the hole 76. It should be noted one or both of the flanges 46 may reside in the gap 75 to secure the connector 40 to the conduit 16.

When the sheath 67 is not provided with a means for easily entering the aorta 61, as shown in the embodiment depicted in Figures 5B, 6B and 8B, a trochar 80 having a blade 83 may be installed in the sheath 67. Figure 13 shows an embodiment of the trochar 80 with blade 83 installed in the sheath 67. To insert the sheath 67, the trochar 80 is pushed toward the aorta 61 to cause the blade 83 to cut and enter the aorta 61. The trochar 80 is pushed toward the aorta 61 until a portion of the sheath 67 resides inside the aorta 61. Then the trochar 80 is removed leaving the sheath 67 partially in the aorta 61. Next, the coupling device 10 is inserted into the sheath 67, as shown in Figures 5B, 6B and 8B. Then the sheath 67 is removed and the coupling device 10 is connected to the aorta 61 as described above. Figure 14 shows one embodiment of the sheath 67 that includes a valve 86 that allows the trochar 80 to be inserted through and removed from the valve 86. The valve 86 reduces blood loss from the aorta 61 after the sheath 67 is in the aorta and the blade 83 is removed from the sheath 67. The valve 86 may be a heimlich valve, commonly used in medical devices.

Figures 15 and 16 depict a holder 100 that may be used while threading the nut 35 onto the threaded middle section 22. The holder includes a flexible loop 103, a first actuator 106 and a second actuator 109. A first end of the loop 103 is attached to the first actuator 106, and a second end of the loop 103 is attached to the

second actuator 109. The first actuator 106 may be moved relative to the second actuator 109 within a slot 118 in the second actuator 109. As the first actuator 106 moves relative to the second actuator 109, the first end 112 of the loop 103 is moved, and the length of loop 103 extending from the second actuator 109 is changed. In this manner, the loop 103 may be drawn tight around the conduit 16 while the nut 35 is tightened, and then released from the conduit 16 once the nut 35 is tight against the washer 34. The holder 100 reduces movement of the coupling device 10 while the nut 35 is threaded onto the threaded middle section 22.

Figure 17 shows steps of a method according to the present invention. In the method, a coupling device is provided (step 200), the coupling device having a conduit and a resilient filament attached to the conduit. The conduit and filament are placed (step 203)in a sheath, and a portion of the sheath is placed (step 206) in the blood vessel. Next, the sheath is removed (step 209) to leave the filament in the blood vessel, and the filament is allowed to engage the blood vessel (step 209). Then the conduit is secured to the blood vessel (step 212).

As will be recognized by those skilled in the art, the present invention is a device and method for coupling a conduit to an aorta or other blood vessel. It will be recognized that the device and method according to the present invention may be used in conjunction with other surgical devices and methods. Such other surgical devices and methods may include endoscopic means.

Although embodiments of the present invention have been described in detail herein, the present invention

is not limited to such embodiments. It will be understood that other embodiments of the present invention may be made without departing from the spirit and scope of the present invention. Hence, the present invention is deemed limited only by the appended claims and the reasonable interpretation thereof.

What is claimed is:

1. A coupling device, comprising;

a conduit having a first end section and a second end section; and

a resilient filament joined to the second end section.

2. The device of claim 1, further comprising a connector joined to the conduit.

3. The device of claim 2, wherein the connector includes a flange for engaging the conduit.

4. The device of claim 2, wherein the connector includes a circumferential groove.

5. The device of claim 2, further comprising a vein joined to the connector.

6. The device of claim 5, wherein the vein is joined to the connector by a thread surrounding the vein and the connector.

7. The device of claim 1, wherein the first end section is flexible.

8. The device of claim 1, wherein the conduit has a threaded middle section.

9. The device of claim 8, further comprising a nut having threads to engage the threaded middle section.

10. The device of claim 9, further comprising a washer having a hole therethrough for receiving the conduit.

11. The device of claim 1, wherein the filament includes titanium.

12. The device of claim 1, wherein the filament includes nitinol.

13. The device of claim 1, further comprising a stylet removably attached to the conduit.

14. A method of coupling a conduit to a blood vessel, comprising:

inserting a coupling device into a sheath, the coupling device having a conduit and a resilient filament attached to the conduit;

inserting the sheath into the blood vessel;

removing the sheath from the blood vessel;

allowing the filament to engage the blood vessel.

15. The method of claim 14, further comprising joining a connector to the conduit.

16. The method of claim 15, further comprising joining a vein to the connector.

17. The method of claim 14, further comprising:

inserting a blade through the sheath; and

cutting the blood vessel with the blade.

18. The method of claim 14, further comprising, threading a nut onto the conduit.

19. The method of claim 18, further comprising holding the conduit while threading the nut onto the conduit.

20. A method of coupling a conduit to a blood vessel, comprising:

providing a coupling device having a threaded section and a resilient filament;

threading a threaded stylet onto the threaded section;

placing the coupling device within a retaining sheath;

making an incision in the blood vessel;

inserting a portion of the coupling device and sheath into the blood vessel;

holding the portion of the coupling device within the blood vessel using the threaded stylet;

removing the sheath from the blood vessel to allow the filament to engage the blood vessel;

unthreading the stylet from the coupling device;

placing a washer around the coupling device;

threading a nut onto the threaded section until the blood vessel is compressed between the washer and the filament.

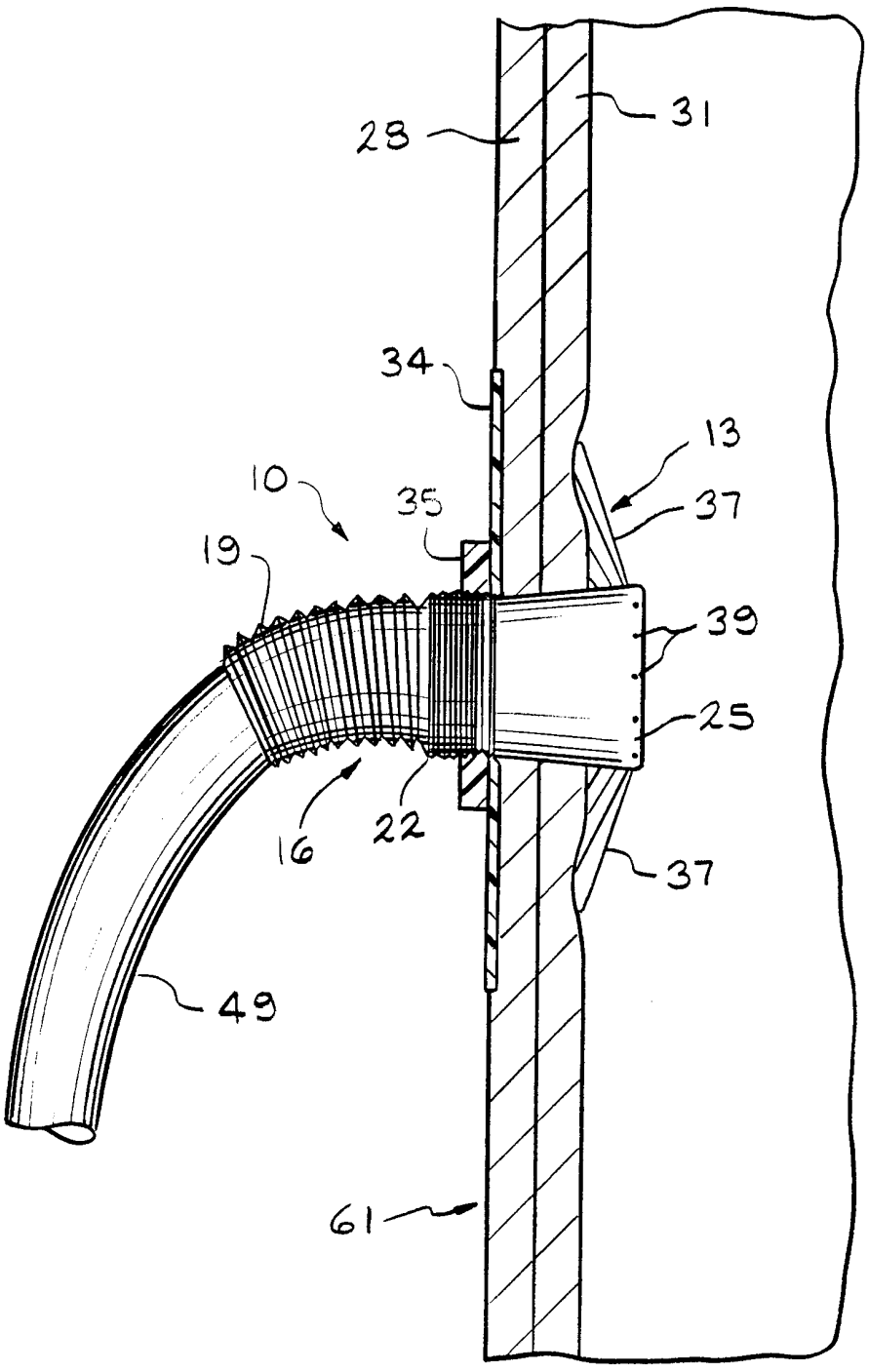

FIG. 1

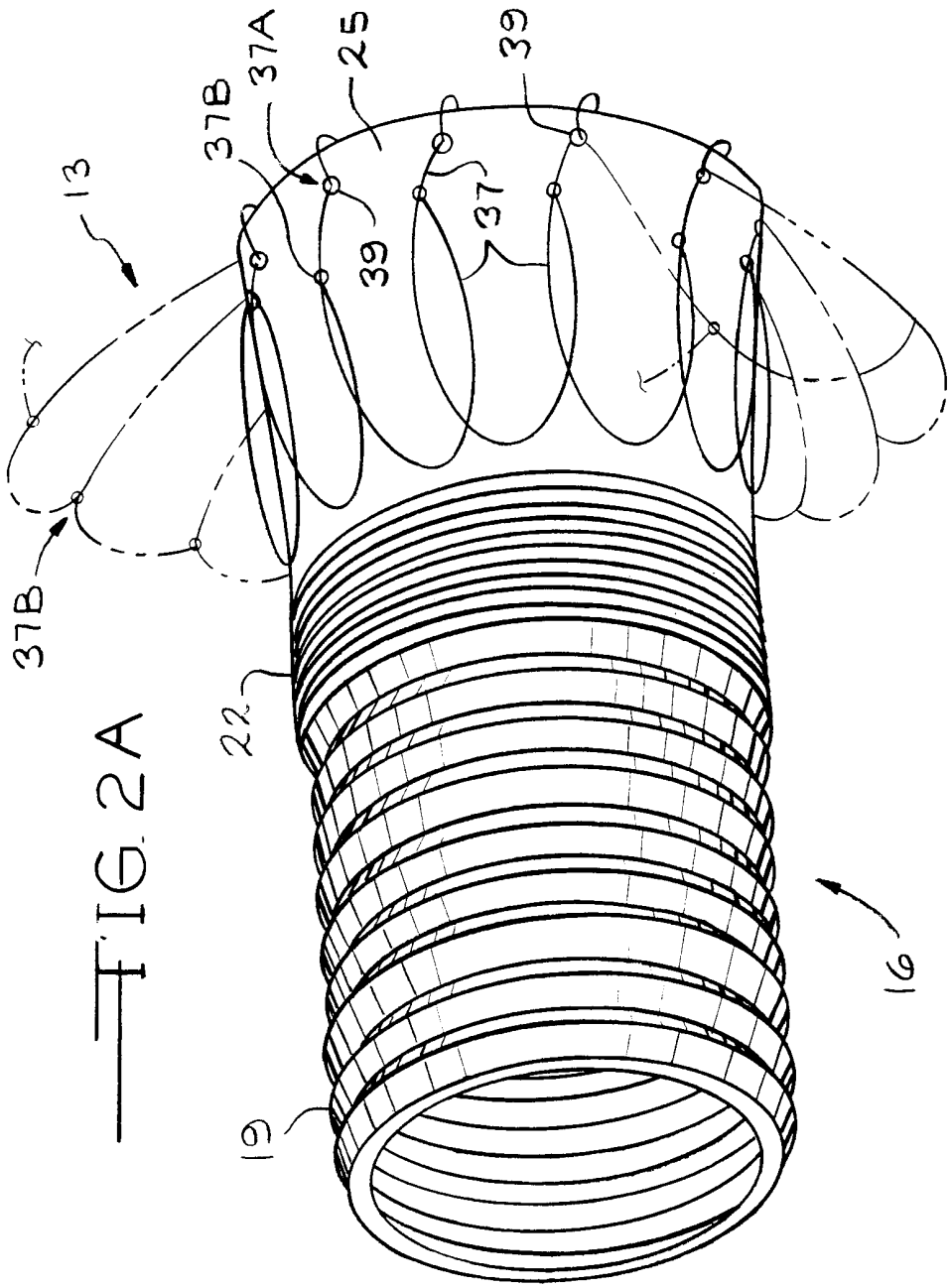

FIG 2A

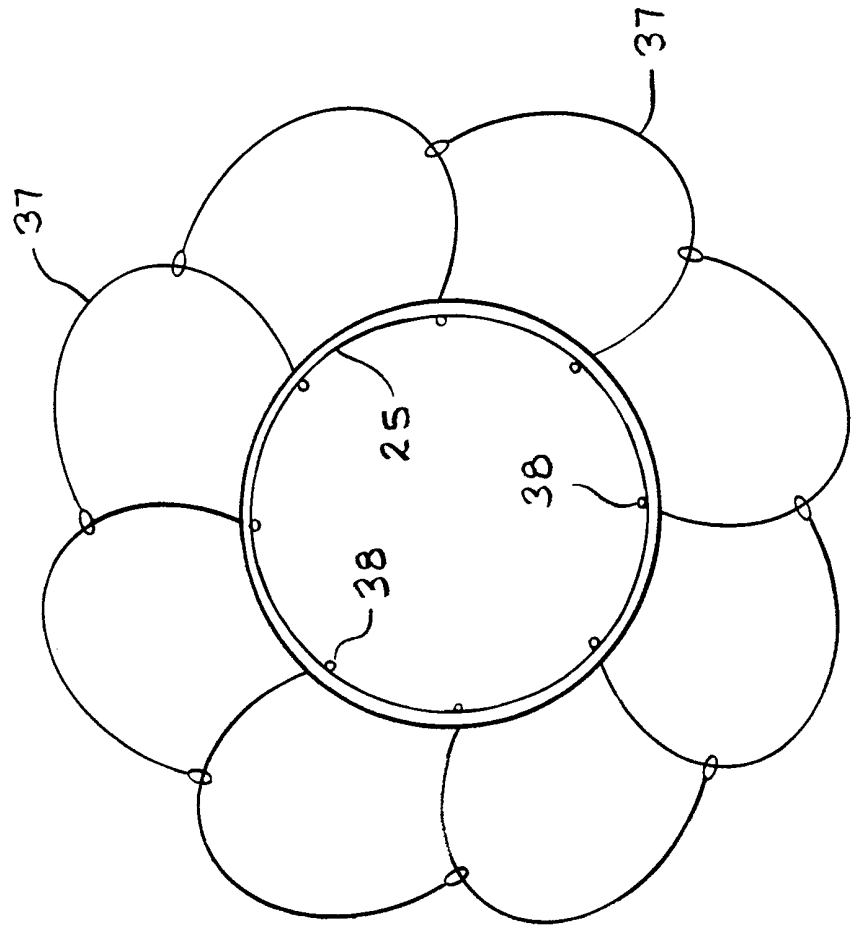

FIG. 2B

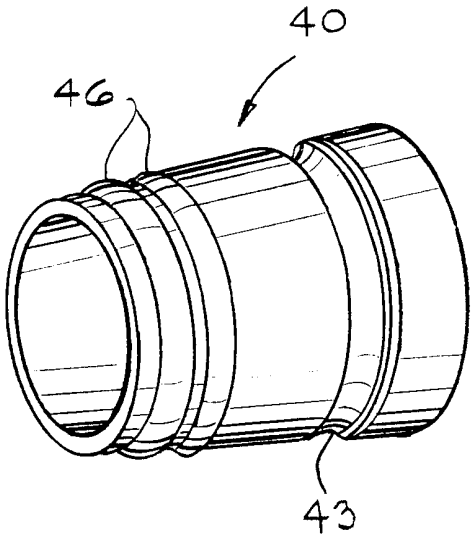

FIG. 3

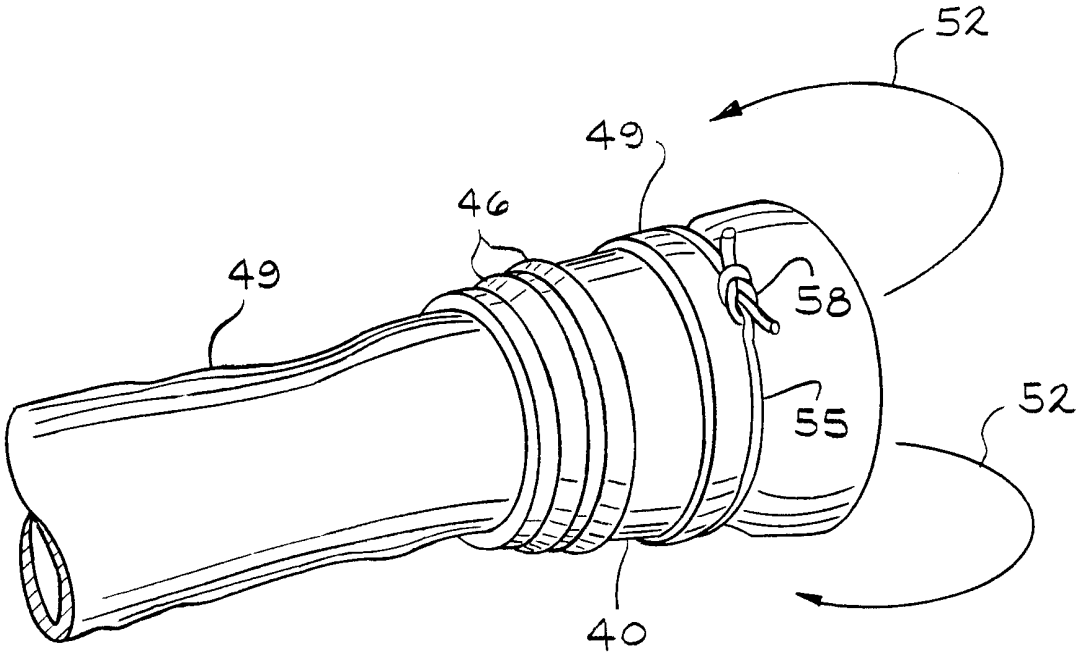

FIG. 4

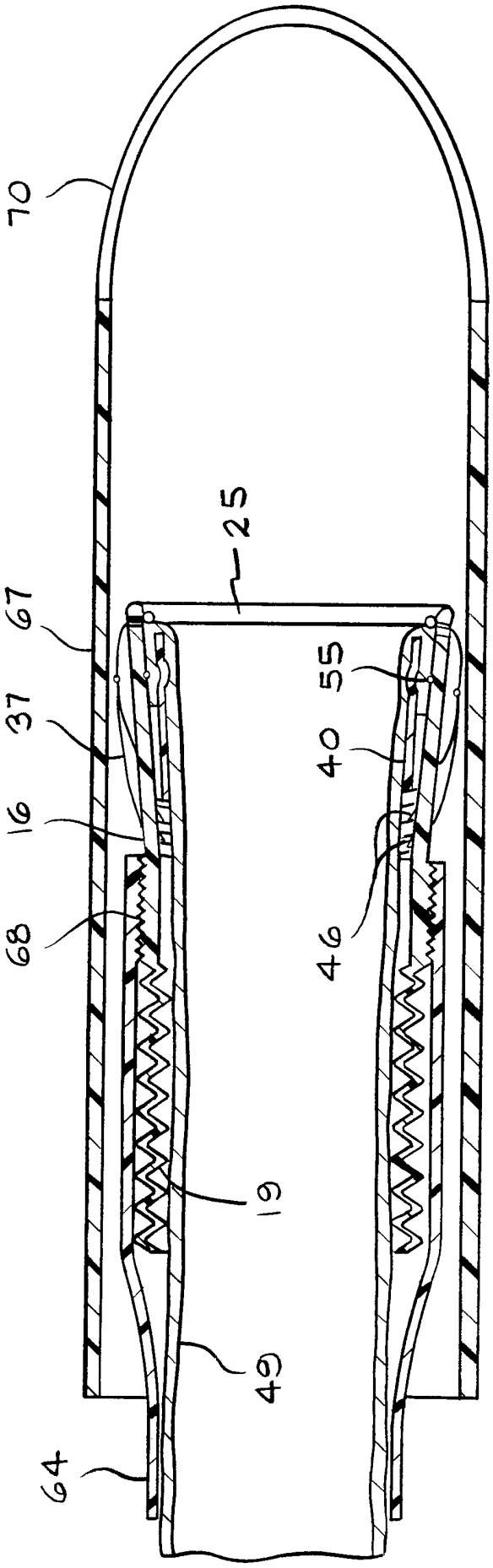

FIG. 5A

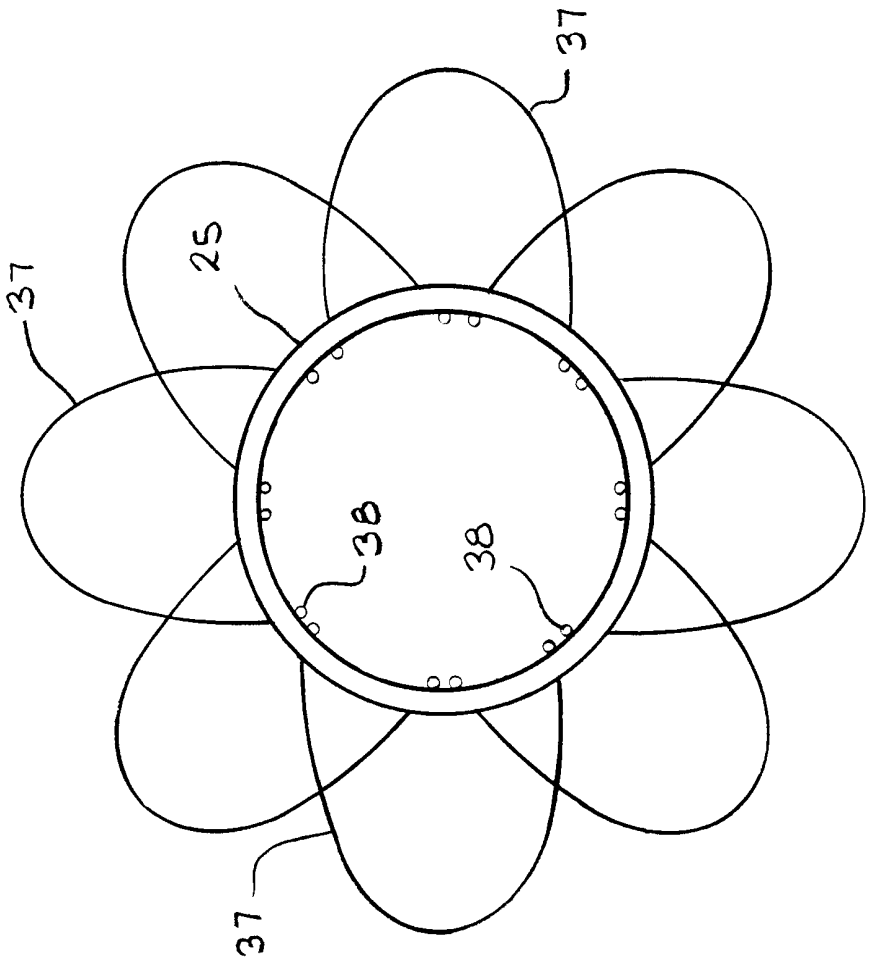

FIG. 2C

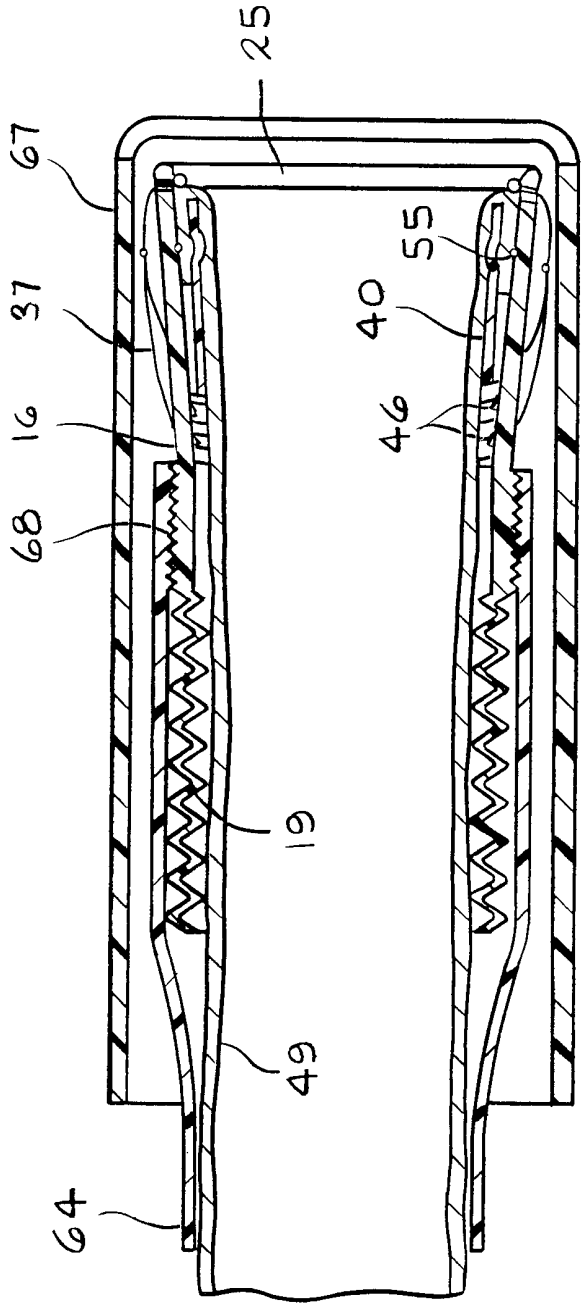

FIG. 5B

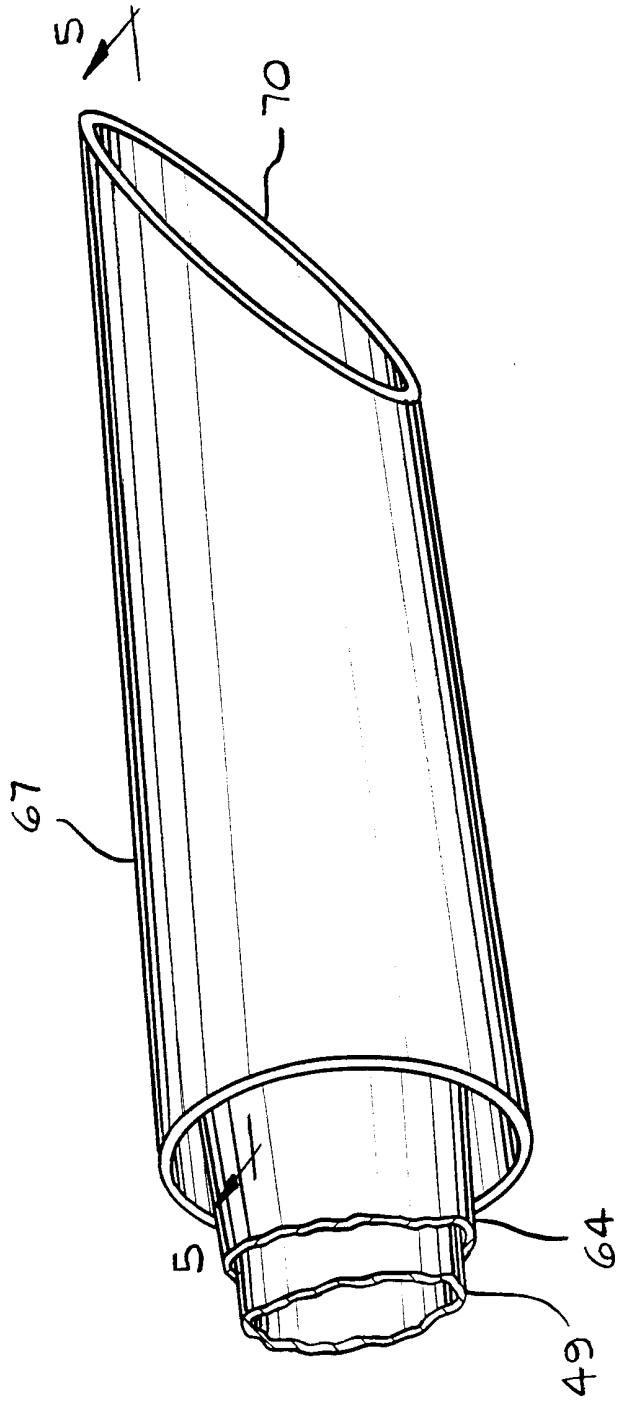

FIG. 6A

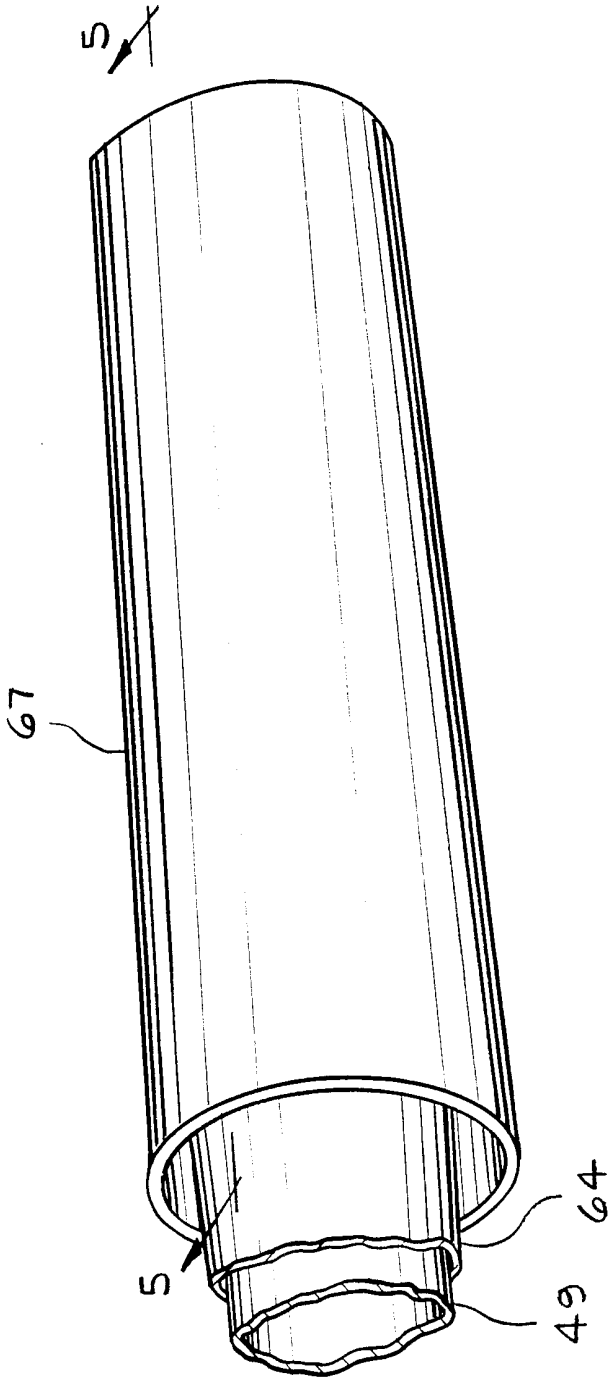

FIG. 6B

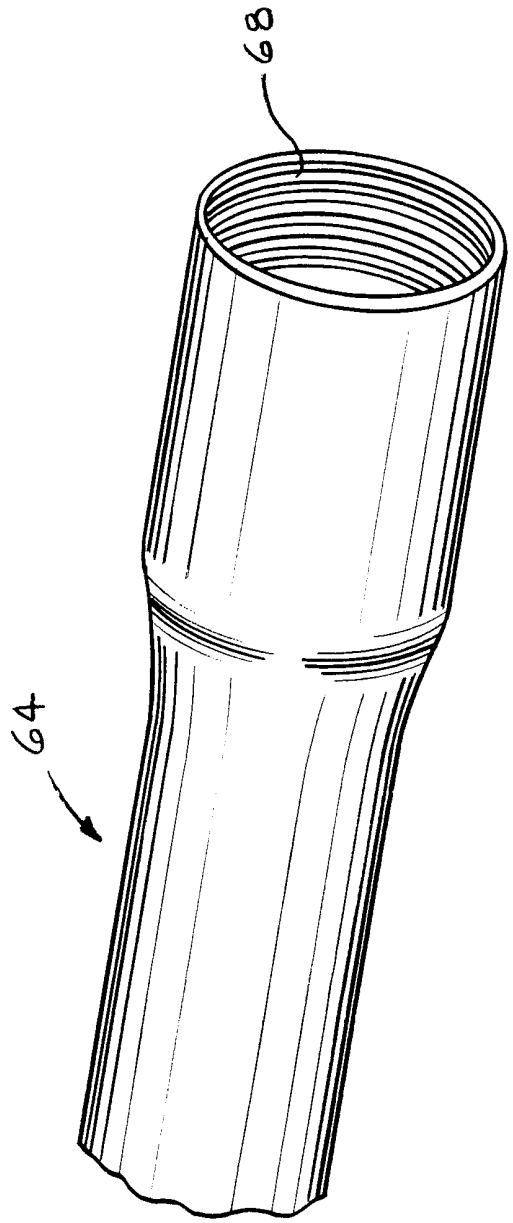

FIG. 7

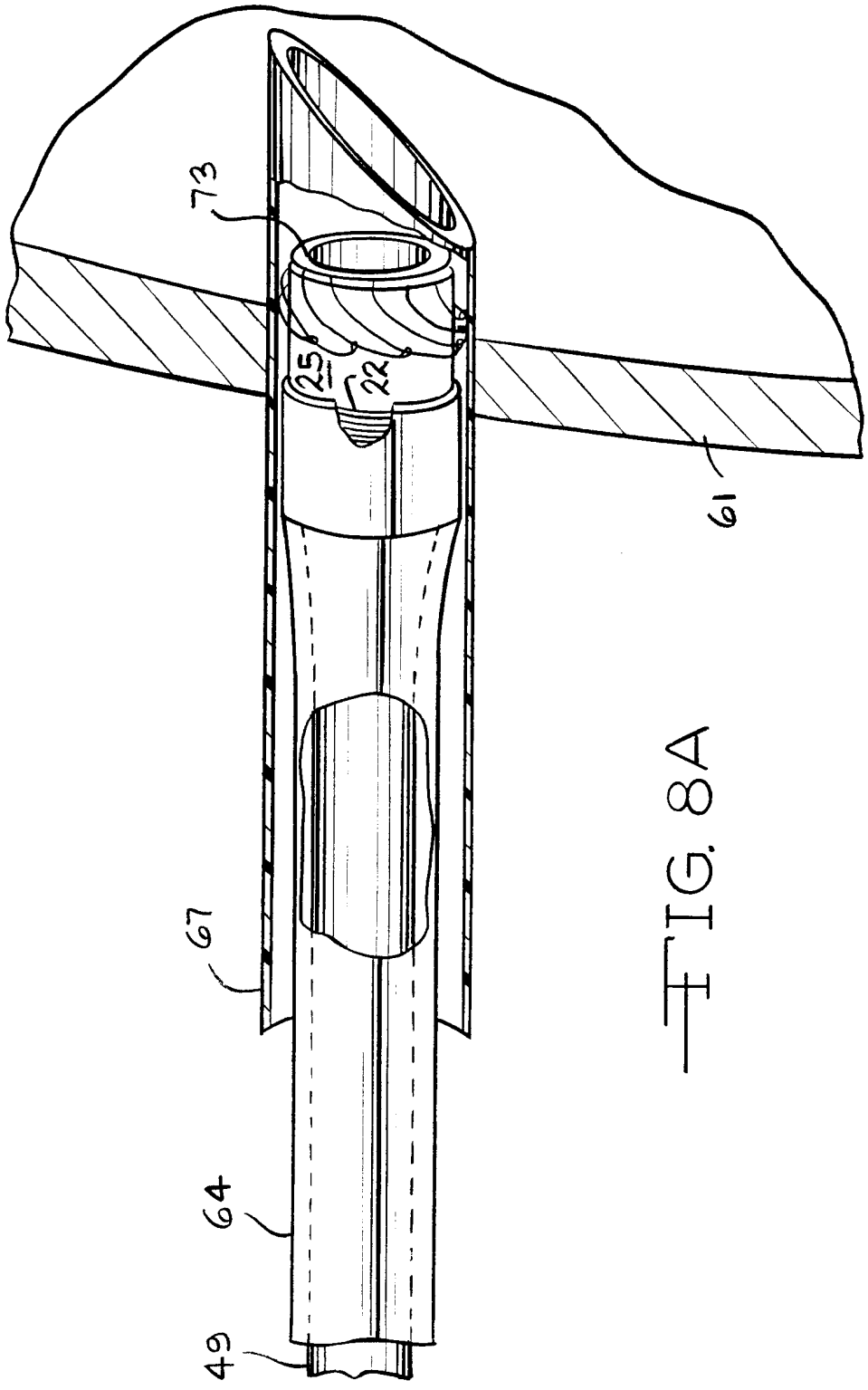

FIG. 8A

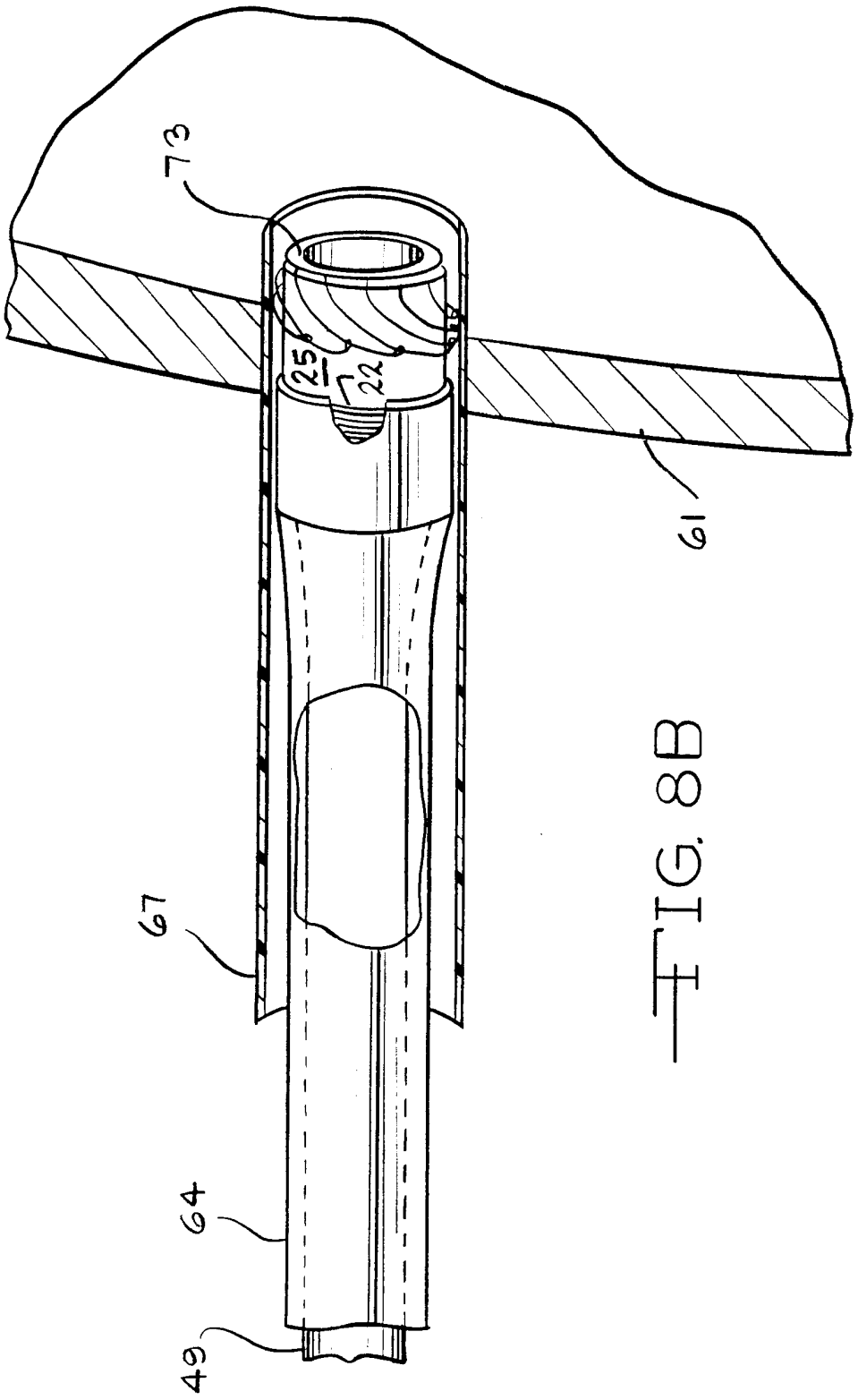

FIG. 8B

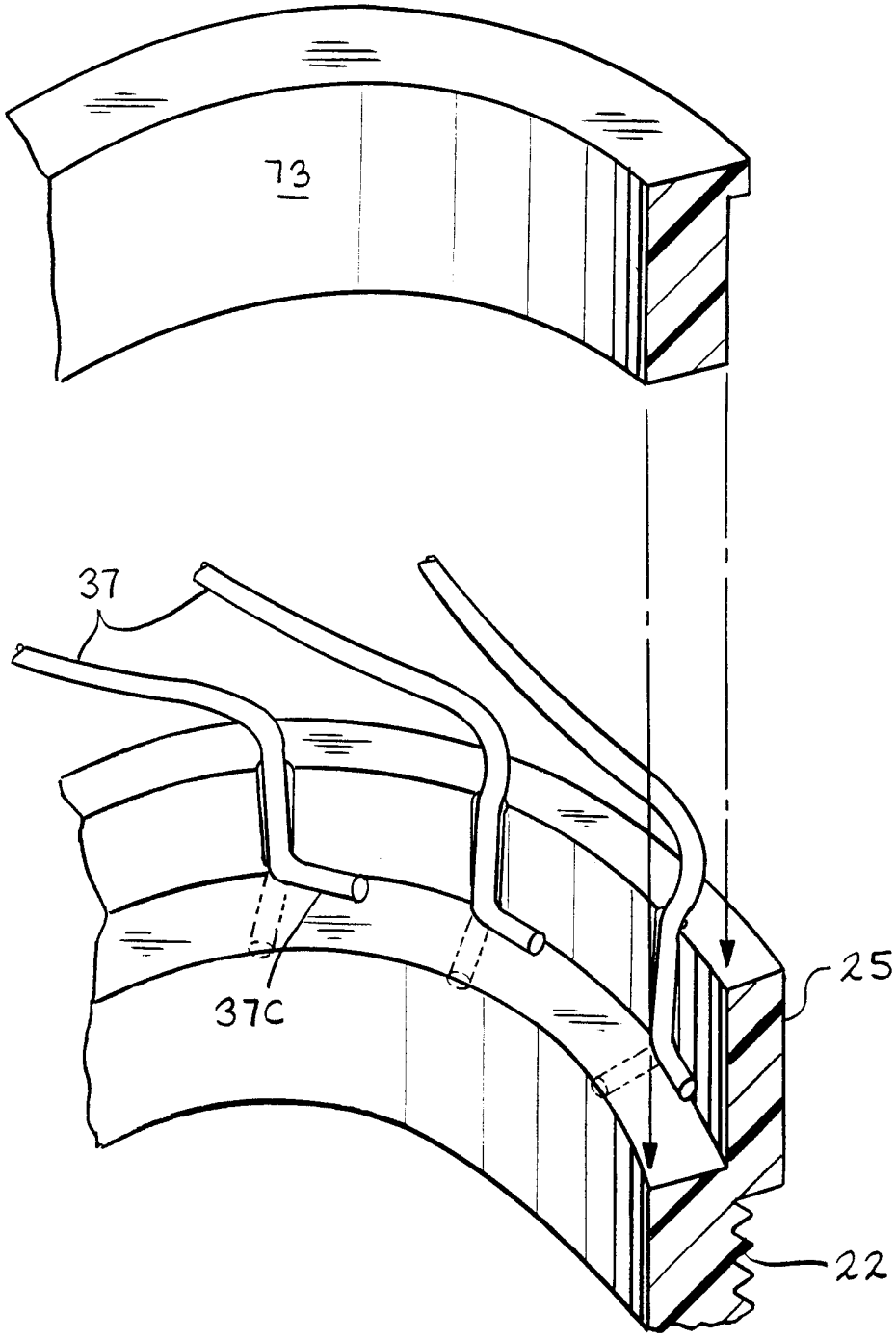

FIG. 9

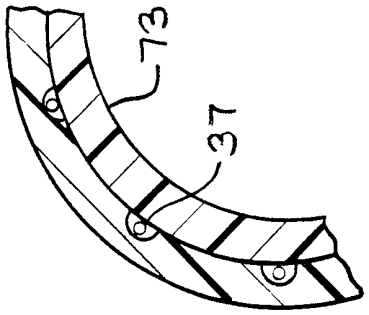

FIG. 11

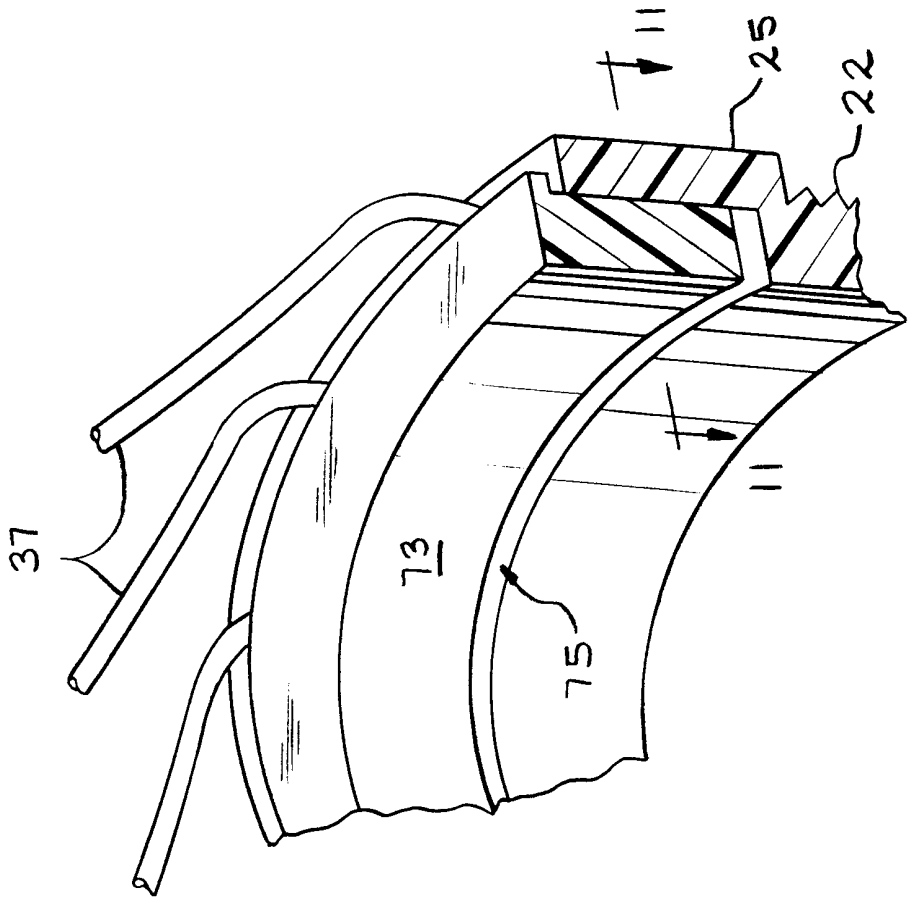

FIG. 10

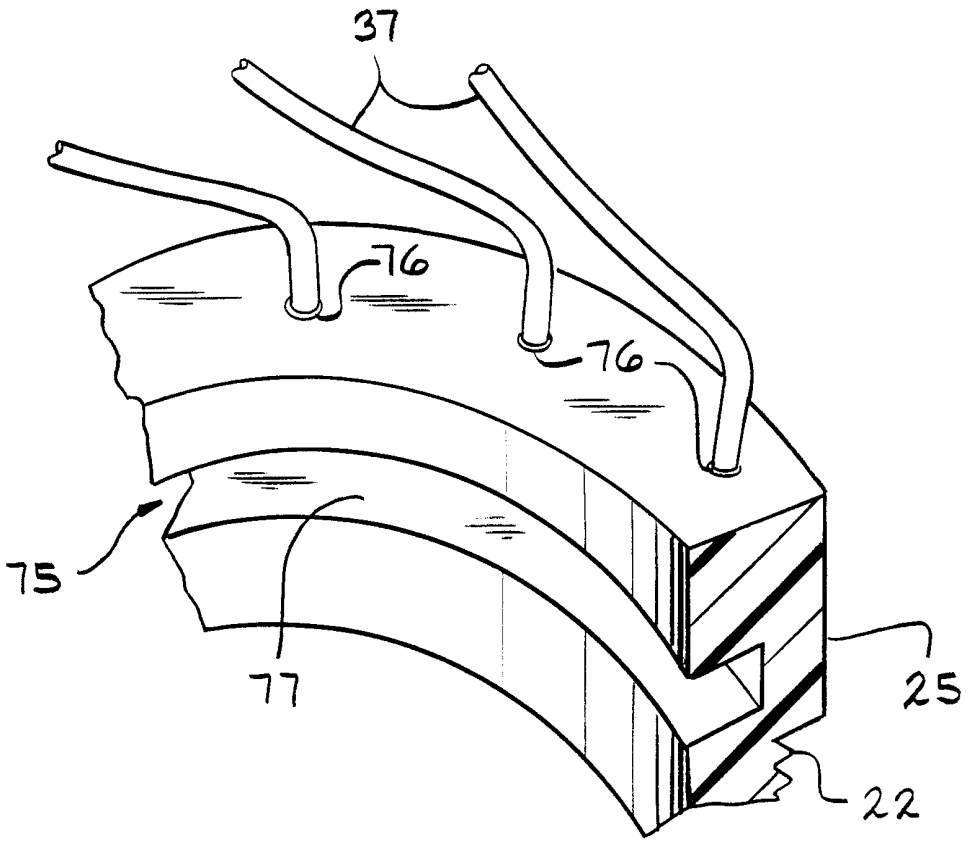

FIG. 12

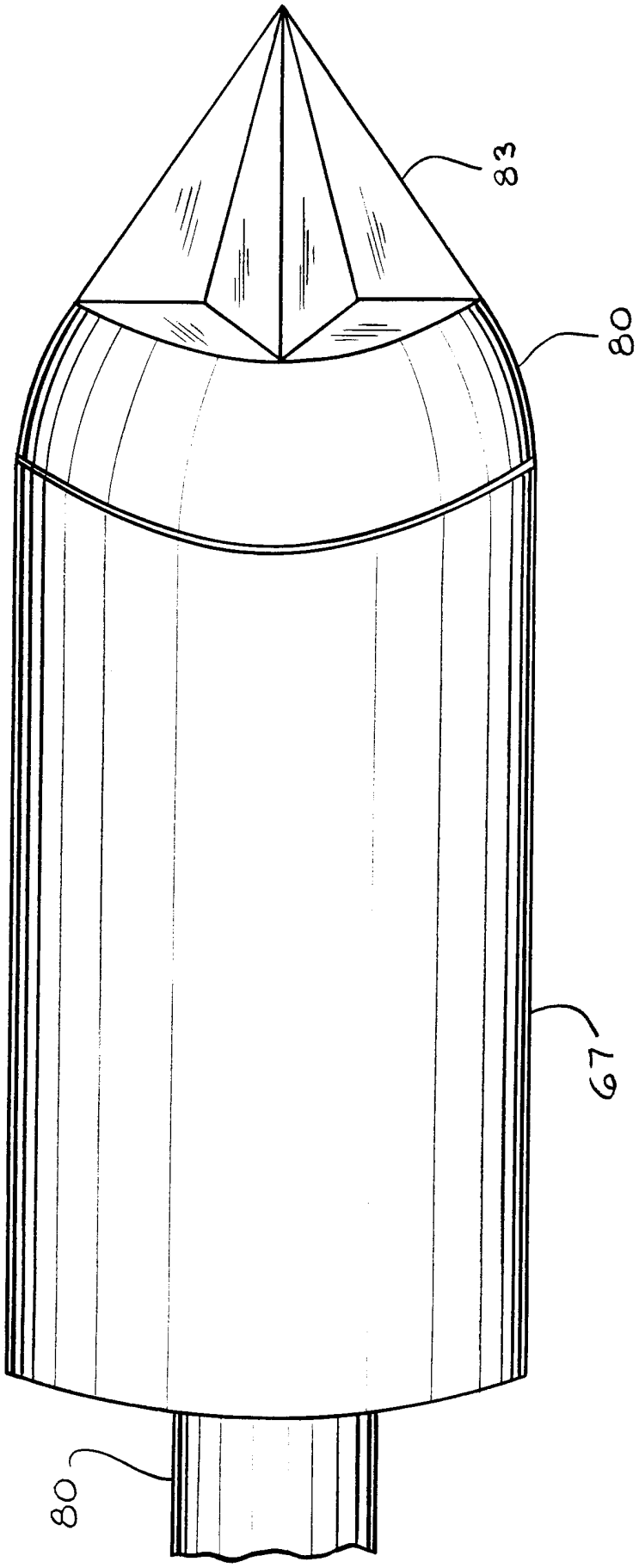

FIG 13

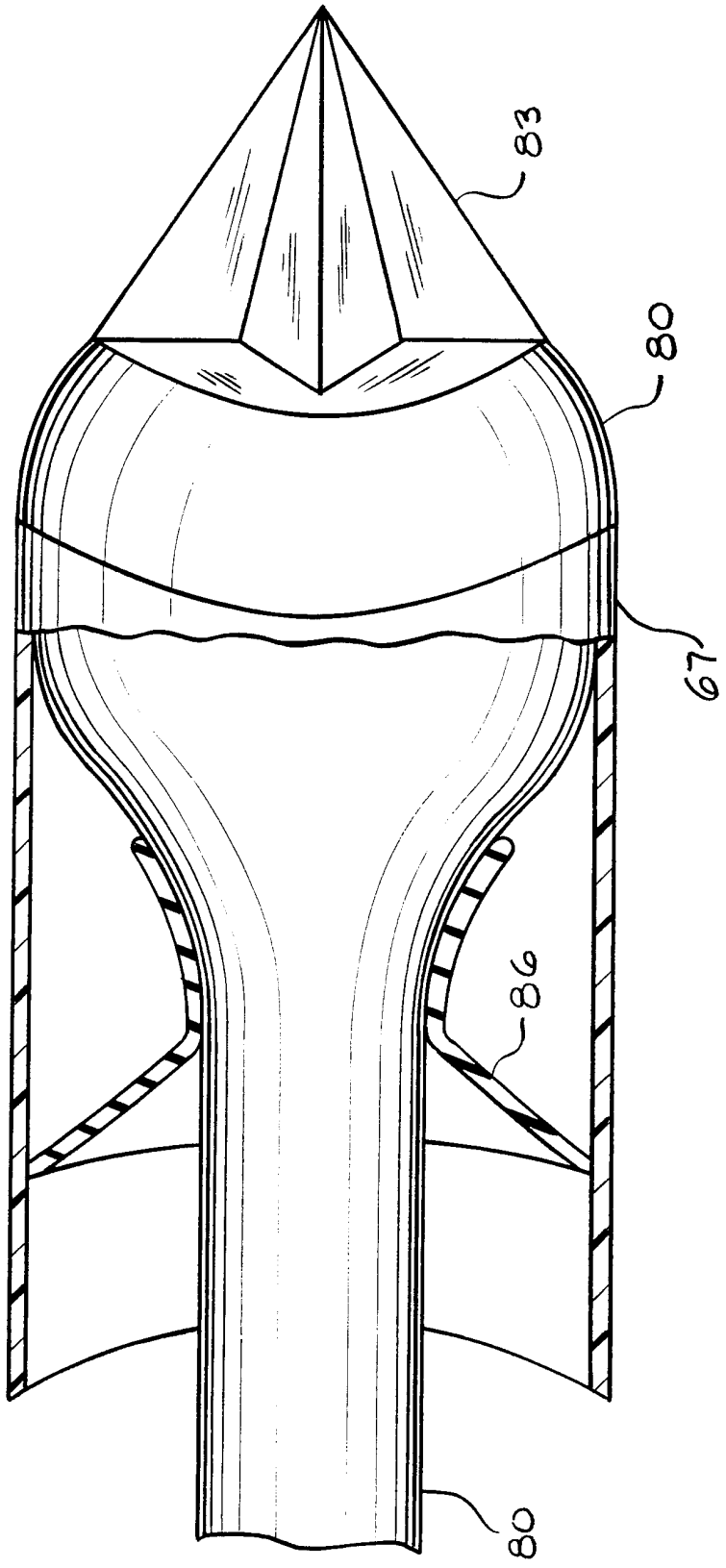

FIG. 14

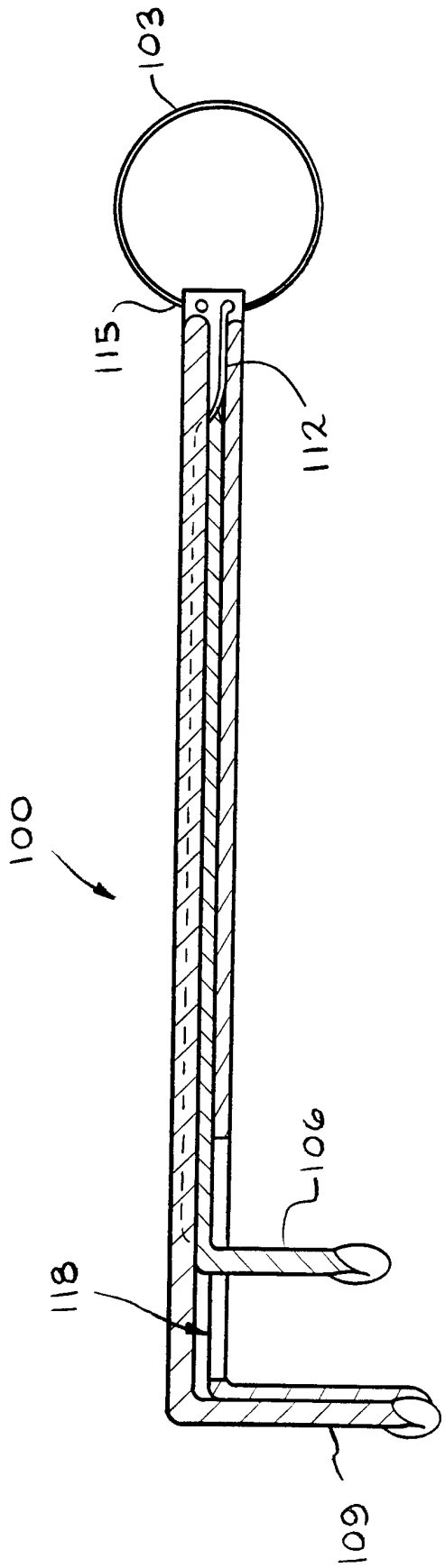

FIG. 15

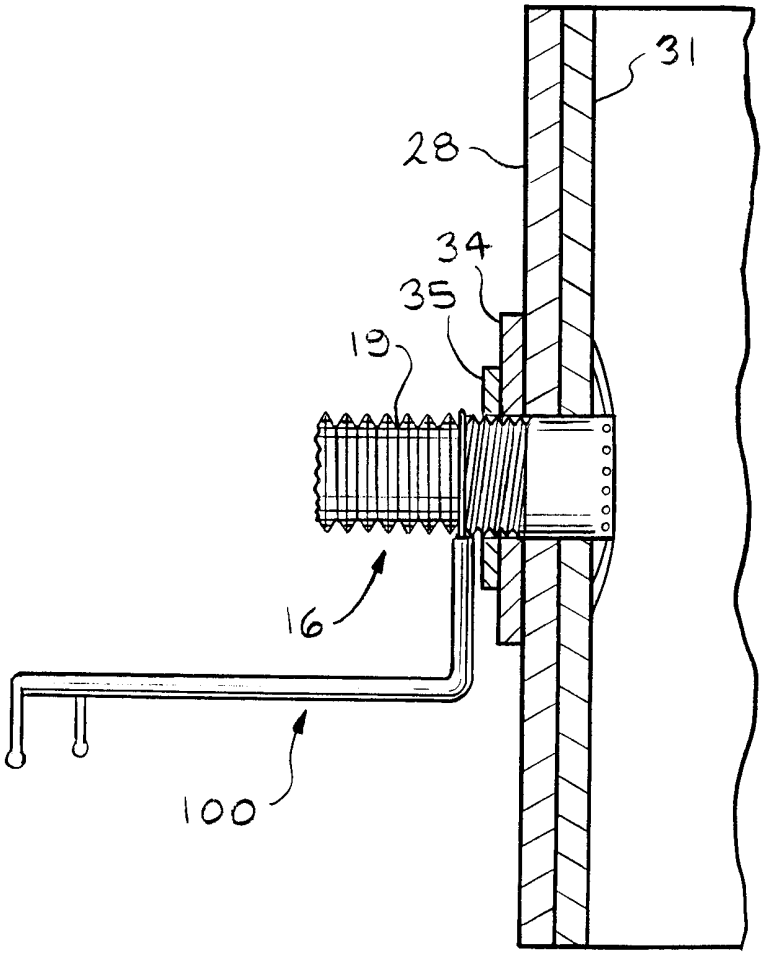

FIG. 16

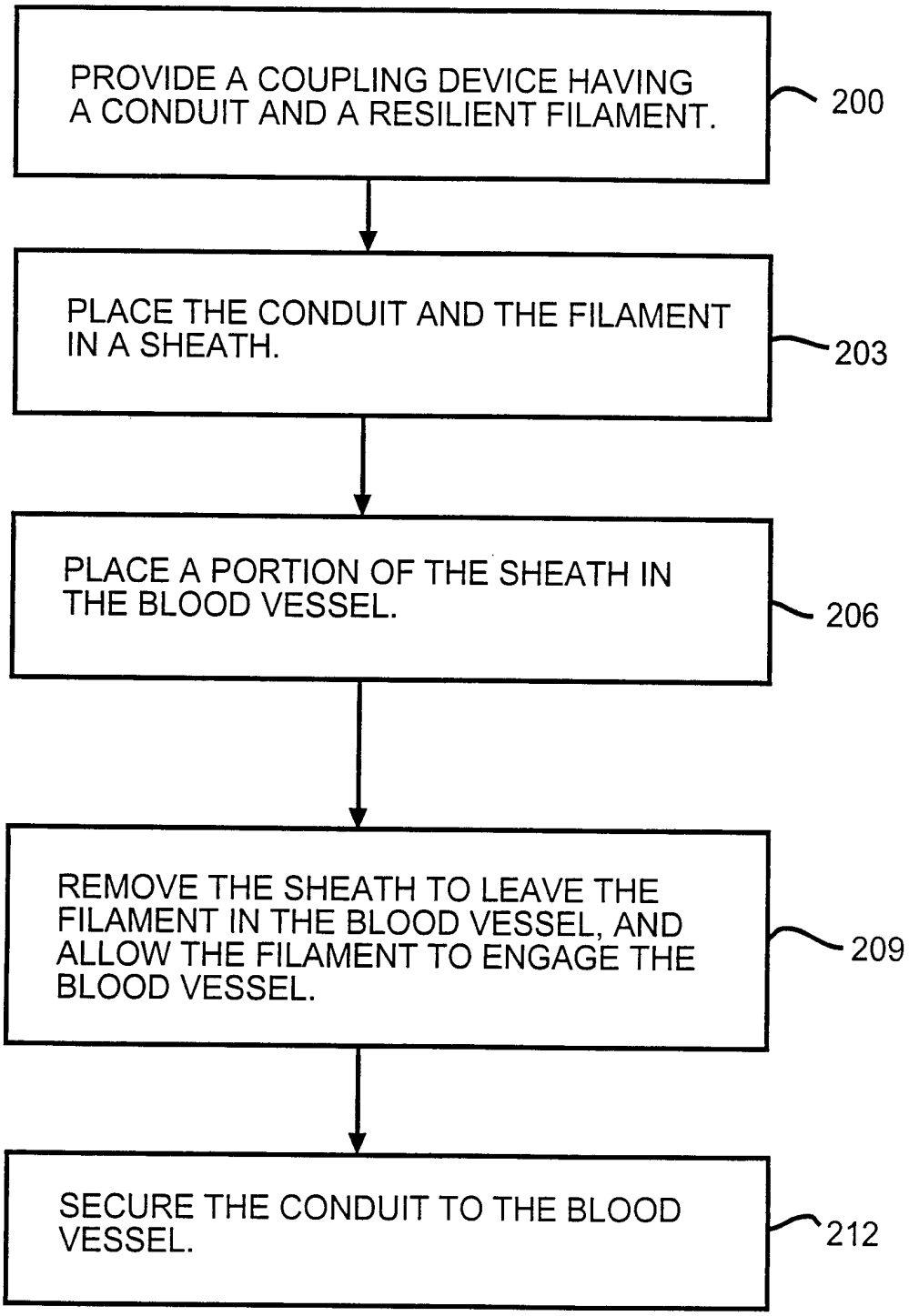
PROVIDE A COUPLING DEVICE HAVING A CONDUIT AND A RESILIENT FILAMENT.
200
PLACE THE CONDUIT AND THE FILAMENT IN A SHEATH.
203
PLACE A PORTION OF THE SHEATH IN THE BLOOD VESSEL.
206
REMOVE THE SHEATH TO LEAVE THE FILAMENT IN THE BLOOD VESSEL, AND ALLOW THE FILAMENT TO ENGAGE THE BLOOD VESSEL.
209
SECURE THE CONDUIT TO THE BLOOD VESSEL.
212

FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/22627

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/08
US CL : 606/153

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)

U.S. : 606/151-153, 157-158

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,397,345 A (LAZARUS) 14 March 1995, see entire document.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer VIKKI TRINH Telephone No. (703) 308-8238

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