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(54) Title: SURGICAL IMPLANT

(57) Abstract: An implant is disclosed including a bio-compatible implant body that can be provided with a tip, or interconnected by one or more filaments. The implant body can be formed of a variety of biocompatible materials, including bioremodelable materials such as small intestine submucosa. Methods are disclosed for assembly of the implant. Additionally, a method is disclosed for delivering the implant to a desired location in a patient.

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# SURGICAL IMPLANT

## RELATED APPLICATIONS

**[0001]** This claims the benefit of U.S. Provisional Application Serial No. 60/494,613, entitled "Tipped Implant," filed on August 11, 2003, and U.S. Provisional Application Serial No. 60/558,163, entitled "Surgical Graft," filed on March 30, 2004.

## TECHNICAL FIELD

**[0002]** This invention relates to medical devices, and more particularly, to surgical implants.

## BACKGROUND

**[0003]** Many surgical or endoscopic applications require the insertion of an implant into an incision in a patient's soft tissue. For example, such implants can be used to add bulk to a target tissue, thereby reinforcing the target tissue area. These procedures are often referred to as "bulking" procedures, and are frequently used in treating urological diseases, including urinary incontinence and vesicourethral reflux disease. "Bulking" procedures are also often used to treat Gastroesophageal Reflux Disease (hereinafter "GERD"). GERD is a form of dyspepsia that afflicts approximately 40% of adults in the United States. More specifically, GERD is a pathophysiologic condition of the esophagus in which gastric fluids escape from the stomach and travel into the esophagus. The symptoms of GERD can include heartburn, regurgitation of gastric contents, or dysphagia, which is a difficulty in swallowing or moving swallowed material into the stomach. GERD often results from, among other things, transient lower esophageal sphincter (hereinafter "LES") relaxations and decreased LES resting tone.

**[0004]** One endoscopic procedure used to treat GERD involves transmurally inserting one or more implants into preformed incisions in the LES, and

particularly into the submucosal tissue layer, as described in U.S. Patent No. 6,098,629 to Johnson *et al.*, which is fully incorporated herein by reference. In general, the implants effectively treat GERD by increasing the mass of the LES, thus improving the LES resting tone. The procedure involves first endoscopically identifying an insertion site to access the submucosa adjacent the LES. The layer of mucosa that covers the submucosa is then pierced by a sharp dissection tool. Next, a pouch sized to receive the prosthesis is created in the submucosa. The pouch can be created by liquid infusion (i.e., by forming a blister) or by blunt dissection using a blunt tool. Once the pouch is created, the implant is inserted into the pouch. The implant is typically inserted by a grasper, a clamshell deployment device, or another similar insertion tool. After insertion, the mucosal opening is closed by using an appropriate conventional closing technique.

**[0005]** Soft tissue implants can also be used for brachytherapy. Brachytherapy involves inserting a radioactive implant directly into or adjacent a tumor to effect remission of the tumor. Similarly, soft tissue implants can be used to deliver various drugs to a target location. That is, once an implant impregnated or coated with a drug is implanted in a patient's soft tissue, the implant releases the drug into the patient.

**[0006]** However, presently available procedures for inserting an implant have several significant drawbacks, including implant migration. Implants migrate when, for example, the pouch created to accommodate the implant is too large for the implant. In this situation, the implant can be displaced from its target position into a less ideal position. In more serious cases, implant migration renders the implant entirely ineffective, thus requiring follow-up or additional medical procedures.

**[0007]** Another drawback is the size of presently available implants. Often times a single implant is simply too small to achieve the desired bulk in the target area. Thus, the insertion of multiple implants in the target area is often required. Delivering multiple implants, however, can require that a physician reinsert the delivery tool into a target tissue for each implant, thus increasing the time required for the procedure and causing unnecessary trauma.

[0008] Presently available procedures for transmurally inserting an implant, for example, into the LES, have several additional drawbacks. First, creating a pouch for the implant typically causes excessive trauma to the surrounding tissues, especially if a blunt tool is used to create the pouch. Another drawback is that insertion of an implant into the target tissue can be difficult because the implant can catch or snag on the edges of the mucosal incision. Moreover, implants can be difficult to deliver into a target tissue along a desired trajectory and in a desired spatial orientation.

## BRIEF SUMMARY

[0009] Accordingly, it is an object of the present invention to provide a medical device having features that resolve or improve upon one or more of the above-described drawbacks.

[0010] According to a first aspect of the present invention, the foregoing object of the present invention is obtained by providing a linked implant having two or more bio-remodelable implant bodies disposed along a length of string. The implant bodies can be formed of an extra-cellular matrix material, such as small intestine submucosa, and can be shaped as desired for a given application. For example, the implant bodies can be spherical, ellipsoid, cuboid, or cylindrical in shape. Additionally, radiopaque markers can be provided to assist in visualization of the device during delivery within a patient. According to another aspect of the present invention, the foregoing object is obtained by providing a linked implant that forms a net or matrix. According to yet another aspect of the present invention, methods are provided for assembling a linked implant.

[0011] According to yet another aspect of the present invention, the foregoing object of the present invention is obtained by providing a tipped implant including an implant body having a first outside periphery, and a penetrating member connected to the implant body. The penetrating member can be formed from a biocompatible material such as stainless steel, plastic, or even a rigid bio-resorbable material. The penetrating member includes a penetrating portion and

an expanding portion located adjacent to the penetrating portion. The penetrating portion can form a leading edge or a leading point. The expansion portion expands the opening created by the penetrating portion to a diameter that is sufficiently large to receive the implant.

**[0012]** According to another aspect of the present invention, a passageway that extends axially through the implant body and/or the penetrating member can be provided. The passageway permits the tipped implant to be directed over a guidewire to the target site.

**[0013]** According to another aspect of the present invention, a method is provided for assembling a tipped implant. According to yet another aspect of the invention, a method is provided for simultaneously creating an opening sized to receive an implant and inserting the implant into the opening.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0014]** Figure 1 is a side view of one embodiment of the present invention including several cylindrical implant bodies and a string;

**[0015]** Figure 2 is a side view of one embodiment of the present invention including several ellipsoid implant bodies and a string;

**[0016]** Figure 3 is a side view of one embodiment of the present invention including several spherical implant bodies and a string;

**[0017]** Figure 4 is a side view of one embodiment of the present invention including a bulking net;

**[0018]** Figure 5 is a cross-sectional side view of one embodiment of the present invention including radiopaque markers;

**[0019]** Figure 6 is a cross-sectional side view of one embodiment of the present invention including an assembly mold;

**[0020]** Figure 7-12 sequentially illustrate a method of inserting a linked surgical implant according to one embodiment of the present invention;

**[0021]** Figure 13 is a cross-sectional side view of one embodiment of the present invention including a guidewire lumen;

**[0022]** Figure 14 is a cross-sectional side view of one embodiment of the present invention including an assembly tube;

**[0023]** Figure 15 is a perspective side view of one embodiment of the present invention including an implant and an implant tip;

**[0024]** Figure 16 is a perspective side view of one embodiment of the present invention including an implant, an implant tip, a channel, and a guidewire;

**[0025]** Figure 17 is a cross-sectional side view of one embodiment of the present invention including an implant, and an implant tip;

**[0026]** Figure 18 is a cross-sectional side view of one embodiment of the present invention including an implant, an implant tip, and a channel;

**[0027]** Figure 19 is a cross-sectional side view of one embodiment of the present invention including an assembly mold; and

**[0028]** Figures 20-26 sequentially illustrate one embodiment of the method according to the present invention to implant a medical device having an implant with an implant tip.

## DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

**[0029]** The invention is described with reference to the drawings in which like elements are referred to by like numerals. The relationship and functioning of the various elements of this invention are better understood by the following detailed description. However, the embodiments of this invention as described below are by way of example only, and the invention is not limited to the embodiments illustrated in the drawings. It should also be understood that the drawings are not to scale and in certain instances, details which are not necessary for an understanding of the present invention, such as conventional details of fabrication and assembly, have been omitted.

**[0030]** Referring to the drawings, Figure 1 illustrates a first embodiment of the present invention, and particularly, linked implant **10**. As illustrated in Figures 1-4, linked implant **10** normally comprises two or more implant bodies **14** attached

to a string **18**. In general, linked implant **10** is delivered to a location adjacent the target tissue (e.g., the esophageal lumen, superior to the LES). Linked implant **10** is then introduced into the target tissue, thereby bulking the surrounding tissue.

**[0031]** Implant body **14** can be formed of a variety of desirable, biocompatible implant materials suitable for bulking and supporting a target tissue. In a preferred embodiment of the present invention, the implant body is formed of a bio-remodelable, extra-cellular matrix. One suitable form of extra-cellular matrix is harvested from porcine or bovine small intestine submucosa (hereinafter "SIS"). SIS is a preferred material because it has special bio-remodeling characteristics. Because of these characteristics, SIS has been used successfully in various surgical applications. One such application is described in U.S. Patent No. 6,358,284 to Fearnot *et al.*, which is incorporated herein by reference. That surgical application involves the application of purified submucosa as a ureter graft. As an alternative to using a bio-remodelable material such as SIS, the implant body can be formed from a variety of other bio-compatible materials, including for example, stainless steel, polymers, and biocompatible foams such as silicone foam or polyurethane foam.

**[0032]** As shown in Figures 1-4, the implant bodies **14** can be provided in a wide variety of shapes. For example, implant bodies **14** can be formed into cylindrical bodies (Figure 1), ellipsoid bodies (Figure 2) or spherical bodies (Figures 3 and 4). Likewise, the size of each implant body can vary depending on the particular medical application for the linked implant. Moreover, depending on the therapeutic needs of a patient, e.g., treatment of a tumor, the implant body also can be impregnated or covered with a drug suitable for causing the desired therapeutic outcome.

**[0033]** As shown in Figure 5, a biocompatible, radio-opaque powder, ball, or other marker, for example stainless steel ball **34**, can also be added to the implant body. As a result, a physician can track the position of the implant body relative to the surrounding anatomy and/or the target tissue, thereby facilitating proper placement of the linked implant within the patient. For example, the physician can

track the position of the implant body fluoroscopically during the delivery of the linked implant.

**[0034]** As illustrated in Figures 1-5, linked implant **10** includes a string **18** that is used to link two or more implant bodies **14**. Once properly placed in a target tissue, string **18** secures and stabilizes implant bodies **14**. In particular, string **18** prevents implant bodies **14** from individually migrating into an undesired or ineffective position. String **18** can be a biocompatible mono-filament or thread. One preferred material is the thread or filament utilized in resorbable sutures. Alternatively, non-resorbable sutures can be used.

**[0035]** It should also be noted that implant bodies **14** can be disposed closely together, as shown in Figure 2, or spread apart from each other, as shown in Figures 1, 3, and 4. That is, the separation between implant bodies can be tailored to a particular desired position along the string or filament. Further, the implant bodies need not be disposed along the string equidistantly. Rather, the distances between adjacent implant bodies can by varied as desired. Moreover, as illustrated in Figure 4, implant bodies **14** can be disposed on a net of filaments. Such a net arrangement allows a physician to extend the implants laterally and longitudinally relative to a wound or surgical site, thus reinforcing and bulking the wound or surgical site.

**[0036]** A variety of methods can be employed to assemble linked implant **10**. A preferred method of assembly is illustrated in Figure 6. Mold **26** is configured to form cylindrical implant bodies **14**. A mold capable of forming spherical, cuboid, and/or elliptical implant bodies could alternatively be used. While illustrative mold **26** is configured to form a linked implant **10** having ten (10) implant bodies **14**, molds capable of forming a linked implant with additional or fewer implant bodies could be used.

**[0037]** Linked implant **10** is assembled as illustrated in Figure 6. First, a string **18** is threaded through cylindrical forms **30**. After string **18** is in place, the desired implant material is packed into each cylindrical form **30**. In one method, the implant material comprises a liquid that is injected into the form. Before cylindrical form **30** has been completely filled with the implant material, such as

SIS, a radio-opaque marker **34** can be optionally inserted into the cylinder. Once the linked implant is assembled, it is dried. The linked implant can be air-dried or freeze-dried, preferably overnight. The dried, linked implant can then be removed from mold **26** and cut to a desired length with a scalpel or scissors. It should be noted that alternative curing methods can be used for various materials. For example, linked implants formed of epoxy materials are cured through polymerization or cross-linking reactions, and linked implants formed of cement materials are cured through hydrolysis reactions. Additional exemplary methods of forming a linked implant include insert molding, wherein a plastic can be injected into a molding and an additional object can be inserted into the plastic.

**[0038]** Linked implant **10** can also be assembled as illustrated in Figure 14. Figure 14 illustrates a tubular mold used to assemble implant bodies **14** and string **18**. To assemble linked implant **10**, the desired implant material is packed into tubular mold **44**. The linked implant can be air-dried or freeze-dried, preferably overnight. The dried, linked implant **10** can then be removed from tubular mold **44** and cut to a desired length with a scalpel or scissors.

**[0039]** Linked implant **10** can be used for a wide variety of applications, including minimally invasive or open surgical applications. An exemplary minimally invasive procedure is the treatment of GERD by bulking the LES. For applications involving GERD, a preferred method of delivering the linked implant generally includes first identifying the desired implant location with an endoscope and then inserting the linked implant into that location. Referring to Figure 7, an illustrative endoscope **74** (which is preferably an X-Ray fluoroscope, ultrasound endoscope, or conventional endoscope) is passed through the mouth and esophagus **70** of a patient and delivered to the vicinity of LES **82**, superior to the stomach **84** and adjacent to diaphragm **78**. A needle **86** is passed through the working channel of endoscope **74** and into the LES **82**, as shown in Figure 8. As illustrated in Figure 9, once needle **86** is in the LES **82**, guidewire **90** is inserted to maintain access to the target tissue. Needle **86** is withdrawn, while guidewire **90** remains in the target tissue, as illustrated in Figure 10. Subsequently, catheter **94** is inserted over the guidewire and into the desired implant location to deliver

linked implant **10**, as shown in Figure 11. Linked implant **10** can be pushed into the LES by a conventional pusher tool inserted through the lumen of the catheter **94** (Figure 11) into the desired implant location. As illustrated in Figure 11, throughout the delivery of the linked implant, the position of catheter **94** can be changed to distribute additional implant bodies **14** throughout the target tissue area. Once the linked implant is in the target tissue, catheter **94** and endoscope 74 are withdrawn, as illustrated in Figure 12.

**[0040]** As shown in Figure 13, the linked implant can alternatively be configured for delivery directly over a guidewire. In this delivery configuration, the implant body **14** is provided with a passageway **60**, which is adapted to receive a guidewire. Before delivery, a plurality of implant bodies **14** are back-loaded onto a guidewire. Once the implant bodies are loaded, the distal end of the guidewire can be inserted into the target tissue, as shown in Figure 10. A conventional pusher tool (not shown) is then used to push the implant bodies into the target tissue.

**[0041]** It should also be noted that the linked implant can alternatively be delivered without the use of a guidewire. For example, the linked implant can be delivered into a target tissue through a catheter inserted directly into the LES. In another alternative, a cannula can be used to deliver the linked implant.

**[0042]** Linked implant **10** can alternatively be used in various open surgical procedures in which tissue bulking or reinforcement is necessary. Linked implant **10** can be directly inserted into an incision by a physician. In either open or minimally invasive procedures, the physician can tailor the linked implant **14** for the particular incision by, for example, using several separate linked implants, joining two or more linked implants to increase overall implant length, or cutting a linked implant to reduce its overall length. Alternatively, a physician can insert a net of interconnected linked implants (see Figure 4). Indeed, a physician can wad or bundle the net of interconnected linked implants and insert the wadded or bundled net into an incision. A net configuration can be particularly useful where a physician desires to reinforce or bulk a large incision.

**[0043]** Referring to the drawings, Figures 15 and 16 illustrate a second embodiment of the present invention, and particularly, tipped implant **110**. As best seen in Figure 15, tipped implant **110** generally comprises implant body **126** (often having a rough or non-uniform edge), and a smooth implant tip **114** having a penetrating portion and an expanding portion. As illustrated in Figure 17, tip **114** also includes a proximal end having shank **132** with threads **134**. As discussed in greater detail below, shank **132** secures implant body **126** to tip **114**.

**[0044]** In general, tipped implant **110** is delivered to a location adjacent the target tissue (e.g., the esophageal lumen, superior to the LES) through the working channel of an endoscope. Tip **114** is then introduced into the target tissue such that the penetrating portion of the tip punctures the target tissue. As the tip is advanced into the target tissue, the expansion portion of the tip widens the puncture created by the penetrating portion, thus forming a cavity sized to receive the tipped implant. Additionally, the shape of the tip is preferably configured to control or guide the orientation and trajectory of the implant body as the tip penetrates and enters the target tissue. That is, the tip can be configured to dilate the target tissue as necessary to achieve a desired orientation and trajectory for the implant body. For example, the tip can be curved, thereby guiding the implant body over a curved trajectory as the implant body enters the target tissue. Alternatively, the tip can be formed to simply puncture and/or dilate a target tissue.

**[0045]** As best illustrated in Figure 15, tip **114** comprises a distal end having a penetrating portion or point **118**. The leading point of the tip is preferably sharp so as to easily pierce or puncture the target tissue while avoiding unnecessary trauma to adjacent tissues. Of course, in alternative embodiments of the present invention, the penetrating portion can be formed into a variety of shapes configured to penetrate, cut, tear, stretch, or otherwise dilate the target tissue. Alternatively, the penetrating portion can be provided with a cutting edge to further facilitate penetration of the tipped implant into a target tissue. For example, a wedge-shaped tip having a sharpened leading edge can be used. As illustrated in Figure 15, tip **114** has a round cross-section. However, other shapes

having different cross-sections can alternatively be used. For example, the tip can be triangular, square, elliptical, or otherwise asymmetrical in cross section.

**[0046]** The tip can be formed of a variety of materials that are sufficiently rigid to penetrate the target tissue. For example, the tip can be formed of metals, ceramics, polymers, composites, natural materials, bio-resorbable materials, or dissolvable materials. In a preferred embodiment of the present invention the implant tip is formed from surgical grade stainless steel.

**[0047]** As best illustrated in Figure 15, tip **114** also includes an expanding portion **122**. Expanding portion **122** is adapted to enlarge the puncture the incision initially created by point **118** to a shape that closely approximates the projected shape of the tipped implant. As shown in Figures 15 and 17, expanding portion **122** is funnel-shaped so as to reduce trauma to the dilated tissue. Additionally, as illustrated in Figure 15, the maximum circumference of expanding portion **122** is preferably about the same size as or slightly larger than implant body **126**. This ensures that the opening created by the tip is large enough so that the implant body does not catch or snag on the tissue surrounding the opening. Alternatively, the expanding portion can be configured to expand the opening created by point **118** to a circumference that is significantly larger than the circumference of the implant body. The expanding portion of the tip can also be configured to resist migration of the tipped implant **110** in an undesirable direction. This can be accomplished by the addition of an arrow-shaped or lanciform expanding portion that readily penetrates and expands the target tissue as the tipped implant is moved in a first direction, yet resists movement in a second direction opposite the first direction.

**[0048]** Tip **114** further includes shank **132**, as illustrated in Figure 17. Shank **132** is located at the proximal end of tip **114**, and is adapted to secure tip **114** to implant body **126**. In addition, threads **134** are provided as a gripping surface to securely fasten implant body **126** to tip **114**. Implant body **126** is fastened to shank **132** and abuts the proximal end of the tip, as described in detail below.

**[0049]** In a third embodiment of the present invention, shown in Figures 16, 18 and 19, medical device **110** is provided with passageway **138**. Passageway **138** extends axially through both tip **114** and implant body **126**. Passageway **138** is

adapted to slide over a guidewire, needle, or a cannula. The tip of the tipped implant **110** can therefore be inserted into the target tissue with the proper orientation relative to the target tissue. As a result, passageway **138** facilitates insertion of tipped implant **110**. When the medical device is used in conjunction with a catheter, needle, or cannula, the target tissue can easily be pierced and infused with a desired fluid before insertion of the medical device. Other than the inclusion of passageway **138**, the third embodiment of the tipped implant **110** is the same as the second embodiment described above.

**[0050]** The implant body **126** can be formed of a variety of desirable implant materials, such as those discussed with respect to the implant bodies of the first embodiment. As noted above, in a preferred embodiment of the present invention, the implant body is formed of purified submucosa, which is a bio-remodelable material that can be derived from, among other things, the small intestine submucosa of vertebrates. A biocompatible, radio-opaque powder or other marker can also be added to the implant body. This facilitates proper placement of the tipped implant within the patient.

**[0051]** A variety of methods can be employed to assemble tipped implant **110**. A preferred method of assembly includes securing the distal end of the tip, either manually or by a clamp. A rod is then inserted through the tip passageway. Thin strips of SIS are coiled around the shank and the rod as necessary to create an implant body having a desired diameter. Once the tipped implant is assembled, it is dried. The tipped implant can be air-dried or freeze-dried, preferably overnight. The dried implant body can then be cut to a desired size with a scalpel.

**[0052]** Another method of assembly is illustrated in Figure 19 and involves tamping strips of SIS material into a mold that grips the implant tip. In this particular method, a rod **146** is first inserted through tip **114**. An end of a strip of SIS material is then temporarily pinned to shank **132** (for example, by pressing the end of the strip to shank **132**) and the remainder of the strip of SIS is loosely wrapped around shank **132** and a proximal portion of rod **146**. Tip **114** is thereafter inserted into mold **142** far enough so that tip **114** engages and is retained by edge **158** of mold **142**. Once the tip and strip of SIS are inserted into mold **142**,

packing rod **154** is used to tamp the strip, or strips, of SIS to shank **132**. The tip and strip of SIS is then dried in the mold, as described above with respect to the manually assembled implant. After the implant is dried in the mold, pusher rod **150** is used to remove the assembled implant body and tip from mold **142**. As necessary, additional strips of SIS can be added to the tip by repeating the same process. Notably, drying the implant in the mold results in a smooth, low-profile implant that can be implanted more smoothly.

**[0053]** As shown in Figures 20-26, a preferred method of delivering the tipped implant generally includes first identifying the desired implant location with an endoscope and then inserting the tipped implant into that location. In particular, with reference to Figure 20, endoscope **74** is passed through the mouth and esophagus **70** of a patient and delivered to the vicinity of LES **82**. Thereafter, a needle **86** is passed through the working channel of endoscope **74**, as shown in Figure 21. Once needle **86** is located in a desired position within the LES **82**, guidewire **90** is used to maintain access to the target tissue (Figure 22). Guidewire **90** ultimately serves as a pilot for the delivery of the tipped implant into a precise location. Once the desired implant location is accessed by guidewire **90**, needle **86** is removed (Figure 23). The tipped implant **110** is subsequently threaded over guidewire **90** (Figure 24). The tipped implant is then pushed along guidewire **90** toward the desired implant location. When the tipped implant reaches the target tissue, the tipped implant is pushed into the target tissue by conventional pusher tool **94**. Once the tipped implant is in the target tissue, guidewire **90** is withdrawn (see Figure 25). As illustrated in Figure 26, this procedure may be repeated to insert as many tipped implants **110** as necessary for a given medical condition. Preferably, an ultrasound endoscope can be used to identify the target area and serve as a working channel for the delivery of the tipped implant. It should be noted that the tipped implant can alternatively be delivered without the use of a guidewire. For example, the tipped implant can be delivered into a target tissue through a cannula or catheter, or over a needle by using a conventional pusher instrument.

**[0054]** Any other undisclosed or incidental details of the construction or composition of the various elements of the disclosed embodiment of the present invention are not believed to be critical to the achievement of the advantages of the present invention, so long as the elements possess the attributes needed for them to perform as disclosed. Certainly, in view of the present disclosure, one skilled in the medical arts would be able to conceive of a wide variety of additional implant body shapes, tips, sizes, strings, and successful combinations thereof. Indeed, the selection of these and other details of construction are believed to be well within the ability of one of even rudimental skills in this area, in view of the present disclosure. Likewise, one skilled in the medical arts would be able to conceive of a wide variety of applications and uses for linked or tipped implants in view of the present disclosure. Illustrative embodiments of the present invention have been described in considerable detail for the purpose of disclosing a practical, operative structure whereby the invention may be practiced advantageously. The designs described herein are intended to be exemplary only. The novel characteristics of the invention may be incorporated in other structural forms without departing from the spirit and scope of the invention. The invention encompasses embodiments both comprising and consisting of the elements described with reference to the illustrative embodiments. Unless otherwise indicated, all ordinary words and terms used herein shall take their customary meaning as defined in *The American Heritage Dictionary*, third edition. All technical terms shall take on their customary meaning as established by the appropriate technical discipline utilized by those normally skilled in that particular art area. All medical terms shall take their meaning as defined by *Stedman's Medical Dictionary*, 27th edition.

CLAIMS

What is claimed is:

1. A medical device comprising a plurality of implant bodies and a first filament, wherein the plurality of implant bodies are disposed on the first filament.

2. The medical device of claim 1, wherein the plurality of implant bodies comprise a bio-remodelable material.

3. The medical device of claim 2, wherein the bio-remodelable material comprises an extracellular matrix.

4. The medical device of claim 3, wherein the extracellular matrix is small intestine submucosa.

5. The medical device of claim 3, wherein one or more of the plurality of implant bodies is spherical in shape.

6. The medical device of claim 3, wherein one or more of the plurality of implant bodies is cylindrical in shape.

7. The medical device of claim 3, wherein one or more of the plurality of implant bodies is cuboid in shape.

8. The medical device of claim 3, wherein one or more of the plurality of implant bodies is ellipsoid in shape.

9. The medical device of claim 3, further comprising a passageway extending through one or more of the plurality of implant bodies, the passageway being configured to receive a wire guide.

10. The medical device of claim 3, further comprising a radiopaque marker operably connected to at least one of the plurality of implant bodies.

11. The medical device of claim 1, wherein the first filament comprises a plurality of filaments operably connected to form a net, wherein the plurality of implant bodies are further disposed on the plurality of filaments.

12. A medical device, comprising:
an implant body comprising an exterior periphery; and
a penetrating member connected to the implant body, the penetrating member comprising a penetrating portion and an expanding portion located adjacent to the penetrating portion.

13. The medical device of claim 12, wherein the penetrating portion is configured to pierce a bodily tissue.

14. The medical device of claim 13, further comprising a passageway extending axially through the implant body and the penetrating member.

15. The medical device of claim 14, wherein the penetrating member further comprises a shank located adjacent to the expanding portion, the shank being adapted to secure the implant body to the penetrating member.

16. The medical device of claim 15, wherein the penetrating member further comprises an exterior periphery that is larger in size than the exterior periphery of the implant body.

17. The medical device of claim 15, wherein the penetrating member further comprises an exterior periphery that is substantially equal in size to the exterior periphery of the implant body.

18. The medical device of claim 15, wherein the penetrating member further comprises an exterior periphery that is smaller in size than the exterior periphery of the implant body.

19. The medical device of claim 12, wherein the penetrating member is formed of a bio-compatible metal.

20. The medical device of claim 19, wherein the implant body is formed of a bio-remodelable material.

21. The medical device of claim 20, wherein the bio-remodelable material is an extracellular matrix.

22. The medical device of claim 12, wherein the implant body is formed of a bio-resorbable material.

23. The medical device of claim 12, wherein the implant body is formed of a synthetic material.

24. The medical device of claim 12, wherein the penetrating portion defines a cutting edge.

25. The medical device of claim 12, further comprising a passageway extending axially through the implant body and the penetrating member.

26. The medical device of claim 25, wherein the penetrating member further comprises a shank located adjacent to the expanding portion, the shank being adapted to secure the implant body to the penetrating member.

27. The medical device of claim 26, wherein the penetrating member further comprises an external periphery that is substantially equal to the size of the external periphery of the implant body.

28. The medical device of claim 27, wherein the penetrating portion is infundibular.

29. The medical device of claim 28 wherein the penetrating portion defines a substantially circular cross-section.

30. The medical device of claim 28 wherein the penetrating portion defines a substantially triangular cross-section.

31. The medical device of claim 28 wherein the penetrating portion defines a substantially square cross-section.

32. The medical device of claim 12, further comprising a solid shank located adjacent to the expanding portion, the shank being adapted to secure the implant body to the penetrating member.

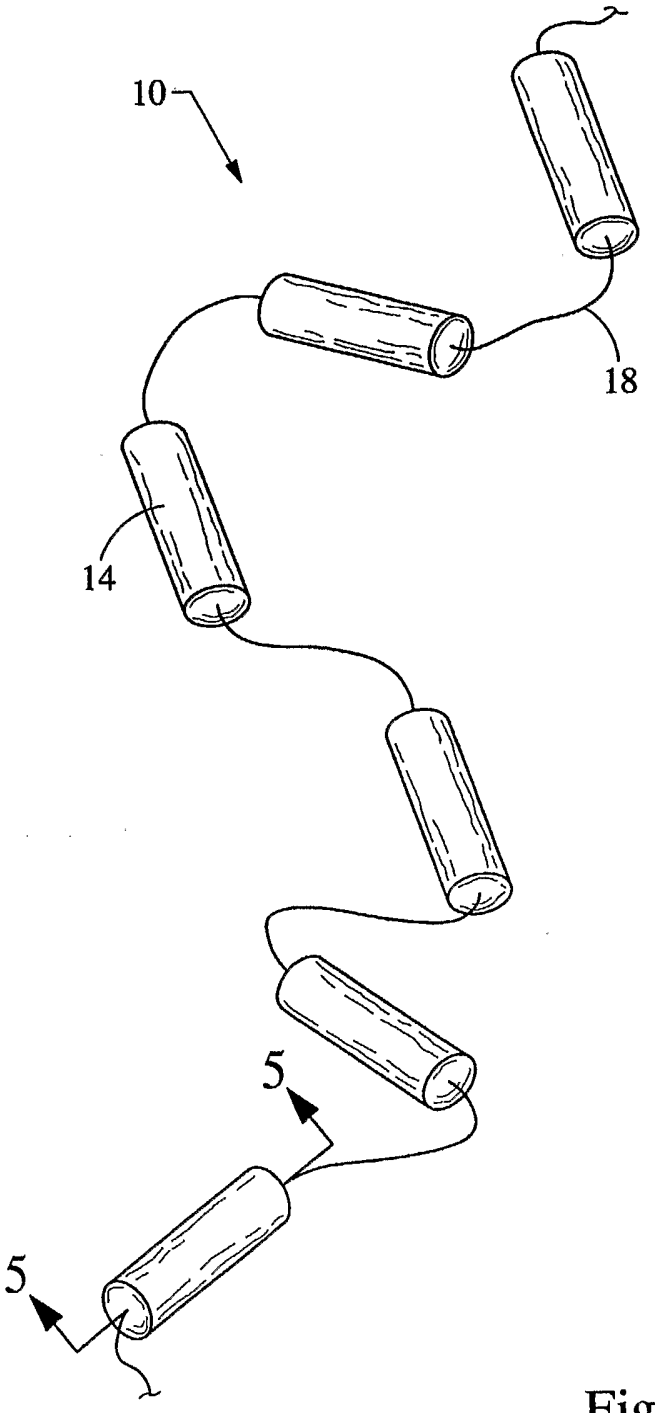



Fig. 1

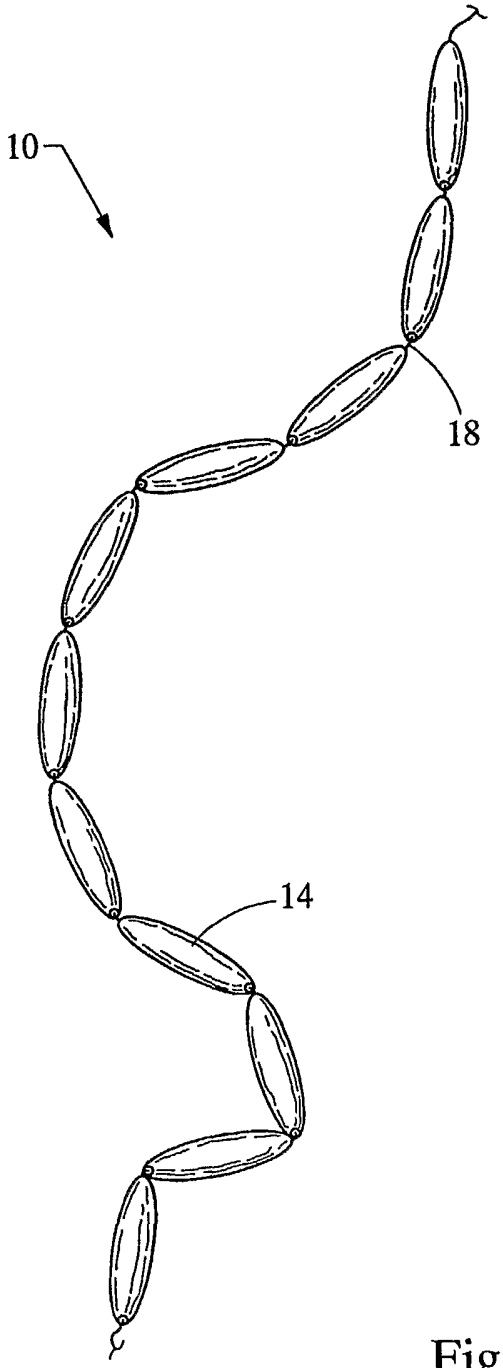



Fig. 2

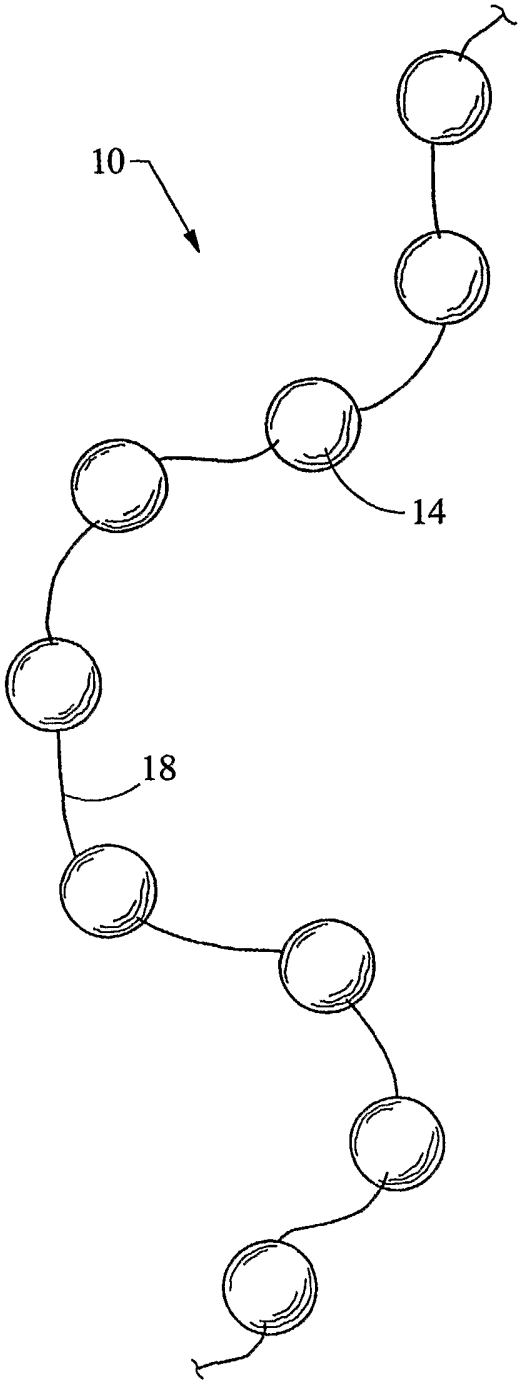



Fig. 3

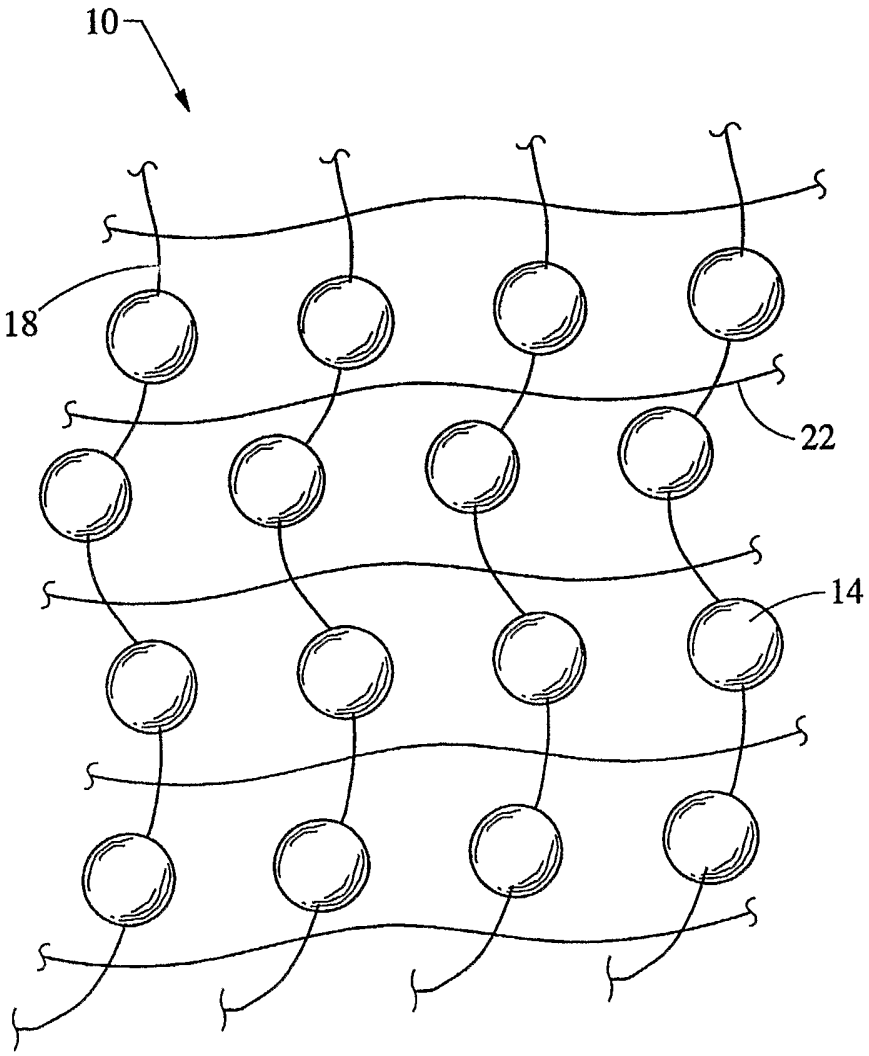



Fig. 4

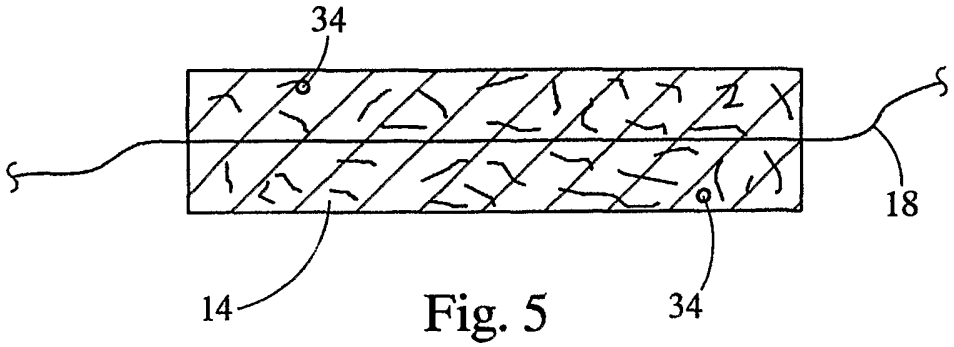
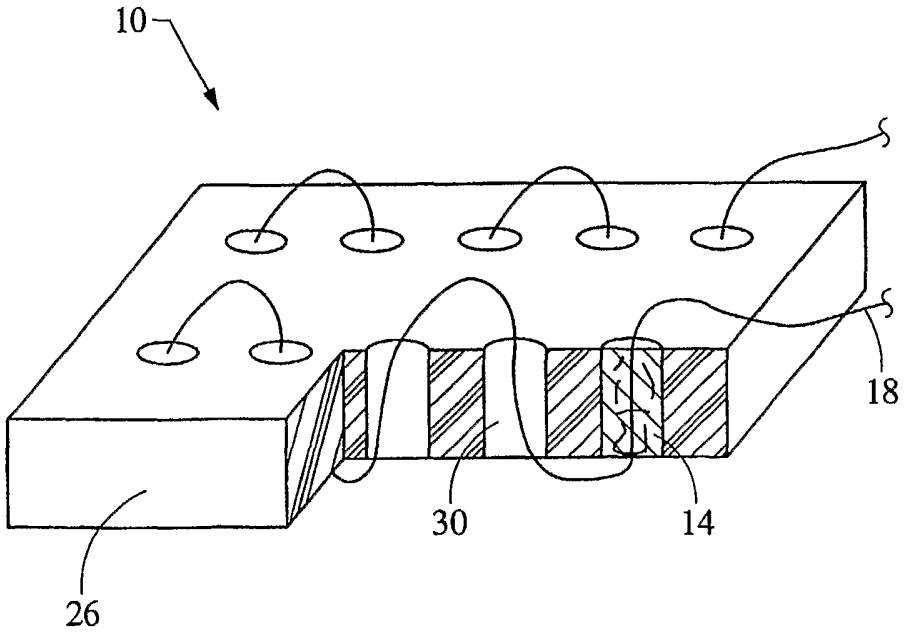



Fig. 5

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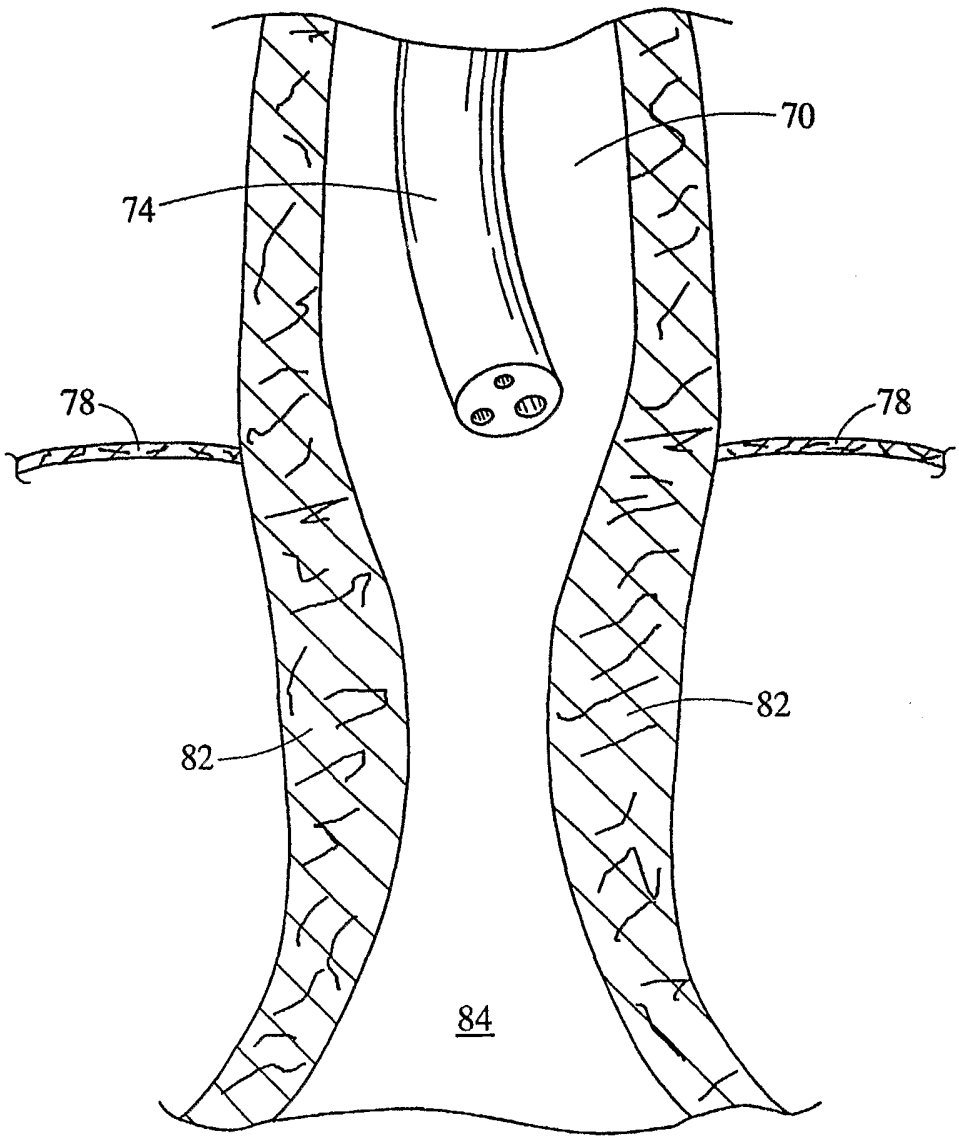
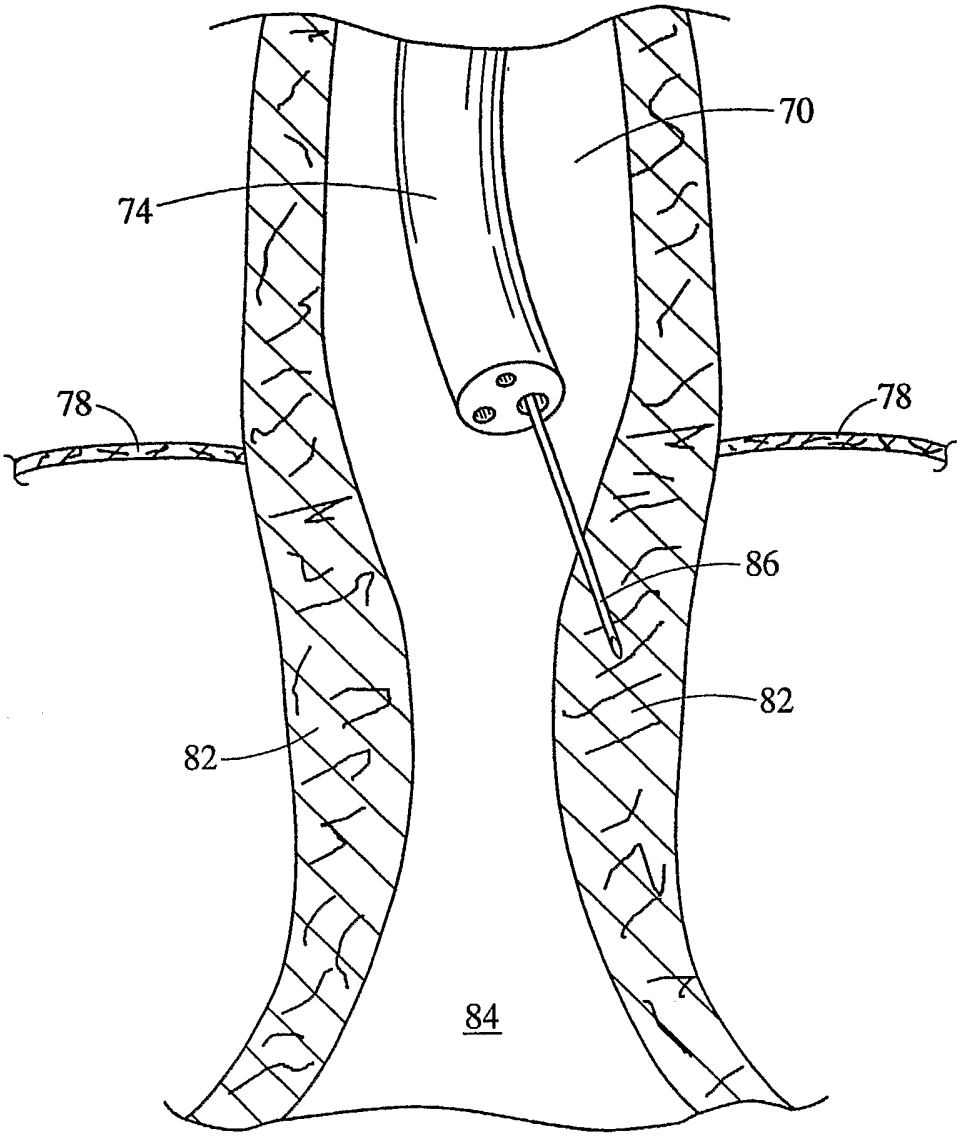



Fig. 7

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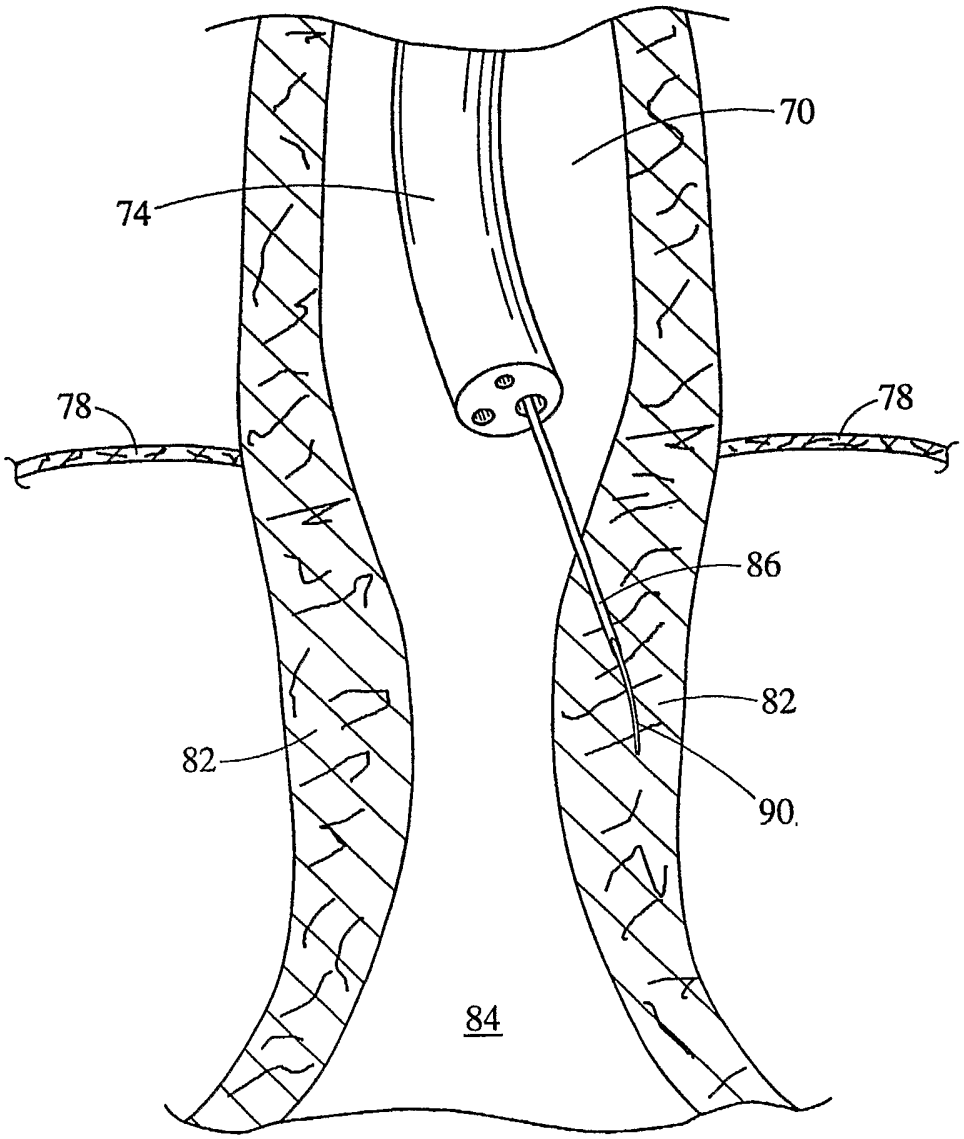



Fig. 9

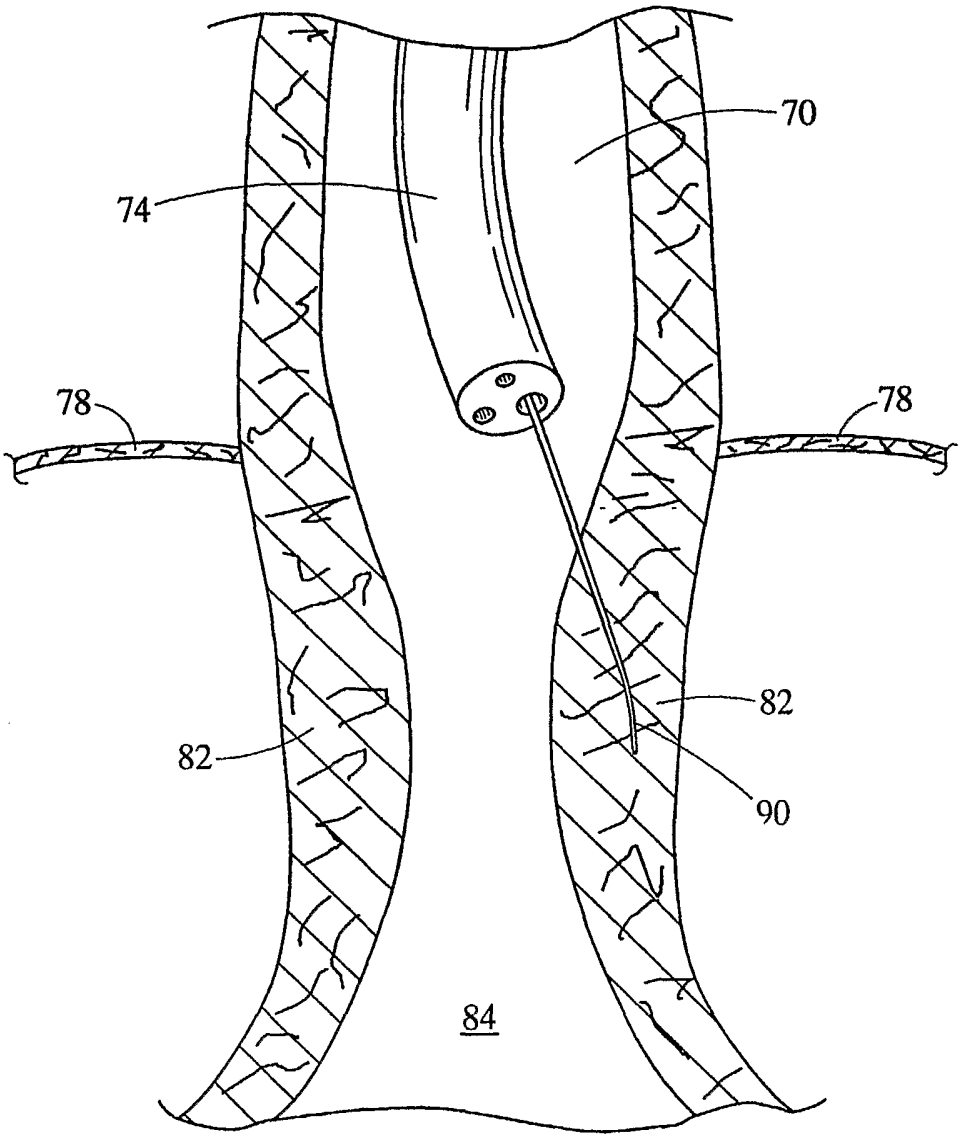
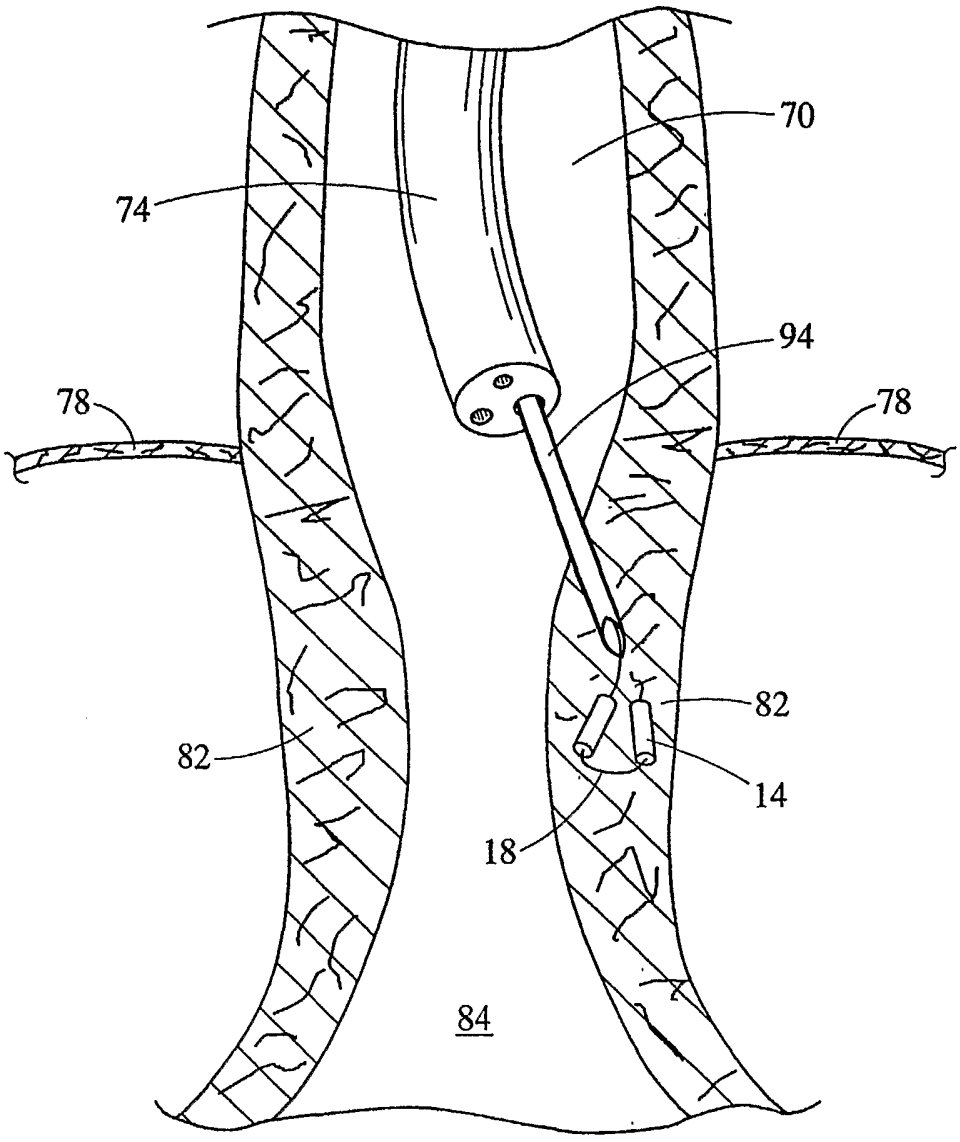



Fig. 10

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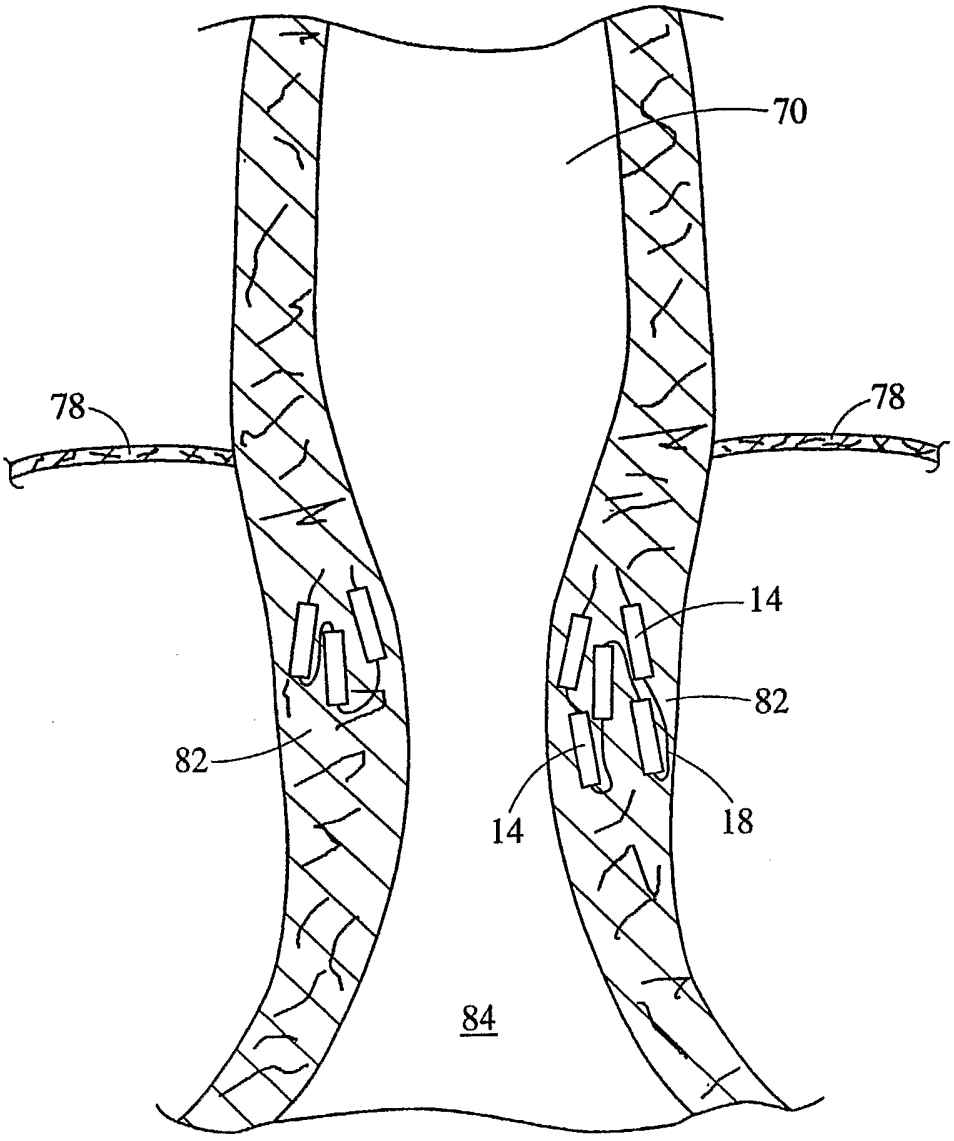


Fig. 12

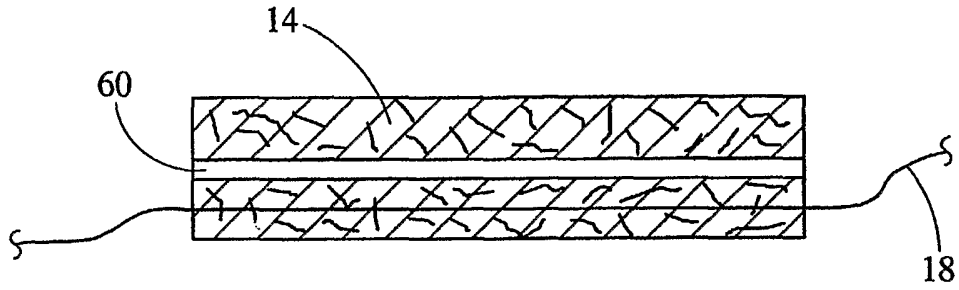


Fig. 13

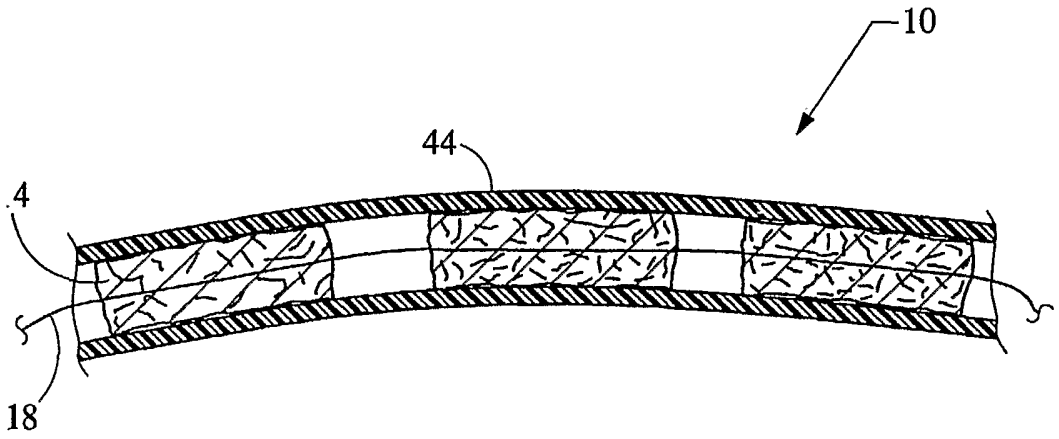


Fig. 14

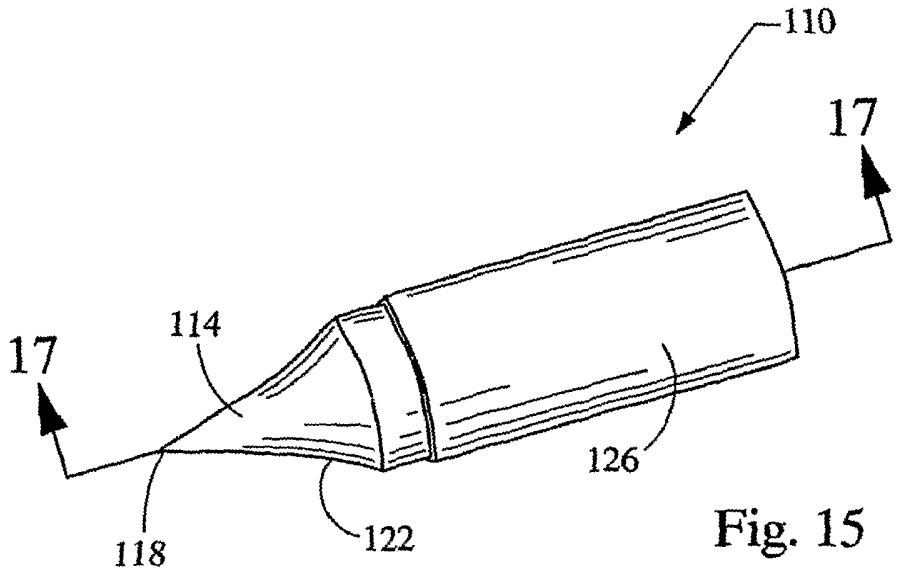


Fig. 15

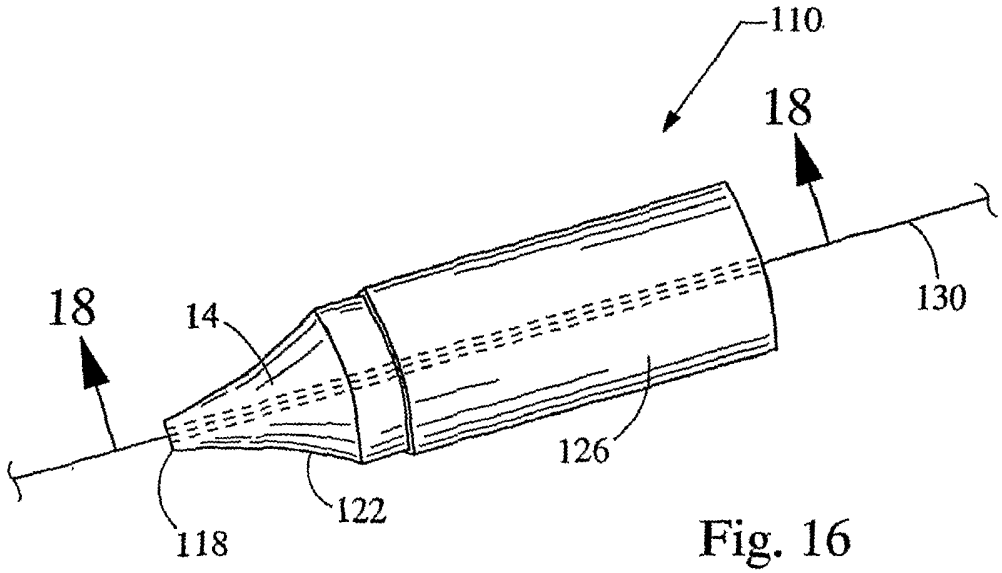


Fig. 16

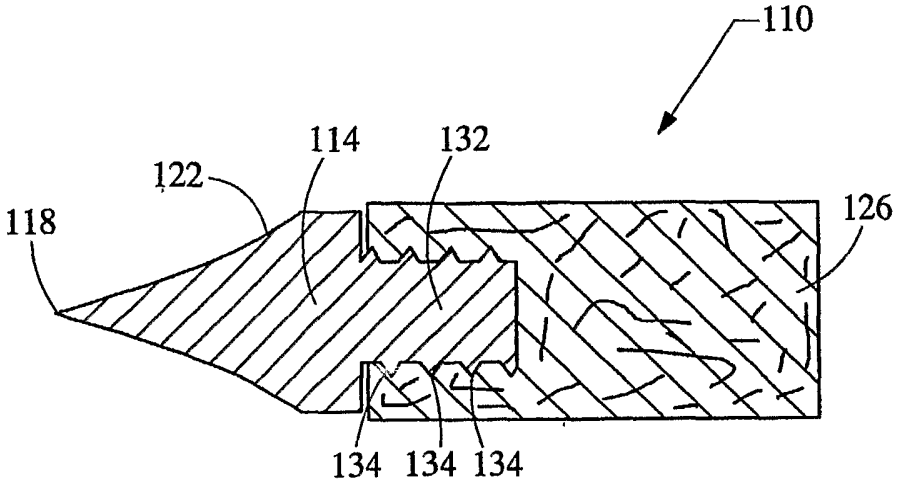
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Fig. 17

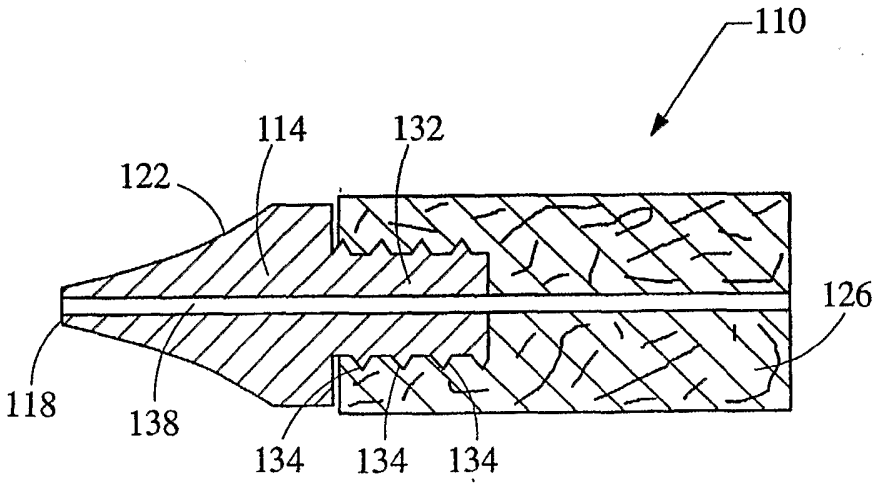
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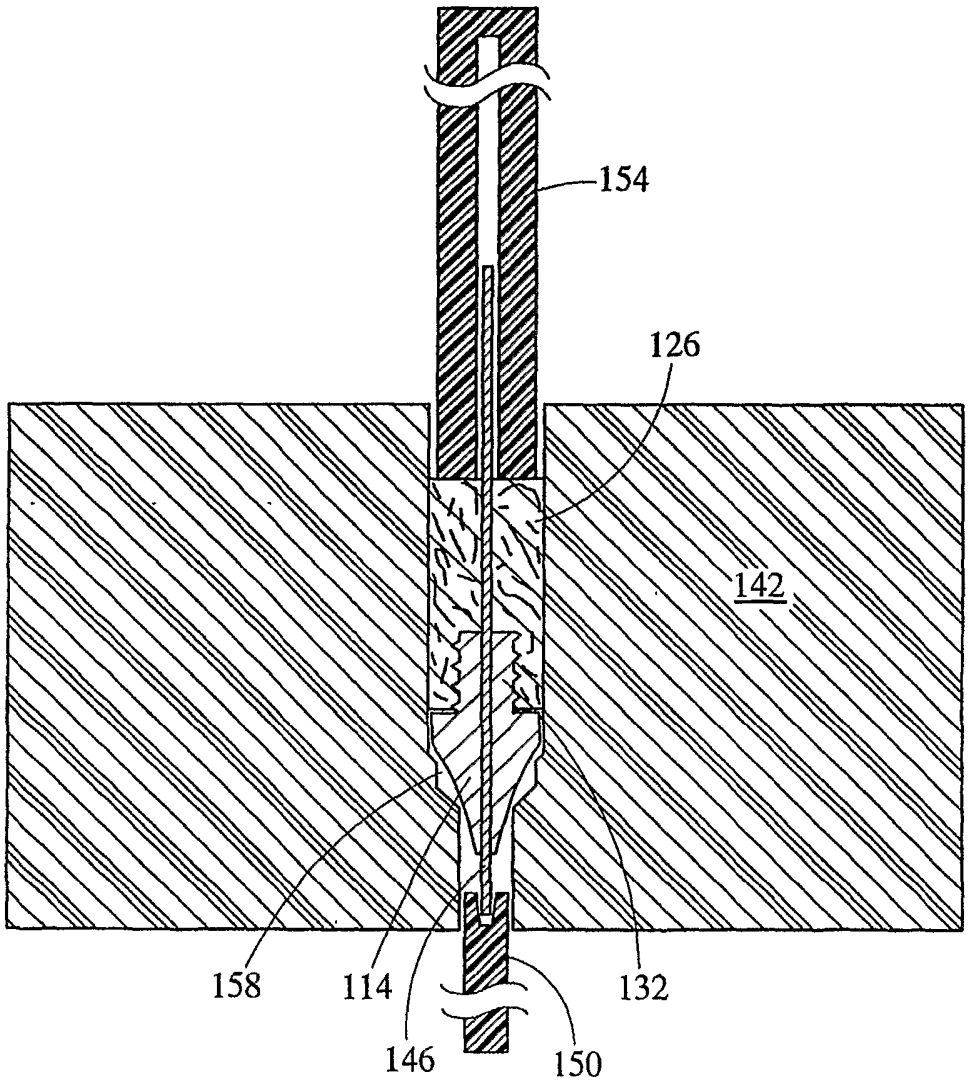
Fig. 18

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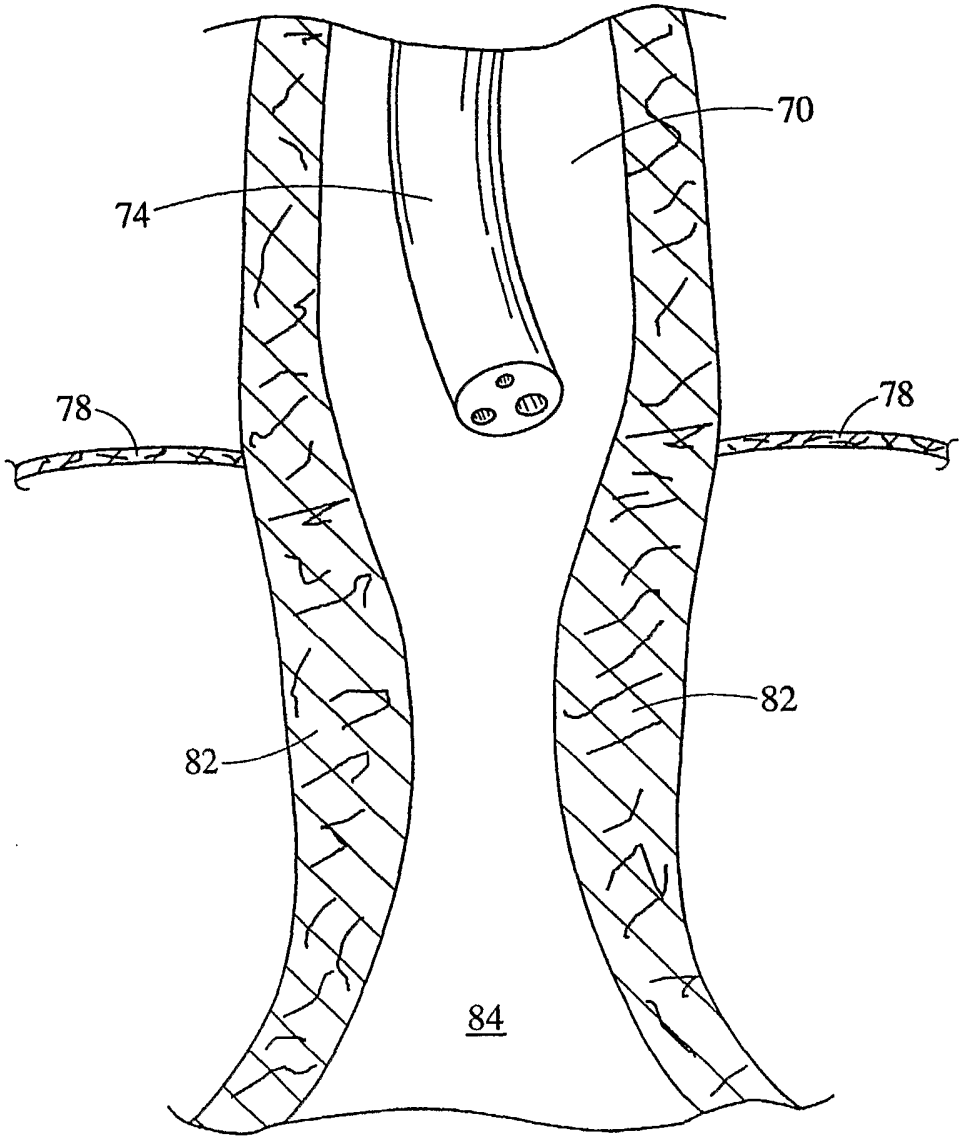
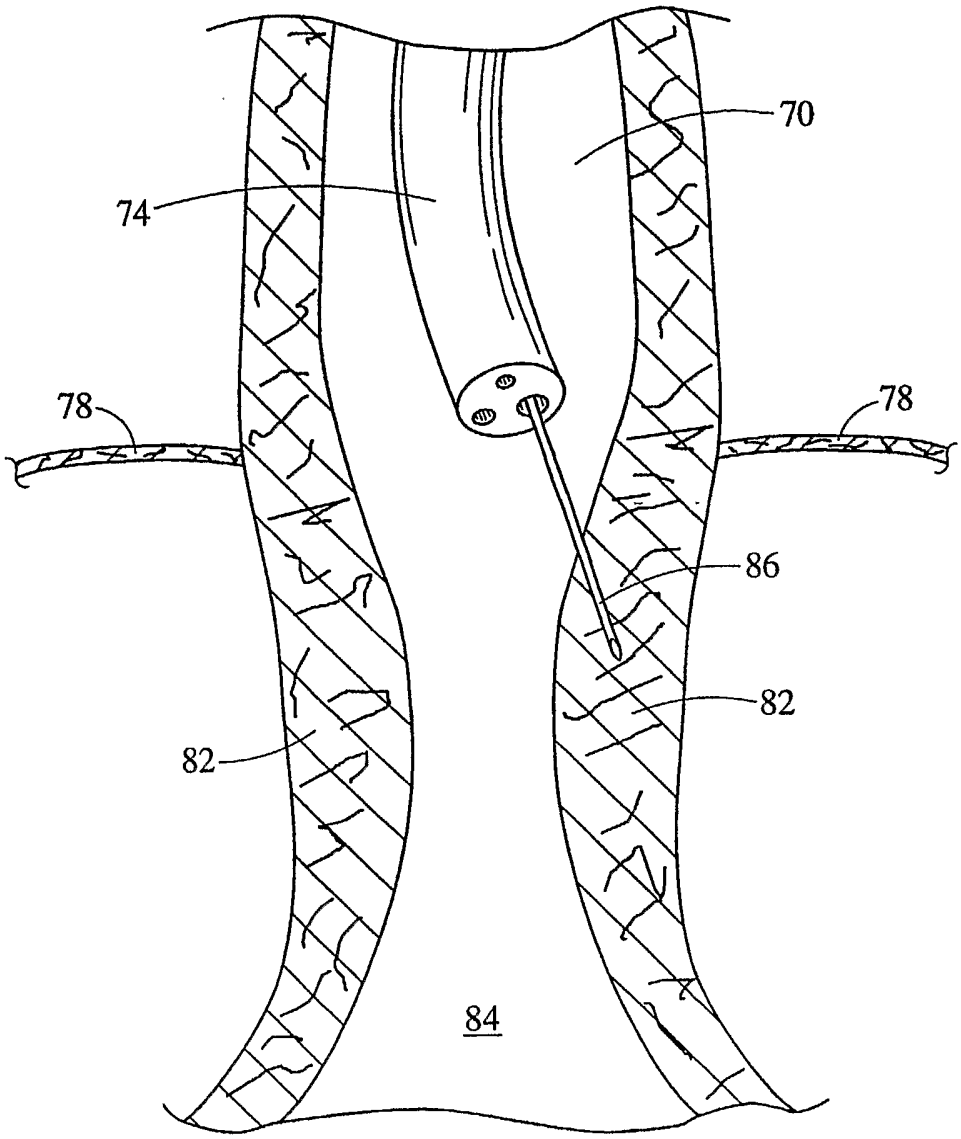



Fig. 20

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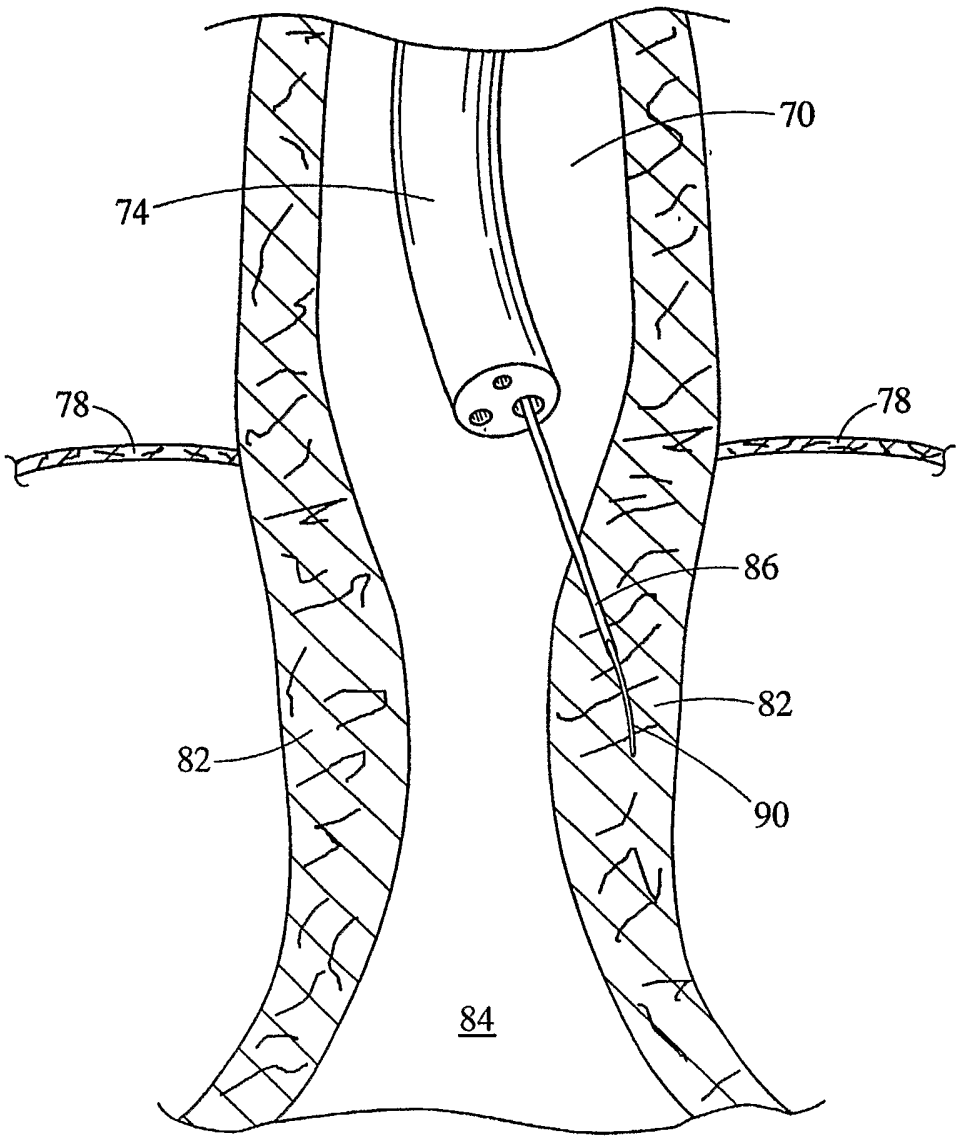


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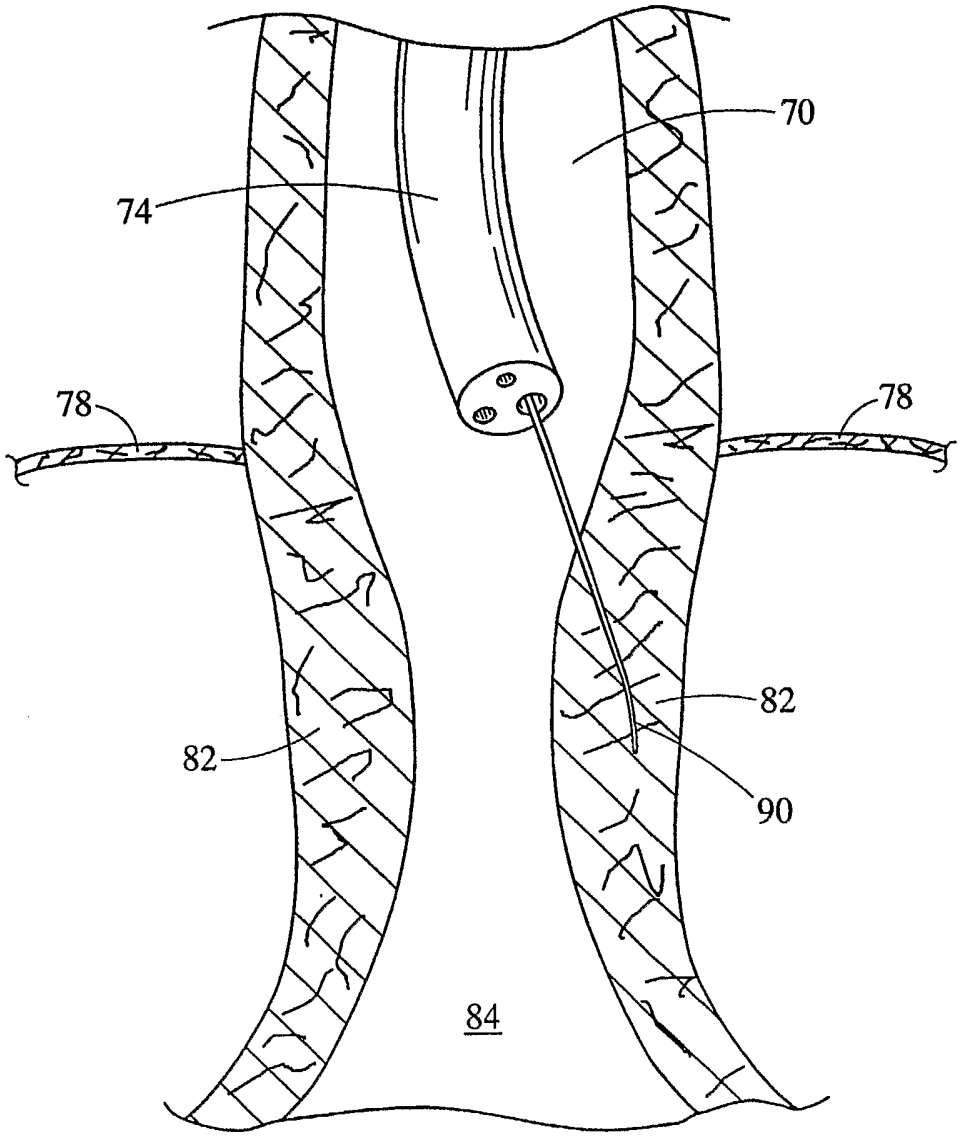


Fig. 23

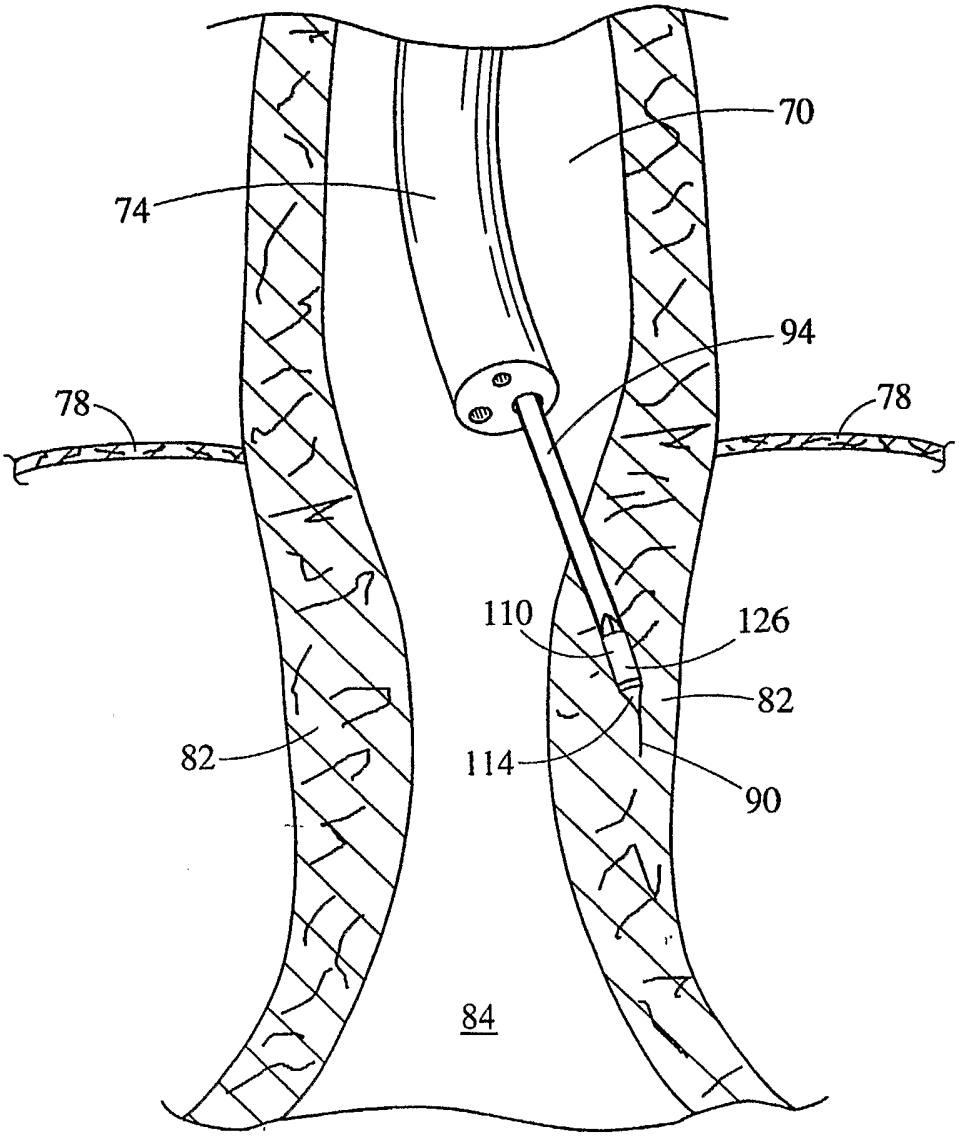


Fig. 24

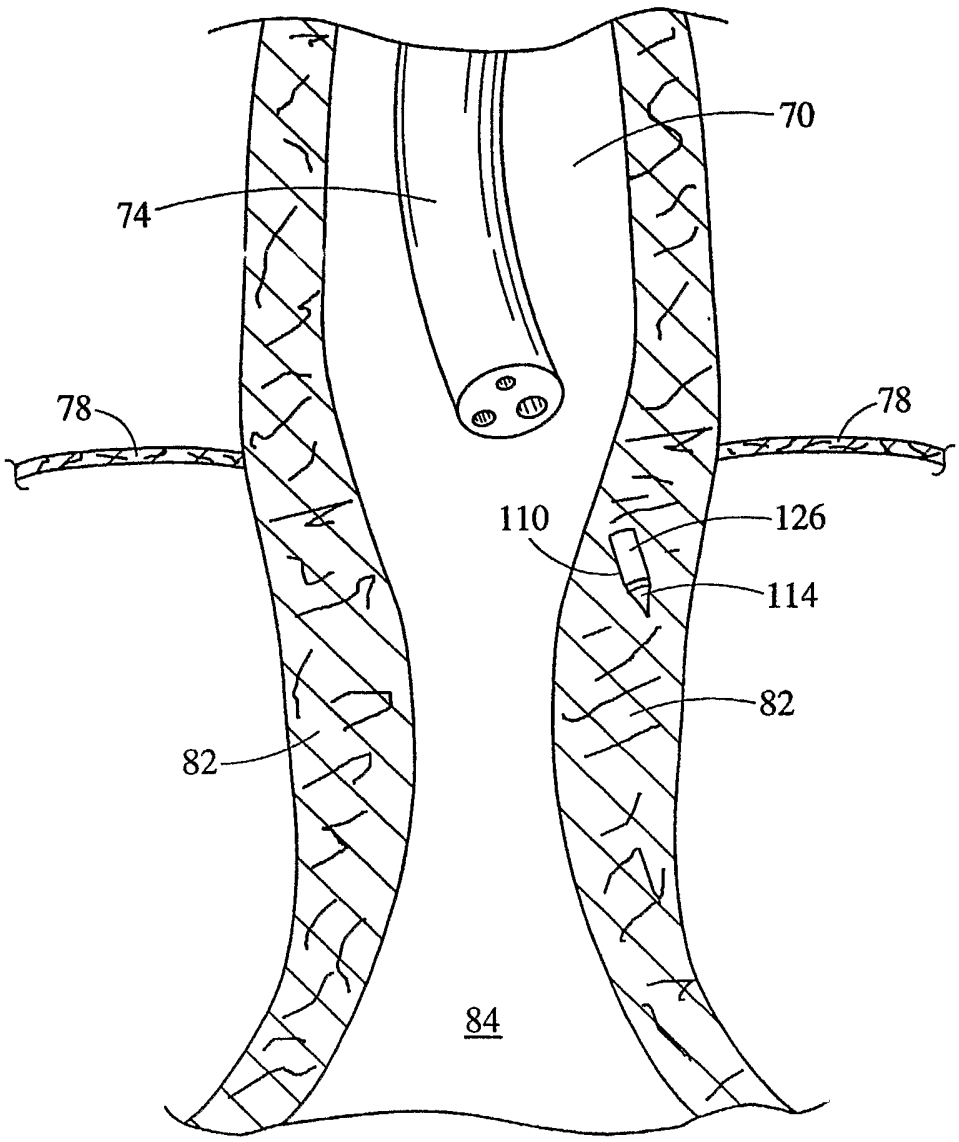


Fig. 25

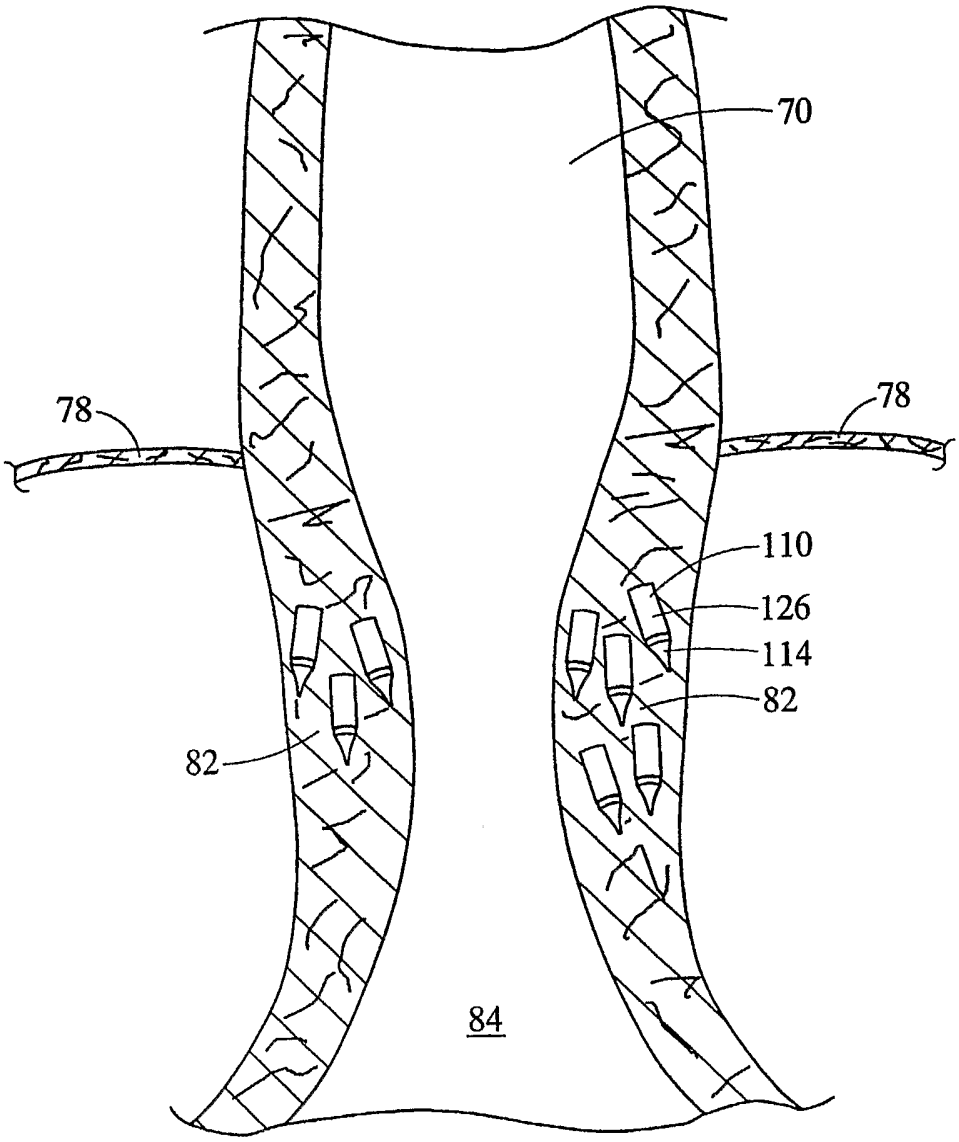


Fig. 26