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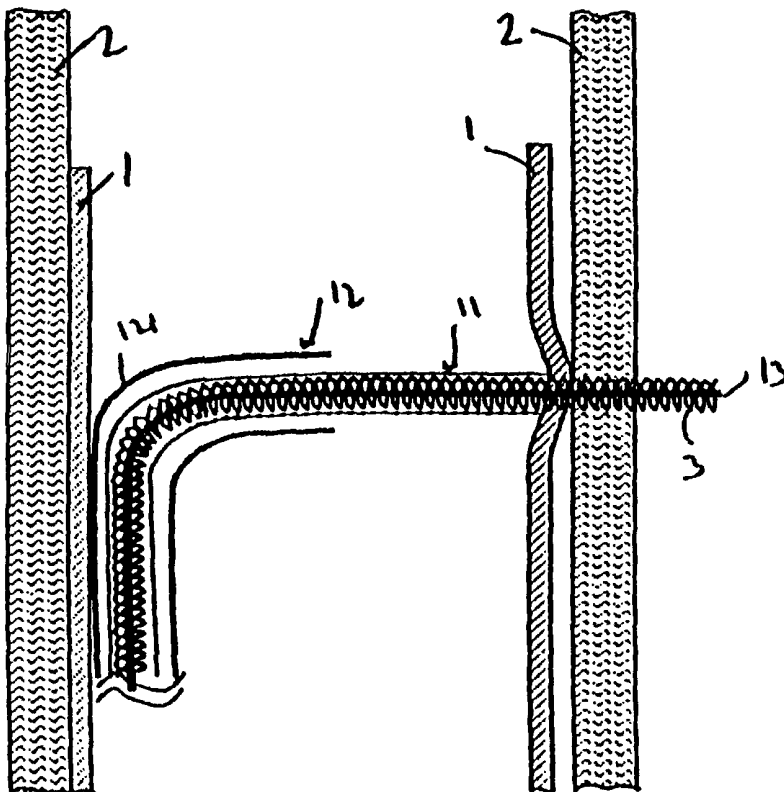
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(54) Title: DELIVERY CATHETER ASSEMBLY AND METHOD OF SECURING A SURGICAL COMPONENT TO A VESSEL DURING A SURGICAL PROCEDURE



(57) Abstract: The present invention is directed to a delivery catheter assembly (10) for advancing a surgical device to a desired location within a vessel (2) during a surgical procedure. The delivery catheter assembly (10) includes an inner sheath assembly (11) through which the surgical device is advanced to the desired location within the vessel. The delivery catheter assembly further includes an outer sheath assembly (12) surrounding the inner sheath assembly.



WO 01/60432 A1

# **DELIVERY CATHETER ASSEMBLY AND METHOD OF SECURING A SURGICAL COMPONENT TO A VESSEL DURING A SURGICAL PROCEDURE**

## **CROSS REFERENCE TO RELATED APPLICATIONS**

The present invention relates to and claims priority on U.S. Provisional Application Serial No. 60/182,543, filed on February 15, 2000.

## **FIELD OF THE INVENTION**

5           The present invention relates to a delivery catheter assembly. In particular, the present invention is directed to a delivery catheter assembly for use in surgical procedures to whereby a first component is secured to a second component using a fastener delivered to the surgical site by the delivery catheter assembly.

## **BACKGROUND OF THE INVENTION**

10           An aneurysm is a ballooning of the wall of an artery resulting from the weakening of the artery due to disease or other conditions. Left untreated, the aneurysm will frequently rupture, resulting in loss of blood through the rupture and death.

          Aortic aneurysms are the most common form of arterial aneurysm and are life threatening. The aorta is the main artery which supplies blood to the circulatory system. The  
15           aorta arises from the left ventricle of the heart, passes upward and bends over behind the heart, and passes down through the thorax and abdomen. Among other arterial vessels branching off the aorta along its path, the abdominal aorta supplies two side vessels to the kidneys, the renal arteries. Below the level of the renal arteries, the abdominal aorta continues to about the level of the fourth lumbar vertebrae (or the navel), where it divides into the iliac arteries. The iliac  
20           arteries, in turn, supply blood to the lower extremities and perineal region.

          It is common for an aortic aneurysm to occur in that portion of the abdominal aorta between the renal arteries and the iliac arteries. This portion of the abdominal aorta is particularly susceptible to weakening, resulting in an aortic aneurysm. Such an aneurysm is often located near the iliac arteries. An aortic aneurysm larger than about 5 cm in diameter in this  
25           section of the aorta is ominous. Left untreated, the aneurysm may rupture, resulting in rapid, and

usually fatal, hemorrhaging. Typically, a surgical procedure is not performed on aneurysms smaller than 5 cm because no statistical benefit exists in performing such procedures.

Aneurysms in the abdominal aorta are associated with a particularly high mortality rate; accordingly, current medical standards call for urgent operative repair. Abdominal surgery, however, results in substantial stress to the body. Although the mortality rate for an aortic aneurysm is extremely high, there is also considerable mortality and morbidity associated with open surgical intervention to repair an aortic aneurysm. This intervention involves penetrating the abdominal wall to the location of the aneurysm to reinforce or replace the diseased section of the aortic aneurysm. A prosthetic device, typically a synthetic tube graft, is used for this purpose. The graft serves to exclude the aneurysm from the circulatory system, thus relieving pressure and stress on the weakened section of the aorta at the aneurysm.

Repair of an aortic aneurysm by surgical means is a major operative procedure. Substantial morbidity accompanies the procedure, resulting in a protracted recovery period. Further, the procedure entails a substantial risk of mortality. While surgical intervention may be indicated and the surgery carries attendant risk, certain patients may not be able to tolerate the stress of intra-abdominal surgery. It is, therefore, desirable to reduce the mortality and morbidity associated with intra-abdominal surgical intervention.

In recent years, methods have been developed to attempt to treat an aortic aneurysm without the attendant risks of intra-abdominal surgical intervention. Among them are inventions disclosed and claimed in Kornberg, U.S. Patent No. 4,562,596 for Aortic Graft, Device and Method for Performing an Intraluminal Abdominal Aortic Aneurysm Repair; Lazarus, U.S. Patent No. 4,787,899 for Intraluminal Graft Device, System and Method; and Taheri, U.S. Patent No. 5,042,707 for Intravascular Stapler, and Method of Operating Same.

Although in recent years certain techniques have been developed that may reduce the stress, morbidity, and risk of mortality associated with surgical intervention to repair aortic aneurysms, none of the systems that have been developed effectively treat the aneurysm and exclude the affected section of aorta from the pressures and stresses associated with circulation. None of the devices disclosed in the references provide a reliable and quick means to reinforce an aneurysmal artery. In addition, all of the prior references require a sufficiently large section of healthy aorta surrounding the aneurysm to ensure attachment of the graft. The neck of the aorta at the cephalad end (i.e., above the aneurysm) is usually sufficient to maintain a graft's

attachment means. However, when an aneurysm is located near the iliac arteries, there may be an ill-defined neck or no neck below the aneurysm. Such an ill-defined neck would have an insufficient amount of healthy aortic tissue to which to successfully mount a graft. Furthermore, much of the abdominal aorta wall may be calcified which may make it extremely difficult to attach the graft to the wall. Furthermore, the prior art does not disclose surgical devices that can be used during a surgical procedure that address these concerns. Others have developed devices that are not easily manipulated or oriented during intraluminal surgical procedures.

### OBJECTS OF THE INVENTION

It is an object of the present invention to provide an assembly for use in connection with securing a surgical component to a vessel during a surgical procedure.

It is another object of the present invention to provide a delivery catheter assembly for delivering and inserting a fastener assembly at a desired location during a surgical procedure.

It is another object of the present invention to provide a delivery catheter assembly that may be easily advanced within a vessel during a surgical procedure.

It is another object of the present invention to provide a procedure for securing a surgical component to a vessel.

It is another object of the present invention to provide an assembly for firmly securing a graft assembly to an aortic wall.

It is another object of the present invention to provide an assembly for use in the repair of an aortic aneurysm.

It is another object of the present invention to provide an apparatus for securing a surgical component to a vessel during a minimally invasive surgical procedure.

It is another object of the present invention to provide a delivery catheter having a tip that is capable of uni-directional deflection.

It is another object of the present invention to provide a delivery catheter having a tip that is capable of multi-directional deflection.

It is another object of the present invention to provide a torqueable delivery catheter.

It is another object of the present invention to provide a delivery catheter having at least one wire assembly embedded within the delivery catheter to permit deflection of the tip of the delivery catheter.

## Summary of the Invention

The present invention is directed to a delivery catheter assembly for advancing a surgical device to a desired location within a vessel during a surgical procedure. The delivery catheter assembly includes an inner sheath assembly through which the surgical device is advanced to the desired location within the vessel. The delivery catheter assembly further includes an outer sheath assembly surrounding the inner sheath assembly. In accordance with the present invention, at least one of the inner sheath assembly and the outer sheath assembly has an angular configuration at a predetermined time during the surgical procedure. The present invention further includes an adjusting assembly for creating the angular configuration of at least one of the inner sheath assembly and the outer sheath assembly. The adjusting assembly may include at least one pull wire positioned within one of the inner sheath and the outer sheath. Furthermore, the inner sheath assembly is movable with respect to the outer sheath assembly. The inner sheath assembly is capable of moving between an extended position and a retracted position at the predetermined time during the surgical procedure.

The present invention is also directed to an assembly for use in securing a surgical component to a vessel during a surgical procedure. The assembly includes a catheter delivery assembly and an insertion assembly. The delivery catheter assembly may include an inner sheath assembly through which the surgical device is advanced to a desired location within the vessel, and an outer sheath assembly surrounding the inner sheath assembly. The insertion assembly may include an assembly for creating an aperture within the surgical component and the vessel such that a fastener assembly may be inserted there through. The assembly may further include an advancing assembly for advancing the delivery catheter assembly to the desired location within the vessel during the surgical procedure. The advancing assembly may include a delivery sheath, wherein the delivery catheter assembly may be slidably received with the delivery sheath.

The assembly of the present invention may also include an inner sheath assembly and an insertion assembly adapted to contain at least one fastener assembly, or adapted to contain at least two fastener assemblies, wherein the at least two fastener assemblies are aligned co-linearly in a distal-proximate orientation. The inner sheath assembly and the insertion assembly may further comprise dispensing means to controllably deliver an individual fastener assembly to secure the surgical component to the vessel. The fastener assembly may be located outside of the insertion assembly, or located within the insertion assembly. The fastener assemblies may

further comprise a diluting tip at their distal end. The fastening assemblies may be attached to one another by a detachable means, wherein the detachable means may comprise at least one of mechanical force, electrical pulse, heat, dissolving a temporary connecting memberane, and shearing a temporary connecting membrane.

The present invention is also directed to a method of securing a surgical component to a vessel, comprising the steps of advancing a delivery sheath containing a catheter assembly through a vessel to a procedure specific area within the vessel, extending the catheter assembly such that an outer sheath of the catheter assembly extends from the delivery sheath, wherein an end portion of the outer sheath assumes an angular configuration, advancing an inner sheath from within the outer sheath such that the outer sheath contacts a surgical component at a location opposite to a point of contact of the inner sheath, further advancing the inner sheath such that the inner sheath applies sufficient pressure on the surgical component to push the surgical component firmly against the vessel, advancing an insertion assembly from within the inner sheath to create an aperture in the surgical component and the vessel through which a fastener assembly extends, advancing the insertion assembly and the fastener assembly through the aperture, and retracting the insertion assembly and the inner sheath such that the fastener assembly secures the surgical component to the vessel. The method according to the present invention may also comprise the steps of activating a laser fiber assembly, prior to advancing the insertion assembly and the fastener assembly through the aperture, to create the aperture through which the fastener assembly extends, or activating a piezoelectric device, prior to advancing the insertion assembly and the fastener assembly through the aperture, to create the aperture through which the fastener assembly extends.

The method according to the present invention may also include the steps of manipulating the catheter assembly within the vessel to another location, after retracting the insertion assembly and the inner sheath. The insertion assembly and the fastener assembly may advance through an aperture simultaneously, or the advancement of the insertion assembly through the aperture may precede the advancement of the fastener assembly through the aperture.

The present invention is also directed to a method of securing a surgical component to a vessel, the method comprising the steps of inserting a surgical component into a vessel at an entry site, moving the surgical component to a location within the vessel remote from the entry site, holding the surgical component in place within the vessel by a securing means, inserting a

delivery catheter into the vessel, wherein the delivery catheter contains a fastening assembly, maneuvering the delivery catheter to a location in close proximity to the surgical component, deploying the fastening assembly to attach the surgical component to the vessel, manipulating the fastener assembly to secure the surgical component to the vessel, and removing the delivery catheter from the vessel. The surgical component, and/or an insertion assembly may be contained within the delivery catheter. The fastening assembly may be inserted into an aperture from the outside of the insertion assembly or from within the insertion assembly.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and are not restrictive of the invention, as claimed. The accompanying drawings, which are incorporated herein by reference, and which constitute a part of this specification, illustrate certain embodiments of the invention, and together with the detailed description serve to explain the principles of the present invention.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

The invention will now be described in conjunction with the following drawings in which like reference numerals designate like elements and wherein:

Fig. 1 is a perspective view of a delivery catheter assembly in accordance with the present invention, wherein the delivery catheter assembly is located within a vessel in an angled configuration;

Fig. 2 is a perspective view of the delivery catheter assembly of Fig. 1, wherein the inner sheath of the catheter assembly is advanced from the outer sheath;

Fig. 3 is a perspective view of the delivery catheter assembly of Fig. 1, wherein the inner sheath is in a fully extended position within the vessel;

Fig. 4 is a perspective view of the delivery catheter assembly of Fig. 1 at the beginning of the process of inserting a fastener to secure a surgical component to a vessel wall;

Fig. 5 is a perspective view of the delivery catheter assembly of Fig. 1 during the process of inserting a fastener to secure the surgical component to the vessel wall;

Fig. 6 is a perspective view of the delivery catheter assembly of Fig. 1 after the fastener assembly has secured the surgical component to the vessel wall;

Fig. 7 is a cross sectional view of the outer sheath 12 of the catheter assembly in accordance with the present invention.

Figs. 8a-e are perspective views of the delivery catheter assembly of Fig. 1, including multiple fastener assemblies during the process of inserting a fastener assembly to secure the surgical component to the vessel wall;

Figs. 9a-d are perspective views of the delivery catheter assembly of Fig. 8 in accordance with another embodiment of the present invention;

Fig. 10 illustrates a dilating tip according to an embodiment of the present invention; and

Fig. 11 illustrates a dilating tip according to an alternative embodiment of the present invention.

### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The following description of the preferred embodiment of the present invention is described, for purpose of example, in connection with the repair of an aortic aneurysm. It is contemplated that the embodiments described herein are capable of use in the repair of other vessels and in other procedures. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they come within the scope of the appended claims and their equivalents.

The delivery catheter assembly **10** will now be described in connection with Figs. 1-6. The delivery catheter assembly **10** includes an inner sheath **11** and an outer sheath **12**. An insertion assembly **13** is located within the inner sheath **11**, as shown in Fig. 1. The insertion assembly **13** preferably creates an aperture within a surgical component **1** and a vessel **2**, as shown in Figs. 4-6, such that a fastener assembly **3** may be inserted through the aperture to secure the surgical component **1** to the vessel **2**, as shown in Fig. 6. As shown in Figs. 1-9, more than one fastener assembly **3** may be contained in the inner sheath **11** aligned co-linearly in a distal-proximate orientation either located outside the insertion assembly **13** or within the insertion assembly **13**.

The fastener assembly **3** is preferably a flexible fastener assembly that applies a force to secure the surgical component **1** to the vessel **2**, as disclosed in the following U.S. Patent applications: U.S. Provisional Patent Application No. 60/181,230, filed February 9, 2000; U.S. Patent Application No. 09/442,768, filed November 18, 1999; U.S. Patent Application No. 09/213,233, filed December 17, 1998, now U.S. Patent No. 5,997,556; U.S. Patent Application No. 08/958,524, filed October 27, 1997, now U.S. Patent No. 5,957,940, U.S. Patent Application No. 08/896,415, filed July 18, 1997, now U.S. Patent No. 5,944,750; and U.S. Provisional Patent



Application No. 60/051,209, filed June 30, 1997. The subject matter of these patent applications is incorporated herein specifically by reference.

The inner sheath **11** of the delivery catheter assembly **10** is movable with respect to the outer sheath **12**. The delivery catheter assembly **10** is advanced to the surgical procedure specific area within the vessel **2** through a delivery sheath **4**. The delivery catheter assembly **10** and the delivery sheath **4** have sufficient length such that the assembly **10** and sheath **4** may extend from either an axillary incision, a brachial incision or a femoral or common iliac arteriotomy to the procedure specific area within the vessel **2**.

The catheter assembly **10** has an end portion **121** having an angular configuration, as shown in Figs. 1-6. The catheter assembly **10** is flexible such that it may be advanced through the delivery sheath **4**. The outer sheath **12** is formed from a suitable material that permits the end portion **121** to be flexed to maintain its angular configuration during the process of inserting a fastener **3** through the surgical component **1** and the vessel **2**, as show in Figs. 1-6. The outer sheath **12** preferably has a braided construction.

The angular configuration of the end portion **121** is achieved with at least one pull wire **14** positioned within the outer sheath **12**, as shown in Fig. 7. The end portion of the outer sheath **12** is deflected when the at least one pull wire **14** is tensioned. Each of the at least one wire **14** extends through the outer sheath **12**. A free end portion of each pull wire **14** exits the outer sheath **12** at a point that is located outside the body of the patient during the surgical procedure. The free end portion of the pull wire **14** maybe manipulated/tensioned by the surgeon by hand. Alternatively, the free end portion of the pull wire **14** may be connected to a control assembly (not shown) for operation by the surgeon. Each pull wire **14** is separated from the exterior of the deflectable tip section by a wall thickness less than .010". This permits deflection of the end portion of the outer sheath **12** when one of the pull wires **14** are tensioned. Each pull wire **14** is preferably surrounded by an elastomeric sleeve of a polymeric material of a recoverable elongation of 500-1000%. Examples of such materials are polyurethane and silicone elastomer. The pull wires **14** are protected from tissue abrasion by the elastomeric sleeve. Further, this construction prevents the release of fragments in the vessel in the event a pull wire fails. Also, the failure of a pull wire does not produce a permanently curved shape that would be difficult to remove from the vessel. The elastomeric sleeve, the inner sheath **11** and the outer sheath **12**

provide a driving force that allows the tip to straighten once when the tension on the pull wire **14** is relaxed.

The outer sheath **12** preferably has a braided construction with increasing less durometer in the distal direction in order to optimize torque transmission. The lesser durometer sections of the outer sheath **12** correspond to areas where the catheter is expected to negotiate bends in the anatomy. These more flexible areas of the outer sheath **12** can more efficiently transmit torque around a bend than stiffer high durometer areas. Typical materials used to form the outer sheath **12** may be polyether amide compounds and polyurethane, or any other suitable material. Each pull wire **14** permits deflection of the end portion of the outer sheath **12** in a single direction. In a preferred embodiment, the outer sheath **12** includes a plurality of pull wires **14**, as shown in Fig. 7, to permit multi-directional deflection of the end portion of the outer sheath **12**. The wire **14** extends out of the circumferential envelope of catheter diameter when the wire **14** is under tension to effect tip deflection. The outer sheath **12** being deflected out of the normal diameter of the catheter.

The operation of the delivery catheter assembly **10** will now be described. The delivery sheath **4** and delivery catheter assembly **10** are advanced through the vessel **2** to the procedure specific area within the vessel **2**. The catheter assembly **10** is extended such that the end portion **121** of the catheter assembly **10** extends from the sheath **4**. The end portion **121** then assumes its angular configuration, as shown in Fig. 1, by manipulating one of the pull wires **14**. The inner sheath **11** is then advanced such that it extends to contact the surgical component **1**, as shown in Fig. 2. The inner sheath **11** is further advanced such that the outer sheath **12** contacts the surgical component **1** at a location opposite to the point of contact of the inner sheath **11**, as shown in Fig. 3. The inner sheath **11** is still further advanced such that it applies sufficient pressure on the surgical component **1** to push the surgical component **1** firmly against the vessel **2**, as shown in Fig. 4. The insertion assembly **13** is then activated and advanced to create an aperture in the surgical component **1** and the vessel **2** through which the fastener assembly **3** extends, as shown in Fig. 5. The insertion assembly **13** preferably includes a laser fiber assembly that is capable of creating an aperture through which the fastener assembly **3** is inserted to secure the surgical component **1** to the vessel **2**. The insertion assembly **13** in accordance with the present invention is not limited to a laser fiber assembly; rather, a piezoelectric penetration device, as disclosed in U.S. Patent No. 5,997,556, U.S. Patent No. 5,957,940 and U.S. Patent No.

5,944,750 and the embodiments disclosed therein are considered to be well within the scope of the present invention.

The insertion assembly **13** advances through the aperture that it has created as well as a fastener assembly **3**, as shown in Fig. 5. The advancement of the fastener assembly **3** may occur simultaneously with the advancement of the insertion assembly **13**, or may follow the advancement of the insertion assembly **13**. In addition, the fastener assembly **3** may be located around the outside of insertion assembly **13**, or the fastener assembly **3** may be located within a hollow core of insertion assembly **13**. The insertion assembly **13** advances a fixed distance through and beyond the vessel **2** such that one portion of the fastener assembly **3** is located on one side of the vessel **2** and another portion of the fastener assembly **3** is located on an opposite side of the surgical component **1**. The insertion assembly **13** and the inner sheath **11** are then retracted to the position shown in Fig. 6 leaving behind the fastener assembly **3** in an inserted position. The catheter assembly **10** is then manipulated within the vessel **2** to another location whereby the process of inserting a fastener assembly **3** is repeated to secure the surgical component **1** to the vessel **2**. The catheter assembly **10** may be manipulated by releasing the tension in one of the pull wires **14** and applying tension to another pull wire **14**. Thus changing the deflection of the outer sheath **12**.

The operation of the catheter assembly **10** is controlled by a controller, such as for example, a hand controller (not shown) located outside the body.

According to another embodiment of the present invention, the fastener assembly **3** is designed such that it is possible to place a string of fastener assemblies **3** in a continuous head to tail fashion within the inner sheath **11** as shown in Fig. 8. This arrangement provides a method of sequentially dispensing multiple fastener assemblies **3** to attach the surgical component **1** to the vessel **2**. The methods described herein permit more than one fastener assembly **3** to be contained in the inner sheath **11** and to be sequentially advanced into the surgical component **1** and vessel **2**. The fastener assemblies **3** may be deployed from around the insertion assembly **13**, or may be deployed from within a hollow insertion assembly **13**.

Fig. 8 illustrates a method according to the present invention. Fig. 8a depicts the positioning of the delivery catheter assembly in preparation for employing the fastening assembly **3**. Fig. 8b illustrates the creation of a treatment specific hole in the surgical component **1** and vessel **2** by an insertion assembly **13**. A fastener assembly **3** may advance simultaneously

with the insertion assembly **13**, or may advance into the treatment specific hole following the advancement, and prior to the retraction, of the insertion assembly **13**. Once the distal end of the fastener assembly **3** is inserted through the surgical component **1** and vessel **2** through the treatment specific hole, the insertion assembly **13** is retracted as shown in Fig. 8c. A backstop tube **31**, located at the proximal end of the string of fastener assemblies **3**, holds the linear position of the fastener assemblies **3** and maintains their position while the insertion assembly **13** is retracted. Upon retraction of the insertion assembly **13** the fastener assembly **3** assumes a secondary orientation, securely attaching the surgical component **1** to the vessel **2** as shown in Figs. 8c and d. Fig. 8e illustrates a view of the attached fastener assembly from the outside of the vessel.

Fig. 9 illustrates an alternative method for advancing multiple fastener assemblies **3** in relation to the insertion assembly **13** according to an embodiment of the present invention. The method is similar to that described in Figs. 8a-d. This method incorporates a pusher tube assembly **32** and an o-ring assembly **33**. The pusher tube assembly **32** is responsible for maintaining the position of each fastener assembly **3**. The pusher tube assembly **32** further includes spring loaded tabs **321** that seat securely to the proximal edge of each fastener assembly **3**. The spring loaded tabs **321** engage an o-ring assembly **33** which ensures that a positive and reproducible engagement takes place between the pusher tube **32** and the edge of the fastener assembly **3**. Fig. 9 illustrates two spring loaded tabs **321** per fastener assembly **3**. The spring loaded tabs **321** open during fastener assembly **3** advancement thereby allowing the next fastener assembly **3** into position.

The above methods describe an embodiment of the present invention in which the fastener assemblies **3** are loaded as a continuous string in which the head of one fastener assembly **3** immediately abuts the tail of another fastener assembly **3**. The fastener assemblies **3** may be separated from one another at the point of deployment by any number of means. These means include, but are not limited to, those means discussed above, as well as retracting the string of fastener assemblies **3** once the deployed fastener is correctly positioned within the surgical component **1** and vessel **2** such that a thin connecting membrane between the deployed fastener assembly **3** and the next fastener assembly **3** located in the inner sheath **11** is sheared. Methods of shearing may include, but are not limited to, mechanical force, application of an appropriately controlled electrical pulse, the application of heat, or by dissolving a temporary

connecting membrane. The fastener assembly **3** inserted into the surgical component **1** and the vessel **2** may be held in place by a number of different methods, including but not limited to, threading, bonding, rehydration, thermal changes, deformation, expansion, friction, or torsion.

Figs. 8 -11 illustrate an embodiment of the fastener assembly **3** according to the present invention. A method of facilitating the insertion of fastener assemblies **3** includes a dilating tip **34** that is secured to the leading edge of the fastener assembly **3**. During penetration of the surgical component **1** and vessel **2** the presence of dilating tip **34** may reduce the force required to insert the fastener assembly **3**.

Figs. 10 and 11 illustrate a dilating tip **34** illustrating at least one cutting edge **341** on the leading end of the dilating tip **34**. The cutting edge **341** facilitates the insertion of fastener assembly **3** into the surgical component **1** and vessel **2**. The cutting edge **341** may be ground into the surgical fastener **3** or can be a feature molded into fastener assembly **3**. The dilating tip **34** may be constructed of commonly known surgical implant materials including, but not limited to, bioresorbables, metals such as MP-35N titanium, etc., and ultrahigh molecular weight polyurethane, UHMWPE, or any other suitable material. The dilating tips **34** are designed to be securely fixed to the leading edge fastener assembly **3**.

While this invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Although the present invention is described in connection with securing a surgical component **1**, which may be a graft assembly, to a vessel, which may be an aortic wall, the present invention is not limited to securing a surgical component to a vessel; rather, it is contemplated that the present invention may be used in connection with securing a vessel to another vessel, tissue to tissue, surgical components to surgical components and any variations thereof. Furthermore, it is contemplated that the delivery catheter assembly **10** may be used to deliver and/or advance other surgical devices including but not limited to a visualization device of other monitoring equipment, rather than the insertion assembly **13**. Accordingly, the preferred embodiments of the invention as set forth herein are intended to be illustrative, not limiting. Various changes may be made without departing from the spirit and scope of the invention as defined in the following claims.

**WHAT IS CLAIMED IS:**

1. A delivery catheter assembly for advancing a surgical device to a desired location within a vessel during a surgical procedure, said delivery catheter assembly comprising:

an inner sheath assembly through which the surgical device is advanced to the desired location within the vessel; and

an outer sheath assembly surrounding said inner sheath assembly, wherein at least one of said inner sheath assembly and said outer sheath assembly having an angular configuration at a predetermined time during the surgical procedure.

2. The delivery catheter assembly according to Claim 1, wherein said outer sheath assembly includes adjusting means for creating said angular configuration.

3. The delivery catheter assembly according to claim 2, wherein said adjusting means includes at least one pull wire located within said outer sheath assembly.

4. The delivery catheter assembly according to Claim 2, wherein said adjusting means permits multi-directional manipulation of said outer sheath assembly.

5. The delivery catheter assembly according to Claim 1, wherein said inner sheath assembly is movable with respect to said outer sheath assembly.

6. The delivery catheter assembly according to Claim 5, wherein said inner sheath assembly is capable of moving between an extended position and a retracted position at the predetermined time during the surgical procedure.

7. An assembly for use in securing a surgical component to a vessel during a surgical procedure, said assembly comprising:

a delivery catheter assembly having an inner sheath assembly through which a surgical device is advanced to a desired location within the vessel, and an outer sheath assembly surrounding said inner sheath assembly, wherein at least one of said inner sheath assembly and said outer sheath assembly having an angular configuration at a predetermined time during the surgical procedure; and

an insertion assembly located within said inner sheath assembly for securing the surgical component to the vessel.

8. The assembly according to Claim 7, wherein said insertion assembly includes means for creating an aperture within the surgical component and the vessel such that a fastener assembly may be inserted there through.

9. The assembly according to Claim 7, further comprising advancing means for advancing said delivery catheter assembly to the desired location.

10. The assembly according to Claim 9, wherein said advancing means includes a delivery sheath, wherein said catheter assembly is slidably received within said delivery sheath.

11. The assembly according to Claim 7, wherein said outer sheath assembly includes adjusting means for creating said angular configuration.

12. The assembly according to Claim 7, wherein adjusting means permits multi-directional manipulation of said outer sheath assembly.

13. A method of securing a surgical component to a vessel, comprising the steps of:  
advancing a delivery sheath containing a catheter assembly through a vessel to a procedure specific area within the vessel;

extending said catheter assembly such that an outer sheath of said catheter assembly extends from said delivery sheath, wherein an end portion of said outer sheath assumes an angular configuration;

advancing an inner sheath from within said outer sheath such that said outer sheath contacts a surgical component at a location opposite to a point of contact of said inner sheath;

further advancing said inner sheath such that said inner sheath applies sufficient pressure on the surgical component to push the surgical component firmly against the vessel;

advancing an insertion assembly from within said inner sheath to create an aperture in the surgical component and the vessel through which a fastener assembly extends;

advancing said insertion assembly and said fastener assembly through said aperture;

retracting said insertion assembly and said inner sheath such that said fastener assembly secures the surgical component to the vessel.

14. The method of delivering a catheter assembly according to Claim 13, further comprising the step of:

activating a laser fiber assembly, prior to advancing said insertion assembly and said fastener assembly through said aperture, to create said aperture through which said fastener assembly extends.

15. The method of delivering a catheter assembly according to Claim 13, further comprising the step of:

activating a piezoelectric device, prior to advancing said insertion assembly and said fastener assembly through said aperture, to create said aperture through which said fastener assembly extends.

16. The method of delivering a catheter assembly according to Claim 13, further comprising the step of:

manipulating said catheter assembly within said vessel to another location, after retracting said insertion assembly and said inner sheath.

17. The assembly according to Claim 7, wherein said inner sheath assembly and said insertion assembly are adapted to contain at least one fastener assembly.

18. The assembly according to Claim 7, wherein said inner sheath assembly and said insertion assembly are adapted to contain at least two fastener assemblies, wherein said at least two fastener assemblies are aligned co-linearly in a distal-proximate orientation.

19. The assembly according to Claim 18, wherein said inner sheath assembly and said insertion assembly further comprise dispensing means to controllably deliver an individual fastener assembly to secure the surgical component to the vessel.

20. The assembly according to Claim 17, wherein said at least one fastener assembly is located outside of said insertion assembly.

21. The assembly according to Claim 17, wherein said at least one fastener assembly is located within said insertion assembly.

22. The method of securing a surgical component to a vessel according to Claim 13, wherein said insertion assembly and said fastener assembly are advanced through said aperture simultaneously.

23. The method of securing a surgical component to a vessel according to Claim 13, wherein advancement of said insertion assembly through the aperture precedes the advancement of said fastener assembly through the aperture.

24. An assembly for use in securing a surgical component to a vessel during a surgical procedure, said assembly comprising:

a delivery catheter assembly having an inner sheath assembly through which the surgical device is advanced to a desired location within the vessel, and an outer sheath assembly surrounding said inner sheath assembly, wherein at least one of said inner sheath assembly and



said outer sheath assembly having an angular configuration at a predetermined time during the surgical procedure;

an insertion assembly located within said inner sheath assembly for securing the surgical component to the vessel; and

at least two fastener assemblies located within the inner sheath assembly.

25. The assembly according to Claim 24, wherein each of said at least two fastener assemblies further comprise a diluting tip at the distal end.

26. The assembly according to Claim 24, wherein said at least two fastening assemblies are attached to one another by a detachable means.

27. The assembly according to Claim 26, wherein said detachable means comprises at least one of mechanical force, electrical pulse, heat, dissolving a temporary connecting memberane, and shearing a temporary connecting membrane.

28. A method of securing a surgical component to a vessel, said method comprising the steps of:

inserting a surgical component into a vessel at an entry site;

moving the surgical component to a location within the vessel remote from the entry site;

holding the surgical component in place within the vessel by a securing means;

inserting a delivery catheter into the vessel, wherein said delivery catheter contains a fastening assembly;

maneuvering said delivery catheter to a location in close proximity to the surgical component;

deploying said fastening assembly to attach the surgical component to the vessel;

manipulating the fastener assembly to secure the surgical component to the vessel; and

removing said delivery catheter from the vessel.

29. The method according to Claim 28, wherein the surgical component is contained within said delivery catheter.

30. The method according to Claim 28, wherein an insertion assembly is contained within said delivery catheter.

31. The method according to Claim 30, wherein said insertion assembly creates an aperture in the surgical component and the vessel.

32. The method according to Claim 30, wherein said fastening assembly is inserted into the aperture from the outside of said insertion assembly.

33. The method according to Claim 30, wherein said fastening assembly is inserted into the aperture from within said insertion assembly.

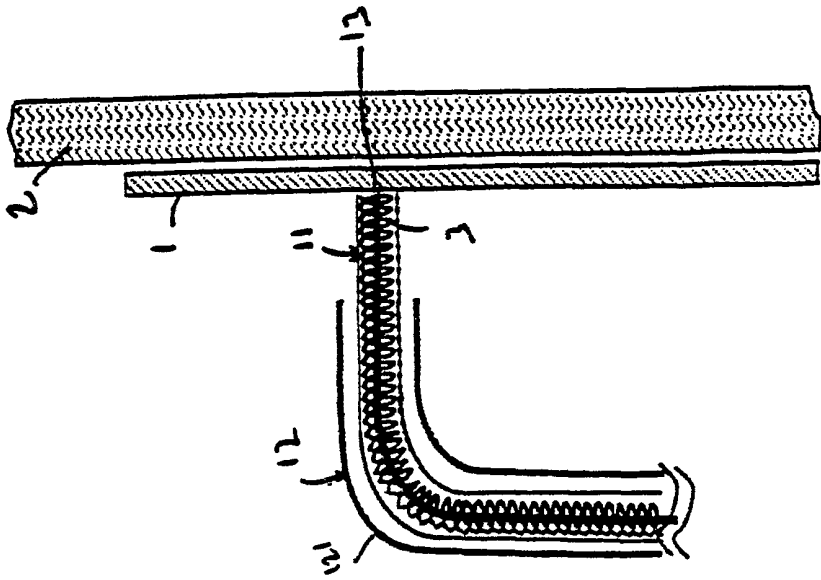


FIG. 2

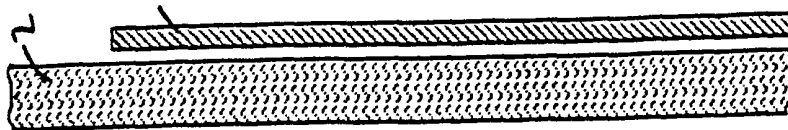
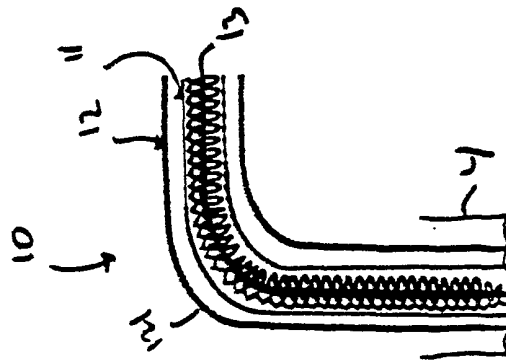
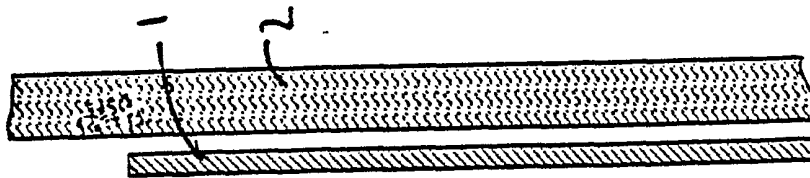
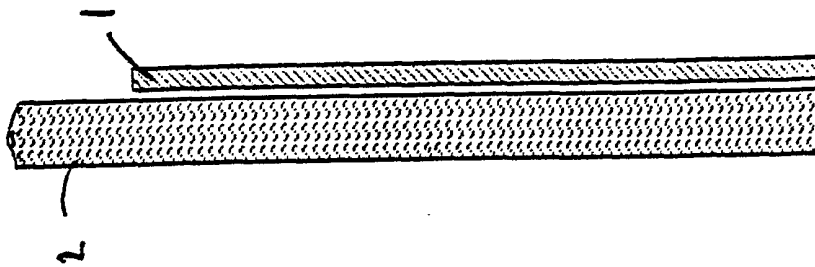


FIG. 1

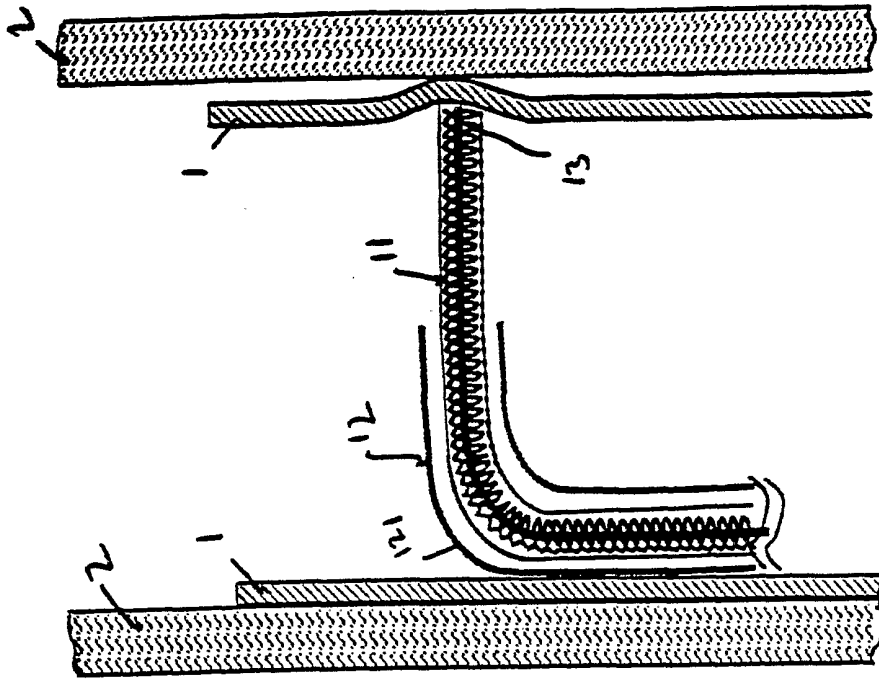


FIG. 4

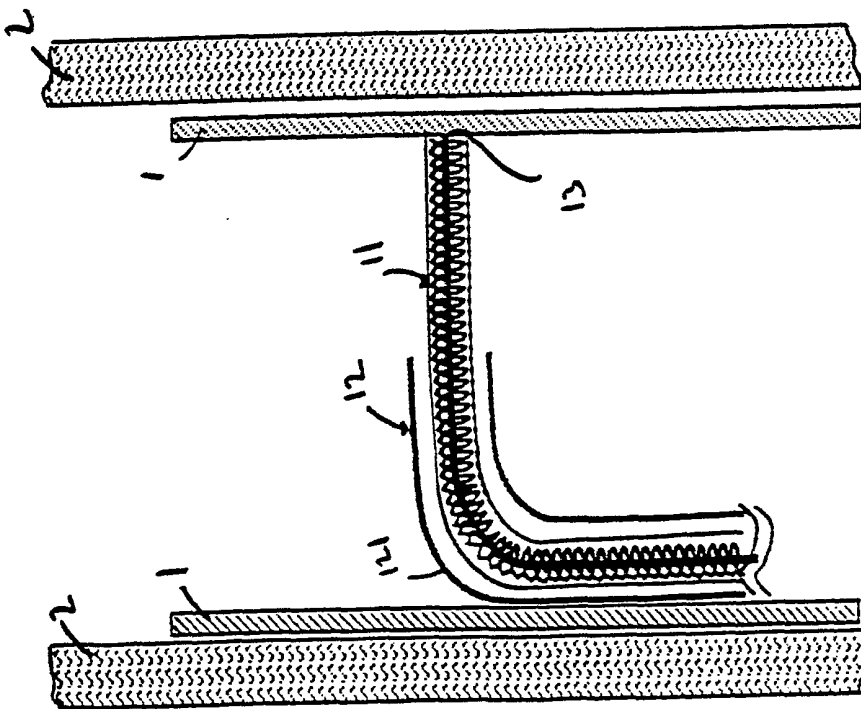


FIG. 3

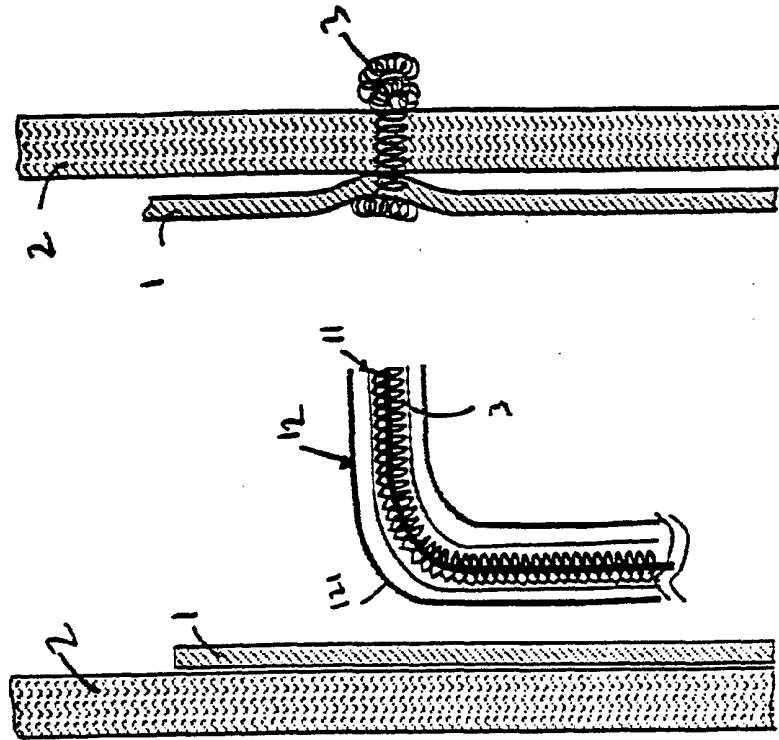


FIG. 6

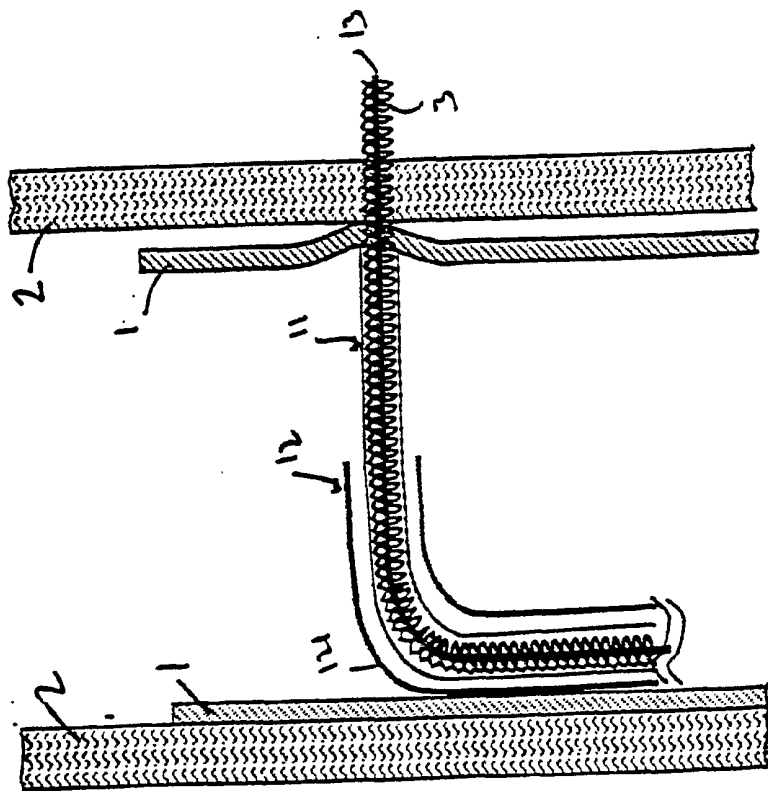


FIG. 5

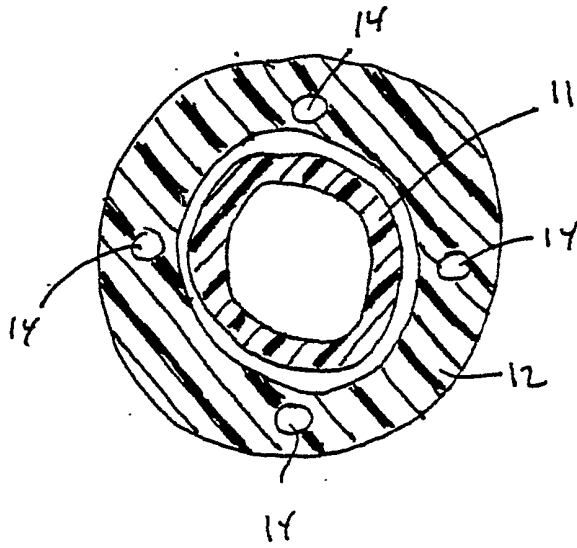


FIG. 7

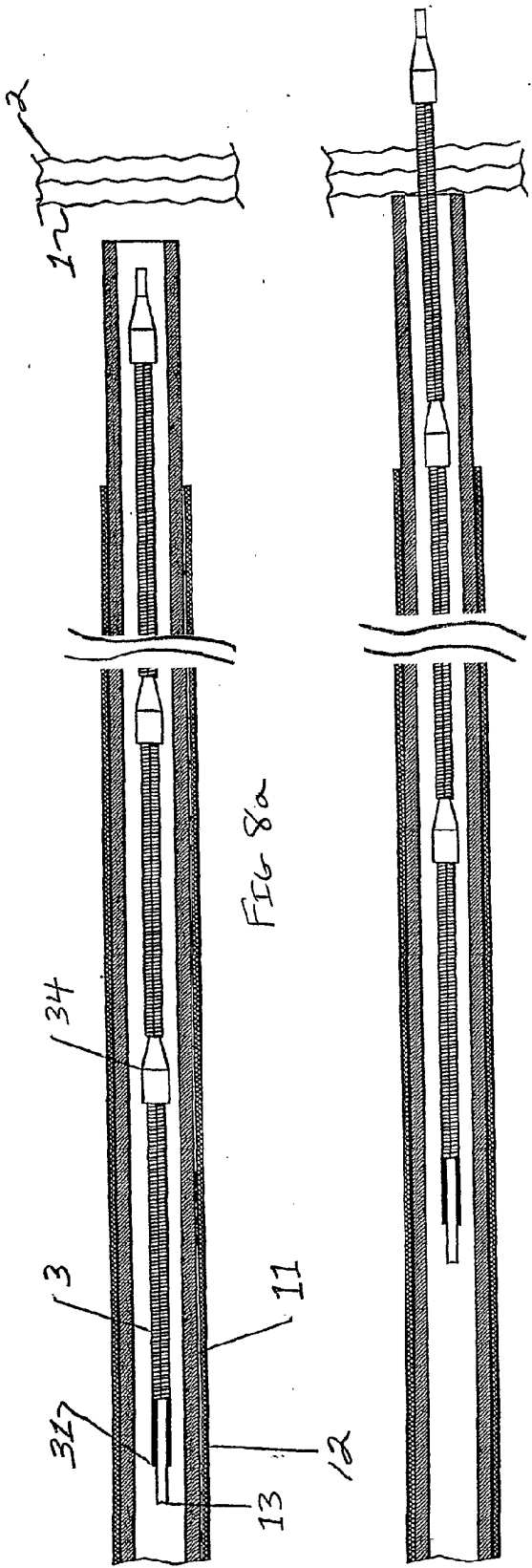


FIG. 8a

FIG. 8b

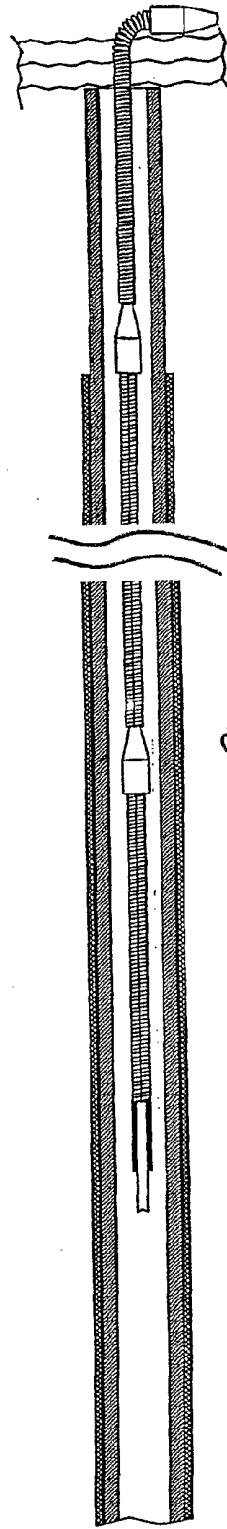


FIG. 8c

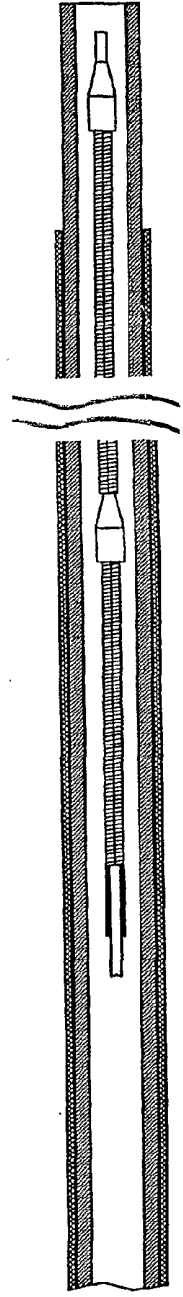
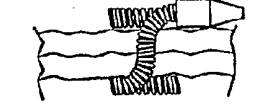
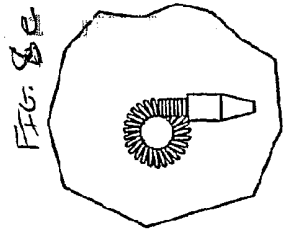


FIG. 8d

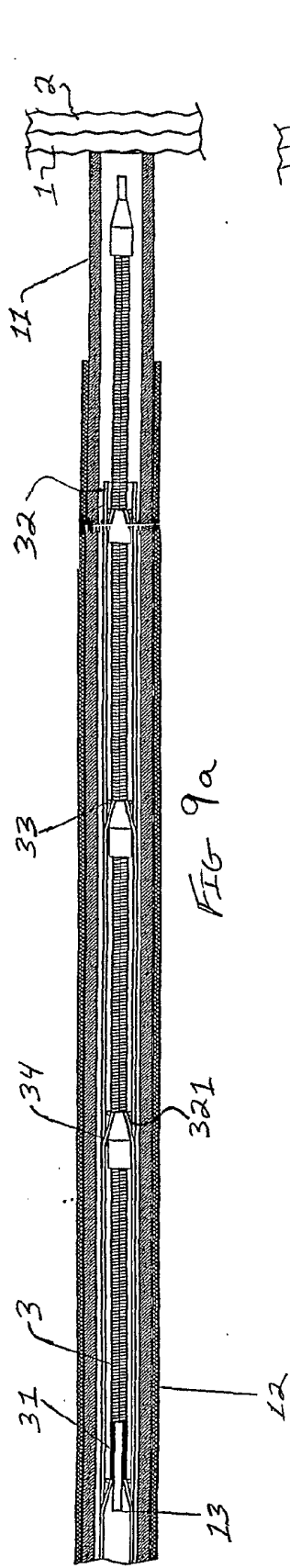


FIG. 9a

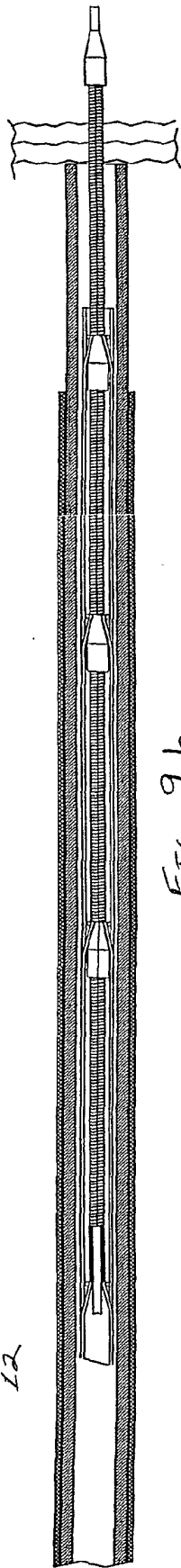


FIG. 9b

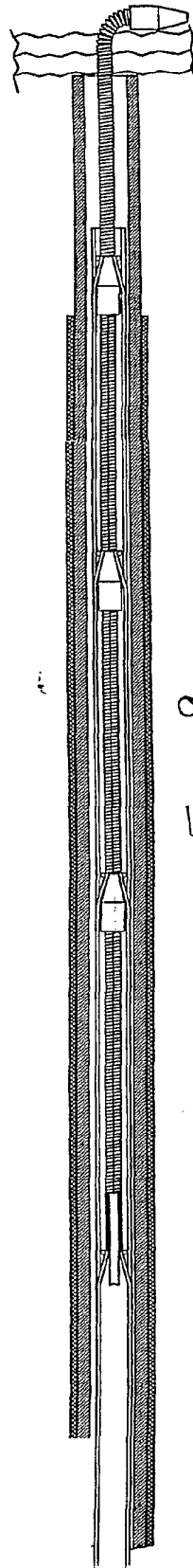


FIG. 9c

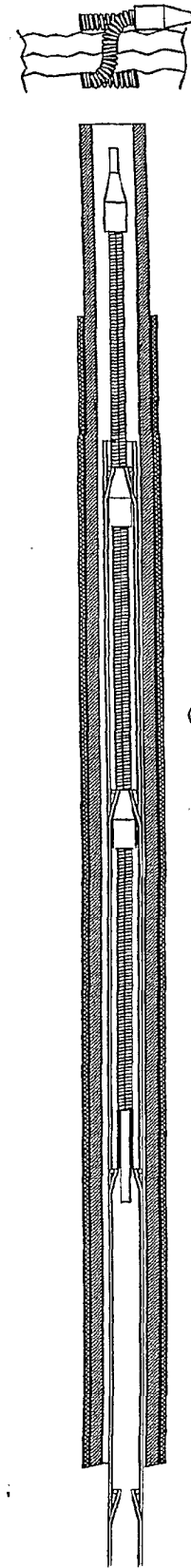


FIG. 9d



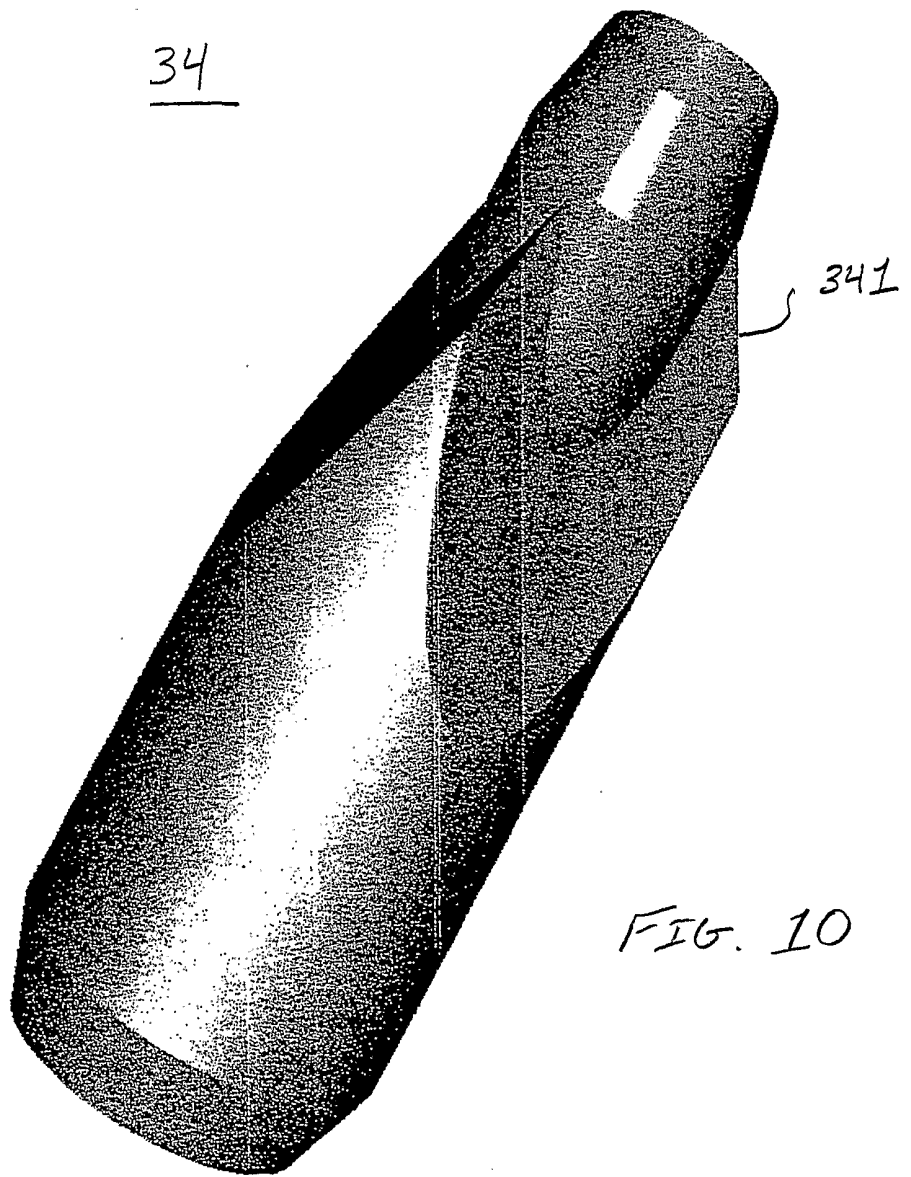


FIG. 10

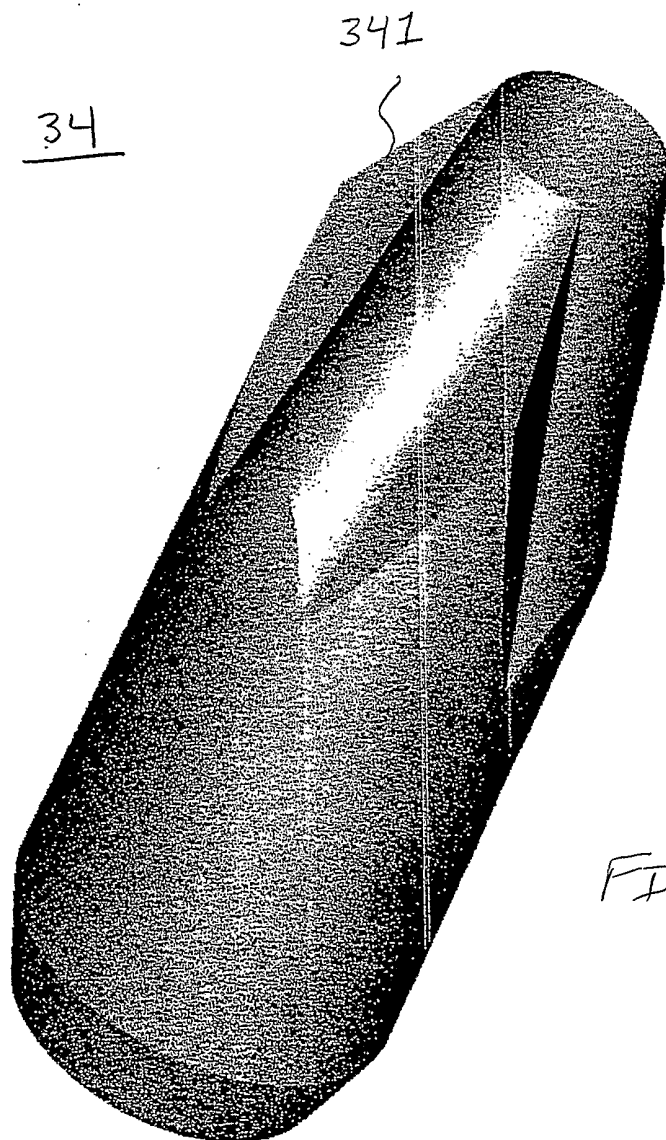


FIG. 11

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/04764

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
IPC(7) :A61M 5/178 US CL :604/164.12 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) U.S. : 604/164.12, 164.08, 171, 198, 525, 528		
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)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 5,462,561 A (VODA) 31 October 1995, see fig. 3.	1, 7-10, 13, 16 and 24-25, 28-33
X	US 5,797,905 A (FLEISCHMAN et al) 25 August 1998, figs. 1-6.	1-7, 11-12, 17, 18, and 20
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* "A" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance earlier document published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
Date of the actual completion of the international search 22 APRIL 2001		Date of mailing of the international search report 13 JUL 2001
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 KEVIN C. SIRMONS <i>Diane Smith</i> Telephone No. (703) 306-5410