US 20090082852A1

(19) United States

(12) Patent Application Publication

(10) Pub. No.: US 2009/0082852 A1

(43) Pub. Date: Mar. 26, 2009

Bolduc et al.

(54) **CATHETER-BASED FASTENER IMPLANTATION APPARATUS AND METHODS**

(75) Inventors: **Lee Bolduc**, Sunnyvale, CA (US); **Juan C. Parodi**, St. Louis, MO (US)

Correspondence Address:
Daniel D. Ryan
RYAN KROMHOLZ & MANION, S.C.
Post Office Box 26618
Milwaukee, WI 53226-0618 (US)

(73) Assignee: **Aptus Endosystems, Inc.**

(21) Appl. No.: **12/315,015**

(22) Filed: **Nov. 26, 2008**

Related U.S. Application Data

(60) Division of application No. 10/669,881, filed on Sep. 24, 2003, which is a continuation-in-part of application No. 10/307,226, filed on Nov. 29, 2002, which is a continuation-in-part of application No. 10/271,334, filed on Oct. 15, 2002, now Pat. No. 6,960,217, which is a continuation-in-part of application No. 10/099,149, filed on Mar. 15, 2002, now Pat. No. 6,800,081, which is a division of application No. 09/787,135, filed on Jun. 4, 2001, now Pat. No. 6,592,593.

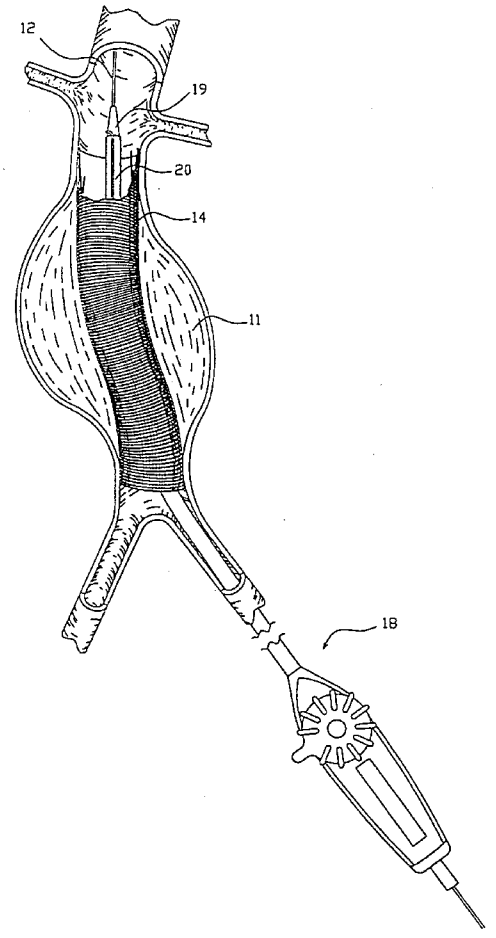
Publication Classification

(51) **Int. Cl.**
A61F 2/06 (2006.01)

(52) **U.S. Cl.** **623/1.36**; 623/1.15; 623/1.11

(57) **ABSTRACT**

Apparatus and methods utilize an intraluminal fastener applier having a guide body with a longitudinal axis. The guide body is sized and configured for intraluminal deployment in a hollow body organ. An actuated assembly is carried by the guide body that is selectively operable to generate an implantation force to implant at least one fastener into tissue within the hollow body organ. The actuated assembly includes a driven member extending generally along the longitudinal axis, which is sized and configured to engage a selected fastener. The actuated assembly also includes a drive member coupled to the driven member to impart the implantation force to the driven element in a direction that is at an angle to the longitudinal axis of the guide body.



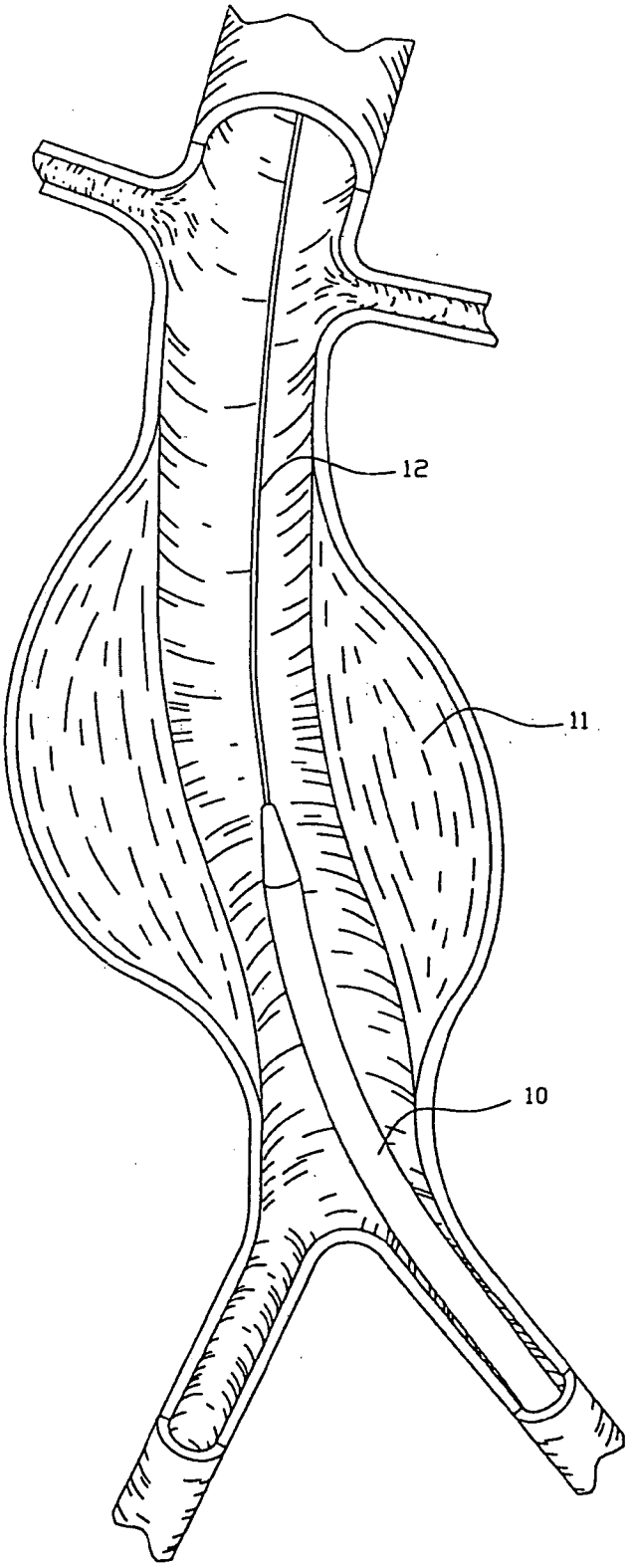


Fig. 1

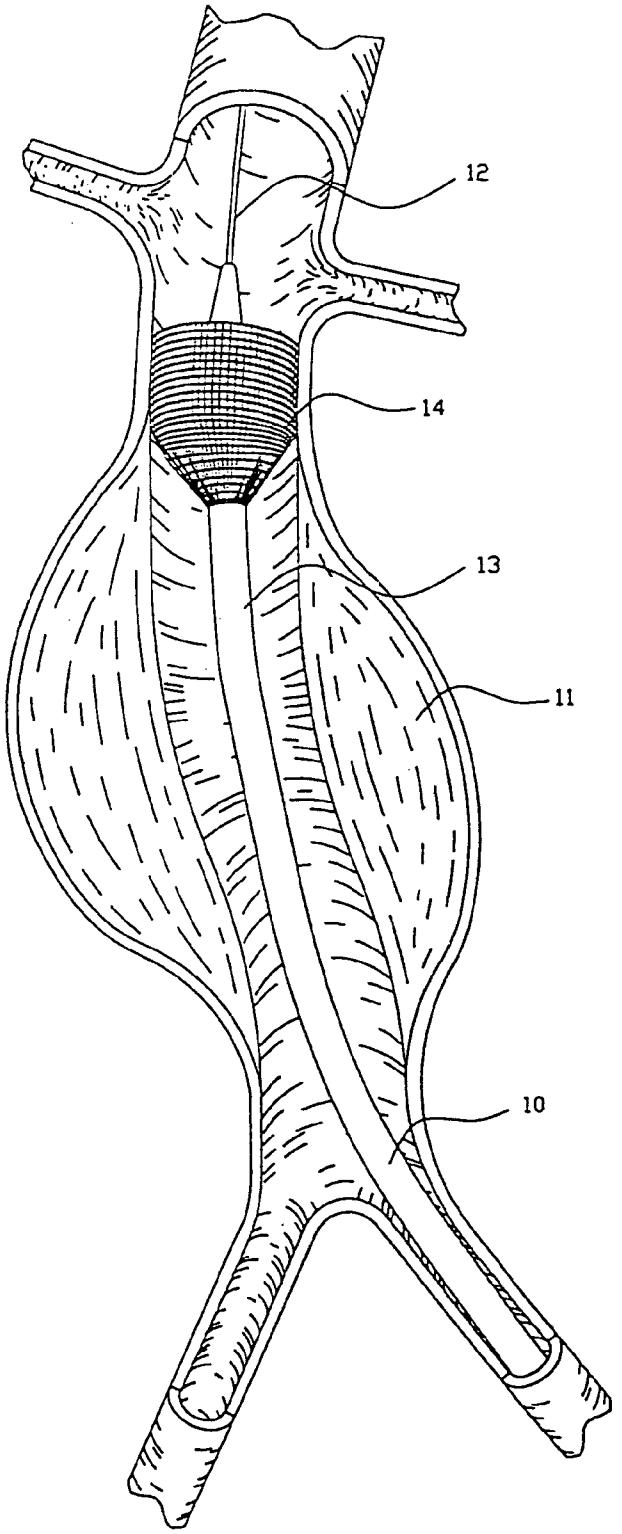


Fig. 2

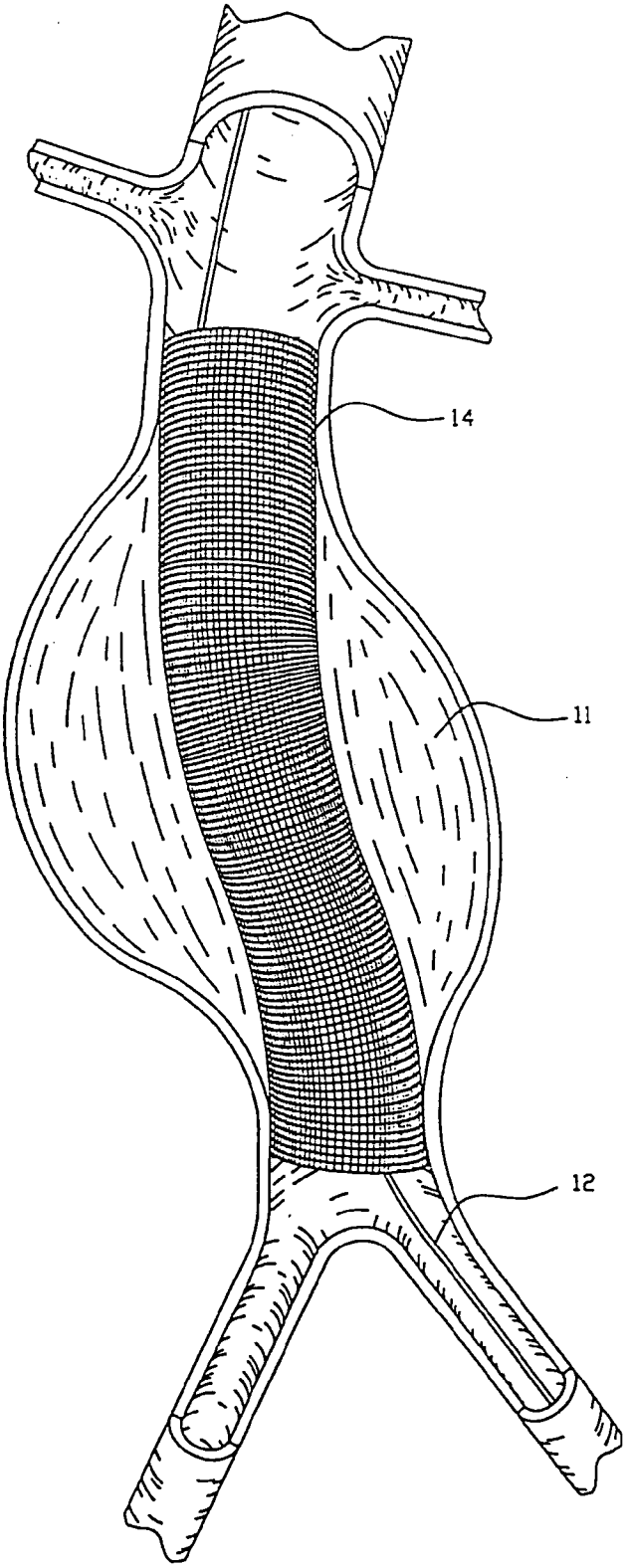


Fig. 3

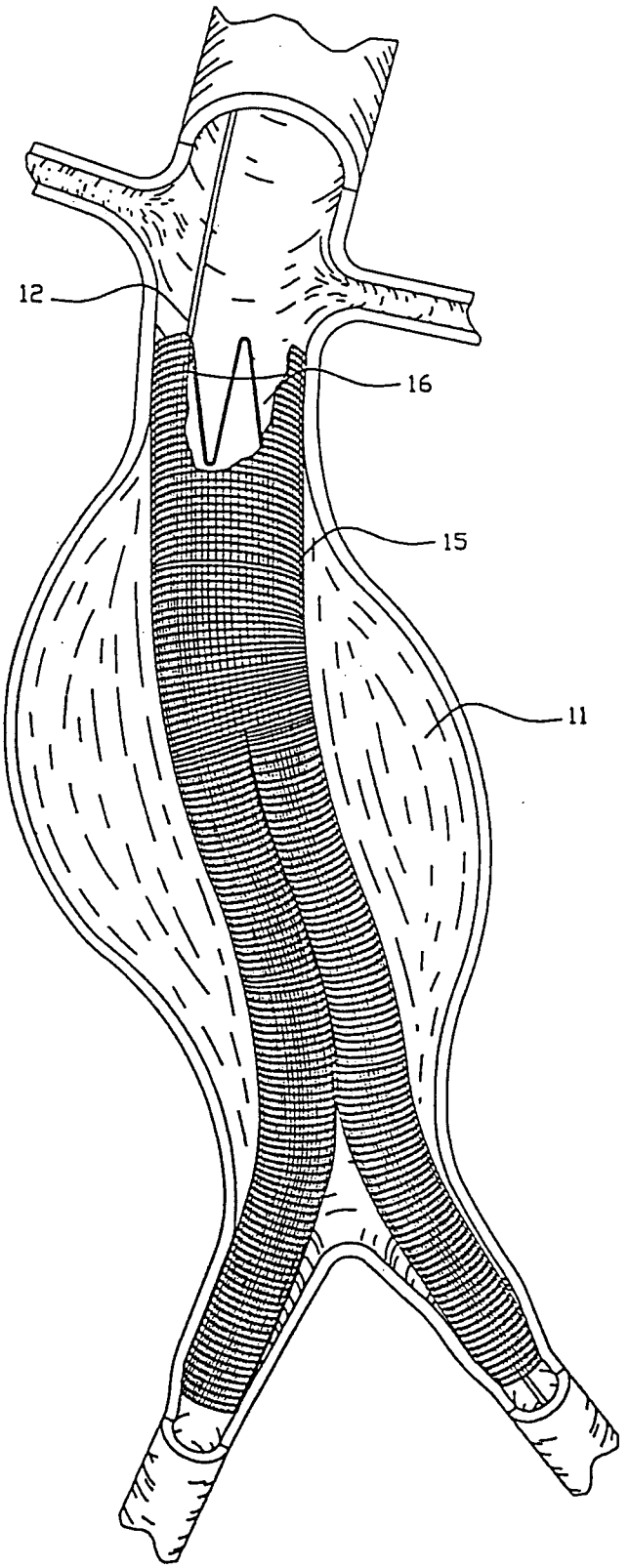


Fig. 4

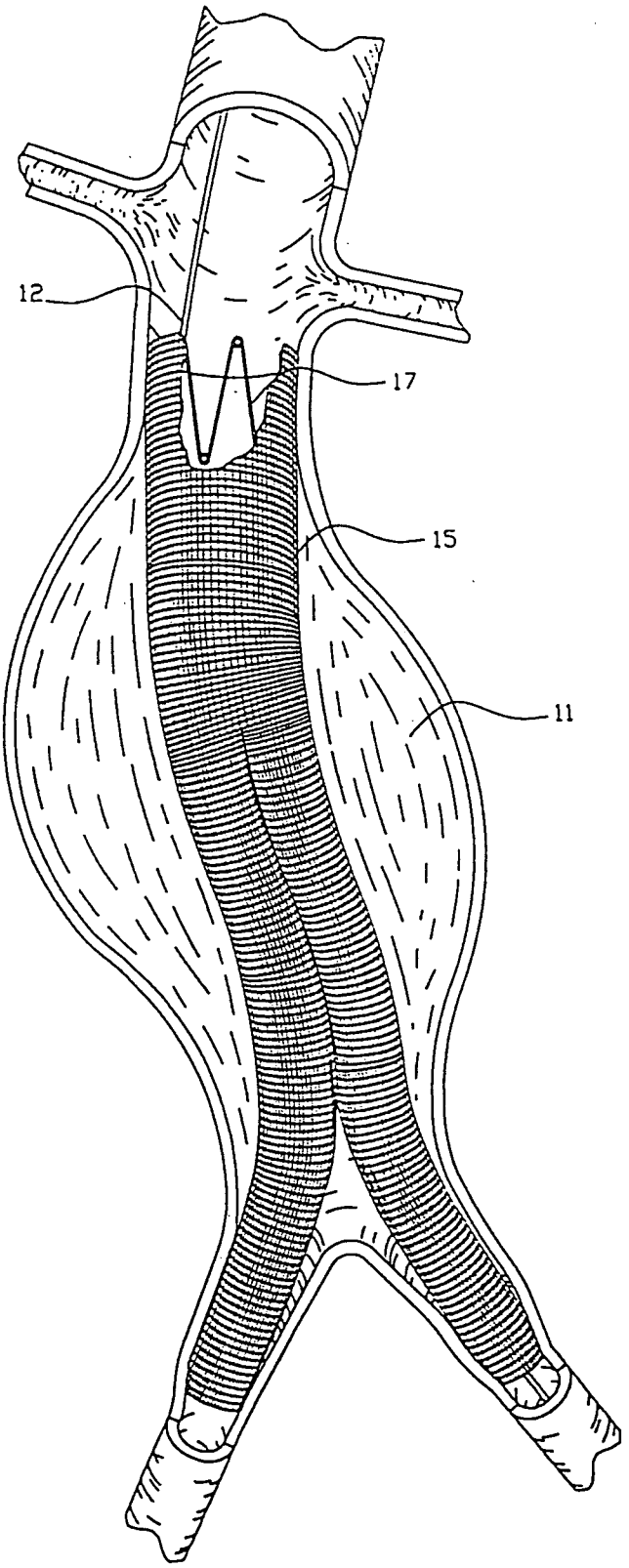


Fig. 5

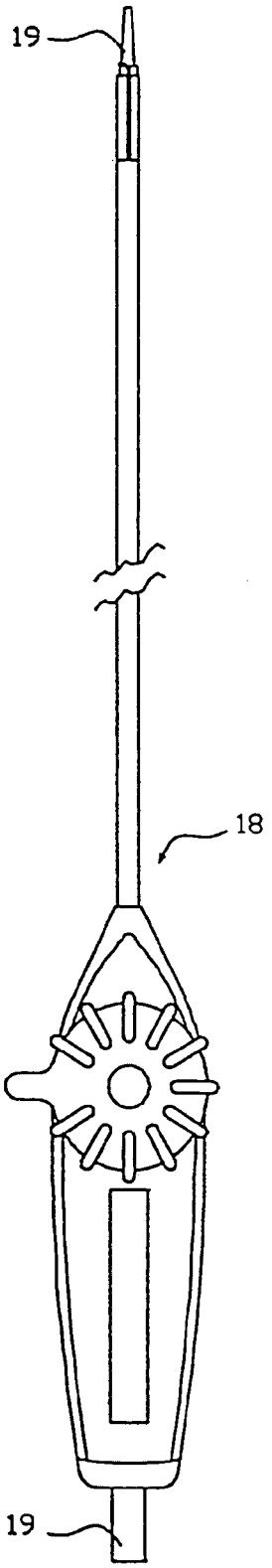


Fig. 6

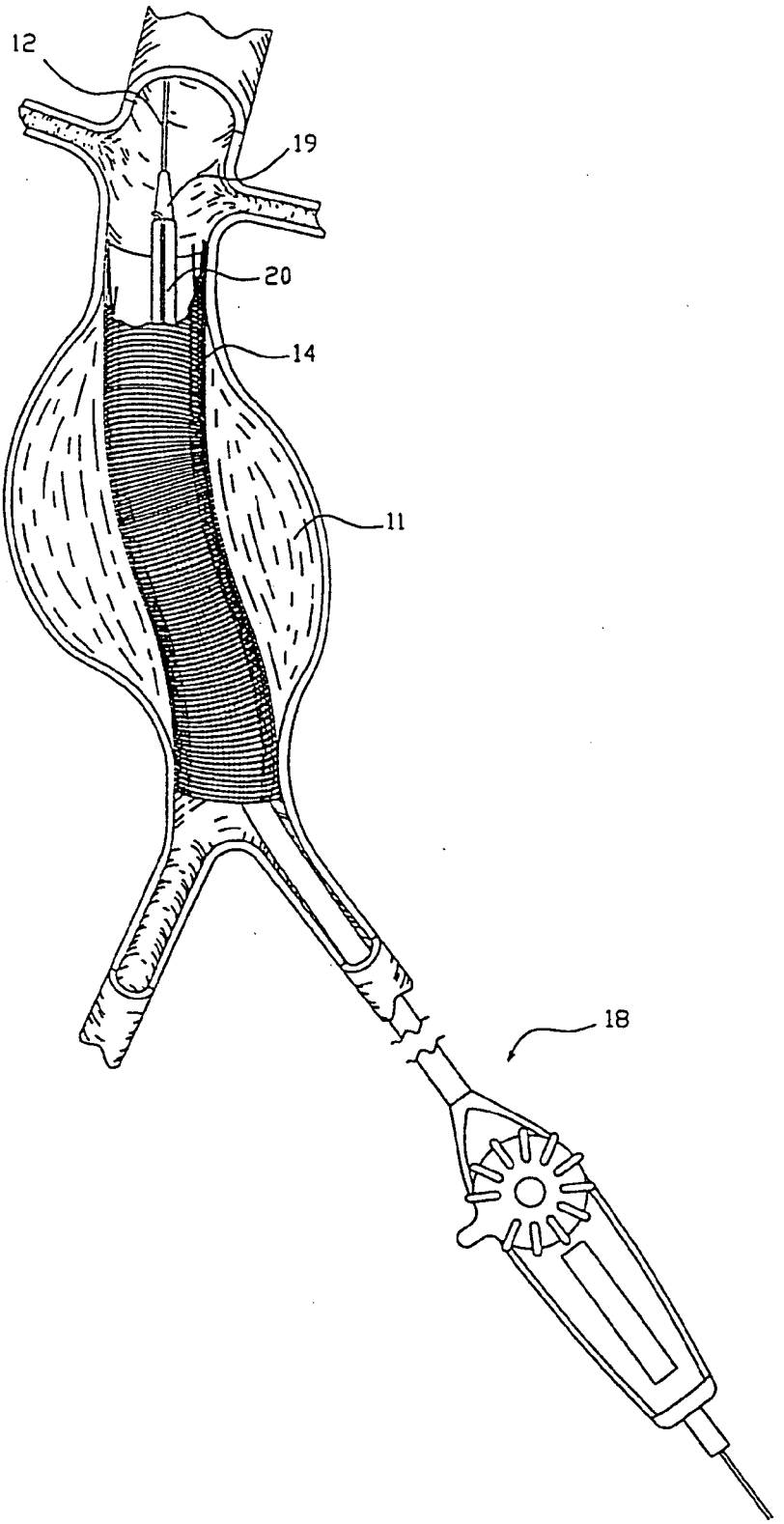


Fig. 7

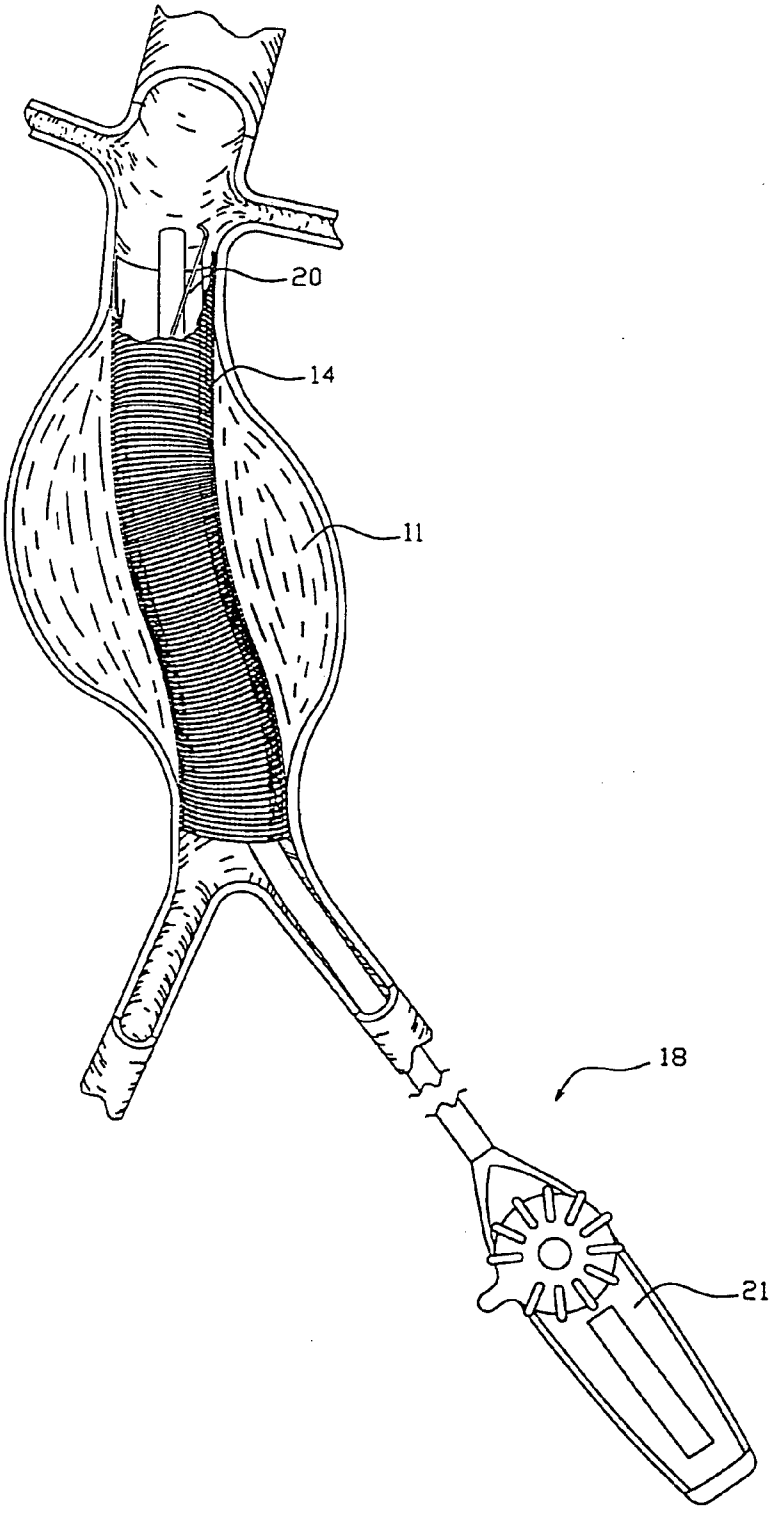


Fig. 8

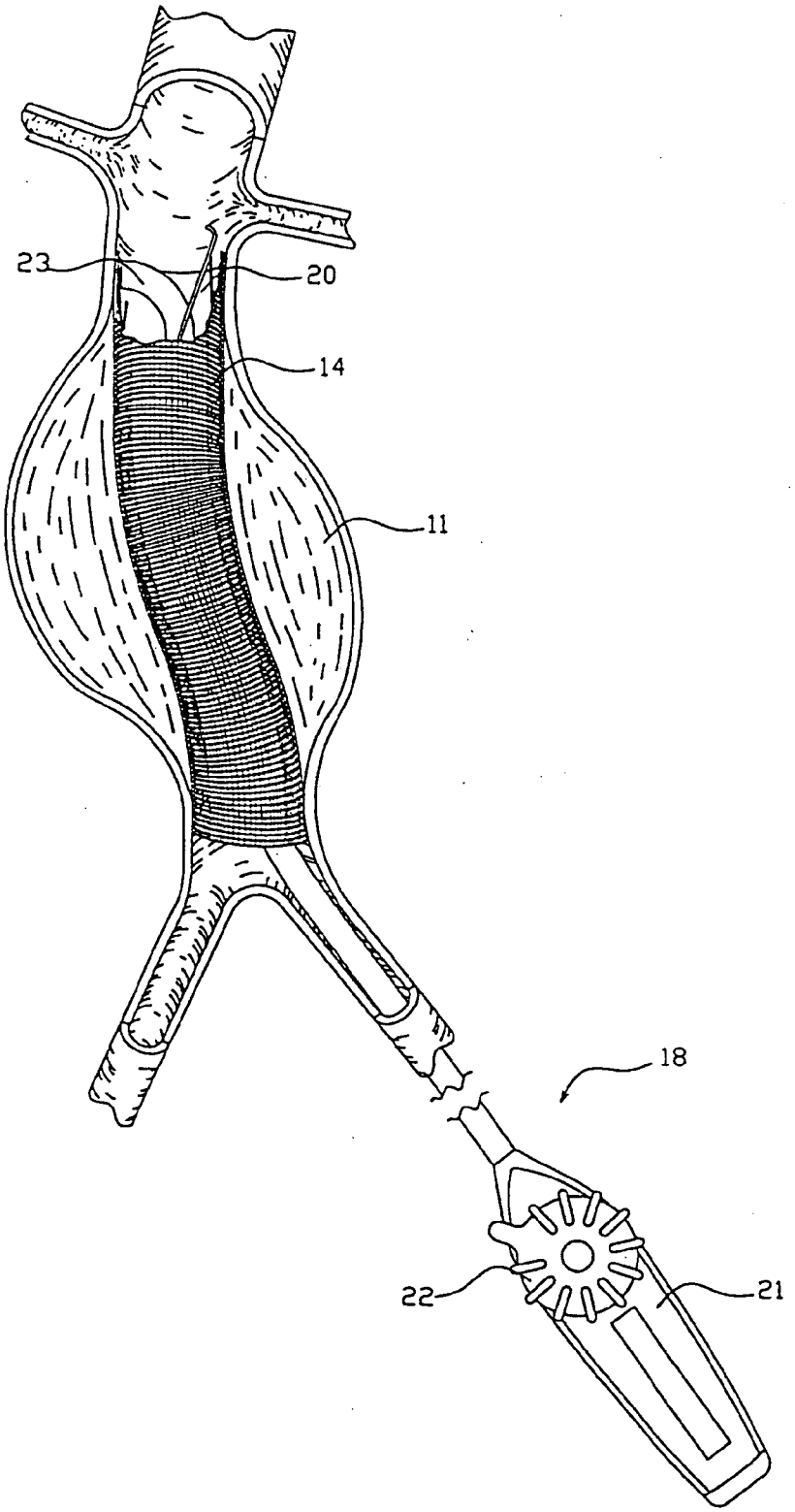


Fig. 9

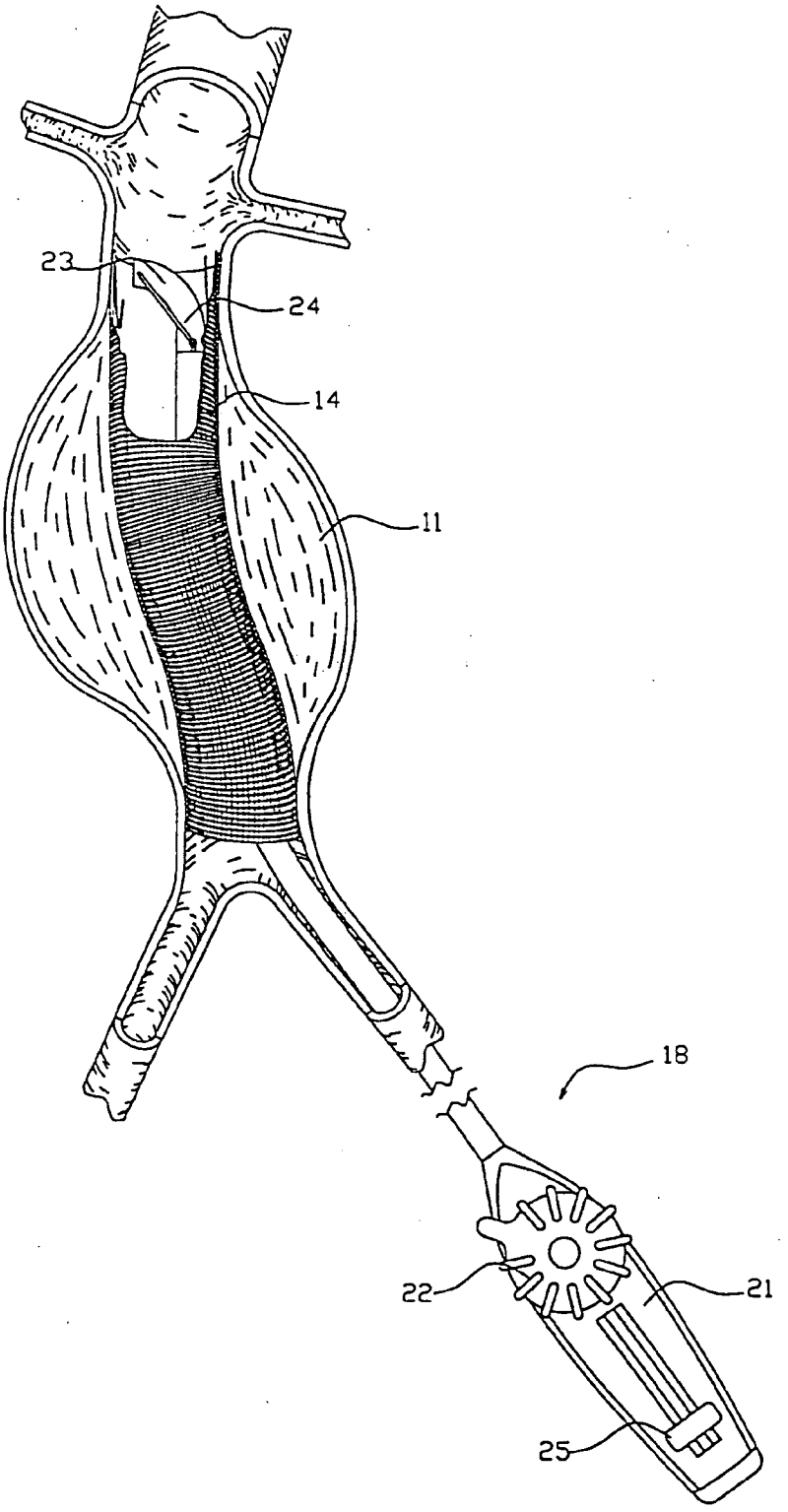


Fig. 10

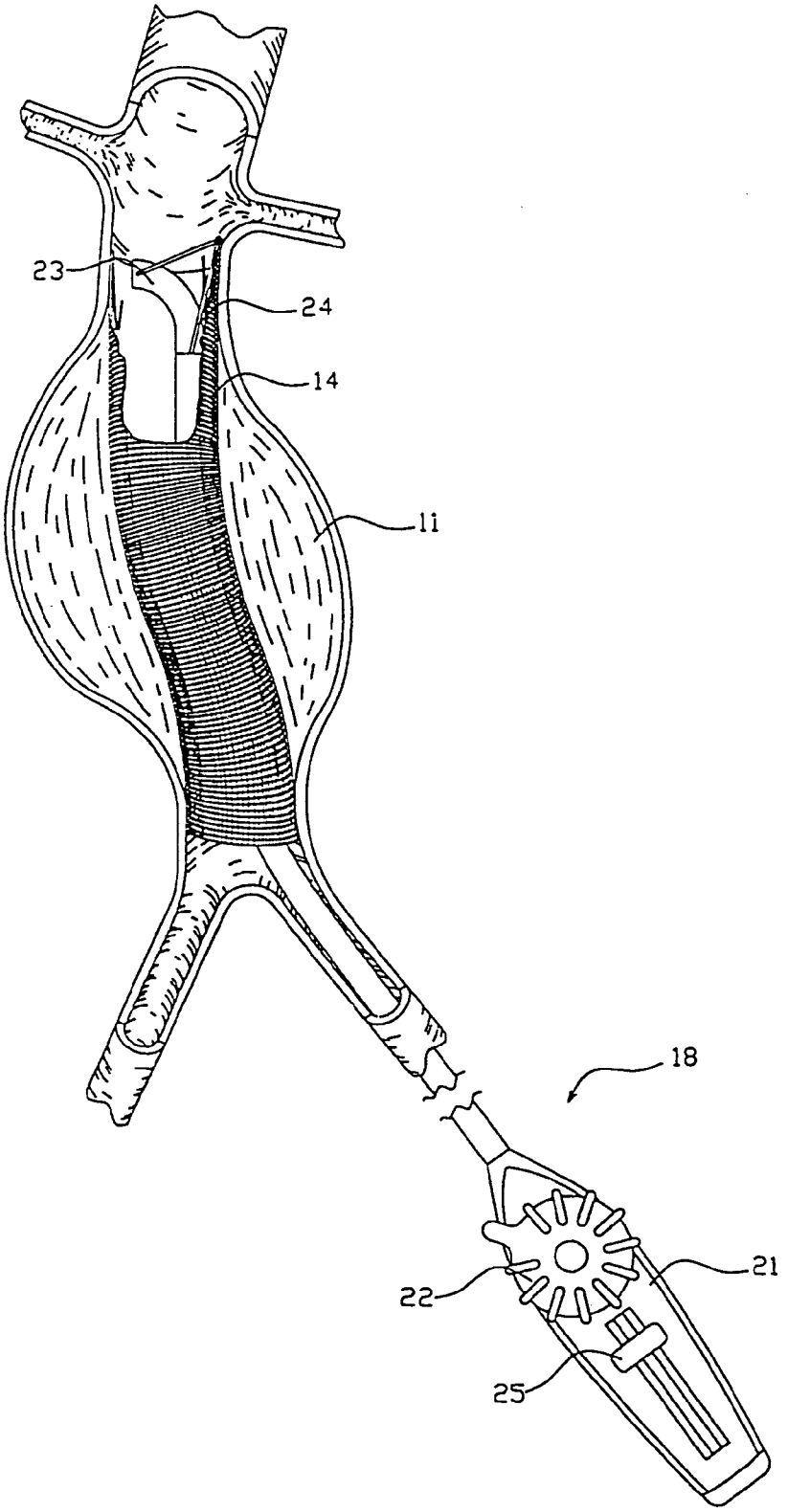


Fig. 11

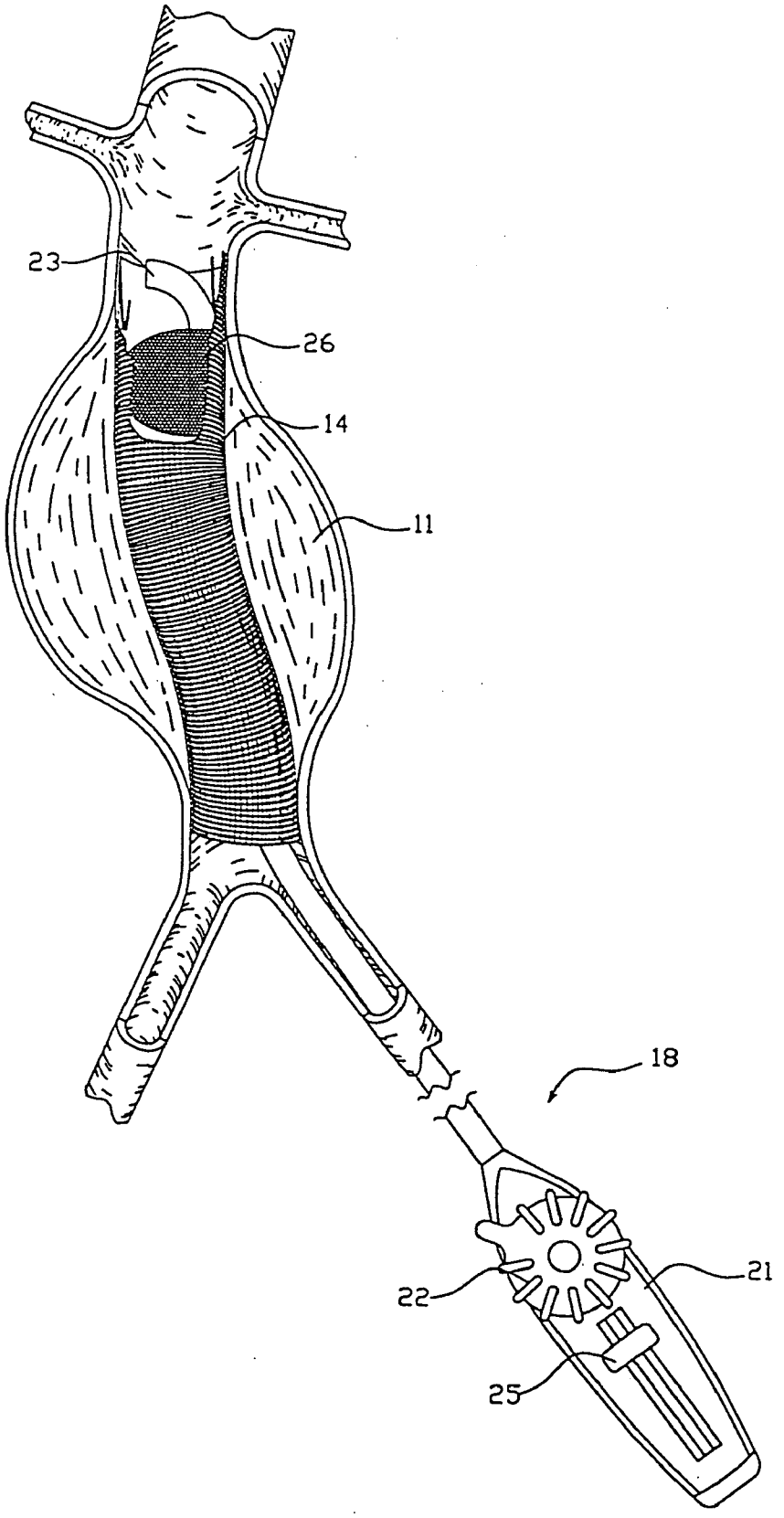


Fig. 12

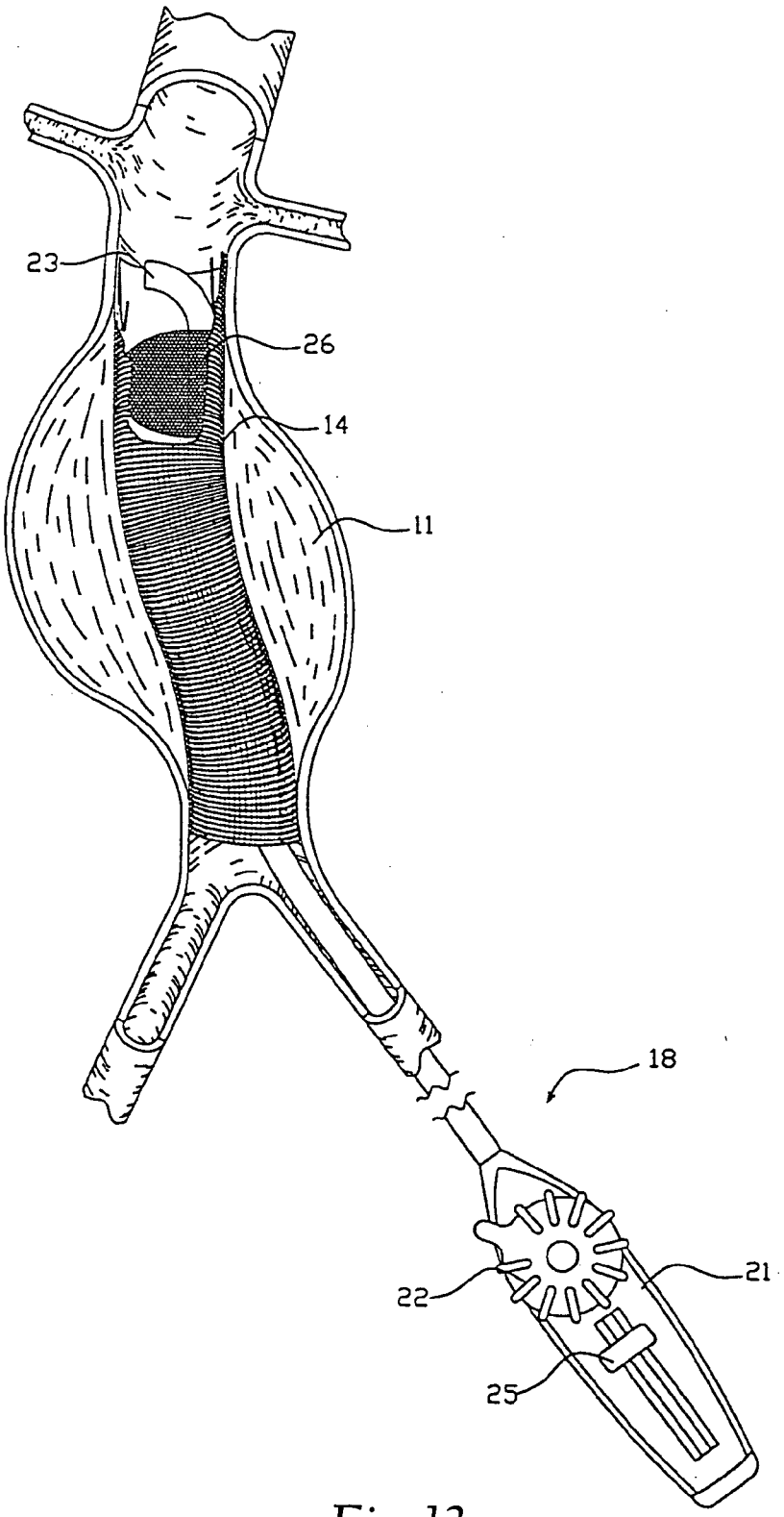


Fig. 13

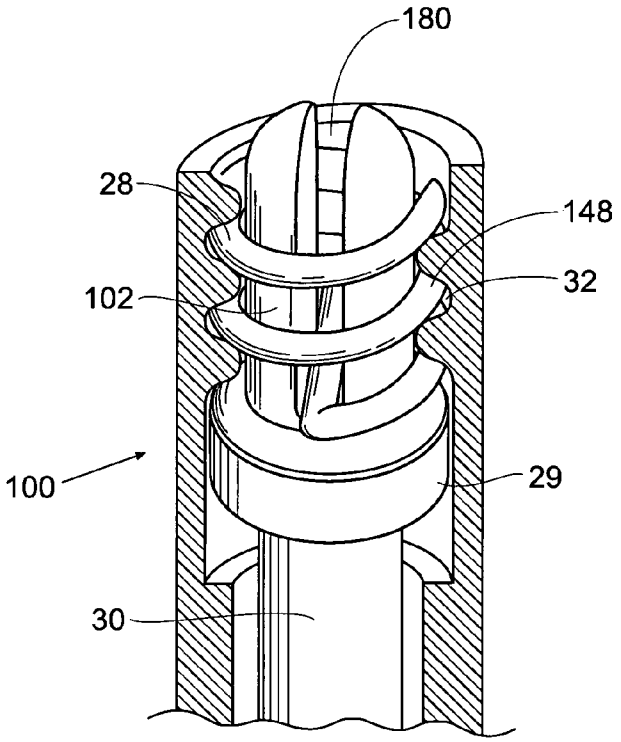


Fig. 14A

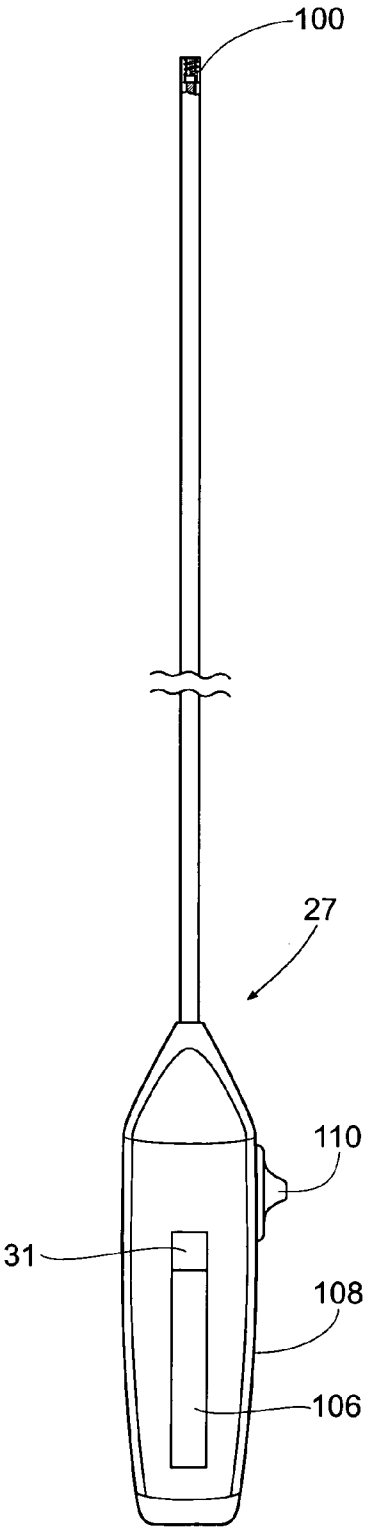


Fig. 14

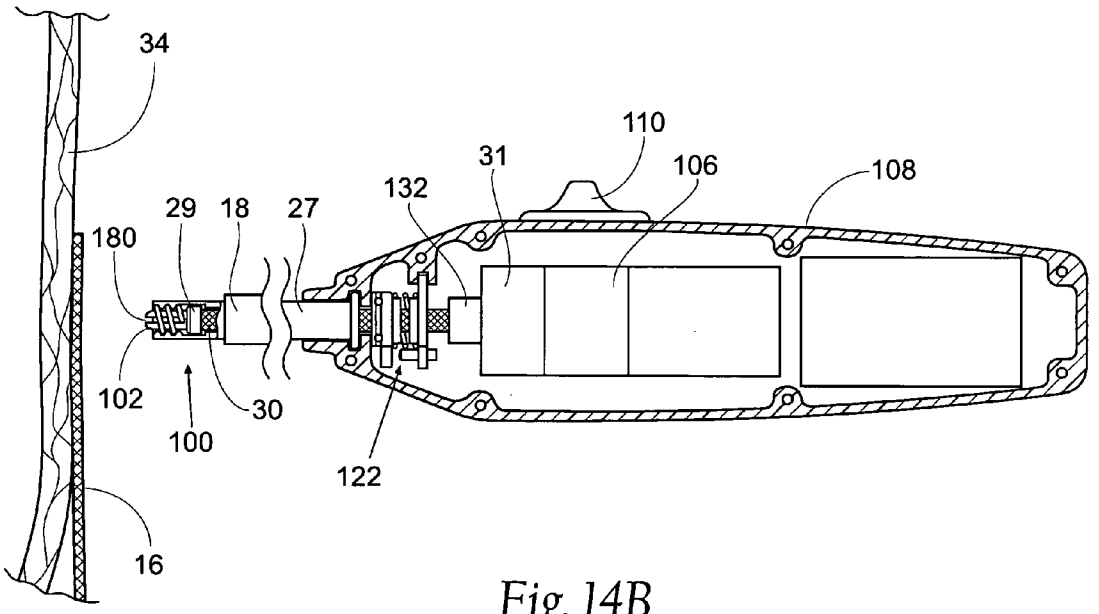


Fig. 14B

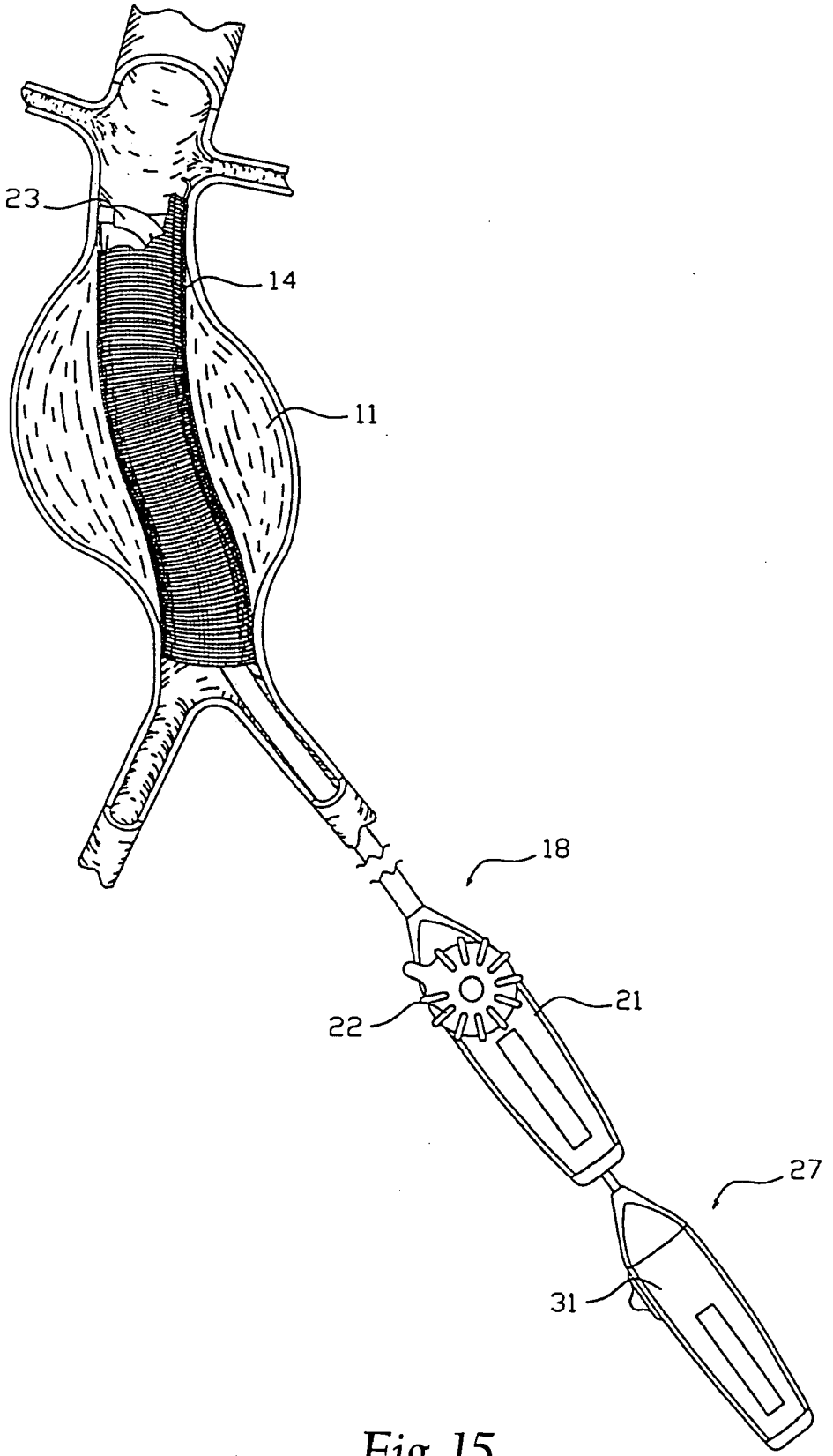


Fig. 15

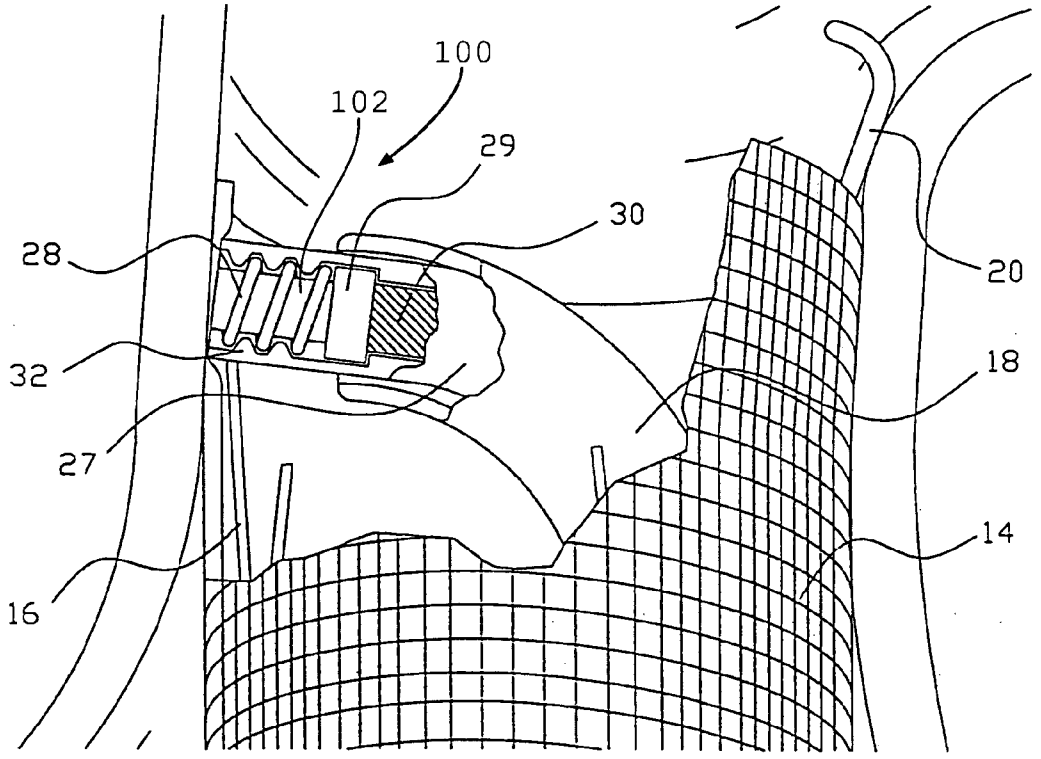

100
102
29
30
28
20
32
18
27
14
16

Fig. 16

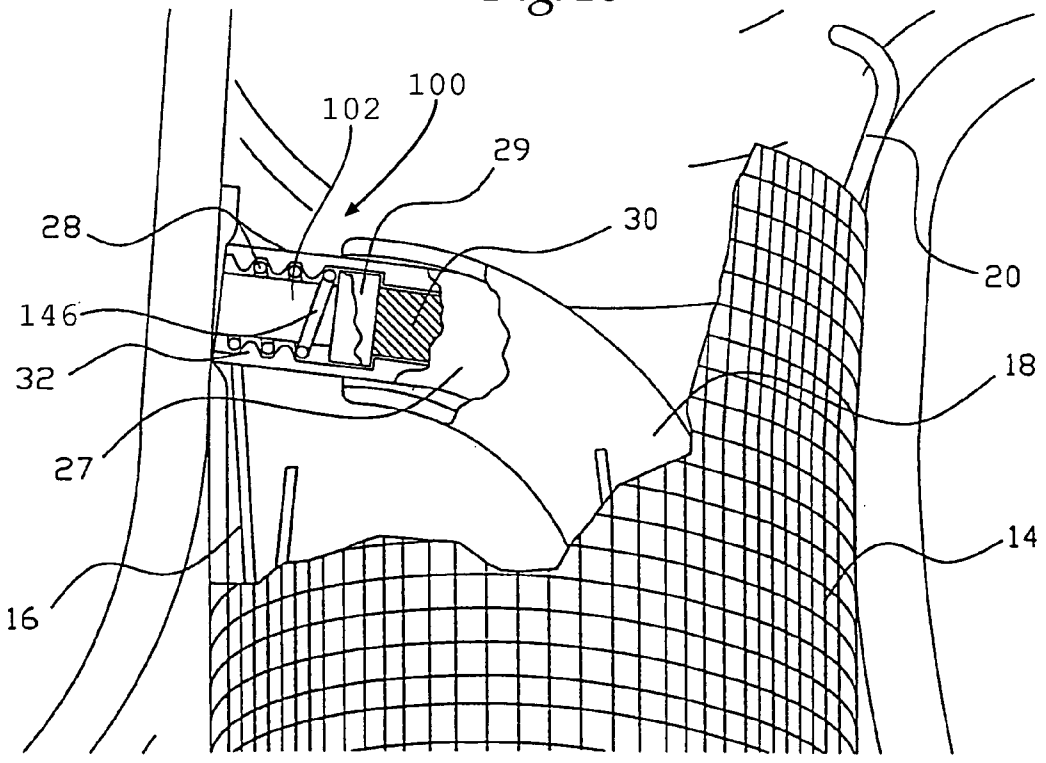

100
102
29
28
30
20
146
32
18
27
14
16

Fig. 17

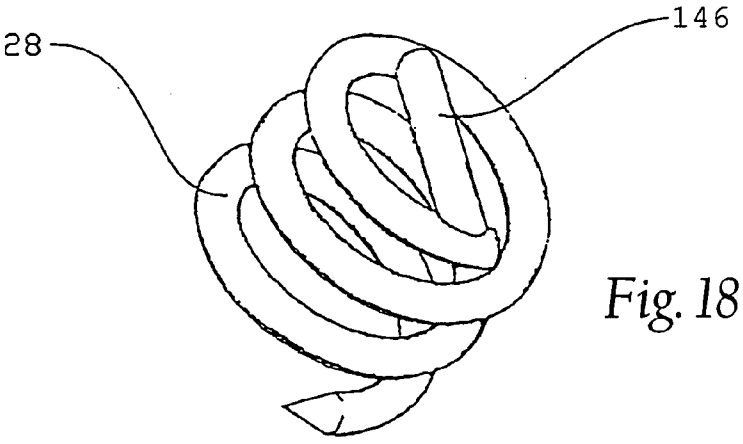


Fig. 18

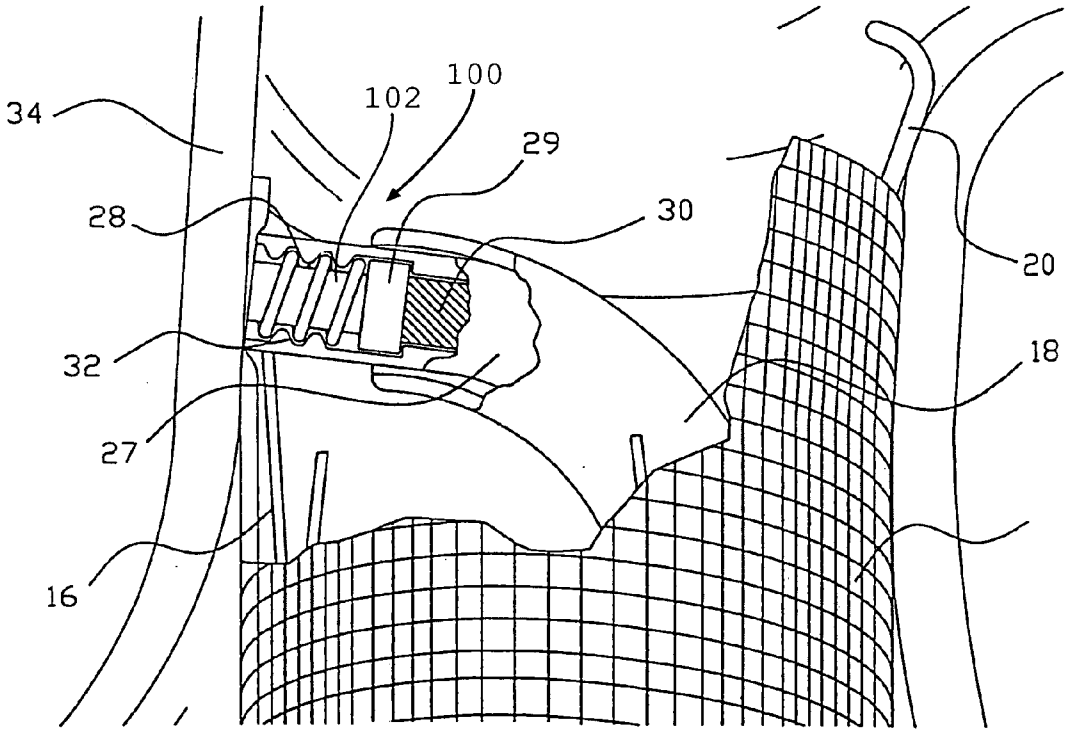


Fig. 19

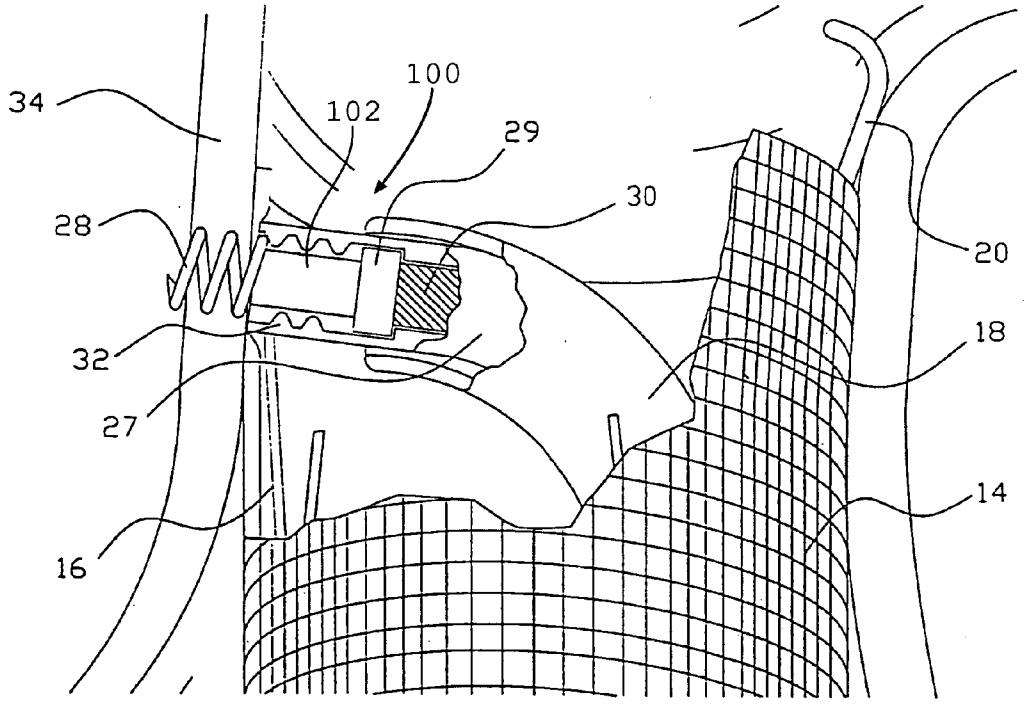


Fig. 20

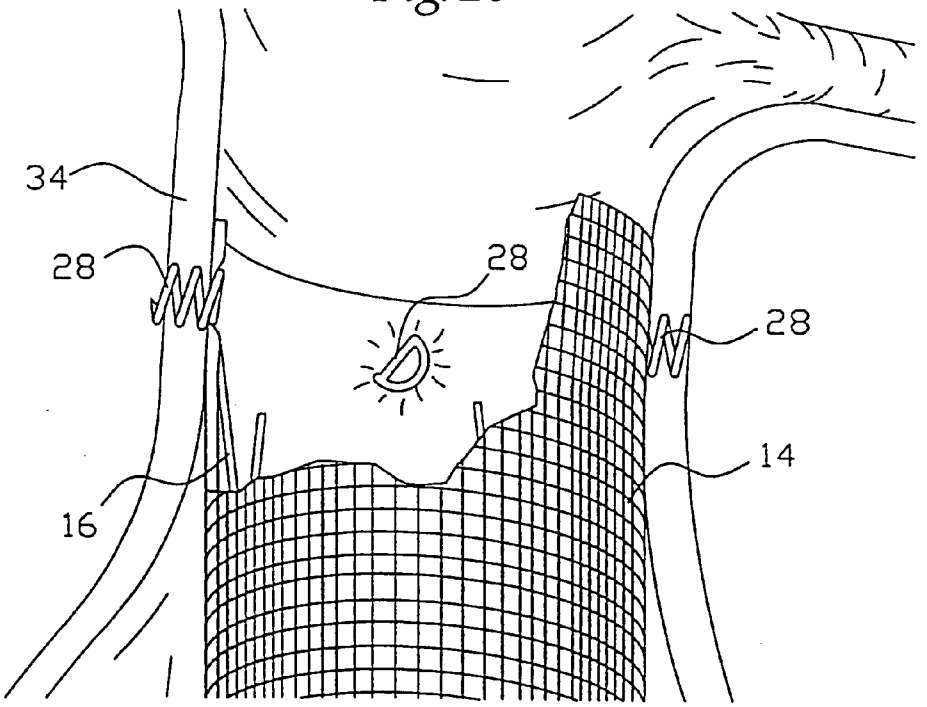


Fig. 21

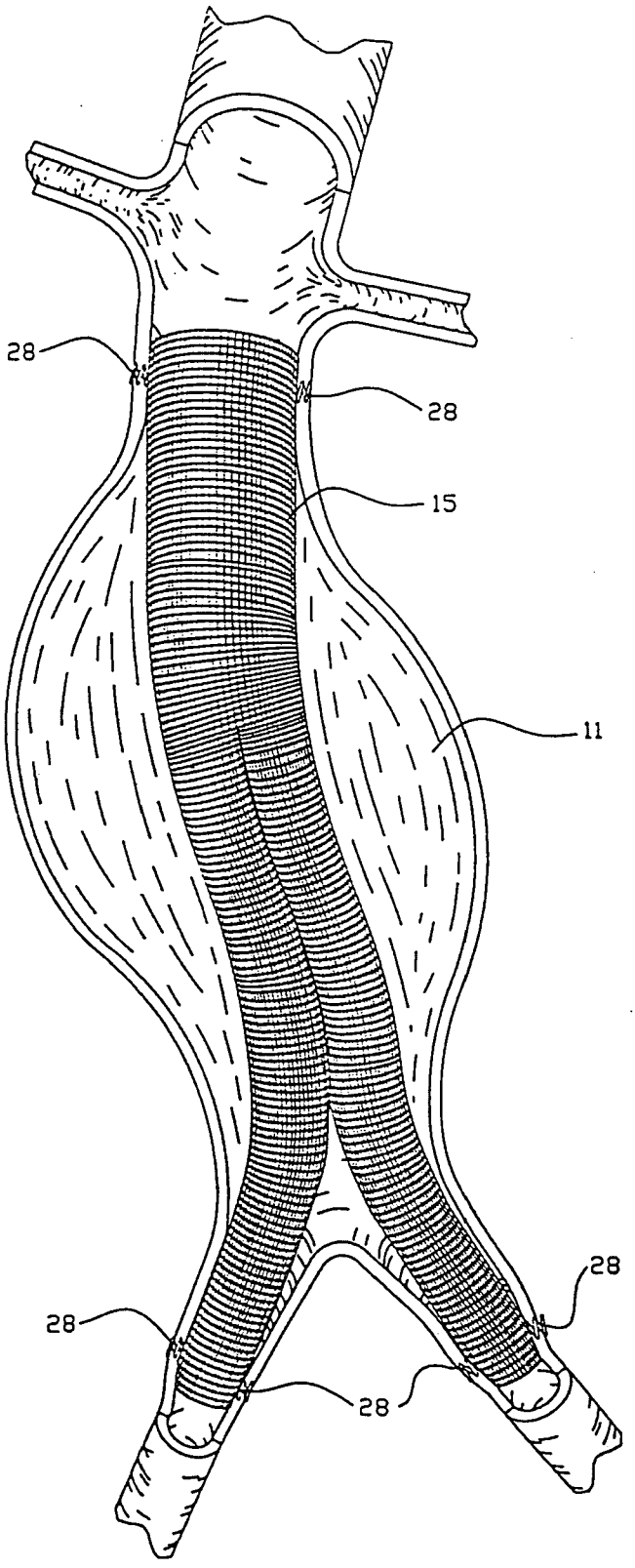


Fig. 22

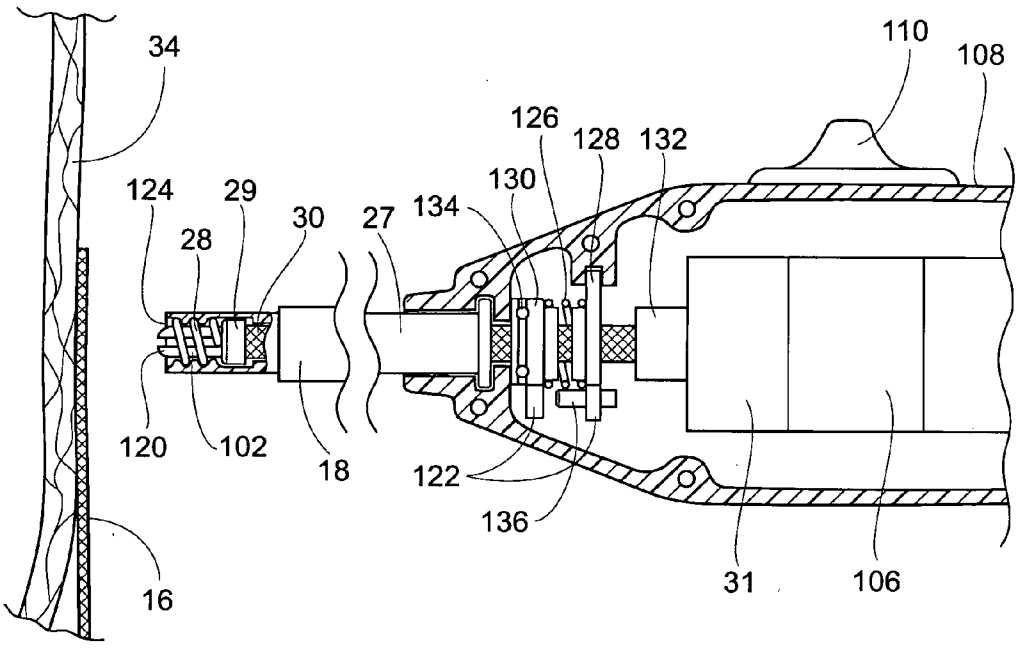

34
110
108
126
128
132
124
29
130
30
27
134
28
120
102
18
122
136
31
106
16

Fig. 23

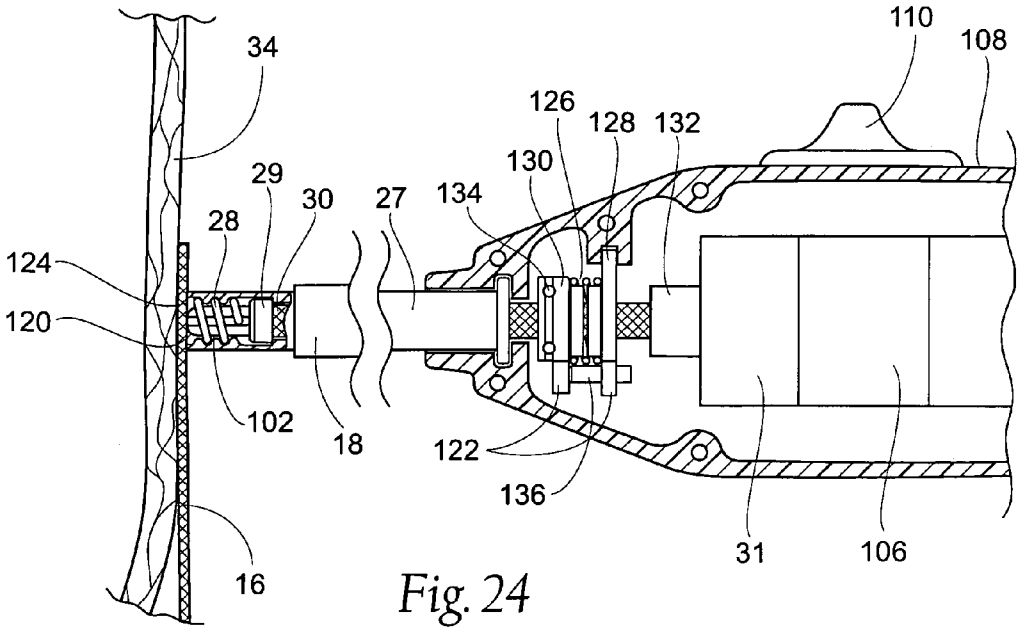


Fig. 24

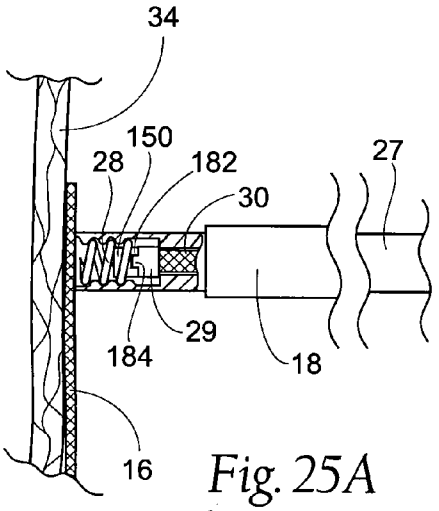


Fig. 25A

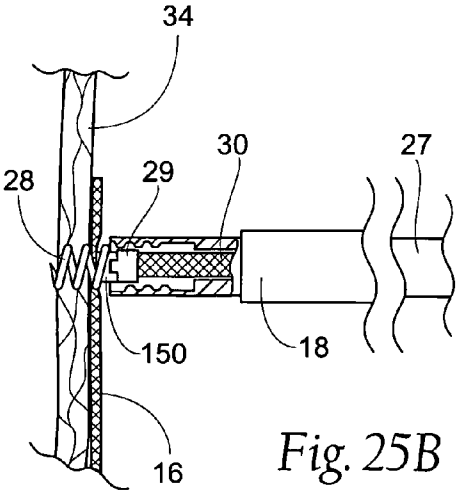


Fig. 25B

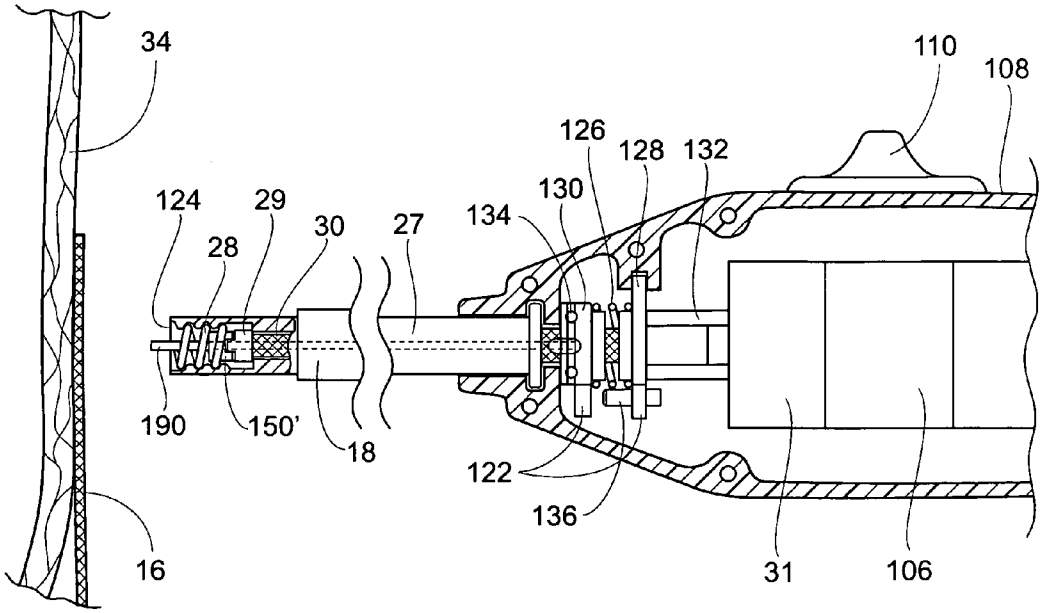


Fig. 26A

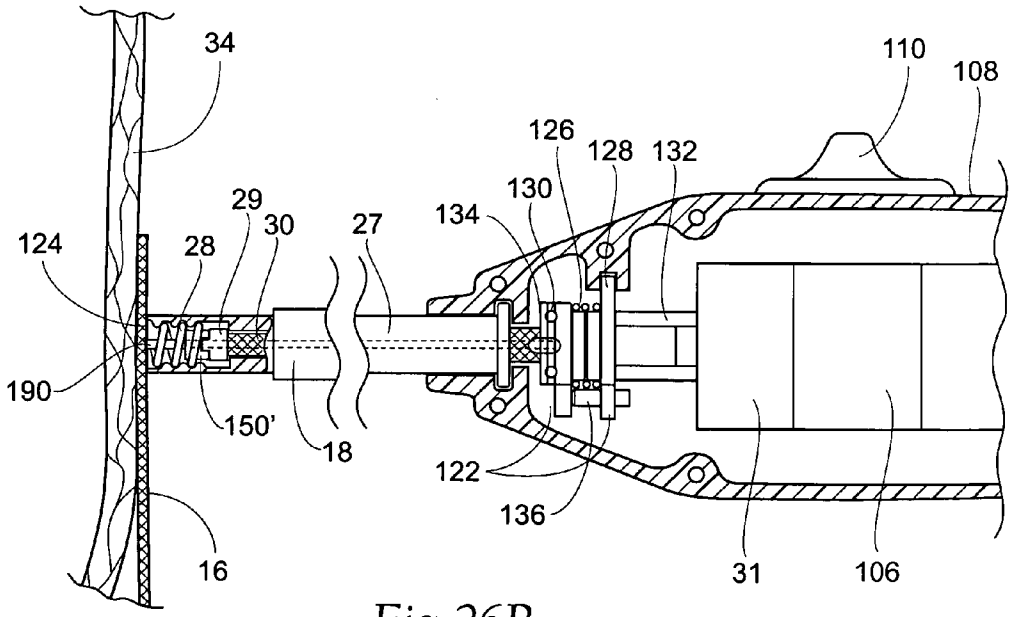


Fig. 26B

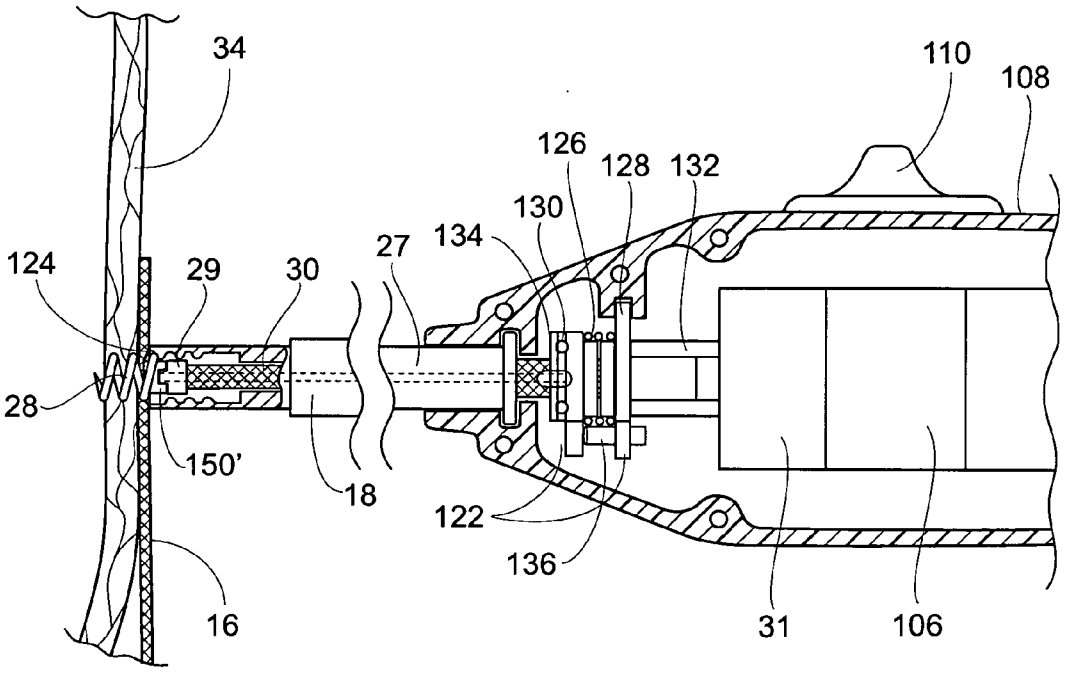

34
110
108
126
128
132
130
134
27
124
29
30
28
150'
18
122
136
16
31
106

Fig. 26C

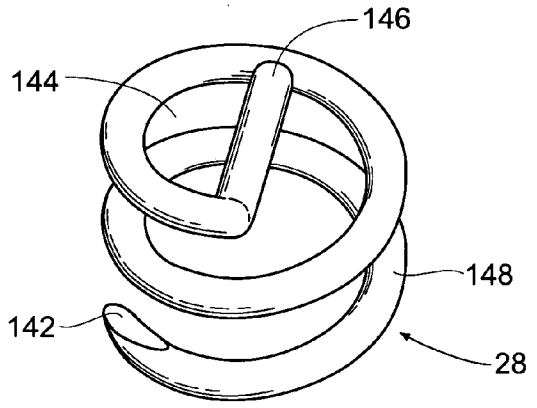


Fig. 27

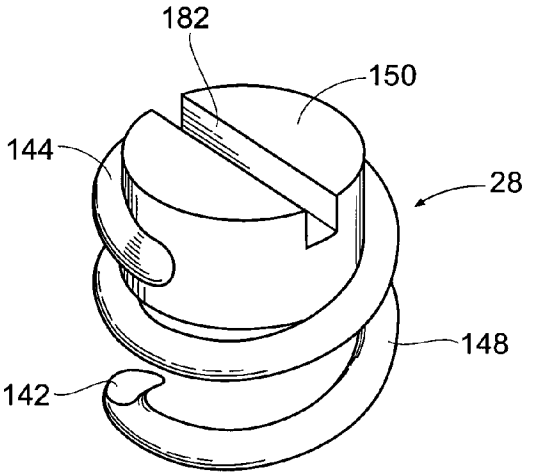


Fig. 28A

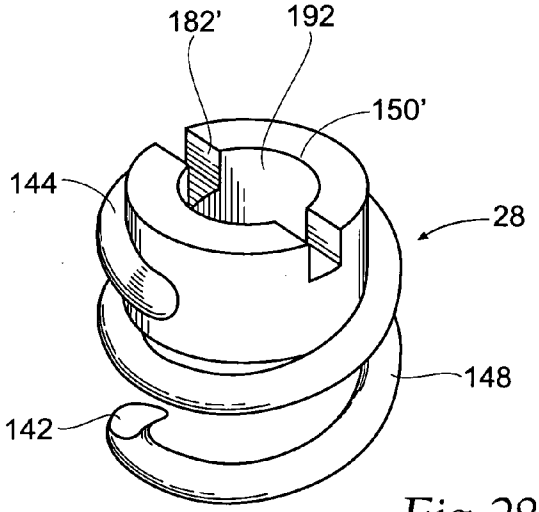


Fig. 28B

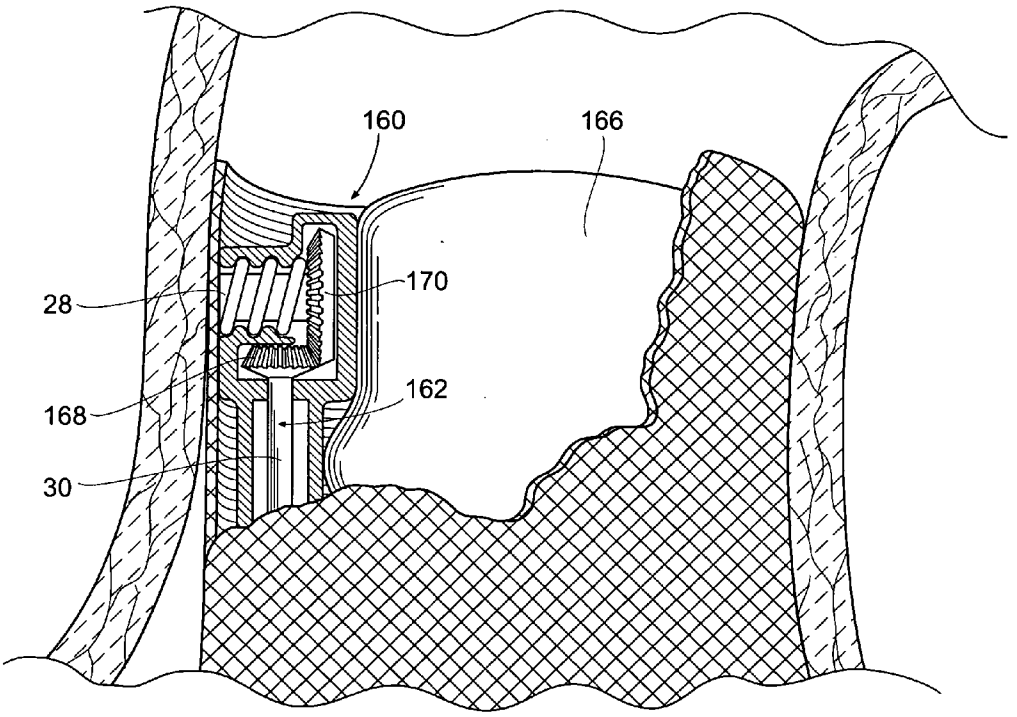


Fig. 29

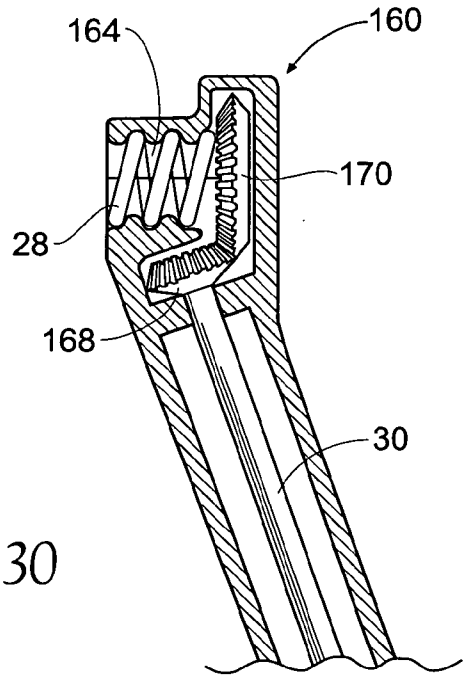


Fig. 30

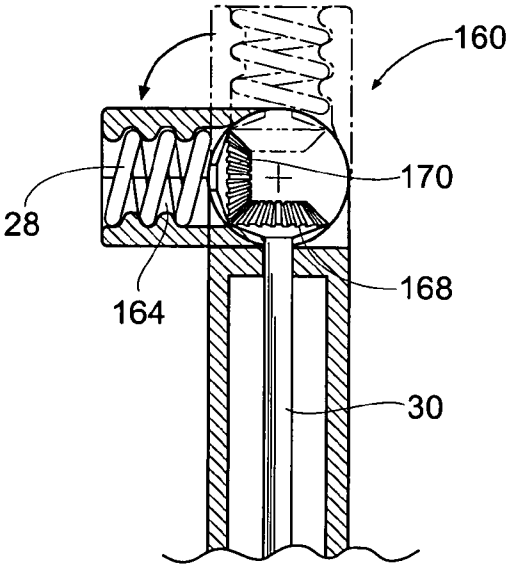


Fig. 31

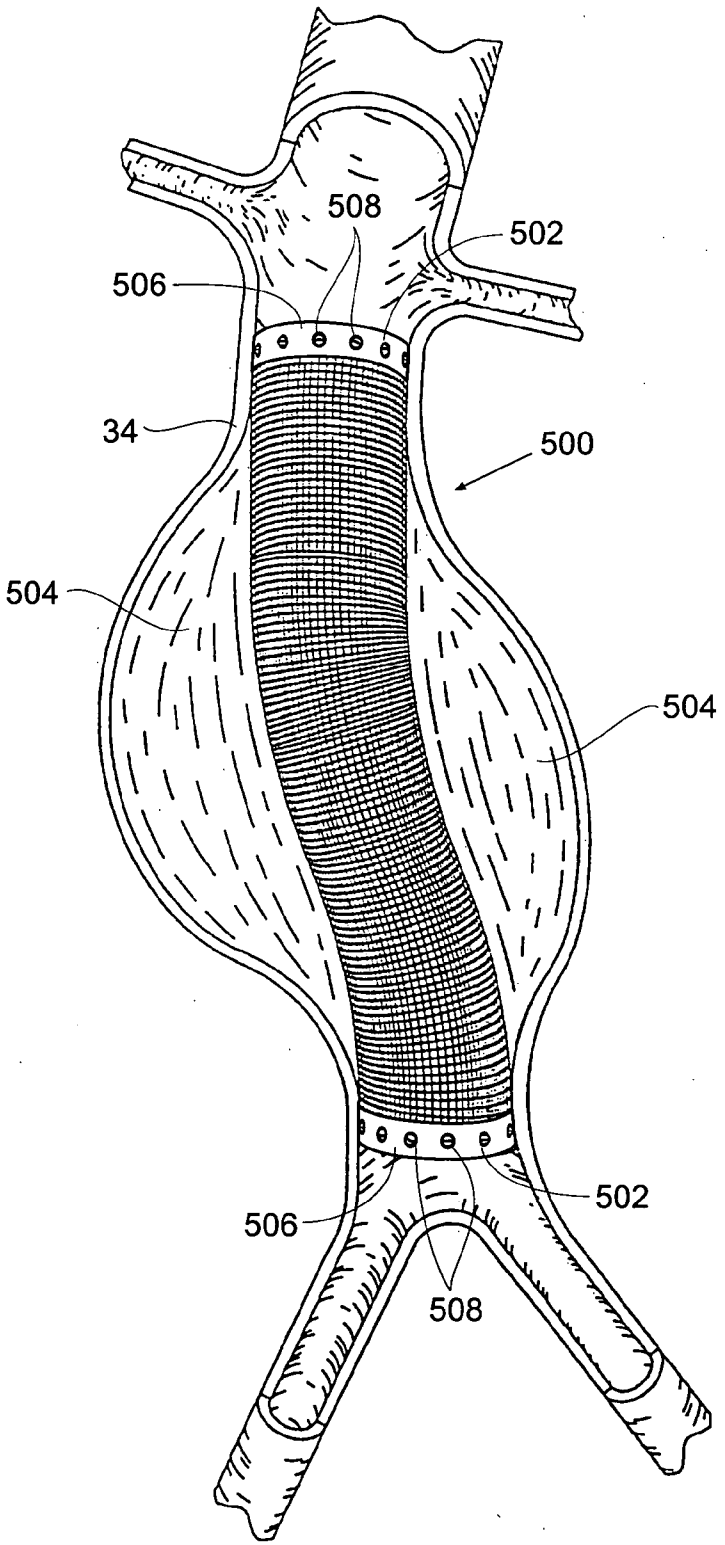


Fig. 32

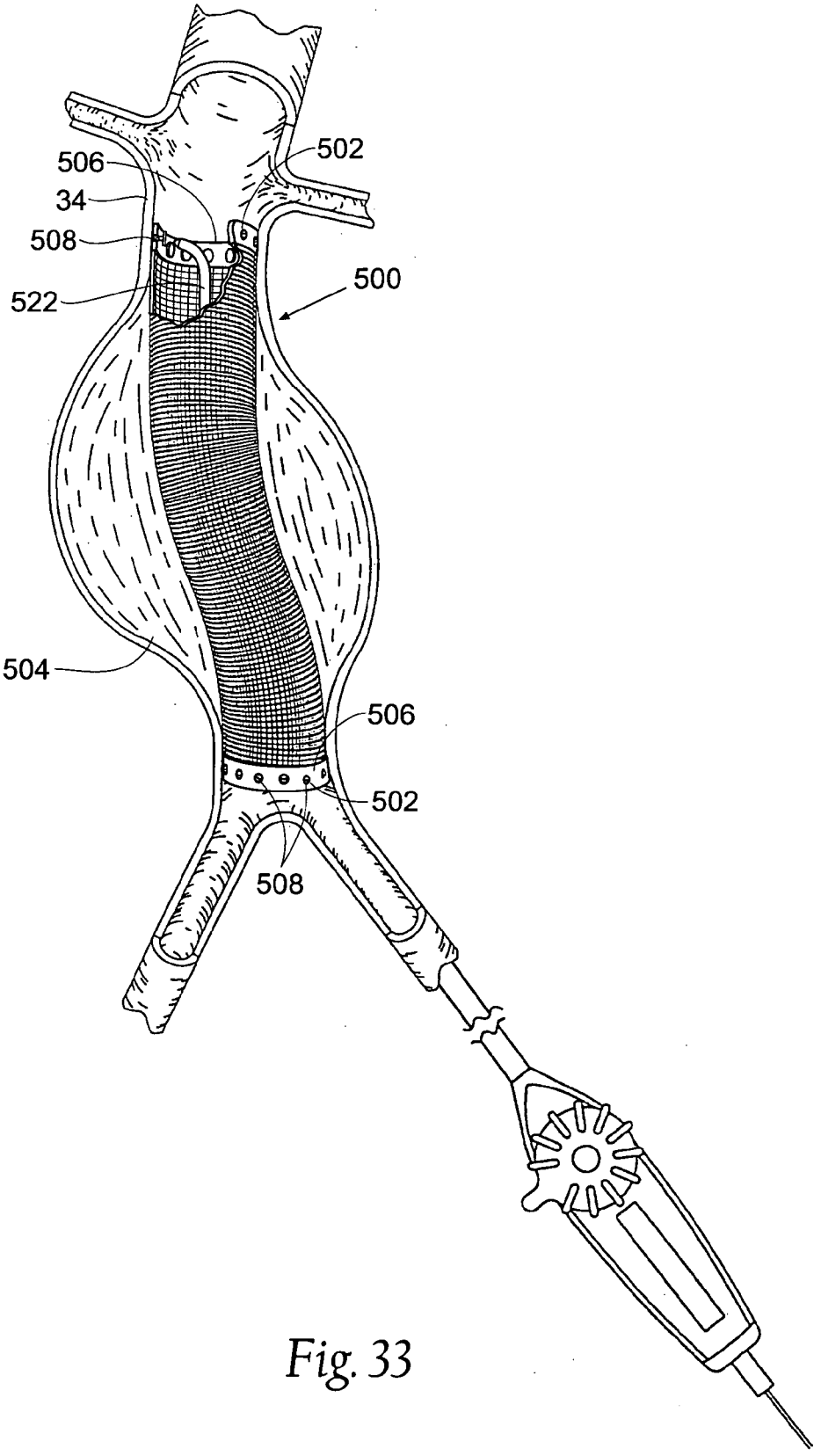


Fig. 33

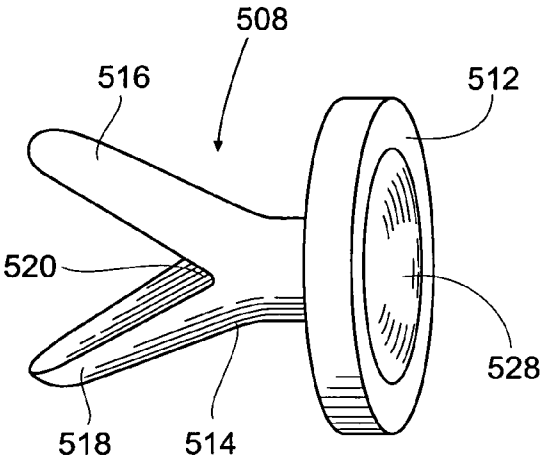

508
516
512
520
528
518
514

Fig. 34

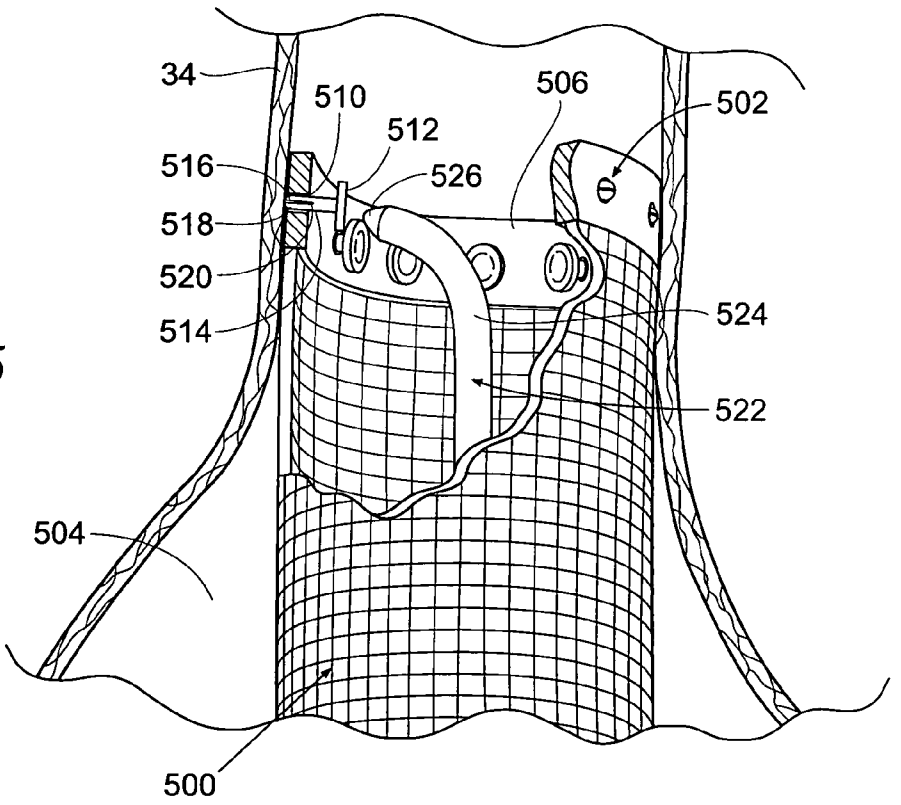

34
510
506
502
512
516
526
θ
518
520
524
514
522
504
500

Fig. 35

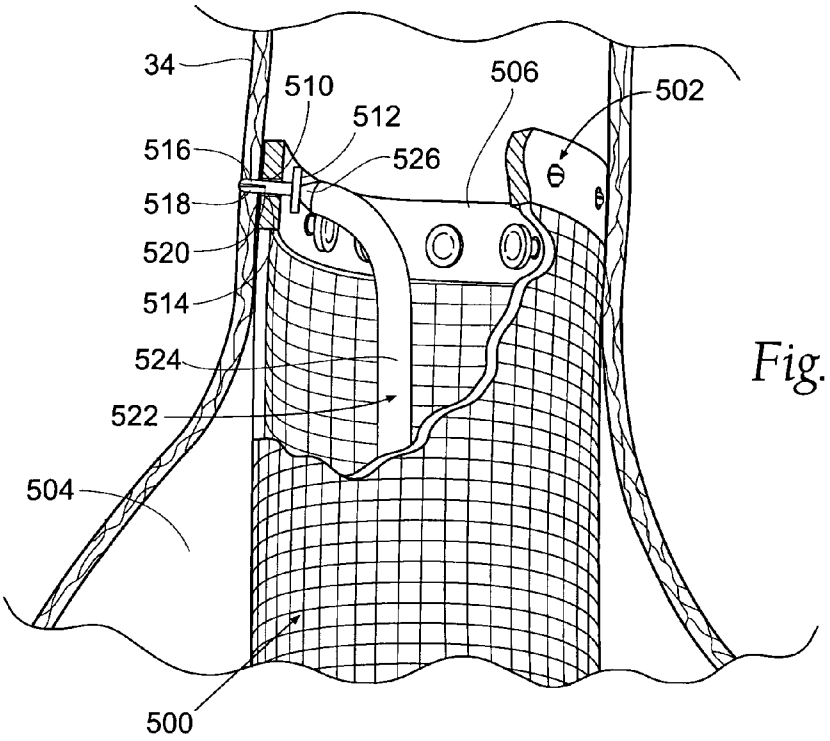

34
510
512
506
502
516
526
θ
θ
518
520
514
524
522
504
500

Fig. 36

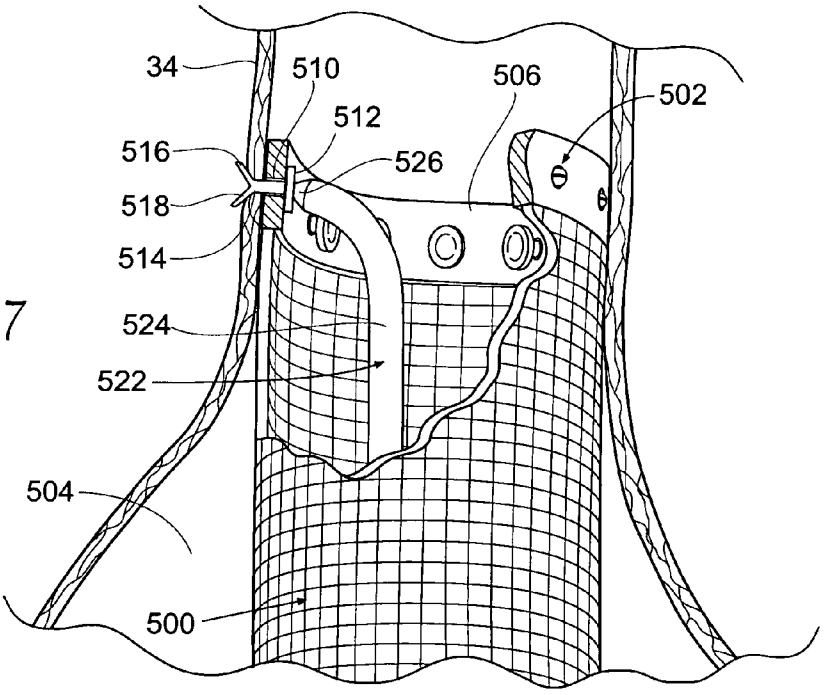

34
510
512
506
502
516
526
θ
θ
518
514
524
522
504
500

Fig. 37

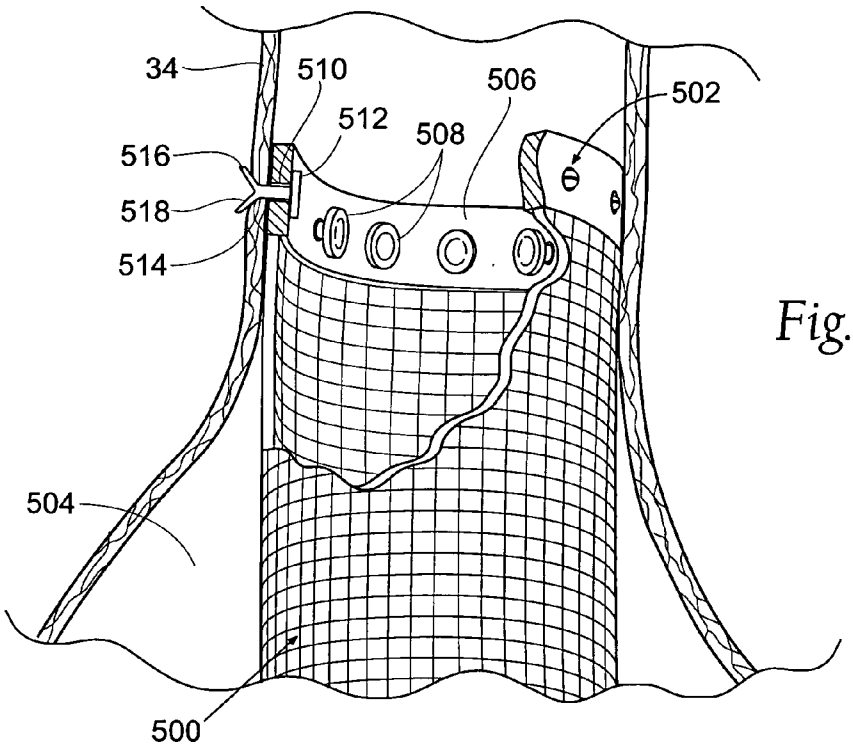

34
510
506
502
512
508
516
518
514
504
500

Fig. 38

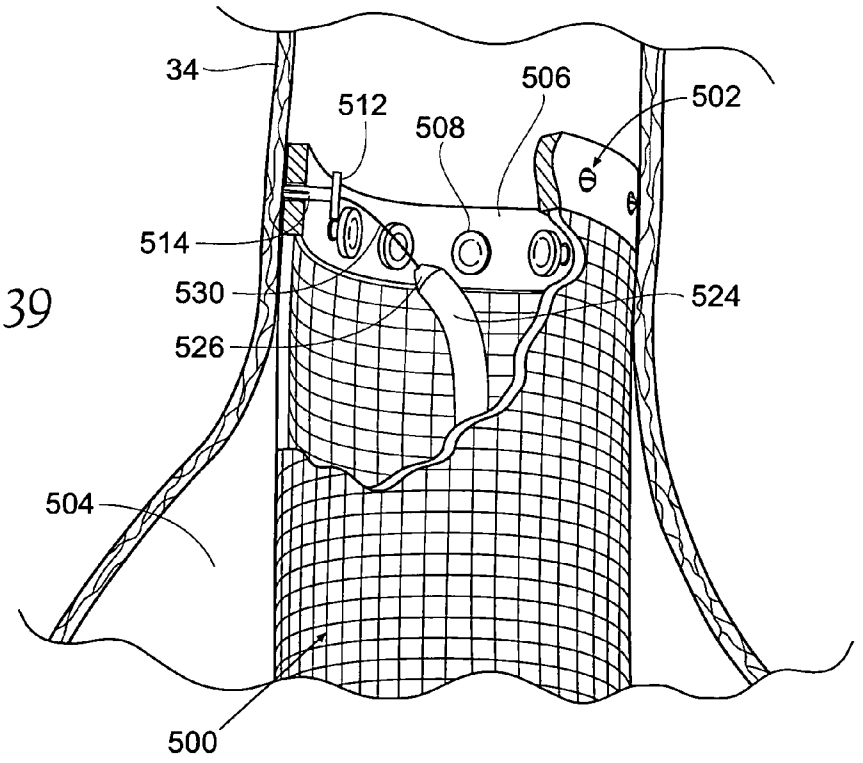

34
506
502
512
508
514
530
524
526
504
500

Fig. 39

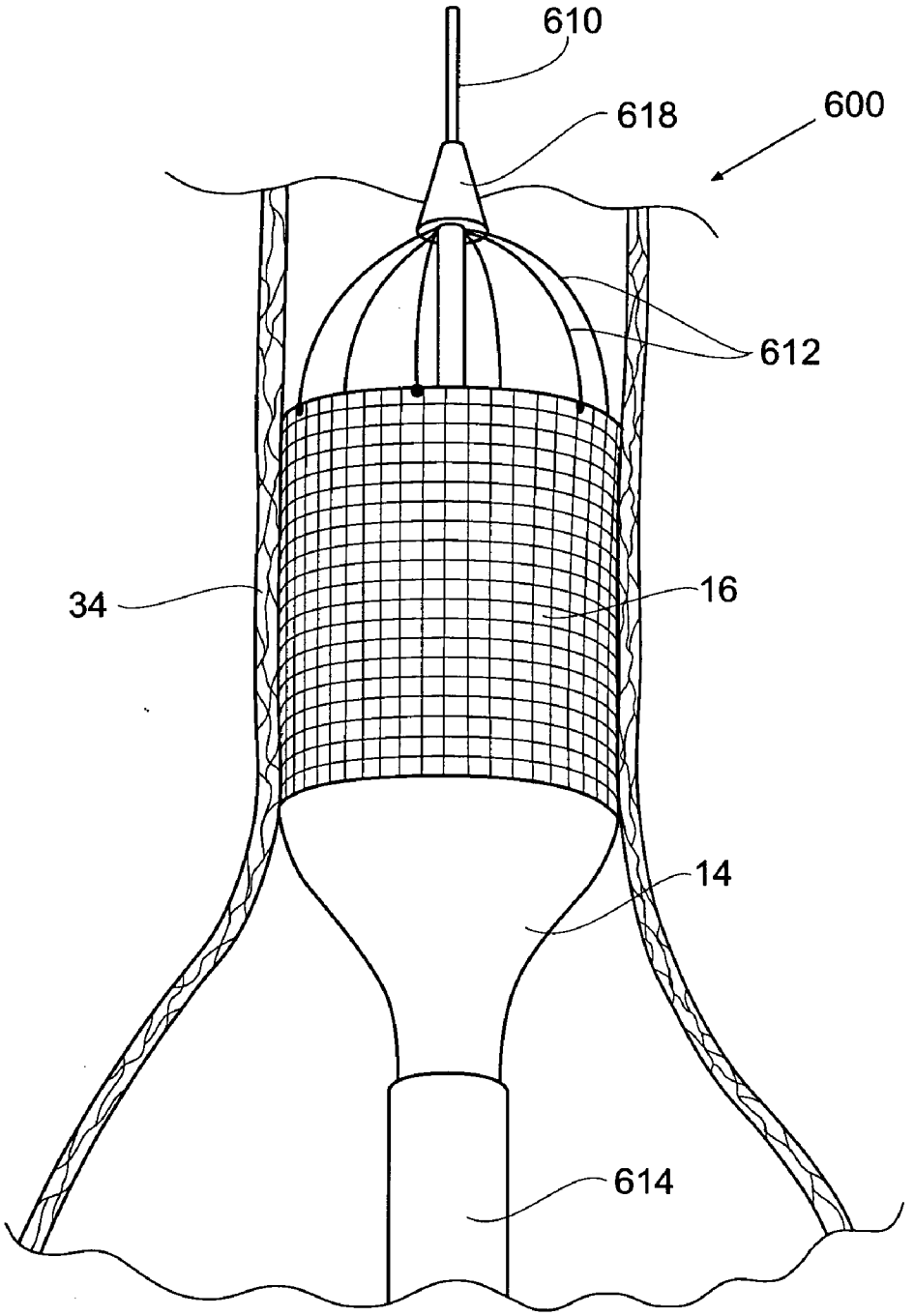


Fig. 40

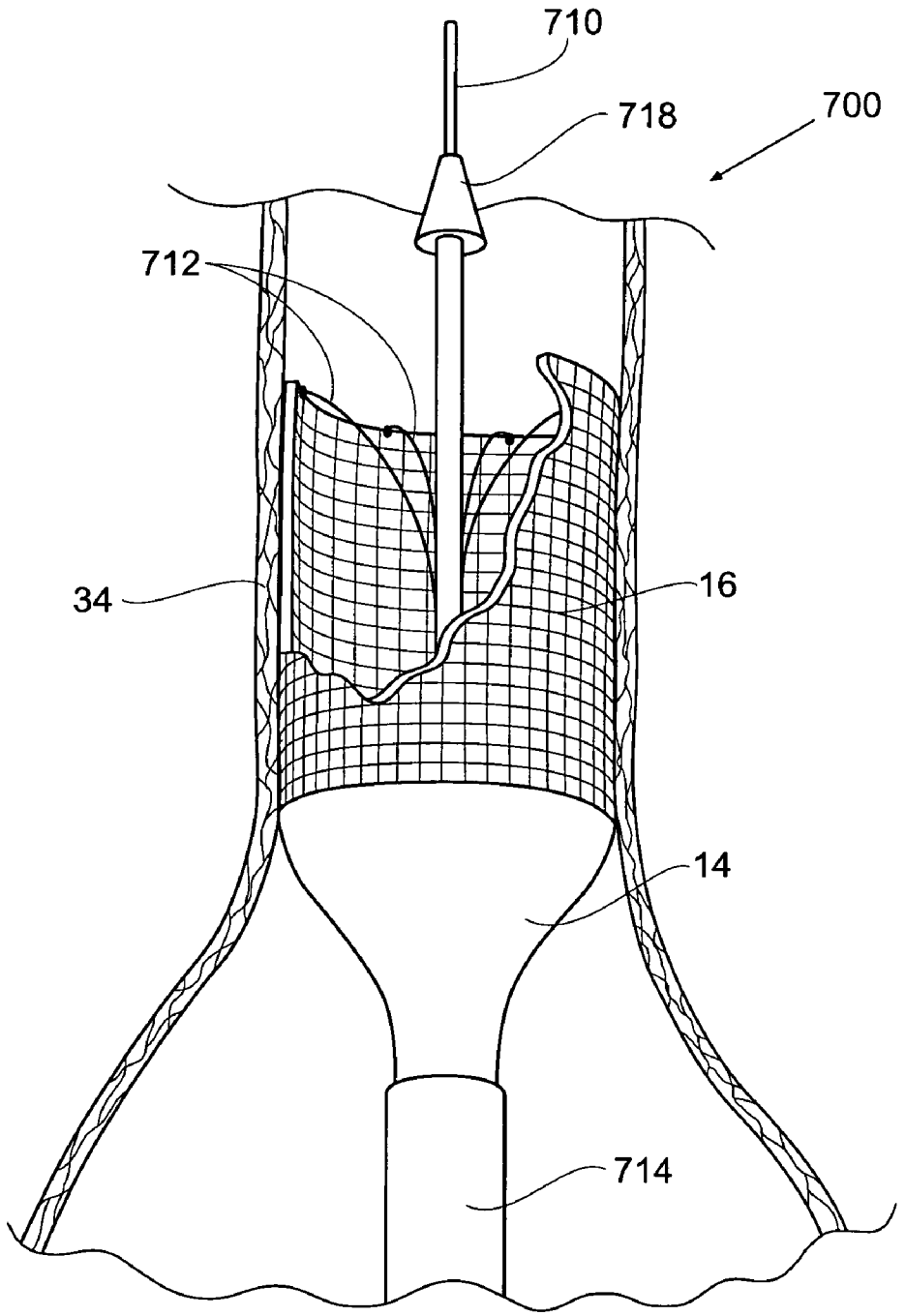


Fig. 41

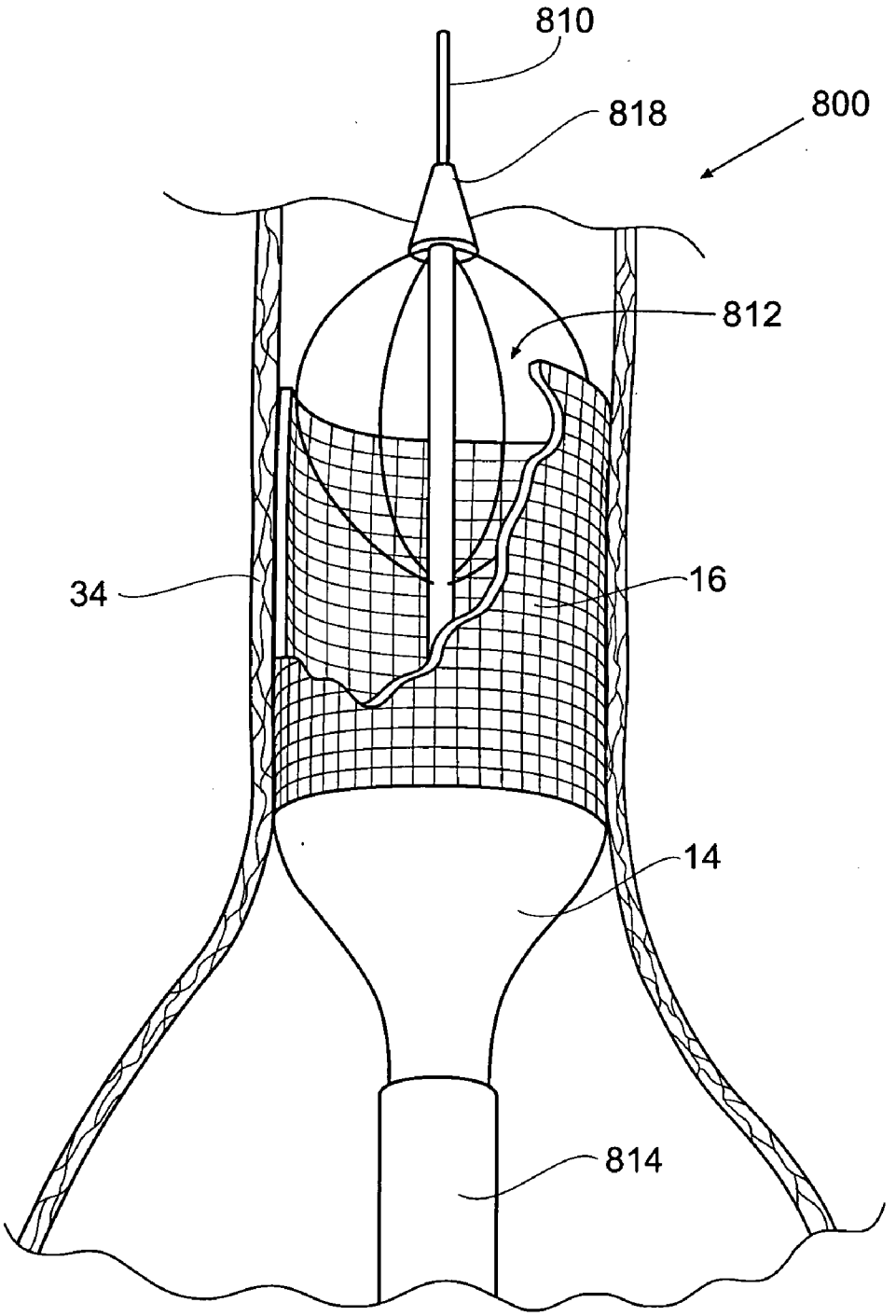


Fig. 42

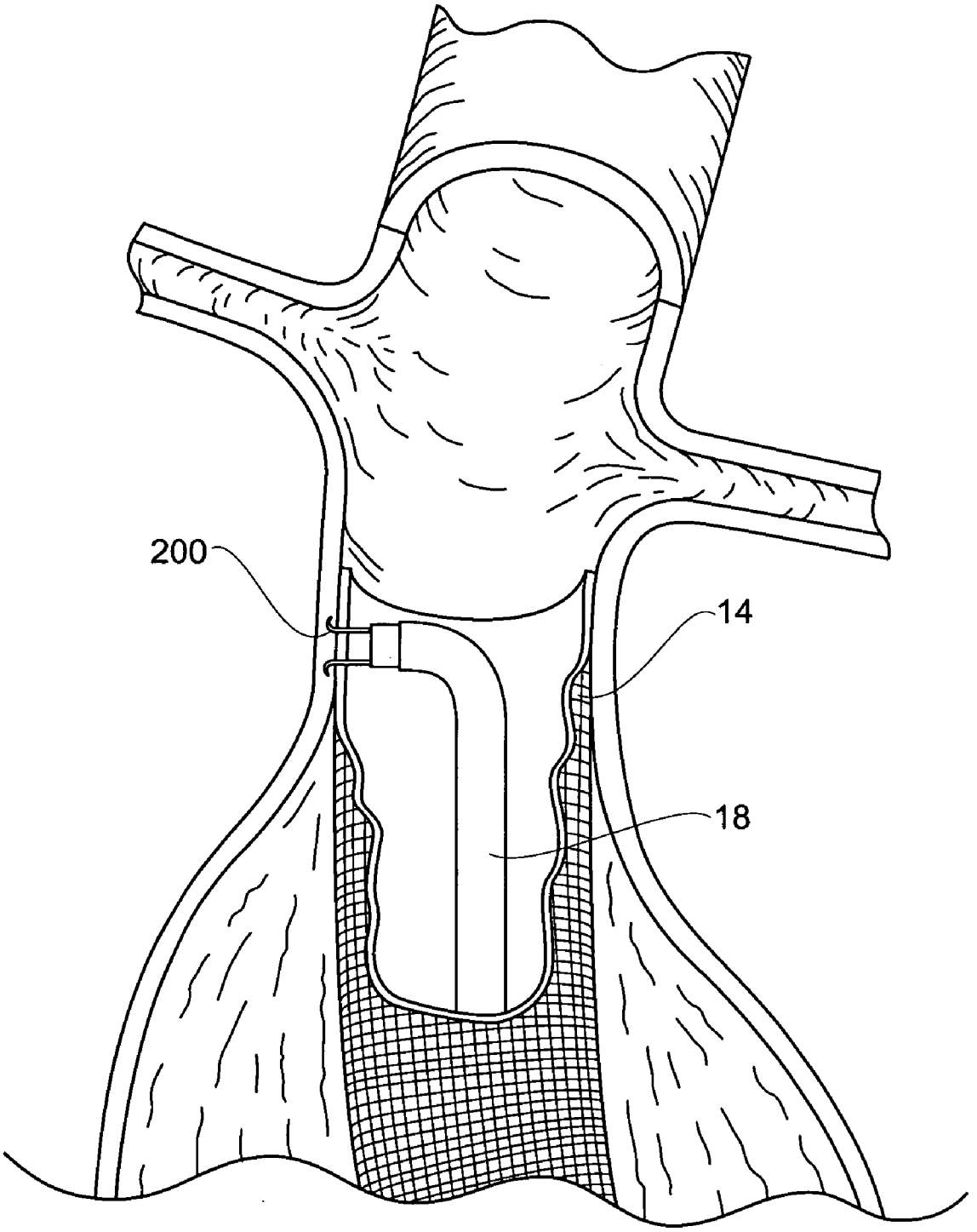


Fig. 43

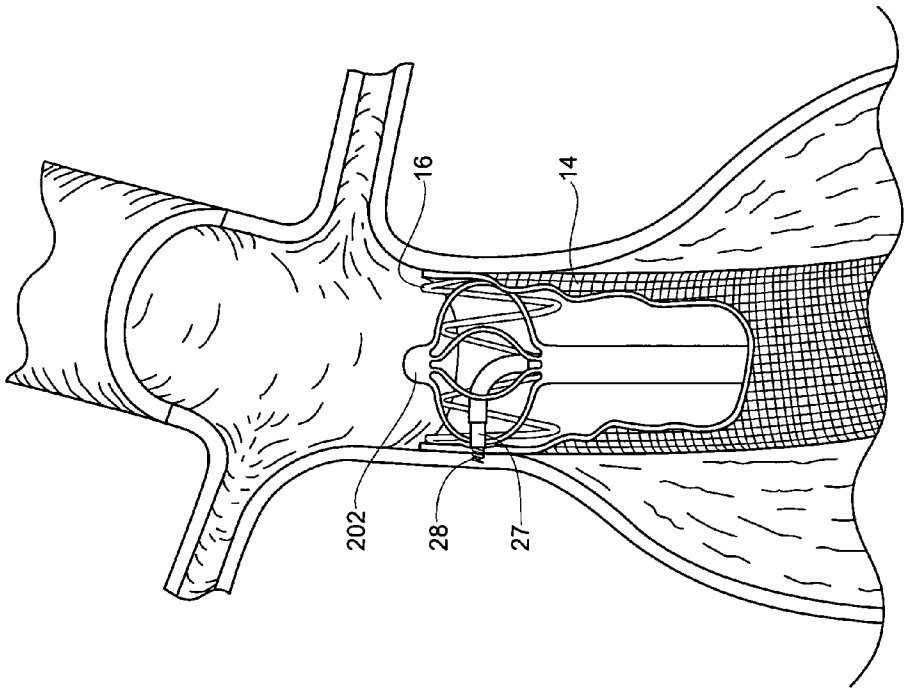


Fig. 44B

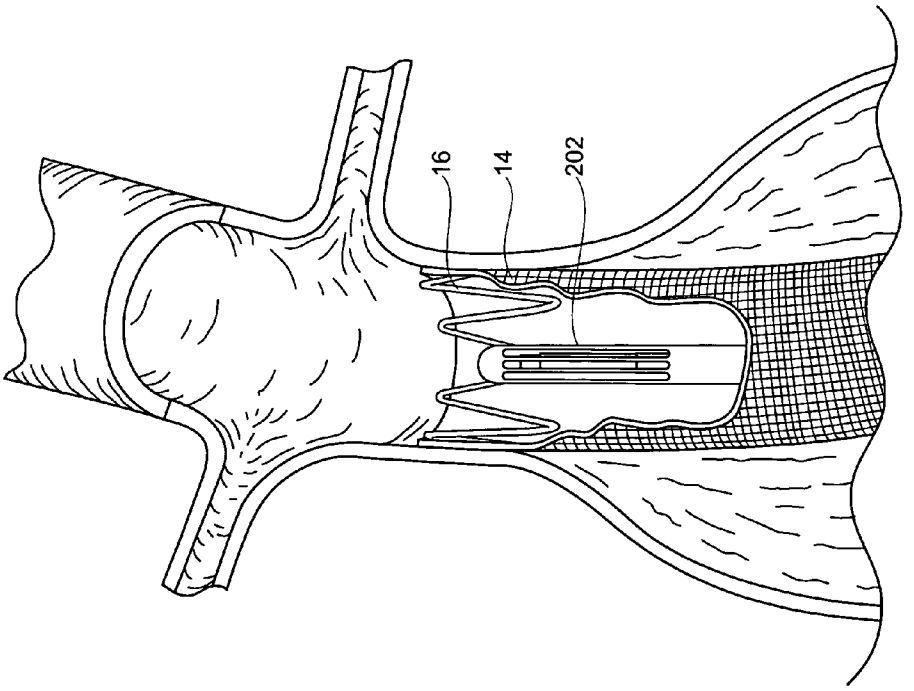


Fig. 44A

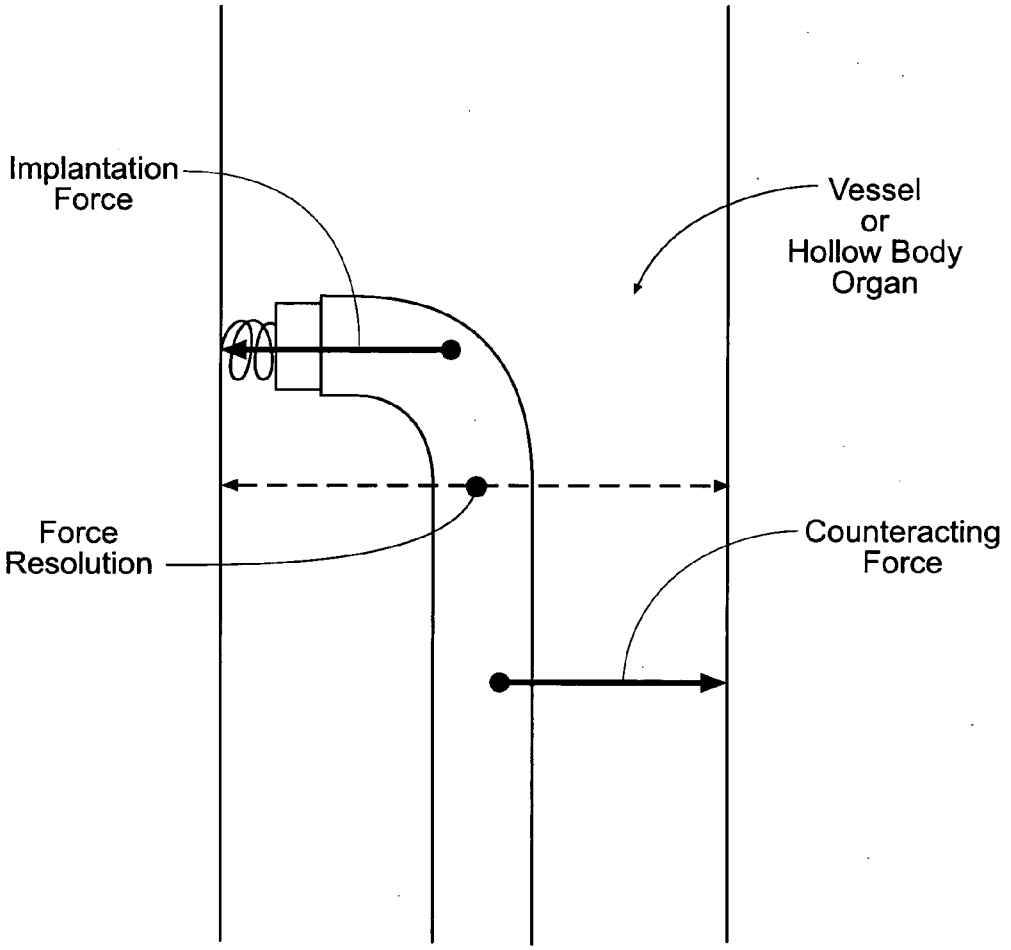

Implantation Force
Vessel or Hollow Body Organ
Force Resolution
Counteracting Force

Fig. 45

CATHETER-BASED FASTENER IMPLANTATION APPARATUS AND METHODS

RELATED APPLICATIONS

[0001] This application is a divisional of co-pending U.S. patent application Ser. No. 10/669,881, filed Sep. 24, 2003, entitled "Catheter-Based Fastener Implantation Apparatus and Methods With Implantation Force Resolution, which is a continuation-in-part of U.S. patent application Ser. No. 10/307,226, filed Nov. 29, 2002, and which is also a continuation-in-part of U.S. patent application Ser. No. 10/271,334, filed Oct. 15, 2002 (now U.S. Pat. No. 6,960,217), and which is also a continuation-in-part of U.S. patent application Ser. No. 10/099,149, filed Mar. 15, 2002, which is a divisional of U.S. patent application Ser. No. 09/787,135, filed Sep. 17, 1999, entitled "Endovascular Fastener Applicator," which claims the benefit of U.S. Provisional Application Ser. No. 60/101,050 filed Sep. 18, 1998.

FIELD OF THE INVENTION

[0002] The invention relates generally to the delivery of a prosthesis to a targeted site within the body, e.g., for the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel.

BACKGROUND OF THE INVENTION

[0003] The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation of an aneurysm. Left untreated, an aneurysm can grow in size and may eventually rupture.

[0004] For example, aneurysms of the aorta primarily occur in abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. Aneurysms can also occur in the thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

[0005] Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthetic graft, made either in a straight of bifurcated configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture. The prosthetic grafts for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The grafts are longitudinally unsupported so they can accommodate changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

[0006] Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prosthetic grafts for aortic aneurysms are delivered collapsed on a catheter through the femoral artery. These grafts are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open surgical aneurysm repair, intraluminally deployed grafts are not sutured to the native vessel, but rely on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force of the stent itself is utilized to hold the graft in position. These graft attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment.

SUMMARY OF THE INVENTION

[0007] The invention provides apparatus and methods for implanting a fastener in a targeted body region, e.g., within a hollow body organ or an intraluminal space.

[0008] One aspect of the invention provides an intraluminal fastener applier comprising a guide body having a longitudinal axis sized and configured for intraluminal deployment in a hollow body organ. The fastener applier includes an actuated assembly carried by the guide body that is selectively operable to generate an implantation force to implant at least one fastener into tissue within the hollow body organ. The actuated assembly includes a driven member extending generally along the longitudinal axis, which is sized and configured to engage a selected fastener. The actuated assembly also includes a drive member coupled to the driven member to impart the implantation force to the driven element in a direction that is at an angle to the longitudinal axis of the guide body.

[0009] In one embodiment, the actuated assembly includes structure that maintains the angle between the driven member and the drive member at about ninety-degrees or less.

[0010] In one embodiment, the actuated assembly includes structure that maintains a fixed angle between the driven member and the drive member, which can be, e.g., ninety-degrees or less.

[0011] In one embodiment, the actuated assembly includes a control mechanism to articulate the driven member relative to the drive member to adjust the angle.

[0012] In one embodiment, stabilization means is associated with the guide body for applying a resolving force in a direction different than the implantation force direction to resolve at least a portion of the implantation force within the hollow body organ.

[0013] Another aspect of the invention provides a method that deploys an intraluminal fastener applier hollow body organ. The intraluminal fastener applier comprises a guide body having a longitudinal axis sized and configured for intraluminal deployment in a hollow body organ. The fastener applier includes an actuated assembly carried by the guide body that is selectively operable to generate an implantation force to implant at least one fastener into tissue within the hollow body organ. The actuated assembly includes a driven member extending generally along the longitudinal axis, which is sized and configured to engage a selected fastener. The actuated assembly also includes a drive member coupled to the driven member to impart the implantation force to the driven element in a direction that is at an angle to the longitudinal axis of the guide body.

[0014] The method places the driven member into contact with tissue along a side wall of the hollow body while the longitudinal axis of the guide body remains substantially aligned with a long axis of the hollow body organ. The method operates the drive member to impart the implantation force to the driven element in the direction that is at an angle to the longitudinal axis of the guide body, to thereby implant

the fastener in the side wall while the guide body remains substantially aligned with the long axis of the hollow body organ.

[0015] In one embodiment, the method applies a resolving force at or near the drive member to resolve within the hollow body organ at least a portion of the implantation force.

[0016] In one embodiment, the guide body includes a catheter body having a column strength that applies a resolving force in a direction different than the implantation force direction to resolve at least a portion of the implantation force within the hollow body organ.

[0017] Another aspect of the invention provides a method that advances an intraluminal fastener applier to a location within a prosthesis that has been deployed at a target site along a side wall of an aorta where a diseased or damaged section exists. The intraluminal fastener applier comprises a guide body having a longitudinal axis sized and configured for intraluminal deployment in a hollow body organ. The fastener applier includes an actuated assembly carried by the guide body that is selectively operable to generate an implantation force to implant at least one fastener into tissue within the hollow body organ. The actuated assembly includes a driven member extending generally along the longitudinal axis, which is sized and configured to engage a selected fastener. The actuated assembly also includes a drive member coupled to the driven member to impart the implantation force to the driven element in a direction that is at an angle to the longitudinal axis of the guide body.

[0018] The method places the driven member in alignment with a desired fastening site on the prosthesis along the side wall of the aorta. Due to the angle, the longitudinal axis of the guide body remains substantially aligned with a long axis of the aorta. The method anchors the prosthesis to a side wall of the aorta by operating the drive member to impart the implantation force to the driven element in the direction that is at an angle to the longitudinal axis of the guide body. The method thereby implants the fastener into tissue in a side wall of the aorta, while the longitudinal axis of the guide body remains substantially aligned with a long axis of the aorta.

[0019] In one embodiment, the method applies a resolving force at or near the drive member to resolve within the aorta at least a portion of the implantation force.

[0020] In one embodiment, the guide body includes a catheter body having a column strength that applies a resolving force in a direction different than the implantation force direction to resolve at least a portion of the implantation force within the aorta.

[0021] According to any aspect of the invention, the fastener includes a tissue-piercing fastener having a sharpened distal tip for piercing and penetrating tissue. The tissue-piercing fastener can comprise, e.g., a helical fastener.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The invention will be understood from the following detailed description of preferred embodiments, taken in conjunction with the accompanying drawings, wherein:

[0023] FIG. **1** is a perspective view of one embodiment of an endovascular graft delivery device shown positioned within an abdominal aortic aneurysm;

[0024] FIG. **2** is a perspective view of one embodiment the deployment of an endovascular graft within the aneurysm of FIG. **1**;

[0025] FIG. **3** is a perspective view of a fully deployed straight endovascular graft of FIG. **2**;

[0026] FIG. **4** is a perspective view of a fully deployed bifurcated endovascular graft broken away to show an anchoring scaffold at one end;

[0027] FIG. **5** is a perspective view similar to FIG. **5** showing an alternative scaffold structure;

[0028] FIG. **6** is a perspective view showing one embodiment of a device for directing the fastener applier;

[0029] FIG. **7** is a perspective view showing the device of FIG. **6** upon insertion within the deployed endovascular graft of FIG. **3** with both the graft and scaffolding broken away;

[0030] FIG. **8** is a perspective view of the device of FIG. **6** showing activation of one embodiment of a stabilizing device attached to the directing device;

[0031] FIG. **9** is a perspective view of the control assembly in FIG. **8** articulating the directing device of FIG. **6**;

[0032] FIG. **10** is a perspective view of an alternative embodiment of the stabilization device of FIG. **8**;

[0033] FIG. **11** is a perspective view showing the activation of the alternative stabilization device of FIG. **10**;

[0034] FIG. **12** is a perspective view showing another embodiment of the stabilization device of FIG. **8**;

[0035] FIG. **13** is a perspective view showing activation of the stabilization device of FIG. **12**;

[0036] FIG. **14** is one embodiment of the fastener applier;

[0037] FIG. **14**A is an enlarged view of the distal end of the fastener applier shown in FIG. **14**, showing the details of the fastener drive mechanism;

[0038] FIG. **14**B is a section view of the interior of the handle of the fastener applier shown in FIG. **14**;

[0039] FIG. **15** is a perspective view of the fastener applier of FIG. **14** being positioned within directing device of FIG. **6**;

[0040] FIG. **16** is an enlarged cross-sectional view of one embodiment of the fastener applier of FIG. **14**;

[0041] FIG. **17** is an enlarged cross-sectional view of the attachment applier showing one embodiment of the proximal end of the helical fastener and the drive mechanism;

[0042] FIG. **18** is a enlarged perspective view of one embodiment of the helical fastener of FIG. **16**;

[0043] FIG. **19** is an enlarged view of the attachment applier showing one embodiment of the control assembly that activates the fastener applier;

[0044] FIG. **20** is an enlarged view of the attachment applied activated with a fastener implanted into the graft and vessel wall;

[0045] FIG. **21** is an enlarged view of the completed attachment of the proximal graft of FIG. **3** to the vessel wall with fasteners;

[0046] FIG. **22** is a perspective view of the graft of FIG. **4** completely attached to the vessel;

[0047] FIG. **23** is an enlarged section view of the drive mechanism of the fastener applier shown in FIG. **14**, showing a contact/force sensing assembly that disables the applier in the absence of desired contact between the fastener and a targeted tissue region;

[0048] FIG. **24** is an enlarged section view of the drive mechanism of the fastener applier shown in FIG. **14**, showing the contact/force sensing assembly enabling use of the applier in response to desired contact between the fastener and the targeted tissue region;

[0049] FIGS. **25**A and **25**B are enlarged views of the distal end of a fastener applier showing the details of an alternative embodiment of the fastener drive mechanism;

[0050] FIG. **26**A is an enlarged section view of the drive mechanism of the fastener applier shown in FIGS. **25**A and

25B showing a contact/force sensing assembly that disables the applier in the absence of desired contact between the fastener and a targeted tissue region;

[0051] FIGS. **26**B and **26**C are enlarged section views of the drive mechanism of the fastener applier shown in FIGS. **25**A and **25**B, showing the contact/force sensing assembly enabling use of the applier in response to desired contact between the fastener and the targeted tissue region;

[0052] FIG. **27** is a perspective view of a helical fastener that can be used in association with the fastener applier shown in FIGS. **14**, **23**, and **24**;

[0053] FIG. **28**A is a perspective view of a helical fastener that can be used in association with the fastener applier shown in FIGS. **25**A and **25**B;

[0054] FIG. **28**B is perspective view of a helical fastener that can be used in association with the fastener applier shown in FIGS. **26**A to **26**C;

[0055] FIG. **29** is an enlarged side view, partially in section, of a fastener applier having an angled applicator end that can be used to deploy the helical fastener shown in FIG. **27** without use of a separate directing device;

[0056] FIG. **30** is an enlarged side view, partially in section, of an alternative embodiment of an angled fastener applier that can be used to deploy the helical fastener shown in FIG. **27** without use of a separate directing device;

[0057] FIG. **31** is an enlarged side view, partially in section, of an alternative embodiment of an angled fastener applier that can be used to deploy the helical fastener shown in FIG. **27** without use of a separate directing device, the fastener applier having an articulating applicator end;

[0058] FIG. **32** is a perspective view of an endovascular prosthesis shown positioned within an abdominal aortic aneurysm, the prosthesis including an integrated fastener assembly;

[0059] FIG. **33** is a perspective view of the endovascular prosthesis shown in FIG. **32**, with an intraluminal tool deployed to operatively interact with the integrated fastener assembly, to temporarily or permanently anchor the prosthesis to the wall of the vessel;

[0060] FIG. **34** is a side view of a fastener that forms a part of the integrated fastener assembly shown in FIG. **33**, the fastener having a stem, which is shown in a normally spread-apart condition before its association with the integrated fastener assembly;

[0061] FIG. **35** is a side view of the fastener shown in FIG. **34**, the fastener stem now being shown in a closed condition and housed within a grommet that forms a part of the integrated fastener assembly;

[0062] FIGS. **36** and **37** are side views showing the use of the intraluminal tool shown in FIG. **33** to apply force to drive the fastener from its position shown in FIG. **35** and through the vessel wall;

[0063] FIG. **38** is the integrated fastener assembly after deployment to anchor a prosthesis to a vessel wall;

[0064] FIG. **39** is a side view showing the use of a tracking wire to guide a intraluminal tool into contact with a fastener, so that force can be applied to drive the fastener through the vessel wall;

[0065] FIG. **40** is an embodiment of a prosthesis delivery catheter for a prostheses in which the stent structure covers only a portion of the prosthesis, the catheter including an array of stabilization struts to help hold the prosthesis in position against the flow of blood;

[0066] FIG. **41** is another embodiment of a prosthesis delivery catheter for a prostheses in which the stent structure covers only a portion of the prosthesis, the catheter including an array of inverted stabilization struts to help hold the prosthesis in position against the flow of blood; and

[0067] FIG. **42** is another embodiment of a prosthesis delivery catheter for a prostheses in which the stent structure covers only a portion of the prosthesis, the catheter including a stabilization basket to help hold the prosthesis in position against the flow of blood.

[0068] FIG. **43** is an elevation view of an alternative stabilization device, comprising tissue gripping elements.

[0069] FIGS. **44**A and **44**B are elevation views of a fastener applier that carries an expandable basket-like structure that serves as a stabilization device, FIG. **44**A showing the basket-like structure in a generally collapsed condition for intravascular deployment and FIG. **44**B showing the basket-like structure in an expanded condition against a vessel wall and graft for deployment of a fastener.

[0070] FIG. **45** shows, in diagrammatic fashion, the resolution of an implantation force with a counteracting force within a vessel or hollow body organ.

DETAILED DESCRIPTION OF THE INVENTION

I. Delivering a Prosthesis

[0071] FIG. **1** depicts an endovascular graft delivery catheter **10** as it is being positioned over a guidewire **12** in a body lumen. The catheter **10** carries a prosthesis **14** (see FIG. **2**), which is placed at a targeted site, e.g., by radial expansion of the prosthesis **14** (see FIG. **3**). After partial or complete expansion of the prosthesis **14**, one or more fasteners **28** (see FIGS. **15** and **16**) are introduced by a fastener attachment assembly (as will be described in greater detail later) to anchor the prosthesis **14** in place.

[0072] For the purposes of illustration, FIG. **1** shows the targeted site as being within an abdominal aortic aneurysm **11**. The targeted site can be elsewhere in the body. In the illustrated arrangement, the prosthesis **14** takes the form of an endovascular graft.

[0073] FIG. **2** depicts the initial stage of graft deployment at the targeted site. While the deployment method can vary, in the illustrated embodiment, the delivery catheter **10** has a movable cover **13**, which overlays the graft **14**. When the cover **13** is pulled proximally, the graft **14** is free to radially expand, thereby enlarging to contact the internal walls of the blood vessel. The graft **14** is shown to be self-expanding. Alternatively, the graft **14** can utilize an expanding member, such as a balloon or mechanical expander.

[0074] The process of graft deployment is continued, until the graft **14** is fully deployed or partially deployed within the vessel. The graft **14** can be sized and configured to be either straight or bifurcated form. FIG. **3** depicts a completely deployed straight graft **14**. FIG. **4** depicts a completely deployed bifurcated graft **15**.

[0075] A. The Prosthesis

[0076] The graft **14** desirably incorporates a support frame or scaffold **16**. The scaffold **16** may be elastic, e.g., comprised of a shape memory alloy elastic stainless steel, or the like. For elastic scaffolds, expanding typically comprises releasing the scaffolding from a constraint to permit the scaffold to self-expand at the implantation site. In the illustrated arrangement, the cover **13** serves as a radial constraint. Alternatively, placement of a tubular catheter, delivery sheath, or the like

over the scaffold **16** can serve to maintain the scaffold in a radially reduced configuration. In this arrangement, self-expansion of the scaffold **16** is achieved by pulling back on the radial constraining member, to permit the scaffold **16** to assume its larger diameter configuration.

[0077] Alternatively, the scaffold **16** may be constrained in an axially elongated configuration, e.g., by attaching either end of the scaffold to an internal tube, rod, catheter or the like. This maintains the scaffold **16** in the elongated, reduced diameter configuration. The scaffold **16** may then be released from such axial constraint in order to permit self-expansion.

[0078] Alternatively, the scaffold **16** may be formed from a malleable material, such as malleable stainless steel of other metals. Expansion may then comprise applying a radially expansive force within the scaffold to cause expansion, e.g., inflating a scaffold delivery catheter within the scaffold in order to affect the expansion. In this arrangement, the positioning and deployment of the endograft can be accomplished by the use of an expansion means either separate or incorporated into the deployment catheter. This will allow the endograft to be positioned within the vessel and partially deployed while checking relative position within the vessel. The expansion can be accomplished either via a balloon or mechanical expansion device. Additionally, this expansion stabilizes the position of the endograft within the artery by resisting the force of blood on the endograft until the endograft can be fully deployed.

[0079] The graft **14** may have a wide variety of conventional configurations. It can typically comprise a fabric or some other blood semi-impermeable flexible barrier which is supported by the scaffold **16**, which can take the form of a stent structure. The stent structure can have any conventional stent configuration, such as zigzag, serpentine, expanding diamond, or combinations thereof. The stent structure may extend the entire length of the graft, and in some instances can be longer than the fabric components of the graft. Alternatively, the stent structure can cover only a small portion of the prosthesis, e.g., being present at the ends. The stent structure may have three or more ends when it is configured to treat bifurcated vascular regions, such as the treatment of abdominal aortic aneurysms, when the stent graft extends into the iliac arteries. In certain instances, the stent structures can be spaced apart along the entire length, or at least a major portion of the entire length, of the stent-graft, where individual stent structures are not connected to each other directly, but rather connected to the fabric or other flexible component of the graft.

[0080] One illustrative embodiment of the graft scaffold **16** or stent structure is illustrated in the area broke away in FIG. **4**. Here, the stent structure is in the form of a simple zigzag pattern, however it is contemplated that the stent design could involve more complex patterns **17** as depicted in FIG. **5**. Although only one stent structure within the graft is depicted, in FIGS. **4** and **5**, it is contemplated that multiple independent stent structures could be incorporated into the graft, as previously described.

[0081] FIG. **40** shows an embodiment of a prosthesis delivery catheter **600** for a prostheses **14** in which the stent structure **16** covers only a portion of the prosthesis, e.g., being present only at the ends. As shown in FIG. **40**, the prosthesis delivery catheter **600** (which is shown deployed over a guidewire **610**) includes an array of stabilization struts **612** that are releasably coupled to the stent structure **16** at the end of the prosthesis **14**, e.g., by sutures that can be released by pulling on a drawstring (not shown) that passes through a lumen in the catheter **600**. The stabilization struts **612** hold the self-expanding stent structure **16** in position against the vessel wall **34**, while the remainder of the prosthesis **14** is being deployed (by withdrawal of a delivery sheath **614**). The struts **612** support the stent structure **16** (and thus the overall prosthesis **14**) against the force of blood flow through the vessel during prosthesis deployment. The catheter **600** can also include a nose cone **618** at its distal end to diffuse blood flow toward the vessel wall, to aid in supporting the prosthesis **14** during its deployment. Upon deployment of the prosthesis **14**, the struts **612** can be detached from the stent structure **14** by pulling upon the drawstring to release the sutures, and the catheter **600** is withdrawn over the guidewire **610** through the delivery sheath **614** (the struts **612**, freed from the stent structure **16**, fold back upon the catheter **600** during passage through the delivery sheath **614**).

[0082] FIG. **41** shows an alternative embodiment of a prosthesis delivery catheter **700** for a prostheses **14** in which the stent structure **16** covers only a portion of the prosthesis, e.g., being present at the ends. As shown in FIG. **40**, the prosthesis delivery catheter **700** (which is also shown deployed over a guidewire **710**) includes an array of inverted stabilization struts **712** that are releasably coupled to the stent structure **16** at the end of the prosthesis **14**, e.g., by sutures that can be released by pulling on a drawstring (not shown) that passes through a lumen in the catheter **700**. The inverted stabilization struts **712**, like the struts **612** shown in FIG. **40**, hold the self-expanding stent structure **16** in position against the vessel wall **34**, while the remainder of the prosthesis **14** is being deployed (by withdrawal of a delivery sheath **714**). Like the catheter **600** in FIG. **40**, the catheter **700** can also include a nose cone **718** at its distal end to diffuse blood flow toward the vessel wall. Upon deployment of the prosthesis **14**, the struts **712** are detached from the stent structure **14** by pulling upon the drawstring not shown), and the catheter **700** is withdrawn over the guidewire **710** through the delivery sheath **714** (the struts **612**, freed from the stent structure **16**, fold back upon the catheter **600** during passage through the delivery sheath **614**).

[0083] FIG. **42** shows another alternative embodiment of a prosthesis delivery catheter **800** for a prostheses **14** in which the stent structure **16** covers only a portion of the prosthesis, e.g., being present at the ends. As shown in FIG. **42**, the prosthesis delivery catheter **800** (which is also shown deployed over a guidewire **810**) includes a self-expanding stabilization basket **812**. The stabilization basket **812** holds the self-expanding stent structure **16** in position against the vessel wall, while the remainder of the prosthesis **14** is being deployed (by withdrawal of a delivery sheath **814**). Like the catheters **600** and **700** in FIGS. **40** and **41**, the catheter **800** can also include a nose cone **818** at its distal end to diffuse blood flow toward the vessel wall. Upon complete deployment of the prosthesis **14**, the stabilization basket can be placed into a collapsed condition by withdrawal through the delivery sheath **814**, as the catheter **800** is withdrawn over the guidewire **810**.

[0084] In all of the just-described embodiments, if the prosthesis **14** has been fully deployed prior to the introduction of the fasteners **28**, and/or the prosthesis delivery catheter **600**, **700**, or **800** has been withdrawn from the targeted site, the guidewire **610**, **710**, **810** can be subsequently used to deploy a fastener attachment assembly for the prosthesis **14** to the targeted site, as will be described in greater detail next. Alter-

natively, if the prosthesis **14** has not been fully deployed at the time the fasteners **28** are applied—or if, for whatever reason, withdrawal of the prosthesis delivery catheter **600**, **700**, or **800** is not desired—the prosthesis delivery catheter **600**, **700**, or **800**, and its respective guidewire **610**, **710**, or **810**, can be retained at the targeted site, while a fastener attachment assembly for the prosthesis **14** is introduced into the targeted site over a separate guidewire from another body access point. In this arrangement, deployment of the prosthesis **14** and/or withdrawal of the prosthesis delivery catheter **600**, **700**, or **800** can be completed after the fasteners **28** have been applied.

II. Fastening the Prosthesis

[0085] In a desired embodiment, a fastener attachment assembly is provided that makes possible intraluminal fastener attachment. The attachment assembly can be variously constructed.

[0086] A. Two Component Fastener Guide and Attachment Assembly

[0087] In one arrangement, the fastener attachment assembly comprises a fastener guide or directing component **18** and a fastener applier component **27**. The guide component **18** desirably has a steerable or deflectable distal tip, which is initially deployed over the guidewire **12**. In use in the illustrated embodiment, the guidewire **12** that is used to deliver and position the prosthesis **14** remains within the vessel for subsequent deployment of the fastener guide component **18**. Alternatively, another guidewire from a different body access point can be used for deployment of the fastener guide component **18**. In either arrangement, the fastener applier component **27** is desirably deployed through the guide component **18** after removal of the guidewire over which the guide component **18** has been delivered. The fastener applier **27** carries at least one fastener **28** and a fastener drive mechanism **100** for advancing the fastener **28**, so that it penetrates the prosthesis **14** and underlying vessel wall, to thereby anchor the prosthesis **14** firmly in place.

[0088] 1. Fastener Directing Component

[0089] FIG. **6** depicts one embodiment of the directing or guide component **18** that forms a part of the fastener attachment assembly. The component **18** includes an interior lumen that accommodates passage of an obturator **19**. The obturator **19** has a lumen to allow for delivery of the directing component **18** over the guidewire **12**, as shown in FIG. **7**. Once deployed in a desired location, the obturator **19** and guidewire **12** are removed, leaving the central lumen open for passage of the fastener applier component **27**, as will be described later.

[0090] In the illustrated embodiment (see FIG. **8**), the directing component **18** includes a control assembly **21**. In one embodiment the control assembly **21** features a movable wheel or lever **22**, which operate interior steering wires in a conventional fashion to deflect the distal tip **23** of the directing component **18** toward a desired location, as seen in FIG. **9**. It is contemplated that the control assembly **21** for the directing component **18** could be activated mechanically, electrically, hydraulically or pneumatically. The control assembly **21** has a through lumen to allow for the passage of the obturator **19** (as just described) and the fastener applier component **27**, as will be described next.

[0091] 2. Fastener Applier Component

[0092] FIG. **14** shows one embodiment of the fastener applier component **27** that forms a part of the fastener attachment assembly. As FIG. **15** depicts, the fastener applier component **27** is deployed through the central lumen of the directing component **18** to the site where a fastener **28** will be installed.

[0093] Located at the distal end of the fastener applier component **27** (see FIG. **14**) is a fastener drive mechanism **100**. In the illustrated embodiment (see FIG. **14**A), the drive mechanism **100** includes a driver **29** that is coupled to a carrier **102**. The coupling between the driver **29** and carrier **102** can take different forms—e.g., magnets, graspers, or other suitable mechanical connection. In the embodiment illustrated in FIG. **14**A, the driver **29** and carrier **102** are integrally connected as a single unit.

[0094] The carrier **102** is sized and configured to engage a selected fastener **28**. In FIG. **14**A, the fastener takes the form of a helical fastener of the type shown in FIGS. **18** and **27**. As best shown in FIG. **27**, and as will be described in greater detail later, the helical fastener **28** in FIG. **26** is an open coil **148** with a sharpened leading tip **142**. The proximal end **144** of the fastener **28** includes an L-shaped leg **146**. The L-shape leg **146** desirably bisects the entire interior diameter of the coil **148**; that is, the L-shaped leg **146** extends completely across the interior diameter of the coil **148**, as FIG. **27** shows. The L-shaped leg **146** serves to engage the carrier **102** of the fastener applier **27**, which rotates the helical fastener to achieve implantation. The L-shaped leg **146** also serves as a stop to prevent the helical fastener from penetrating too far into the tissue.

[0095] The carrier **102** in FIG. **14**A includes a slot **180**, which receives the L-shaped leg **146** to couple the fastener **28** for rotation with the carrier **102**. The turns of the coil **148** rest in complementary internal grooves **32** that surround the carrier **102**. The grooves **32** could be positioned along the entire length of the fastener **28** or within a portion of its length.

[0096] The actuation of the drive mechanism **100** can, of course, be accomplished in various ways, e.g., mechanical (i.e., manual or hand-powered), electrical, hydraulic, or pneumatic. In the illustrated embodiment (see FIG. **14**B), a drive cable **30** couples the fastener driver **29** to an electric motor **106** carried in the applier handle **108**. The drive cable **30** is desirably made of a suitable material that allows for both bending and rotation. Driven by the motor **106** (which is, in turn, under the control of motor control unit **31**, as will be described later), the drive cable **30** rotates the driver **29** and, with it, the carrier **102**. The carrier **102** imparts rotation and torque to the helical fastener **28** for implantation in tissue.

[0097] FIG. **16** is an enlarged cross-sectional view of fastener applier **27** and directing device **18**. FIG. **17** is an enlarged cross-sectional view of the fastener applier **27** with a cross-section of the fastener driver **29** depicting the engagement between the fastener driver **29** and helical fastener **28**. FIG. **19** depicts the fastener applier **27** during activation of the fastener drive mechanism **100**. Activation of the drive mechanism **100** rotates, as a unit, the drive shaft **30**, the driver **29**, the carrier **102**, and helical fastener **28**. This rotation causes the helical fastener **28** to travel within the internal grooves **32** of the fastener applier and into the prosthesis **14** and vessel wall **34** (see FIG. **20**). FIG. **21** illustrates a completed helical fastener **28** attachment of the graft **14** to the vessel wall **34**.

[0098] In use, the applier component **27** is advanced through the directing component **18** and into contact with the prosthesis. The operator actuates the control unit **31** by contacting a control switch **110** (see FIGS. **14** and **14**B). This action causes the helical fastener **28** to be rotated off the carrier **102** and through the prosthesis **14** and into the vessel

wall **34**. The motor control unit **31** desirably rotates the drive cable **30** a specific number of revolutions with each activation command. This can be accomplished by incorporating a mechanical or electrical counter.

[0099] With the deployment of a fastener **28**, the fastener applier component **27** is retrieved through the directing component **18**, and another fastener **28** is loaded into the carrier **102**. The directing component **18** is repositioned, and the applier component **27** is advanced again through the directing component **18** and into contact with the prosthesis **14**. The operator again actuates the control unit **31** by contacting the control switch **110** to deploy another fastener **28**. This process is repeated at both proximal and/or distal ends of the prosthesis **14** until the prosthesis **14** is suitably attached and sealed to the vessel wall **34**. It is contemplated that from about two to about twelve fasteners **28** may be applied at each end of the prosthesis **14** to affect anchorage. The fasteners **28** can be applied in a single circumferentially space-apart row, or may be applied in more than one row with individual fasteners being axially aligned or circumferentially staggered.

[0100] FIG. **22** illustrates a perspective view of a graft prosthesis attached to the vessel wall both proximally and distally. It is contemplated that the present invention can be used for graft attachment of both straight and bifurcated grafts within the aorta and other branch vessels.

[0101] An alternative embodiment of the drive mechanism **100** is shown in FIGS. **25**A and **25**B. In this embodiment, the driver **29** is coupled to a carrier **150**, which forms a part of the helical fastener **28** itself, as also shown in FIG. **28**A. As shown in FIG. **28**A, the helical fastener **28** is, like the fastener shown in FIG. **27**, an open coil **148** with a sharpened leading tip **142**. The proximal end **144** of the fastener **28** includes the carrier **150**.

[0102] The carrier **150** includes a slot **182**. The slot **182** engages a drive flange **184** on the driver **29** (see FIG. **25**A) to impart rotation of the driver **29** to rotation of the helical fastener **28** during the implantation process. Like the L-shaped leg of the fastener shown in FIG. **27**, the carrier **150** also serves as a stop to prevent the helical fastener from penetrating too far into the tissue.

[0103] The coupling engagement between the carrier **150** and the driver **29** could be accomplished in various ways, e.g., by separate graspers or grippers, a magnetic couple, or any other suitable mechanical connecting means. In the illustrated embodiment, the driver **29** is made of a magnetized material, and the carrier **150** is made from a material that is magnetically attracted toward the magnetized material. Of course, a reverse arrangement of magnetized and magnetically attracted materials could be used.

[0104] In this arrangement, the motor coupling **132** between the drive cable **30** and the motor **106** accommodates axial displacement of the motor cable **30** (left and right in FIGS. **25**A and **25**B) without interrupting the drive connection with the motor **106**. With the distal tip of the applier device **27** in contact with the prosthesis **14** (see FIG. **25**A), the operator actuates the control unit **31** by contacting a control switch **110**. The control unit **31** commands the motor **106** to rotate the drive cable **30** to impart rotation to the driver **29** and the magnetically attached helical fastener **28**. This action causes the magnetically attached helical fastener **28** to be rotated into prosthesis **14** and the vessel wall **34** (see FIG. **25**B). Due to the magnetic coupling, as the fastener **28** is deployed to the left in FIG. **25**B, the driver **29** moves in tandem with carrier **150** (also to the left in FIG. **25**B). Due to the magnetic coupling between the carrier **150** and the driver **29**, the operator must exert a deliberate separation force to decouple the carrier **150** (and, with it, the fastener **28**) from the driver **29**. This arrangement prevents inadvertent release of a fastener **28**.

[0105] As before described, with the deployment of a fastener **28**, the applier component **27** is retrieved through the directing device **18**, and another fastener **28** is magnetically coupled to the driver **29**. The directing component **18** is repositioned, and the applier component **27** is advanced again through the directing component **18** and into contact with the prosthesis **14**. The operator again actuates the control unit **31** by contacting a control switch **110** to deploy another fastener **28**. This process is repeated at both proximal and/or distal ends of the prosthesis **14** until the prosthesis **14** is suitably attached and sealed to the vessel wall **34**.

[0106] As indicated in the above description, the outer diameter of the applier component **27** is desirably sized and configured to pass through the lumen of the directing component **18**, which can take the form of a suitable steerable guide catheter, to direct the applier component **27** to the desired location. As also above described, the applier component **27** is desirably configured to implant one fastener **28** at a time (a so-called "single fire" approach). This is believed desirable, because it reduces the complexity of the design and accommodates access of the applier component **27** through tortuous anatomy. A fastener applier component **27** which carries a single fastener can have a lower profile and may be more effective and less traumatic than fastener appliers which carry multiple fasteners. Still, in alternative embodiments, the applier component **27** may, if desired, be configured to carry multiple fasteners. Moreover, the fastener applier **27** may simultaneously deploy multiple fasteners in the preferred circumferentially spaced-apart space pattern described above.

[0107] 3. Force Resolution

[0108] Penetration and implantation of the fastener **28** into tissue using the applier component **27** requires the applier component **27** to exert an implantation force at or near the prosthesis **14** and vessel wall **34**. In the illustrated embodiment, the applier component **27** comprises a driven member for implanting a helical fastener. However, the applier component **27** can comprise virtually any actuated member for exerting an implantation force using, e.g., ultrasonic, laser, or impact concepts.

[0109] Regardless of the particular way that the implantation force is generated, the implantation force of the applier component **27** is desirably resolved in some manner to provide positional stability and resist unintended movement of the applier component **27** relative to the implantation site. Stated differently, a resolution force is desirably applied to counteract and/or oppose the implantation force of the applier component **27**. It is desirable to resolve some or all or a substantial portion of the implantation force within the vessel lumen (or other hollow body organ) itself, and preferably as close to the implantation site as possible.

[0110] The tubular body of the directing component **18** and/or the shaft of the fastener applier component **27** can be sized and configured to possess sufficient column strength to resolve some or all or at least a portion of the implantation force within the vessel lumen or hollow body organ. In addition, or alternatively, the directing component **18** and/or the fastener applier component **27** can include stabilization

means **20** for applying a counteracting force at or near the driven member of the fastener applier component **27** that implants the fastener.

[0111] The illustrated embodiments show various alternative embodiments for the stabilization means **20**. As shown in FIGS. **8** and **9**, the stabilization means **20** takes the form of a spring-loaded arm on the directing component **18** for contacting tissue. In this arrangement, the spring-loaded stabilizing means **20** is positioned for deployment when the obturator **19** and guidewire **12** are removed from the directing component **18** (see FIG. **8**). In the alternative embodiment shown in FIGS. **10** and **11**, the stabilization means **20** takes the form of a movable strut assembly **24** on the directing component **18**, which contacts tissue. In this alternative arrangement, the movable strut assembly **24** can be activated, e.g., through a lever **25** on the control assembly (see FIG. **11**). In both embodiments (FIGS. **7** and **10**) the stabilizing device **20** is distal to the end of the directing component **18**. In the alternative embodiment shown in FIG. **12**, the stabilization means **20** takes the form of an expandable member **26** positioned adjacent the distal tip of the directing component **18**. In this alternative arrangement (see FIG. **13**), the expandable member **26** can be activated, e.g., through a lever **25** on the control assembly **21**. However it also contemplated that this type of stabilizing means **20** could also be inflatable. In another alternative embodiment (see FIG. **43**), the stabilization means **20** includes means **200** carried by the directing component **18** and/or the fastener applier component **27** for grasping and/or anchor to the wall of the hollow body organ, vessel or prosthesis prior to implanting a fastener. The grasping or anchoring means **200** can include penetrating needles and/or hooks or barbs that are deployed by a control assembly or the like prior to implantation of a fastener.

[0112] In all embodiments the stabilizing means **20** could be use to stabilize the directing component **18** either concentrically or eccentrically within the vessel.

[0113] Of course, any of these alternative forms of the stabilization means **20** can be associated with the fastener applier **27** in the same fashion they are shown to be associated with the directing component **18**, or take some other form of a stabilization mechanism having the equivalent function. In yet another embodiment, the stabilization means **20** can take the form of a separate stabilization device used in cooperation with the directing component **18** and/or the fastener applier component **27**. In this arrangement, the separate stabilization device could incorporate any of the alternative forms of the stabilizing devices described above, or some other form of stabilization mechanism.

[0114] For example (see FIGS. **44**A and **44**B), the fastener applier **27** can carry about its distal end an expandable basket **202** or basket-like structure. The basket structure **202** surrounds the fastener drive mechanism **100**, which has been previously described. The basket structure **202** is operable between a low profile, generally collapsed condition (shown in FIG. **44**A) and an expanded profile condition (shown in FIG. **44**B) about the fastener drive mechanism **100**.

[0115] In the generally collapsed condition, the fastener applier **27** can be deployed through a vessel into proximity to a graft **14**. FIG. **44**A shows the graft **14** to include a self-expanding scaffold **16**. When in the generally collapsed condition, the fastener applier **27** can be deployed in its low profile state through the vasculature to the targeted graft site either by itself, or through an associated directing component **18** or suitable guide sheath, which can steerable or non-steerable.

[0116] When situated at the graft site (see FIG. **44**B), the basket structure **202** can be expanded (e.g., by a suitable push-pull control mechanism) into contact with the graft **14**. The fastener applier **27** can be maneuvered within the expanded basket structure **202** into contact with the graft **14** and operated to deploy a fastener **28**, as previously described. The basket structure **202** serves to resolve at least some of the implantation force to provide positional stability and resist unintended movement of the fastener applier **27**.

[0117] In all these alternative embodiments, the stabilization means **20** functions to apply a substantially equal and opposite counteracting resolution force within a vessel (see FIG. **45**) to a location on the vessel wall, desirably generally opposite to the implantation site. As also just described, the column strength of the associated directing component **18** and/or fastener applier **27** can also serve in conjunction with the stabilization means **20** to resolve the intraluminal implantation force at the implantation site.

[0118] The force resolving function that the guiding component **18** and/or the fastener applier component **27** provide serves to counteract or oppose or otherwise resolve the tissue penetration and implantation force of the applier component **27**. The force resolving function thereby also resists movement of the applier component **27** relative to the implantation site, thereby making possible a stable and dependable intraluminal (or intra organ) fastening platform.

[0119] 4. Prosthesis/Tissue Contact Sensing

[0120] The fastener applier component **27** desirably incorporates a function that prevents actuation of the motor **106** until the tip of the applier component **27** is in a desired degree of contact with the prosthesis or tissue surface. This prevents inadvertent discharge of a fastener **28** and/or separation of the fastener **28**. This function can be implemented, e.g., using a contact or force sensor, which is either mechanical or electrical in design.

[0121] When the fastener applier component **27** is of the type shown in FIGS. **14**A. **14**B, and **14**C (see FIGS. **23** and **24**), the contact or force sensing function can, e.g., utilize the distal tip **120** of the carrier **102** to transmit a contact force. This force can be transmitted to a force or contact sensing switch **122** located, e.g., within the fastener applier handle **108**. In this arrangement, the switch **122** can be part of the electrical circuit between the actuator switch **110** and the control unit **31**.

[0122] In the illustrated embodiment, the switch **122** includes a stationary switch element **128** (coupled to the interior of the handle **108**) and a movable switch element **130** (carried by the drive cable **31**). In this arrangement, the motor coupling **132** between the drive cable **30** and the motor **106** accommodates axial displacement of the motor cable **30** (left and right in FIGS. **23** and **24**) without interrupting the drive connection with the motor **106**. The drive cable **30** is coupled by a bearing **134** to the movable switch element **130**, so that the switch element **130** moves in response to movement of the drive cable **30**. The stationary switch element **128** is not coupled to the movable drive cable **30**, which slidably passes through the switch element **130**.

[0123] Due to this arrangement, axial displacement of the drive cable **30** moves the switch element **130** relative to the switch element **128**. More particularly, displacement of the drive cable **30** to the left in FIG. **23** moves the switch element

130 to the left, away from the switch element 128. Conversely, displacement of the drive cable 30 to the right in FIG. 23 moves the switch element 130 to the right, toward the switch element 128.

[0124] A spring 126 normally biases the switch elements 128 and 130 apart, comprising an electrically opened condition. In this condition, operation of the actuating switch 110 does not serve to actuate the control unit 31, as the electrically open switch 122 interrupts conveyance of the actuation signal to the motor control unit 31. When the switch elements 128 and 130 are in the electrically opened condition, the drive cable 30 is displaced to the left to position the carrier tip 120 beyond the distal tip 124 of the fastener applier 27. The carrier tip 120 therefore makes contact with the prosthesis 14 or tissue in advance of the applier tip 124.

[0125] When the carrier tip 120 contacts the surface of the prosthesis or tissue with sufficient force to compress the spring 126, the drive cable 30 is displaced against the biasing force of the spring to the right in FIG. 23. This moves the switch element 130 to the right. Ultimately, contact between the switch elements 128 and 130 will occur, as shown in FIG. 24. The contact establishes an electrically closed condition. In this condition, operation of the actuating switch 110 serves to actuate the control unit 31. As shown in FIGS. 23 and 24, a contact screw 136 can be provided to adjust the amount of displacement required to close the switch elements 128 and 130.

[0126] Upon removal of contact force, or in the absence of sufficient contact force, the spring 126 urges the switch elements 128 and 130 toward the electrically opened condition. The distal tip of the carrier 102 is located distally beyond the distal tip of the applier 27.

[0127] It should be appreciated that the translation of movement of the carrier tip 120 to the switch 122 need not occur along the entire length of the drive cable 30. For example, the switch 122 can be located in a translation space between the carrier 102 and the driver 29. In this arrangement, the driver 29, coupled to the drive cable 30 need not accommodate axial displacement. Instead, relative movement of the carrier 102 toward the driver 29 in response to contact with the prosthesis 14 will mechanically couple the carrier 10 with the driver 29 (e.g., through a slot and flange connection similar to that shown in FIGS. 25A and 25B), while also closing the switch 122 to energize the circuit between the actuator switch 110 and the motor control unit 31.

[0128] When the fastener applier component 27 is of the type shown in FIGS. 25A and 25B (see FIGS. 26A, 26B, and 26C), the contact or force sensing function can, e.g., utilize a force sensing rod 190 that slidably passes through a central passage 192 in the carrier 150' (the carrier 150' is shown in FIG. 28B), the driver 29 and the drive cable 30. The rod 190 is coupled to the movable switch element 130. In this embodiment, the switch element 130 translates left and right over the drive cable 30, which rotates on a bearing 134 within the switch element 130.

[0129] As in the preceding embodiment, the spring 126 normally biases the switch elements 128 and 130 apart, comprising an electrically opened condition. When the switch elements 128 and 130 are in the electrically opened condition, the force sensing rod 190 is displaced to the left beyond the distal tip 124 of the fastener applier component 27. The force sensing rod 190 therefore makes contact with the prosthesis 14 or scaffold structure 16 in advance of the applier tip 124.

[0130] When the rod 190 contacts the surface of the prosthesis or scaffold structure with sufficient force to compress the spring 126, the rod 190 is displaced against the biasing force of the spring 126 to the right in FIG. 26A. This moves the switch element 130 to the right. Ultimately, contact between the switch elements 128 and 130 will occur, as shown in FIG. 26B. The contact establishes an electrically closed condition. In this condition, operation of the actuating switch 110 serves to actuate the control unit 31. This action causes the helical fastener 28 to be rotated into the scaffold structure 16 and into the vessel wall 34 (see FIG. 26C). Due to the magnetic coupling between the driver 29 and carrier 150', the driver 29 is moved in tandem with attached carrier 150' to the left in FIG. 26B, as the fastener 28 is deployed. Also, due to the magnetic coupling between the carrier 150 and the driver 29, the operator must exert a separation force to decouple the carrier 150 (and, with it, the fastener 28) from the driver 29. As before described, this arrangement prevents inadvertent release of a fastener 28. A contact screw 136 can be provided to adjust the amount of displacement required to close the switch elements 128 and 130.

[0131] Upon removal of contact force, or in the absence of sufficient contact force, the spring 126 urges the switch elements 128 and 130 toward the electrically opened condition, moving the tip of the rod 190 out beyond the distal tip 124 of the applier 27.

[0132] The contact or force sensing arrangements just described can also generate an audible and/or visual output to the operator, to indicate that sufficient contact force between the applier device 27 and the prosthesis or tissue exists.

[0133] B. Angled Component Fastener Guide and Attachment Assembly

[0134] In another arrangement (see FIG. 29), the fastener attachment assembly comprises a unitary, angled fastener guide and applier component 160. In this arrangement, the component 160 includes a fastener drive mechanism 162 that places the carrier 164 holding the fastener 28 in a perpendicular or near perpendicular position with respect to the prosthesis or tissue. This configuration eliminates the need for a separate steerable guide component 18 for the fastener component 27, previously described.

[0135] The drive mechanism 162 can vary. In the illustrated embodiment (shown in FIG. 29), the mechanism 162 includes a beveled drive gear 168 coupled to the drive cable 30. The drive gear 168 operatively meshes with a transfer or pinion gear 170, which is coupled to the carrier 164. The axes of rotation of the drive gear 168 and pinion gear 170 are offset about ninety degrees, so that rotation of the drive cable 30 along the axis of the vessel is translated into rotation of the carrier 164 generally perpendicular to the wall of the vessel. The fastener guide and applier component 160 can be positioned and stabilized within the vessel in various ways, e.g., through the use external spring loaded strut or the like (as shown in association with the directing component 18 discussed above), or by use of an expandable member 166 (as FIG. 29 shows). The expansion member 166 can comprise either a balloon or mechanical expansion device. The expansion member 166 stabilizes the position of both the prosthesis and the fastener guide and applier component 160 within the vessel by resisting the force of blood until the prosthesis can be anchored.

[0136] As FIG. 30 shows, the fastener guide and applier component 160 can, if desired, provide an angled deployment between the drive cable 30 and carrier 164 that is somewhat

less than ninety-degrees, to aid in intraluminal manipulation of the carrier into perpendicular contact position against the wall of the vessel. As FIG. **31** shows, the fastener guide and applier component **160** can, if desired, be articulated between the drive cable **30** and carrier **164**. In this arrangement, a remote control mechanism is desirable provided to move the carrier **164** from a first, generally straight position (shown in phantom lines in FIG. **31**) for deployment to the targeted site, to a second, articulated position (shown in solid lines in FIG. **31**) for alignment of the carrier **164** in contact against the vessel wall.

III. The Fasteners

[0137] As illustrated and described thus far, introduction of the fasteners **28** will typically be affected after the prosthesis **14** has been initially placed. That is, initial placement of the prosthesis **14** will be achieved by self-expansion or balloon expansion, after which the prosthesis **14** is secured or anchored in place by the introduction of a plurality of individual fasteners. The fasteners **28** may be placed only through the fabric of the prosthesis **14**, i.e., avoiding the scaffold structure. Alternately, the fasteners **28** can be introduced into and through portions of the scaffold structure itself. The prosthesis **14** may include preformed receptacles, apertures, or grommets, which are specially configured to receive the fasteners. The fasteners **28** may be introduced both through the fabric and through the scaffold structure. The fasteners can be introduced singly, i.e., one at a time, in a circumferentially spaced-apart pattern over an interior wall of the prosthesis **14**.

[0138] In the exemplary embodiment, the fasteners **28** are helical fasteners, so that they can be rotated and "screwed into" the prosthesis **14** and vessel wall. A desired configuration for the helical fastener **28** (see FIGS. **27**, **28**A, and **28**B) is an open coil **148**, much like a coil spring. This configuration allows the fastener **28** to capture a large area of tissue, which results in significantly greater holding force than conventional staples, without applying tissue compression, which can lead to tissue necrosis.

[0139] As FIGS. **27**, **28**A, and **28**B show, the leading tip **142** of the helical fastener **28** is desirable sharp to allow it to penetrate thought the artery wall and/or calcified tissue. This distal tip **142** can be sharpened to cut a helical path through the tissue or it can be sharpened to a point to penetrate the tissue without cutting.

[0140] The proximal end **144** of the fastener serves two design functions. The first function is to engage the carrier **102** of the fastener applier **27**, which rotates the helical fastener during the implantation process. The second function is to act as a stop to prevent the helical fastener from penetrating too far into the tissue.

[0141] In one embodiment (see FIG. **27**), the proximal end **144** of the helical fastener **28** includes an L-shaped leg **146** of the coil **148** bisecting the fastener diameter. The leg **146** of the coil **148** comes completely across the diameter to prevent the fastener from being an open coil and to control the depth of penetration into the tissue. In addition, the leg **146** of the coil **148** can be attached to a previous coil to strengthen the entire structure and provide a more stable drive attachment point for the fastener applier. This attachment could be achieved via welding, adhesive or any other suitable means.

[0142] Alternatively (as shown in FIGS. **28**A and **28**B), the proximal end **144** of the fastener **28** could incorporate a separate cap or carrier **150** or **150'** that serves the same function as the leg **146** of the coil **148** in FIG. **27**. The carrier **150** or **150'** could feature several methods to attach to the fastener applier drive mechanism **100**. These include separate graspers or grippers, a magnetic couple (as previously described), or any other suitable mechanical connecting means. In FIGS. **28**A and **28**B, the carrier **150** and **150'** includes a slot **180** and **182'** to mate with a drive flange (as previously described). As also previously described, a magnetic coupling is implemented between the carrier **150** and **150'** and the corresponding drive member, to prevent inadvertent separation during use.

[0143] In FIG. **28**B, the carrier **150'** also includes a passage **152** for holding the contact/force sensing rod **190** shown in FIGS. **26**A, **26**B, and **26**C.

[0144] The fasteners **28** shown in FIGS. **27**, **28**A, and **28**B can be made from stainless steel or other types of implantable metal, however it is also envisioned that the fasteners in the above descriptions could be made from implantable polymers or from a biodegradable polymer or combinations of all materials thereof. Desirably, a fastener **28** will have between 2 and 10 turns and will be between 1 mm and 10 mm long. The space between the individual coils will be between 0.25 mm and 3 mm. The diameter of the fastener **28** will be between 1 mm and 6 mm.

IV. Prosthesis with Integrated Fastener Assembly

[0145] FIG. **32** shows a prosthesis **500** that includes at least one integrated fastener assembly **502**. FIG. **32** shows the prosthesis **500** deployed in a targeted intraluminal region, in particular, within an abdominal aortic aneurysm **504**. The prosthesis **500** can be deployed elsewhere in the body.

[0146] The prosthesis **500** desirably includes a fabric material or the like carried by a support frame or scaffold **504**, as previously described. The scaffold **504** can be made, e.g., from an elastic material that self-expands radially during deployment from a sheath, or from a malleable material that expands radially in response to a radially expansive force applied within the scaffold by a balloon or a mechanical expansion device.

[0147] Following deployment of the prosthesis **500** in the targeted region, the integrated fastener assembly **502** on the prosthesis **500** is manipulated to anchor the prosthesis **500** to the vessel wall. In the illustrated embodiment, the prosthesis **500** carries two integrated fastener assemblies **502**, one in each end region of the prosthesis **500**.

[0148] In the illustrated embodiment, each fastener assembly **502** is imbedded in a reinforced flange area **506** in the respective end region. Each fastener assembly **502** comprises an array of fasteners **508** circumferentially spaced about the flange **506**. The number of fasteners **508** in the array can vary, e.g., from about two to about twelve fasteners on each flange area **506**. The configuration of the array can also vary, e.g., in the circumferential array, the fasteners **508** can by axially spaced apart as well.

[0149] The fasteners **508** can be formed of a metal or plastic material and can be variously constructed. In the illustrated embodiment, each fastener **508** includes a disc-shaped head **512** and a stem **514** that is bifurcated into two wings **516** and **518**, which are joined by a plastic or memory material hinge region **520**. The material of the hinge region **520** is formed with a resilient memory that biases the wings **516** and **518** to a spread-apart condition (as FIG. **34** shows).

[0150] Each fastener **508** is carried within a grommet **510** on the flange area **506** (see FIG. **35**). When the hinge region **520** is confined within the grommet **510** (as FIG. **35** shows),

the wings **516** and **518** are retained against the resilient memory in an adjacent, closed condition. In response to the application of a pushing or punching force on the head **512** (see FIG. **35**), the wings **516** and **518** are advanced in the closed condition out of the grommet **510**, and into and through the adjacent vessel wall (see FIG. **36**). Upon continued advancement, the hinge region **520** is freed from the confines of the grommet **510** (see FIG. **37**). As a result, the wings **516** and **518** resiliently spring into their normal spread-apart condition.

[0151] In this arrangement, an intraluminal tool **522** (see FIG. **33**) is deployed into the prosthesis **500** to exert a pushing or punching force upon the head **512** of a given fastener **508**. In the illustrated embodiment, the tool **522** comprises a catheter **524** that carries a punch member **526** at its distal end. In a desired arrangement, the distal end of the catheter **524** is steerable, to aid in establishing point contact between the punch member **526** and the head **512** of the given fastener **508**. The head **512** can include a recess **528** to receive and stabilize the tip of the punch member **526** with respect to the head **512** during use (see FIG. **34**).

[0152] In use, the punch member **526** is manipulated to apply a pushing or punching force upon the selected fastener head **512**. As FIGS. **35** and **36** show, the application of the pushing force by the punch member **526** forces the wings **516** and **518** against the near side of the vessel wall **34**. The wings **516** and **518** are still in their closed condition, because the hinge region **520** is still confined within the grommet **510**. The closed wings **516** and **518** form an obturator that penetrates tissue as it advances to the far side of the vessel wall. As the hinge region **510** is freed from the grommet **510** (FIG. **37**), the wings **516** and **518** resiliently return to their spread-apart condition against the far side of the vessel wall. Upon removal of the punch member **526** (see FIG. **38**), the head **512** and spread-apart wings **516** and **518** remain in their mutually opposed condition in the vessel wall, to secure the prosthesis **500** against the vessel wall. In use, the physician locates and manipulates the punch member **526** in succession against each fastener **508**, to complete the anchorage of the prosthesis **500** to the vessel wall.

[0153] In one embodiment (see FIG. **39**), each fastener **508** can include a tracking wire **530** that is releasably coupled to the head **512**. The tracking wire **530** extends from the head **512** outside the body for access outside the vessel. In this arrangement, the punch member **526** includes a lumen to accommodate passage of the tracking wire **530**. The tracking wire **530** guides the punch member **526** in an intraluminal path to the respective fastener **508**. After the punch member **526** is manipulated to drive the fastener **508** into the vessel wall, the punch member **526** can be withdrawn over the tracking wire **530**. The tracking wire **530** can be released from the now-secured head **512**, e.g., by applying a moderate pulling force upon the tracking wire **530**. The tracking wire **530** can then be withdrawn. The punch member **526** is sequentially guided over another tracking wire **530** for interaction with another one of the fasteners **508**, until a desired degree of anchorage is achieved.

[0154] In an alternative embodiment, an integrated fastener assembly **502** on the prosthesis **500** can be used to temporarily tack the prosthesis **500** in place while a permanent anchoring technique is carried out. For example, in this arrangement, after using the integrated fastener assembly **502** to temporarily hold the prosthesis **500** in a desired location, the separate helical fasteners **28** are deployed in the manner previously described, to permanently anchor the prosthesis **500** against the vessel wall.

[0155] It will be appreciated that the components and/or features of the preferred embodiments described herein may be used together or separately, while the depicted methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the directing device, fastener applier and helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic device within the vascular system and generally within the body.

[0156] The preferred embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

We claim:

1. A system comprising

at least one tissue-piercing fastener having a sharpened distal tip for piercing and penetrating tissue,

a fastener attachment assembly sized and configured to be deployed from a remote access site to a targeted endovascular region, the fastener attachment assembly including

an intraluminal directing device defining an access path and including a deflectable distal region, and

an intraluminal fastener applier separate from the intraluminal directing device and being sized and configured for introduction along the access path and including an actuated member that is selectively operable to generate an implantation force in an implantation force direction to implant the tissue-piercing fastener by causing the sharpened distal tip to pierce and penetrate the tissue in the targeted endovascular region, and

means associated with the fastener attachment assembly for applying a resolving force in a direction different than the implantation force direction within the targeted endovascular region to resolve at least a portion of the implantation force.

2. A system according to claim **1**

wherein the means includes a stabilizing member carried by the intraluminal directing device and/or the intraluminal fastener applier.

3. A system according to claim **2**

wherein the stabilizing member includes a strut assembly.

4. A system according to claim **2**

wherein the stabilizing member includes a spring-loaded arm adapted for contact with tissue.

5. A system according to claim **2**

wherein the stabilizing member includes an expandable member adapted for contact with tissue.

6. A system according to claim **2**

wherein the stabilizing member includes a tissue grasping element.

7. A system according to claim **1**
wherein the at least one tissue-piercing fastener comprises a helical fastener, and wherein the actuated member comprises a driven member for implanting a helical fastener.
8. A system according to claim **1**
wherein the intraluminal fastener applier includes a catheter body that carries the actuated member, the catheter body having a column strength, and
wherein the means includes, at least in part, the column strength of the catheter body.
9. A system according to claim **1**
wherein the intraluminal directing device has a column strength, and
wherein the means includes, at least in part, the column strength of the intraluminal directing device.

* * * * *