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(54) SUPERELASTIC ANASTOMOSIS DEVICE

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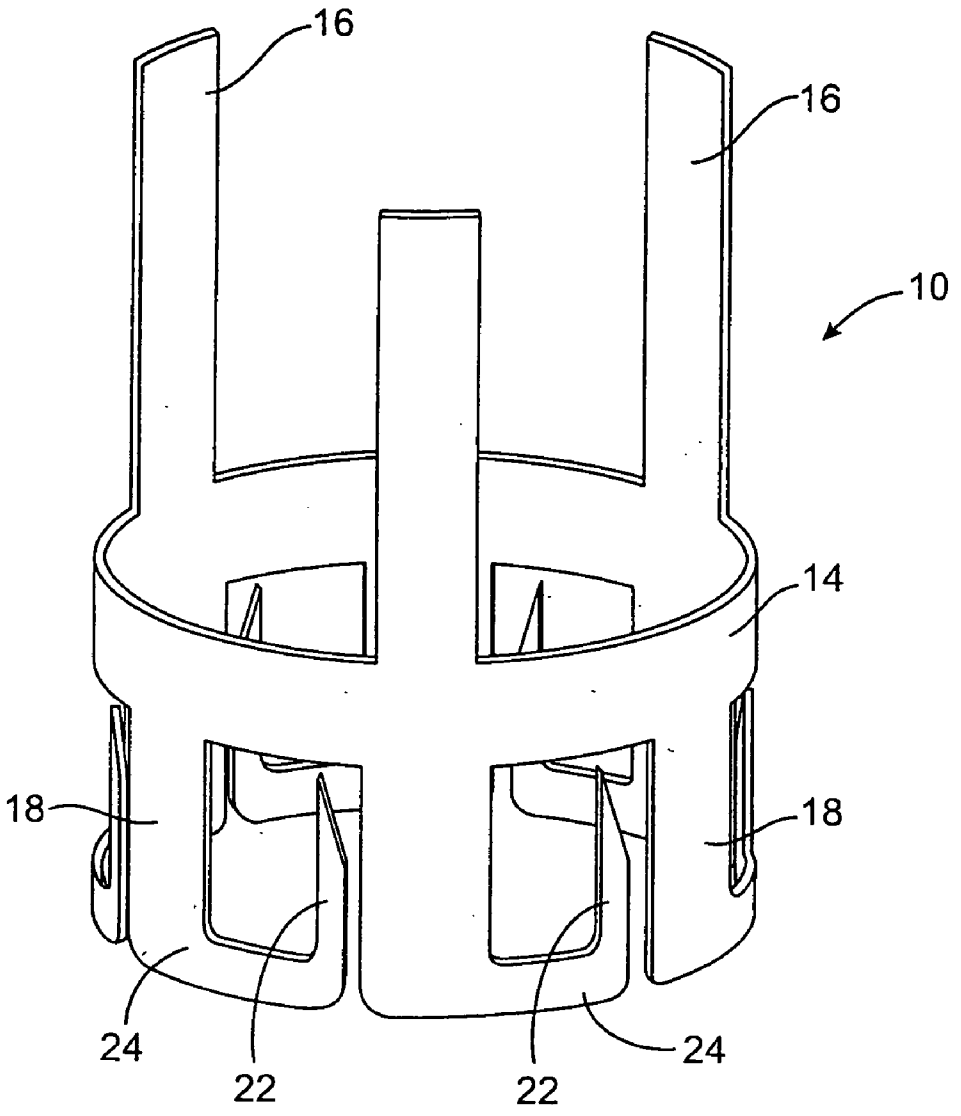
Publication Classification

(51) **Int. Cl.**[7] **A61B 17/08**

(52) **U.S. Cl.** **606/153**

(57) **ABSTRACT**

An implantable superelastic anastomosis device may include a substantially continuous ring, the diameter of which may be substantially fixed. The anastomosis device may include first flange members and second flange members extending from an open central structure, where at least one second flange member has a free end oriented generally toward at least one first flange member after the anastomosis device has been deployed.



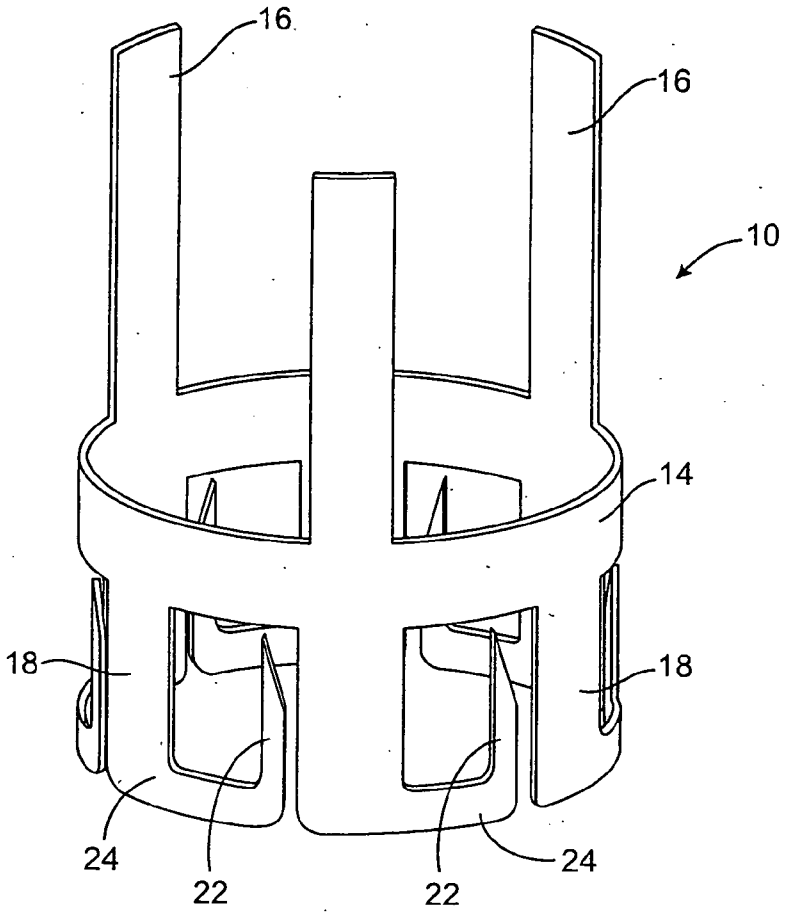


FIG. 1

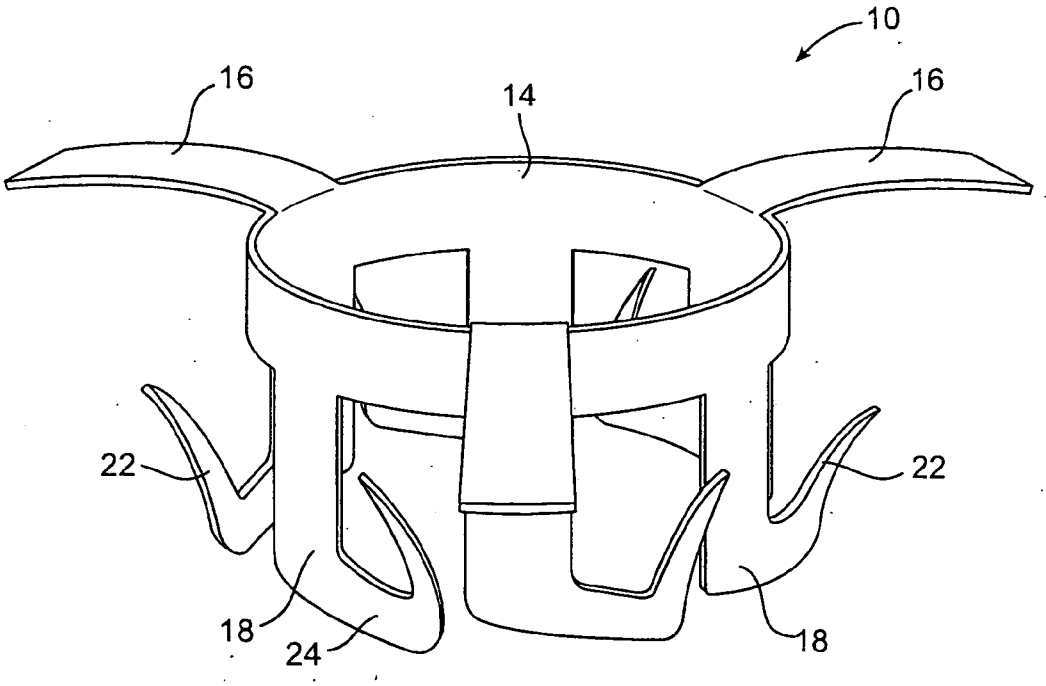


FIG. 2

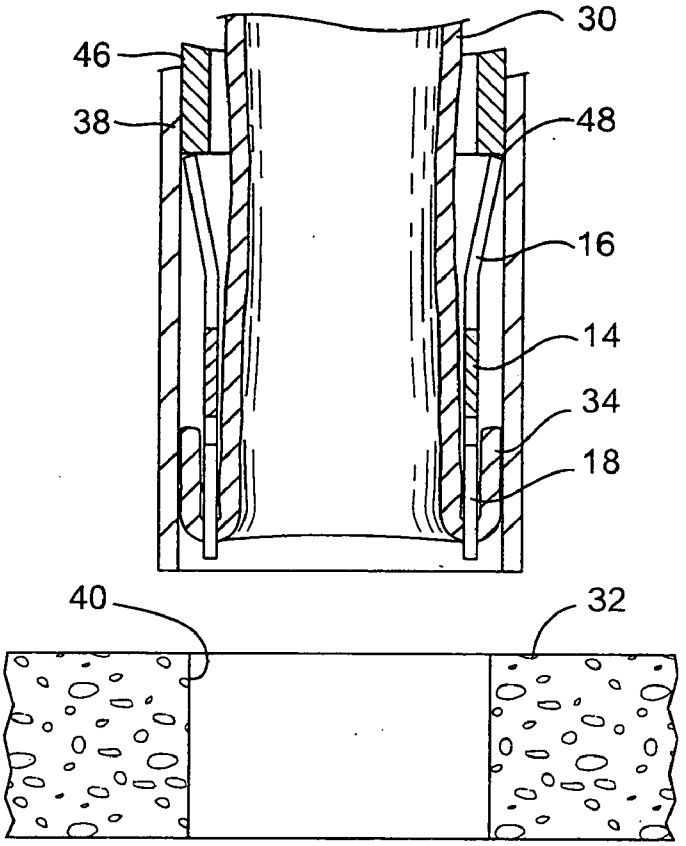


FIG. 3

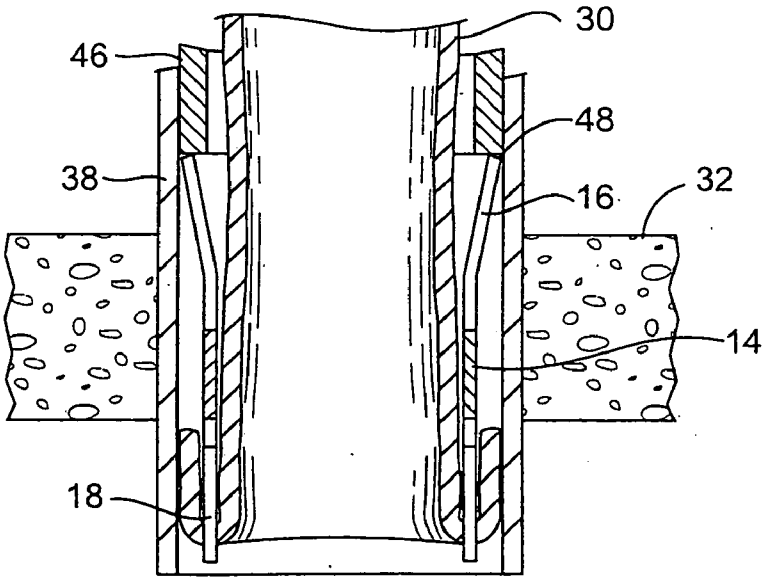


FIG. 4

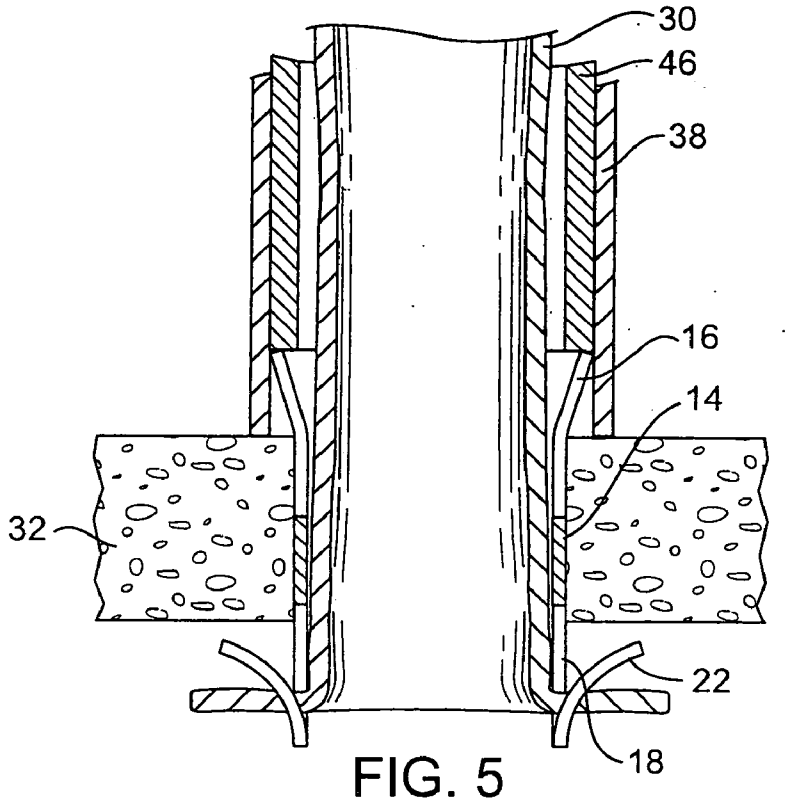


FIG. 5

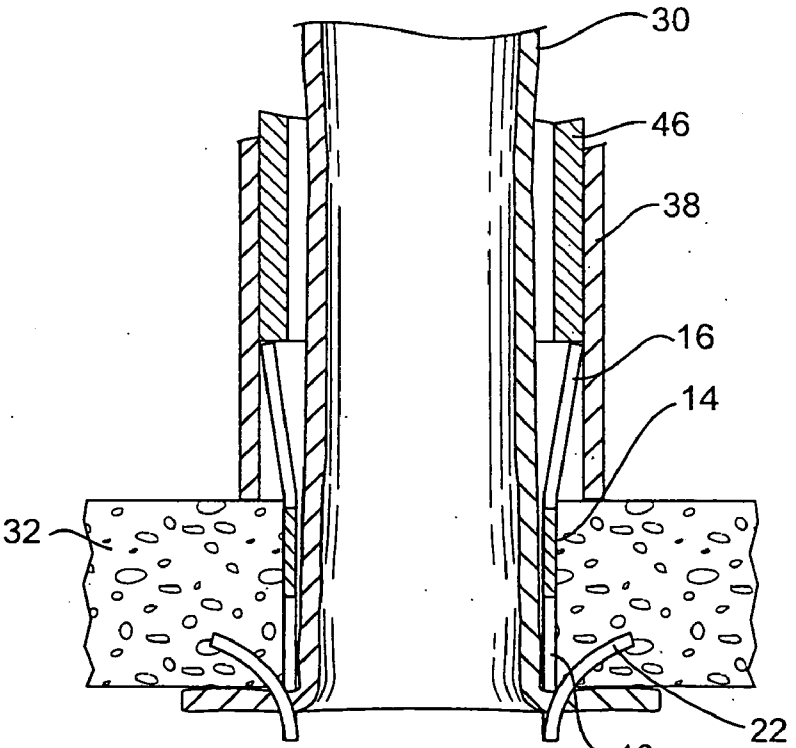


FIG. 6

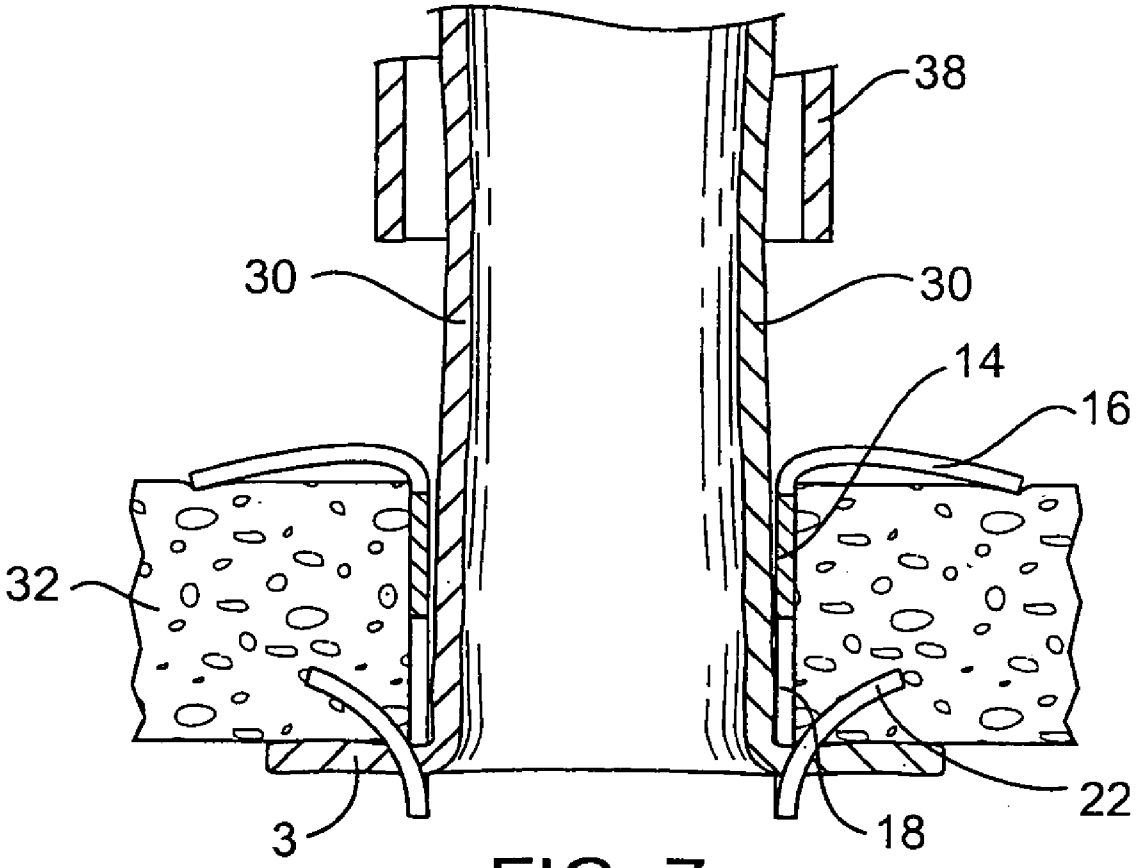


FIG. 7

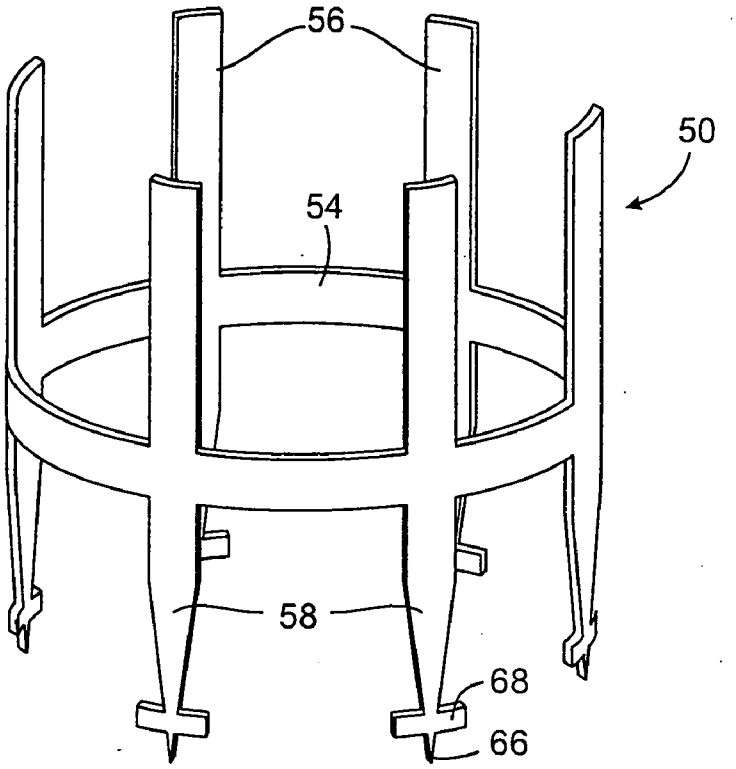


FIG. 8

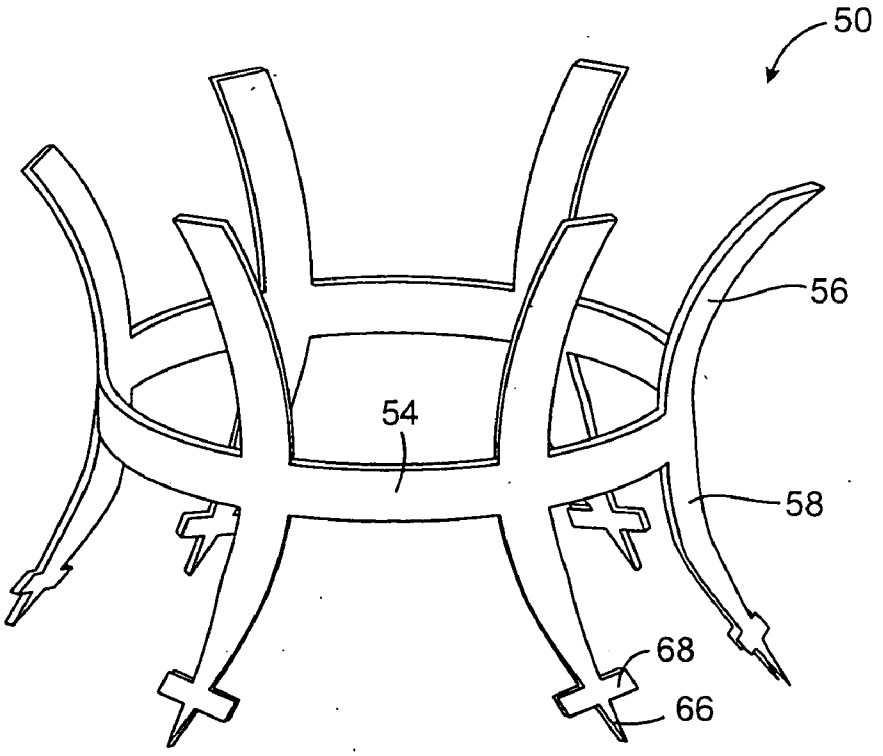


FIG. 9

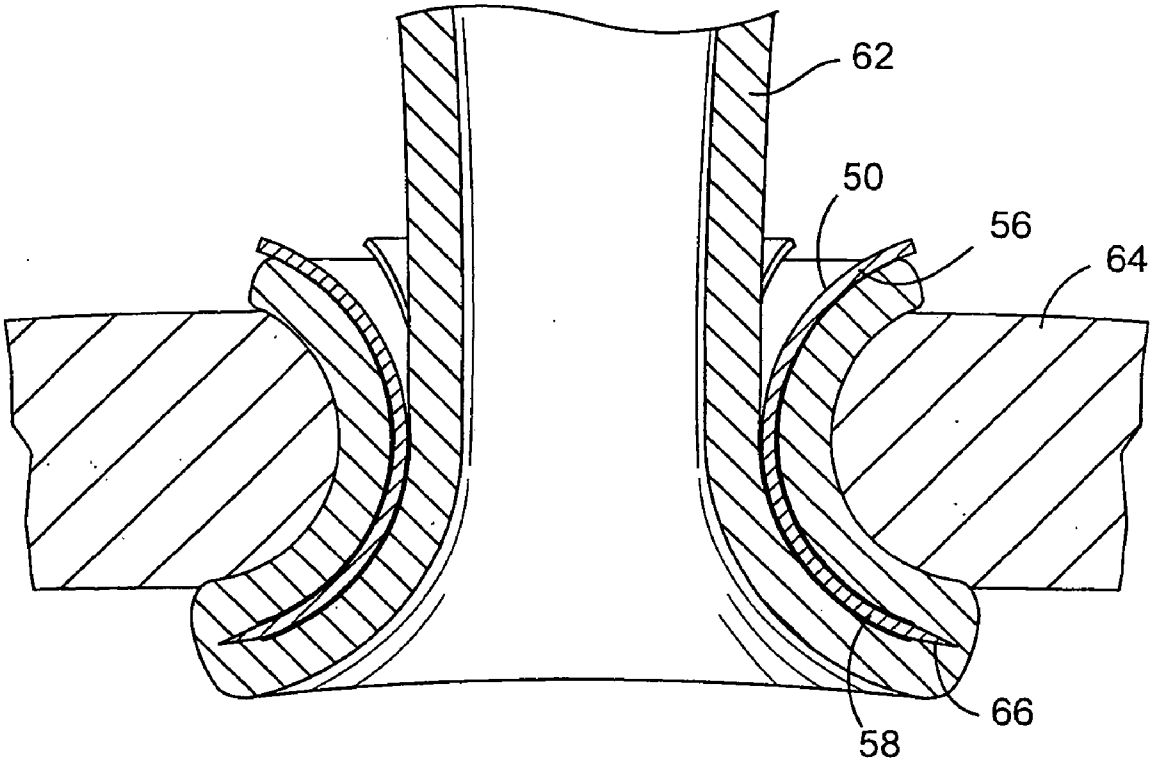


FIG. 10

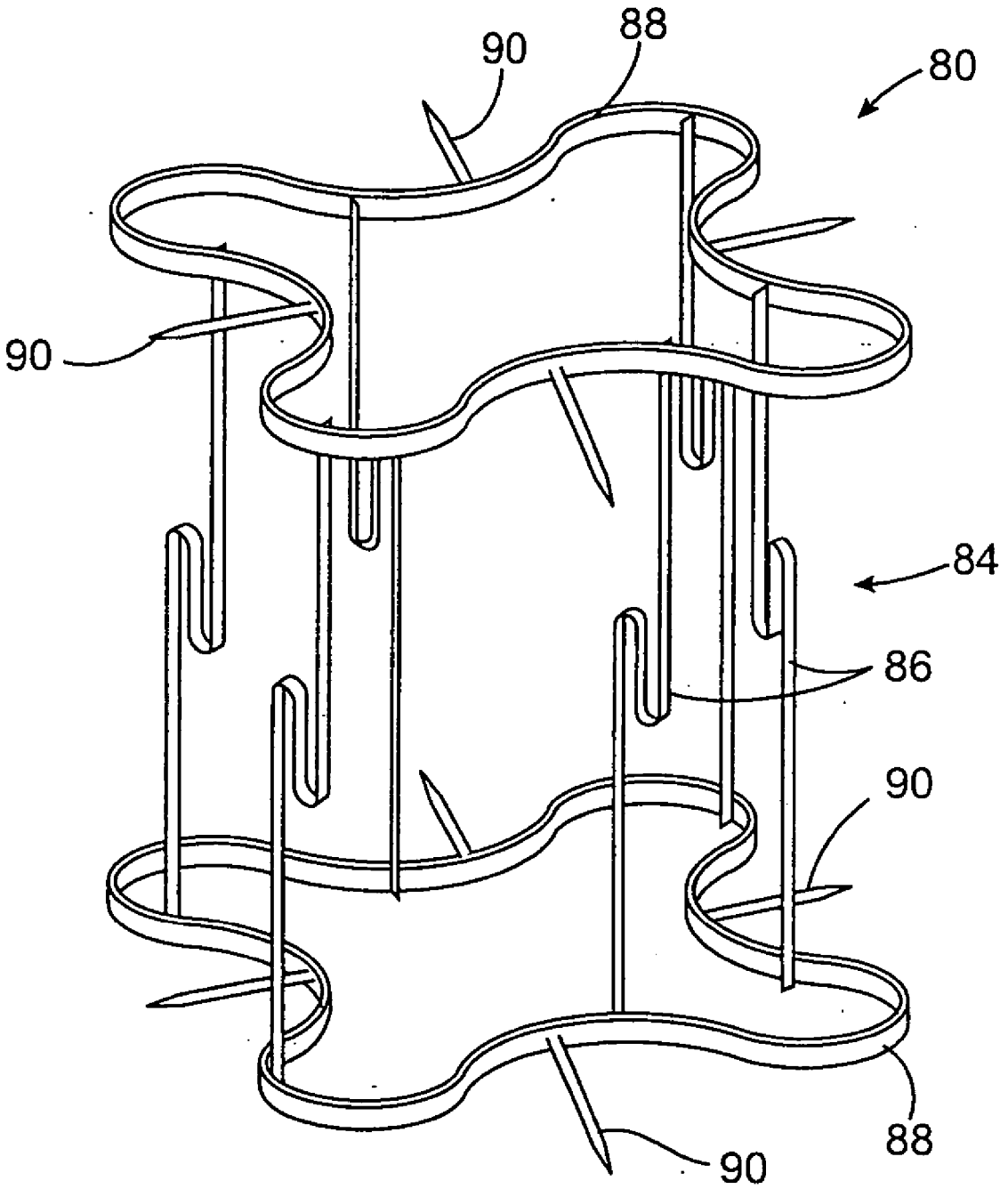


FIG. 11

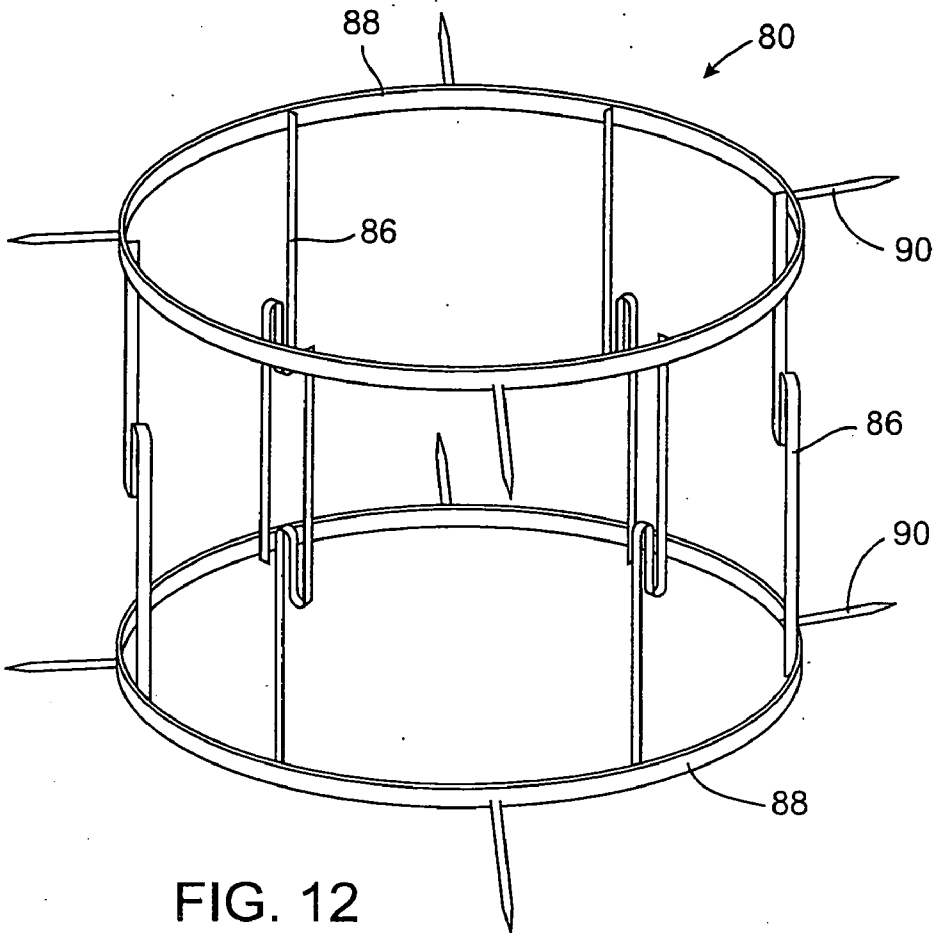


FIG. 12

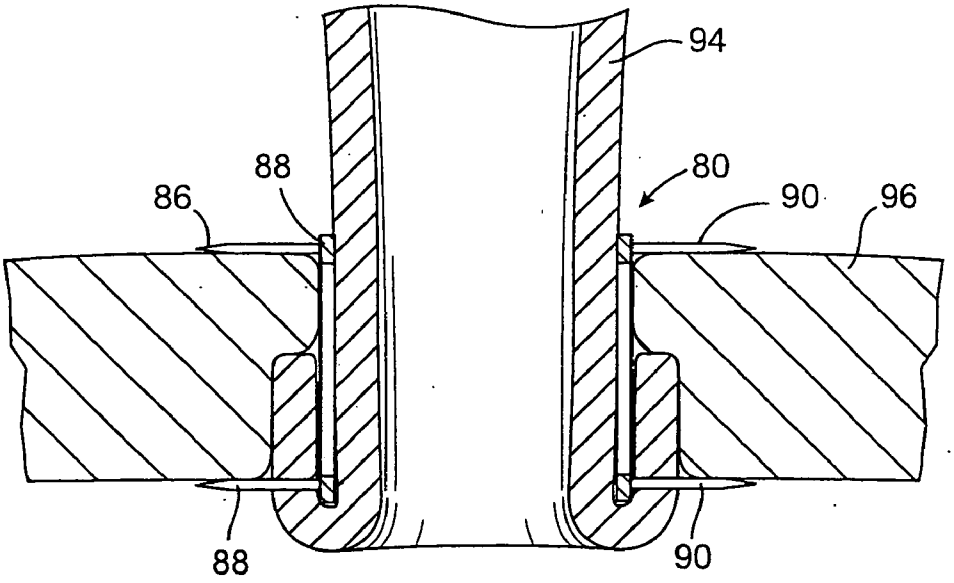


FIG. 13

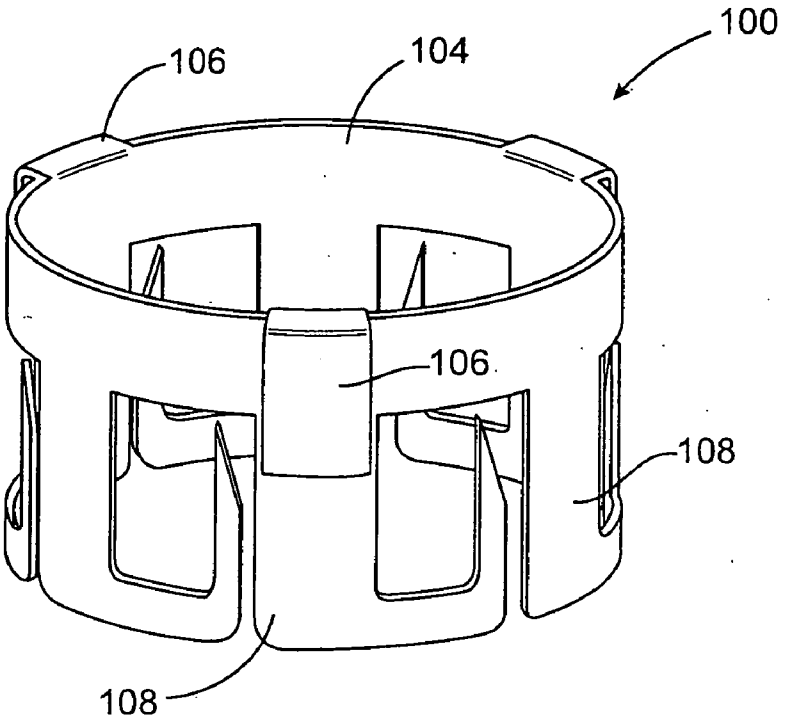


FIG. 14

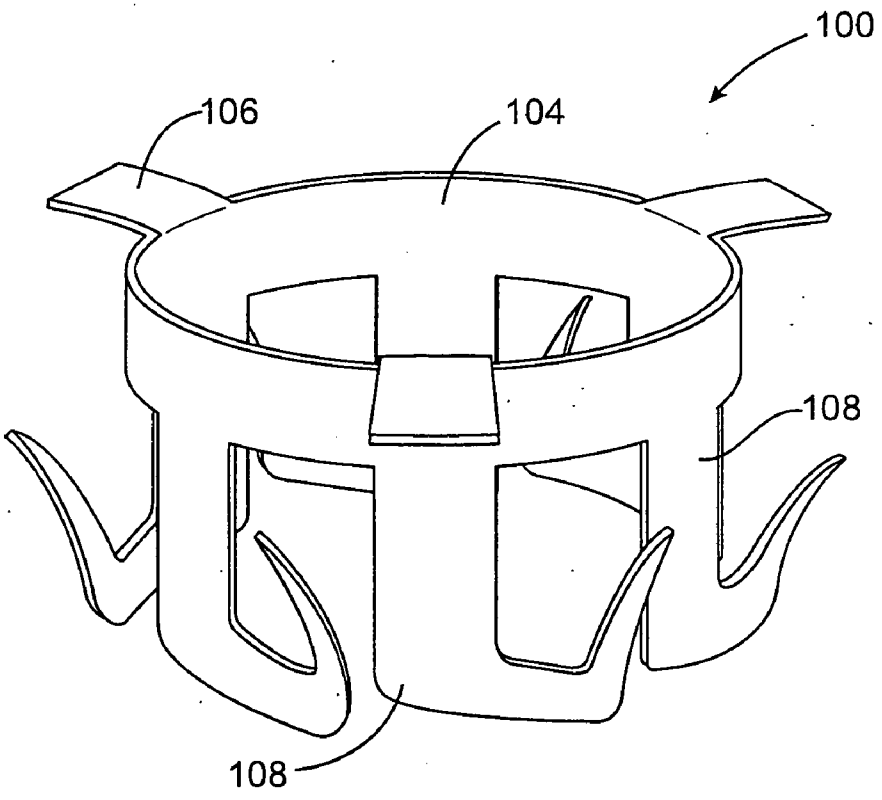


FIG. 15

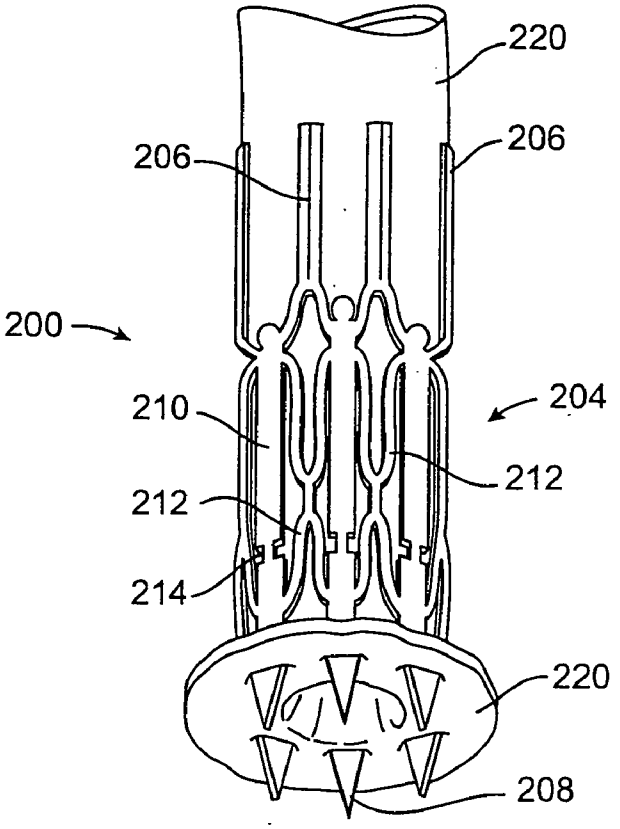

220
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FIG. 16

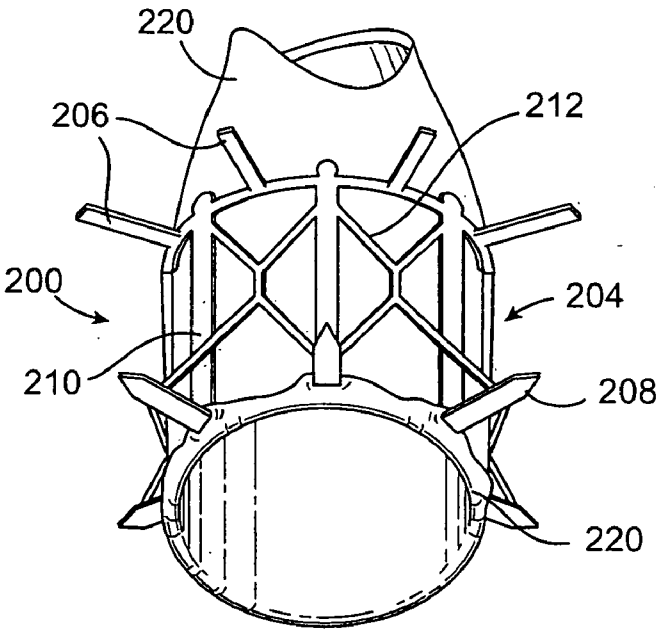
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FIG. 17

SUPERELASTIC ANASTOMOSIS DEVICE

[0001] This application is a continuation of U.S. patent application Ser. No. 09/687,216, filed on Oct. 12, 2000, which is incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The invention relates to an implantable medical device such as an anastomosis device and a deployment system for implanting the device. In a preferred embodiment, the device can be used for forming a sutureless connection between a bypass graft and a graft vessel.

[0004] 2. Brief Description of the Related Art

[0005] Vascular anastomosis is a procedure by which two blood vessels within a patient are surgically joined together. Vascular anastomosis is performed during treatment of a variety of conditions including coronary artery disease, diseases of the great and peripheral vessels, organ transplantation, and trauma. In coronary artery disease (CAD) an occlusion or stenosis in a coronary artery interferes with blood flow to the heart muscle. Treatment of CAD involves the grafting of a vessel in the form of a prosthesis or harvested artery or vein to reroute blood flow around the occlusion and restore adequate blood flow to the heart muscle. This treatment is known as coronary artery bypass grafting (CABG).

[0006] In the conventional CABG, a large incision is made in the chest and the sternum is sawed in half to allow access to the heart. In addition, a heart lung machine is used to circulate the blood so that the heart can be stopped and the anastomosis can be performed. During this procedure, the aorta is clamped, which can lead to trauma of the aortic tissue and/or dislodge plaque emboli, both of which increase the likelihood of neurological complications. In order to minimize the trauma to the patient induced by conventional CABG, less invasive techniques have been developed in which the surgery is performed through small incisions in the patients chest with the aid of visualizing scopes. Less invasive CABG can be performed on a beating or stopped heart and thus may avoid the need for cardiopulmonary bypass.

[0007] In both conventional and less invasive CABG procedures, the surgeon has to suture one end of the graft vessel to the coronary artery and the other end of the graft vessel to a blood supplying vein or artery. The suturing process is a time consuming and difficult procedure requiring a high level of surgical skill. In order to perform the suturing of the graft to the coronary artery and the blood supplying artery the surgeon must have relatively unobstructed access to the anastomosis site within the patient. In the less invasive surgical approaches, some of the major coronary arteries including the ascending aorta cannot be easily reached by the surgeon because of their location. This makes suturing either difficult or impossible for some coronary artery sites. In addition, some target vessels, such as heavily calcified coronary vessels, vessels having very small diameter, and previously bypassed vessels may make the suturing process difficult or impossible.

[0008] Accordingly, it would be desirable to provide a sutureless vascular anastomosis device which easily connects a graft to a target vessel. It would also be desirable to provide a sutureless anastomosis device which is formed of one piece and is secured to the target vessel in a single step.

SUMMARY OF THE INVENTION

[0009] A superelastic or pseudoelastic one piece anastomosis device according to the present invention connects a graft vessel to a target vessel. The anastomosis device deforms from an insertion configuration to a tissue holding configuration due to the superelastic or pseudoelastic properties of the material.

[0010] In accordance with one aspect of the present invention, a one piece anastomosis device for connecting a graft vessel to a target vessel includes a device body formed of a superelastic or pseudoelastic material. The device body has an insertion configuration and a tissue holding configuration in which the body has an inner flange and an outer flange. At least one of the inner and outer flanges is radially constrained in the insertion configuration for insertion into the target vessel. When the device body is released it self deforms to the tissue holding configuration.

[0011] In accordance with another aspect of the present invention, a tube deployed anastomosis system for connecting a graft vessel to a target vessel includes a deployment tube and an anastomosis device formed of a superelastic or pseudoelastic material. The device has an insertion configuration and a tissue holding configuration in which the device has an inner flange and an outer flange. The inner and outer flanges are radially constrained in the deployment tube in the insertion configuration for insertion into the target vessel and when released from the deployment tube, the device self deforms to the tissue holding configuration.

[0012] In accordance with another further aspect of the present invention, a method of deploying an anastomosis system for connecting a graft vessel to a target vessel includes the steps of: connecting a graft vessel to a one piece device formed of a superelastic or pseudoelastic material; poking a portion of the one piece device through the graft vessel; and deploying the one piece device by self deformation to a tissue holding configuration in which the device has an inner flange and an outer flange and traps the target vessel tissue between the inner flange and the outer flange.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The invention will now be described in greater detail with reference to the preferred embodiments illustrated in the accompanying drawings, in which like elements bear like reference numerals, and wherein:

[0014] **FIG. 1** is a perspective view of a first embodiment of an anastomosis device in a constrained configuration prior to use;

[0015] **FIG. 2** is a perspective view of the anastomosis device of **FIG. 1** in a deployed configuration;

[0016] **FIG. 3** is a side cross sectional view of the anastomosis device of **FIG. 1** with a graft vessel everted around the device and the device constrained by a tube prior to deployment;

[0017] **FIG. 4 a** side cross sectional view of the system of **FIG. 3** being inserted into a target vessel:

[0018] **FIG. 5** is a side cross sectional view of the system of **FIG. 3** after release of an inner flange;

[0019] **FIG. 6** is a side cross sectional view of the system of **FIG. 3** with the inner flange imbedded in an inner wall of the target vessel wall;

[0020] **FIG. 7** is a side cross sectional view of the system of **FIG. 3** after release of the outer flange showing the deployment tube being removed;

[0021] **FIG. 8** is a perspective view of an alternative embodiment of an anastomosis device in a constrained configuration prior to use;

[0022] **FIG. 9** is a perspective view of the anastomosis device of **FIG. 8** in a deployed configuration;

[0023] **FIG. 10** is side cross sectional view of the anastomosis device of **FIG. 8** after deployment shown connecting a graft and a target vessel;

[0024] **FIG. 11** is a perspective view of an alternative embodiment of an anastomosis device in a constrained configuration prior to use;

[0025] **FIG. 12** is a perspective view of the anastomosis device of **FIG. 11** in a deployed configuration;

[0026] **FIG. 13** is a side cross sectional view of the anastomosis device of **FIG. 11** after deployment shown connecting a graft vessel to a target vessel;

[0027] **FIG. 14** is a perspective view of an alternative embodiment of an anastomosis device in a constrained configuration prior to use;

[0028] **FIG. 15** is a perspective view of the anastomosis device of **FIG. 14** in a deployed configuration;

[0029] **FIG. 16** is a perspective view of an alternative embodiment of an expandable body anastomosis device in a constrained configuration prior to use; and

[0030] **FIG. 17** is a perspective view of the anastomosis device of **FIG. 16** in a deployed configuration.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0031] The present invention relates to a superelastic or pseudoelastic anastomosis device and method for connecting a graft vessel to a target vessel without the use of conventional sutures. The quick and easy deployment of the anastomosis system according to the present invention greatly increases the speed with which anastomosis can be performed over the known sutured anastomosis methods. The anastomosis devices according to the present invention are particularly designed for use in connecting graft vessels to target vessel in a variety of anastomosis procedures, including coronary artery bypass grafting. In such procedures, a large vessel anastomotic device is used to connect a graft vessel to large diameter target vessels such as the aorta or it's major side branches and a small vessel anastomotic device is used for connecting a graft vessel to a target vessel having a small diameter such as a coronary artery.

[0032] Suturing a graft vessel to a target vessel with conventional procedures is difficult and time consuming, particularly in minimally invasive procedures where space may be limited and in procedures in which it may be desired to perform an anastomosis without stoppage of blood flow through the target vessel. The superelastic or pseudoelastic anastomosis device and method of the present invention allow anastomosis to be performed efficiently and effectively in tight spaces. The anastomosis may also be performed with or without stoppage of blood flow in a target vessel and with or without the use of cardiopulmonary bypass.

[0033] **FIG. 1** illustrates an anastomosis device **10** according to a first embodiment of the present invention in a constrained insertion configuration in which the anastomosis device would be inserted into a target blood vessel. **FIG. 2** illustrates the anastomosis device **10** of **FIG. 1** in an expanded deployed configuration which holds a graft vessel to a target vessel. The superelastic or the pseudoelastic anastomosis device in **FIG. 1** includes a substantially cylindrical body **14**, a plurality of legs **16** extending from a first side of the body, and a plurality of hooks **18** extended from a second side of the body. In the insertion configuration illustrated in **FIG. 1**, the body **14**, the legs **16**, and the hooks **18**, are substantially aligned in a constrained substantially cylindrical shape. The anastomosis device **10** may be held in the constrained substantially cylindrical shape by a deployment tool, such as a substantially cylindrical deployment tube. When the deployment tool is removed from the device **10**, the device returns to a preset expanded shape illustrated in **FIG. 2** due to the superelastic or pseudoelastic properties of the material.

[0034] The anastomosis device **10** is made of a pseudoelastic or superelastic alloy, such as Nitenol or other pseudoelastic or superelastic material. The superelastic or pseudoelastic device **10** will self deform through superelastic or pseudoelastic behavior from the constrained insertion configuration illustrated in **FIG. 1** to the expanded configuration illustrated in **FIG. 2** when the constraining device or deployment tool is removed. The anastomosis device **10** formed of the superelastic or pseudoelastic material is formed in the final shape illustrated in **FIG. 2** and is then isothermally deformed by constraining in a tube or other deployment tool in the substantially cylindrical shape illustrated in **FIG. 1**. The need for temperature control is avoided since the anastomosis device **10** reforms the deployed shape of **FIG. 2** spontaneously when removed from the constraining tube. This allows the accurate placement of the anastomosis device **10** spontaneous and nearly instantaneously upon deployment of the device. The need for a mechanical deployment device to mechanically deform the anastomosis device from the insertion configuration to the deployed configuration is also avoided.

[0035] The anastomosis devices of the present invention may be made of any known superelastic or pseudoelastic material. U.S. Pat. No. 5,597,378 provides a discussion of superelastic and pseudoelastic materials and is incorporated herein by reference in its entirety.

[0036] The deployed anastomosis device **10** as shown in **FIG. 2** includes an inner flange formed by outwardly extruding ends **22** of the J-shaped hooks **18**. The deployed device **10** also includes an outer flange formed by the legs **16** extending outward from the body **14**.

[0037] In use, a graft vessel **30**, shown in **FIG. 3**, is threaded through a center of the anastomosis device **10**. An

end **34** of the graft vessel **30** is everted around the hooks **18** and the hook ends **22** penetrate into or through the everted end **34** of the graft vessel retaining the graft vessel in place on the anastomosis device **10**.

[**0038**] As illustrated in **FIG. 3**, the anastomosis device **10** with the everted graft vessel **30** is positioned within a deployment tube **38** for delivery of the anastomosis device and graft vessel to an opening **40** in a target vessel **32**. In the radially constrained insertion configuration, the leading edge or hook end of the anastomosis device may be substantially cylindrical or slightly conical for ease of insertion.

[**0039**] One embodiment of a method for deploying the anastomosis device **10** of the present invention will be described with reference to FIGS. **3-6**. As shown in **FIG. 3**, the graft vessel **30** is prepared by everting an end **34** of the graft vessel around the hooks **18** of the anastomosis device **10**. The hook ends **22** penetrate the graft vessel tissue to maintain the everted configuration of the graft vessel. The hooks **18** and the legs **16** of the anastomosis device **10** are radially constrained by inserting the anastomosis device **10** and everted end of the graft vessel **30** into a deployment tool **38** in the shape of a tube. When positioned inside the deployment tool **38**, the anastomosis device **10** is in a generally cylindrical configuration for insertion into the target vessel **32**.

[**0040**] As shown in **FIG. 4**, the deployment tool **38** is used to insert the anastomosis device **10** and the graft vessel **30** into the target vessel **32** until the hook ends **22** have passed through the opening **40** and are positioned within an interior of the blood vessel. As shown in **FIGS. 3 and 4**, a retainer tube **36** is positioned around the graft vessel **30** and inside the deployment tool **38** for holding and extruding the anastomosis device **10**. A distal end **48** of the retainer tube **46** is positioned adjacent to a proximal end of the anastomosis device **10**. The distal end **48** of the retainer tube **46** may be attached to or abut the anastomosis device **10** to hold the anastomosis device in place inside the deployment tube **38** during the insertion step of **FIG. 4**.

[**0041**] As shown in **FIG. 5**, the anastomosis device **10** is held in place by the retainer tube **46** while the deployment tube **38** is withdrawn or retracted to release the radial constraining force from the hooks **18**. Upon removal of the deployment tube **38** from the hooks **18**, the hook ends **22** and hook base portion **24** spontaneously spring outward due to the superelasticity or pseudoelasticity of the material.

[**0042**] As shown in **FIG. 6**, after the release of the hooks **18** the anastomosis device **10** is withdrawn by the deployment tool **38** against the interior wall of the target vessel **32** causing the hook ends **22** to be compressed against or penetrate into the tissue of the interior wall of the target vessel. The deployment tube **38** is then completely withdrawn as shown in **FIG. 7** allowing the legs **16** to spontaneously spring outward to trap the wall of the target vessel **32** between the hooks **18** which form an inner flange and the legs **16** which form an outer flange for the deployed anastomosis device **10**.

[**0043**] FIGS. **8-10** illustrate an alternative embodiment of an anastomosis device **50** having a central body portion **54**. A first set of legs **56** extend from one end of the body **54** and a second set of pointed legs **58** extend from the second side of the body. In a constrained configuration illustrated in **FIG. 8**, the anastomosis device **50** is substantially tubular for insertion into a target vessel. In an expanded deployed configuration, illustrated in **FIGS. 9 and 10**, the anastomosis device **50** is substantially C-shaped in cross section with the legs **56** forming an outer flange and the pointed legs **58** forming an inner flange of the anastomosis device **50**.

[**0044**] The embodiment shown in FIGS. **8-10** may be deployed in a manner similar to that of the anastomosis device described above with respect to FIGS. **1-7**. As shown in **FIG. 10**, the graft vessel **62** is everted around the anastomosis device **50**. The anastomosis device **50** and graft vessel **62** are then inserted into an opening in the target vessel **64** in a constrained configuration. A constraining device such as the deployment tool **38** is then removed from the anastomosis device **50** and graft vessel **62** allowing the legs **56** and **58** to spontaneously spring outward by the superelastic or pseudoelastic properties of the material to form inner and outer flanges which trap the tissue of the target vessel **64** between the inner and outer flanges.

[**0045**] According to one preferred embodiment of the anastomosis device **50** the pointed legs **58** each include a pointed tissue penetrating end **66** and a rectangular stop member **68** for limiting the tissue penetration of the penetrating end. As shown in **FIG. 10**, the tissue penetrating end **66** of the pointed legs **58** penetrates into or through the graft vessel **62** to ensure the graft vessel is retained on the anastomosis device **50** during and after deployment.

[**0046**] In the deployed configuration illustrated in **FIG. 10**, the intima of the graft vessel **62** abuts an intima of the target vessel **64**. Thus, the expansion of the inner flange of the anastomosis device **50** forms a vein gasket to seal the graft and target vessels together.

[**0047**] FIGS. **11-13** illustrate an alternative embodiment of the superelastic or pseudoelastic anastomosis device **80** in a radially constrained configuration illustrated in **FIG. 11** and in an expanded tissue retaining configuration illustrated in **FIGS. 12 and 13**. The anastomosis device **80** includes a device body **84** formed of a plurality of substantially parallel spring elements **86** interconnecting to end members **88**. Extending from the end members **88** are a plurality of prongs **90** which in the expanded tissue supporting configuration illustrated in **FIG. 13**, form inner and outer flanges to trap the tissue of the target vessel **96**. As in the previous embodiments, a graft vessel **94** is inserted through a center of the anastomosis device body **84** and is everted around the prongs **90** of at least one end the device body. The prongs **90** penetrate into or through the graft vessel tissue to retain the graft vessel on the anastomosis device.

[**0048**] The anastomosis device **80** with the graft vessel **94** everted around the anastomosis device is inserted in a radially constrained configuration illustrated in **FIG. 11** into an opening in the target vessel **96**. When the radially constraining member such as a retainer tube is removed from the anastomosis device **80**, the anastomosis device spontaneously self deforms and returns to the configuration of **FIG. 12** due to the superelastic or pseudoelastic properties of the material.

[**0049**] As shown in **FIG. 13, a** first set of the prongs **90** forms a flange at the inner wall of the target vessel. The spring elements **86** allow the distance between the end members **88** to adjust somewhat to target vessels **96** having

walls of different thicknesses. The spring elements **86** may also apply a compression force to the wall of the target vessel **96** once the anastomosis device **80** has been deployed to provide improved sealing.

[**0050**] In an alternate embodiment of the anastomosis device **80** of FIGS. **11-13**, the graft vessel **94** may be attached to the anastomosis device without everting. This may be done by providing axial prongs, hooks, or barbs on the inner rail member **88** and hooking an end of the graft vessel on the hooks, prongs, or barbs without everting.

[**0051**] An alternative embodiment of an anastomosis device **100** includes an anastomosis device body **104**, legs **106**, and hooks **108**, as in the embodiment of **FIGS. 1 and 2**. The embodiment of **FIGS. 14 and 15** differs from the embodiment of **FIGS. 1 and 2** in that the legs **106** are folded outward and downward adjacent the body **104** in the radially constrained insertion configuration illustrated in **FIG. 14**. The legs **106** will spontaneously spring out to the flange forming configuration of **FIG. 15** when the radially constraining member such as a retainer tube is removed for deployment of the anastomosis device **100**.

[**0052**] **FIGS. 16 and 17** illustrate an alternative embodiment of an anastomosis device **200** including a device body **204**, legs **206** and pointed legs **208**. The body **204** is formed of axially extending members **210** interconnected by struts **212** which allow the body to expand radially. Positioned between the body **204** and the pointed legs **208** are hinges **214**. **FIG. 16** illustrates the anastomosis device **200** in a radially constrained insertion configuration with a graft vessel **220** extending through an interior of the device body **204** and everted over the pointed legs **208**. The pointed legs **208** penetrate and hold the everted end of the graft vessel **220** on the device **200**.

[**0053**] For insertion, the anastomosis device **200** of **FIG. 16** is radially constrained in a deployment tube (not shown). As the deployment tube is withdrawn from the device **200**, the pointed legs **208** fold outward to form an inner flange, the device body **204** expands radially, and the legs **206** fold outward to form an outer flange. The radially expanding body **204** helps to stretch and support an opening in the target vessel.

[**0054**] Each of the anastomosis devices according to the present invention are preferably single piece devices which are formed in a substantially tubular shape. The anastomosis devices may be formed by laser cutting or punching from a tube or sheet of superelastic or pseudoelastic material. Alternatively, the devices may be formed from superelastic or pseudoelastic wire. The devices may be provided in varying sizes to join vessels of different sizes. The legs, hooks, prongs, and other device elements which have been discussed above with regard to the various embodiments may be used in varying numbers and arrangements depending on the particular application.

[**0055**] The invention has been described as an anastomosis device which is constrained for insertion in a radially constrained configuration with a deployment tool such as tube. However, the deployment tube may take other non-tubular shapes.

[**0056**] Although the invention has been primarily discussed with respect to coronary artery bypass surgery, the anastomosis devices of the present invention may by used in other types of anastomosis procedures. For example, the anastomosis device may be used in femoral-femoral bypass, vascular shunts, subclavian-carotid bypass, organ transplants, and the like. The devices according to the present invention may be used with venous grafts such as a harvested saphenous vein graft, arterial graft, such as a dissected mammal artery, or a synthetic prosthesis, as required.

[**0057**] Finally, the anastomosis devices according to the present invention have been illustrated as substantially cylindrical members. However, the devices can also be shaped into ovals, football shapes, or other shapes. Oval shapes can be particularly useful for accommodating small target vessels.

[**0058**] While the invention has been described in detail with reference to the preferred embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention.

What is claimed is:

1. A one-piece anastomosis device for connecting a graft vessel to a target vessel, comprising:

a body formed from superelastic material, said body deformable from a constrained configuration to an unconstrained configuration; wherein in said unconstrained configuration said body includes at the distal end thereof a plurality of inner flange members forming an inner flange and includes at the proximal end thereof a plurality of outer flange members forming an outer flange; and wherein at least a portion of said body between said inner flange and said outer flange has substantially the same diameter in both said constrained configuration and said unconstrained configuration.

2. The anastomosis device of claim 1, wherein said portion of said body between said inner flange and said outer flange that maintains a substantially constant diameter in both said constrained configuration and said unconstrained configuration includes a substantially rigid ring.

3. The anastomosis device of claim 1, wherein at least one of said inner flange members is substantially blunt.

4. The anastomosis device of claim 1, wherein at least one of said outer flange members is substantially blunt.

5. The anastomosis device of claim 1, wherein at least one of said inner flange members substantially does not pierce the target vessel when said body is in the unconstrained configuration.

6. The anastomosis device of claim 1, wherein at least one of said outer flange members substantially does not pierce the target vessel when said body is in the unconstrained configuration.

7. The anastomosis device of claim 1, wherein said superelastic material is nickel-titanium alloy.

8. The anastomosis device of claim 1, wherein at least one said inner flange member is substantially radially offset from at least one said outer flange member.

9. The anastomosis device of claim 1, wherein the number of said inner flange members is equal to the number of said outer flange members.

10. An anastomosis device for connecting a graft vessel to a target vessel, comprising:

a substantially continuous ring, wherein the diameter of said ring is substantially fixed;

a plurality of inner flange members extending from said ring; and

a plurality of outer flange members extending from said ring.

11. The anastomosis device of claim 10, wherein said ring, said inner flange members and said outer flange members are composed of superelastic material.

12. The anastomosis device of claim 10, wherein at least one said inner flange member is substantially radially offset from at least one said outer flange member.

13. The anastomosis device of claim 10, wherein the number of said inner flange members is equal to the number of said outer flange members.

14. The anastomosis device of claim 10, wherein at least one of said inner flange members is substantially blunt.

15. The anastomosis device of claim 10, wherein at least one of said outer flange members is substantially blunt.

16. An anastomosis device for connecting a graft vessel to a target vessel, comprising:

a open central structure;

a plurality of first flange members extending from said central structure and movable from an insertion state to an expanded state; and

a plurality of second flange members extending from said central structure and movable from an insertion state to an expanded state, at least one said second flange member having a free end; wherein at least one said free end is oriented generally toward at least one said first flange member when said first flange members and said second flange members are in said expanded state.

17. The anastomosis device of claim 16, wherein at least one said free end is pointed, whereby said pointed free end penetrates the target vessel.

18. The anastomosis device of claim 16, wherein at least one said free end is pointed, whereby said pointed free end penetrates the graft vessel.

19. The anastomosis device of claim 16, wherein at least one said free end is angled relative to a remainder of the corresponding said second flange member.

20. The anastomosis device of claim 16, wherein said central structure has a substantially fixed perimeter.

21. The anastomosis device of claim 16, wherein said central structure is a substantially rigid ring.

22. The anastomosis device of claim 10, wherein at least one said first flange member is substantially radially offset from at least one said second flange member.

23. The anastomosis device of claim 10, wherein the number of said first flange members is equal to the number of said second flange members.

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