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(54) **SUTURELESS GASTROESOPHAGEAL ANTI-REFLUX VALVE PROSTHESIS AND TOOL FOR PERORAL IMPLANTATION THEREOF**

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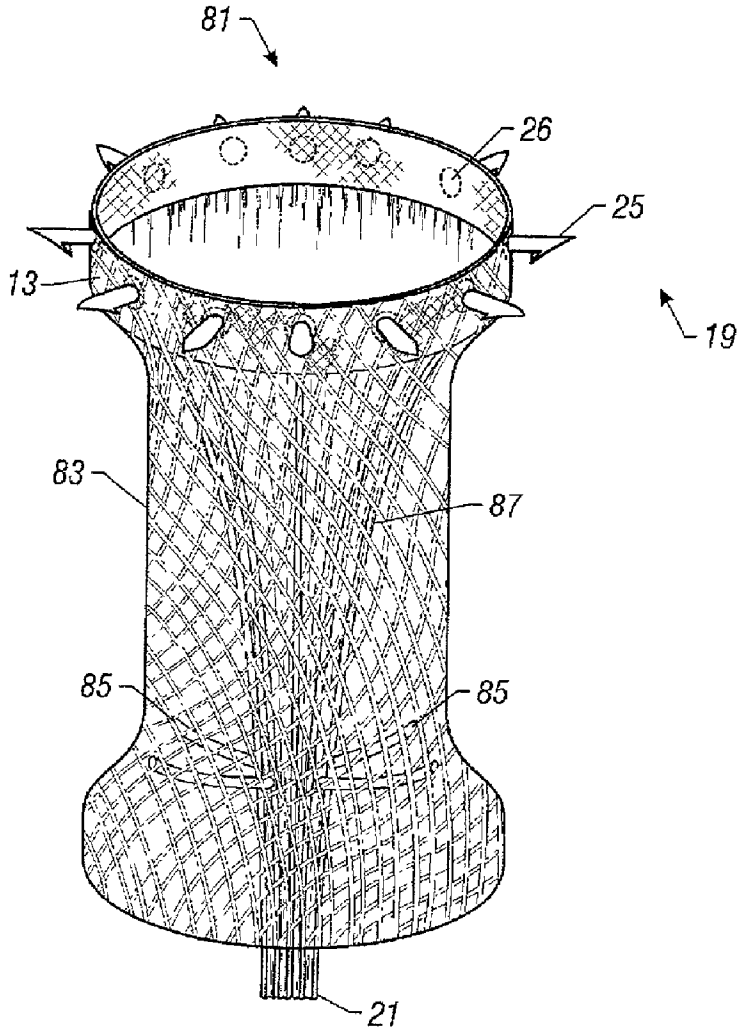
(52) **U.S. Cl.** **623/23.68**

(57) **ABSTRACT**

Disclosed are an instrument, valve prosthesis and procedure for the minimally invasive implantation of a sutureless anti-reflux valve in a patient for the treatment of gastroesophageal reflux disease. A prosthesis is provided that comprises a cylindrical housing, a mounting ring and a one-way anti-reflux valve depending from the mounting ring. The cylindrical housing is constructed of a memory material that can be fixed in the gastroesophageal junction. The mounting ring and the anti-reflux valve are fixed within the housing.



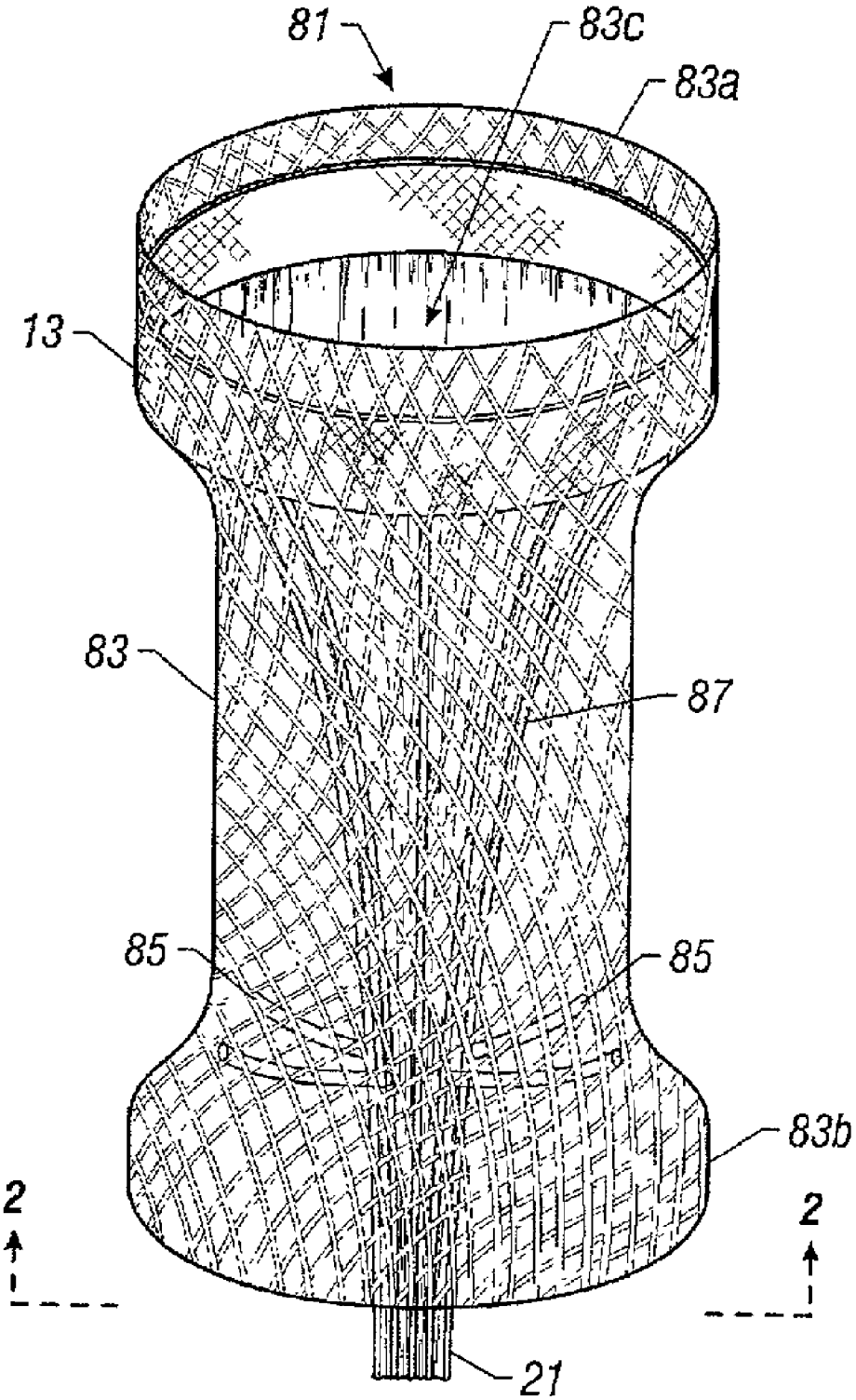


FIG. 1

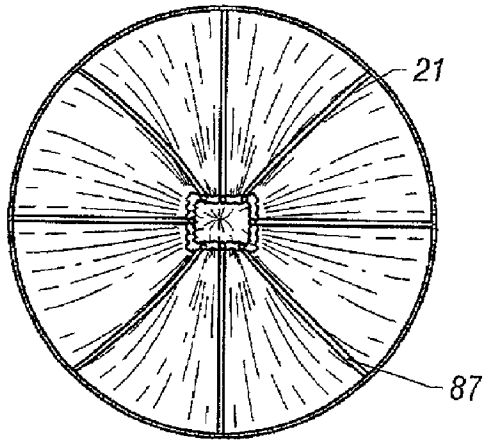


FIG. 2

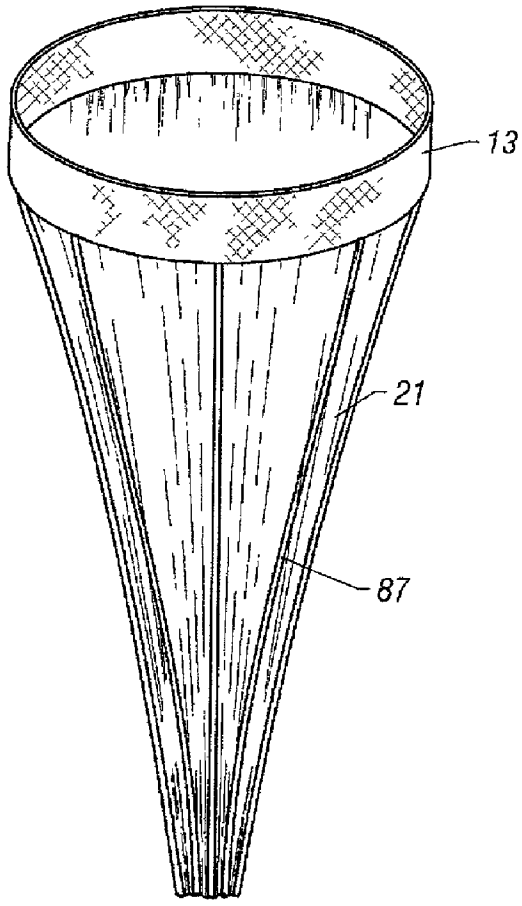


FIG. 3

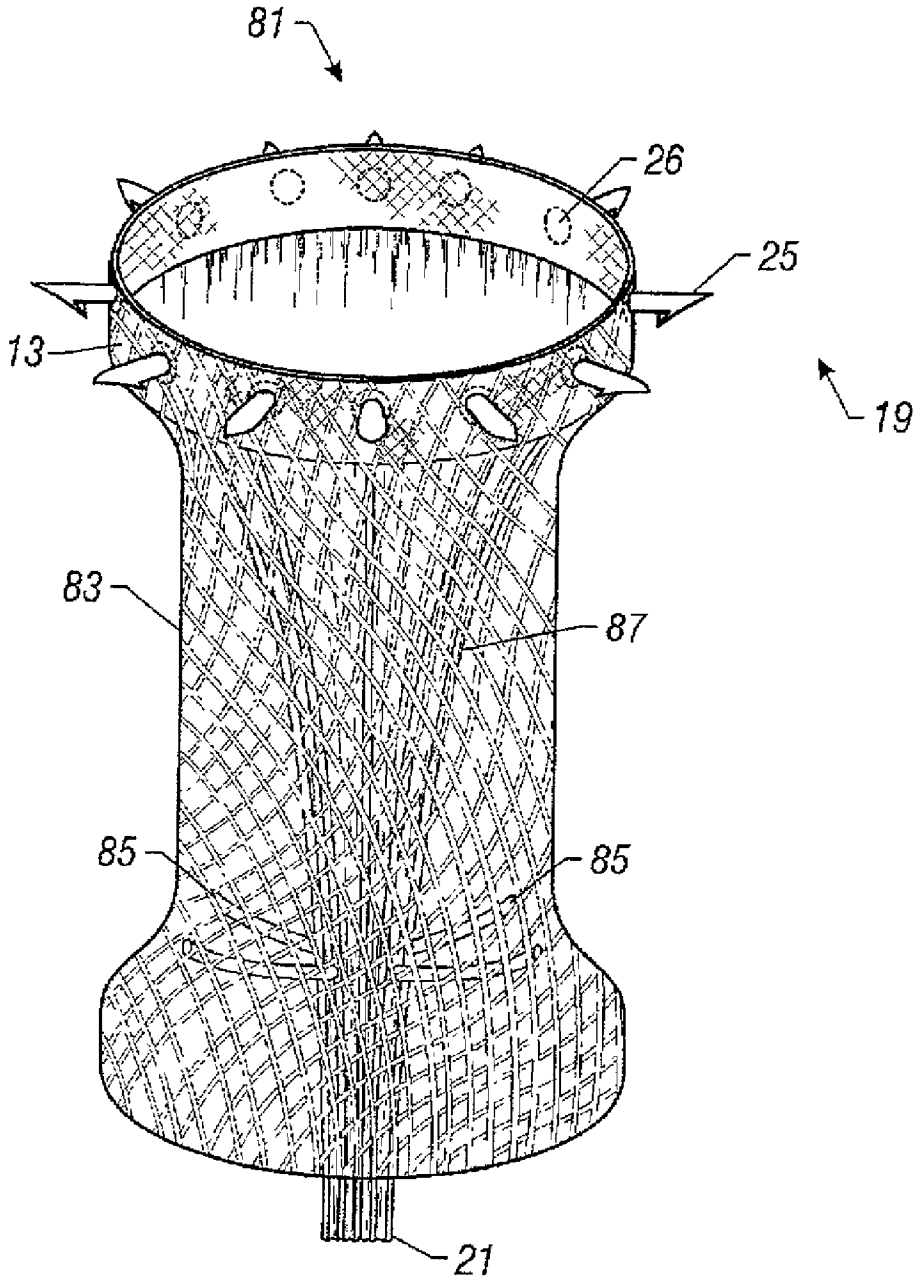


FIG. 4

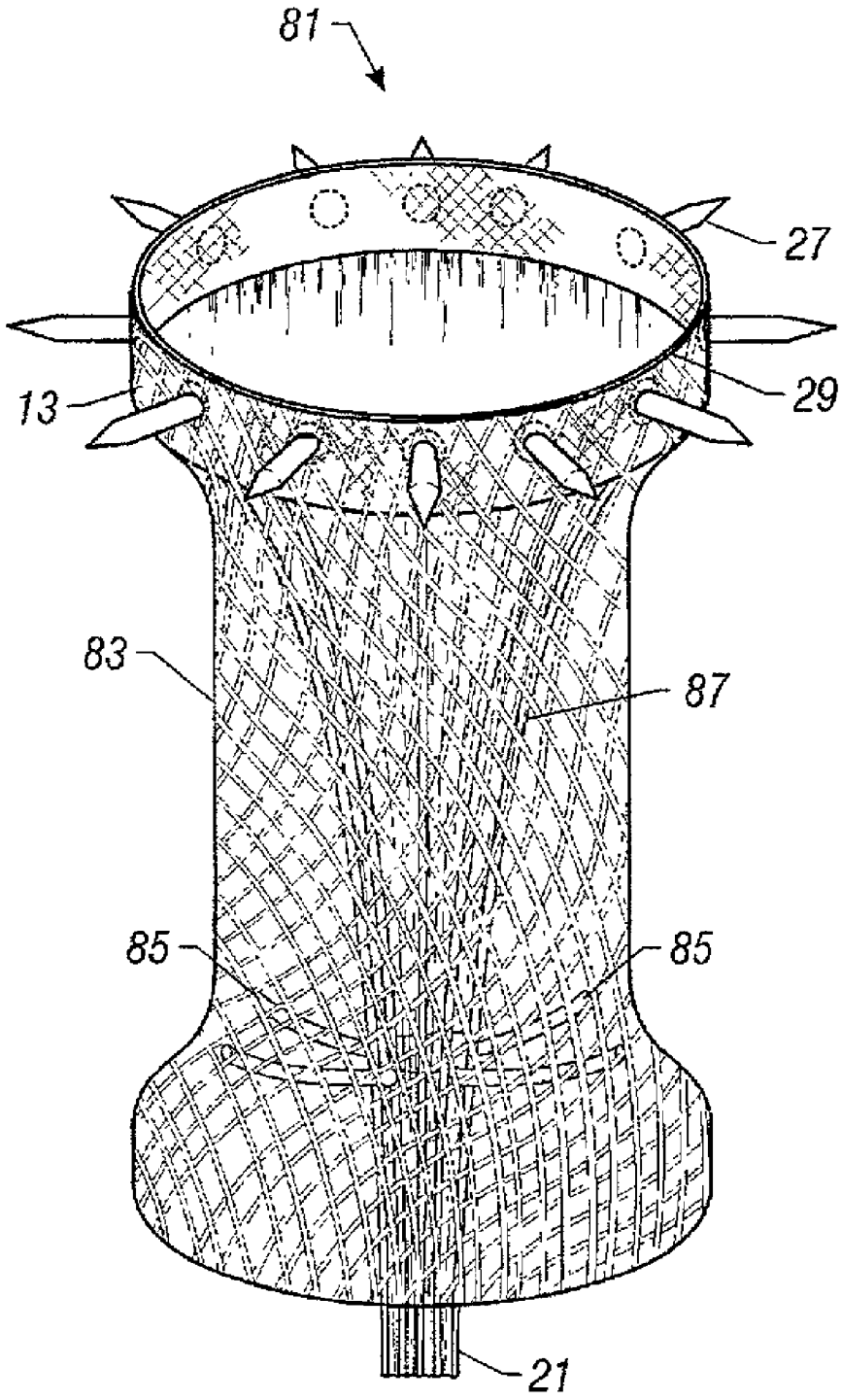


FIG. 5

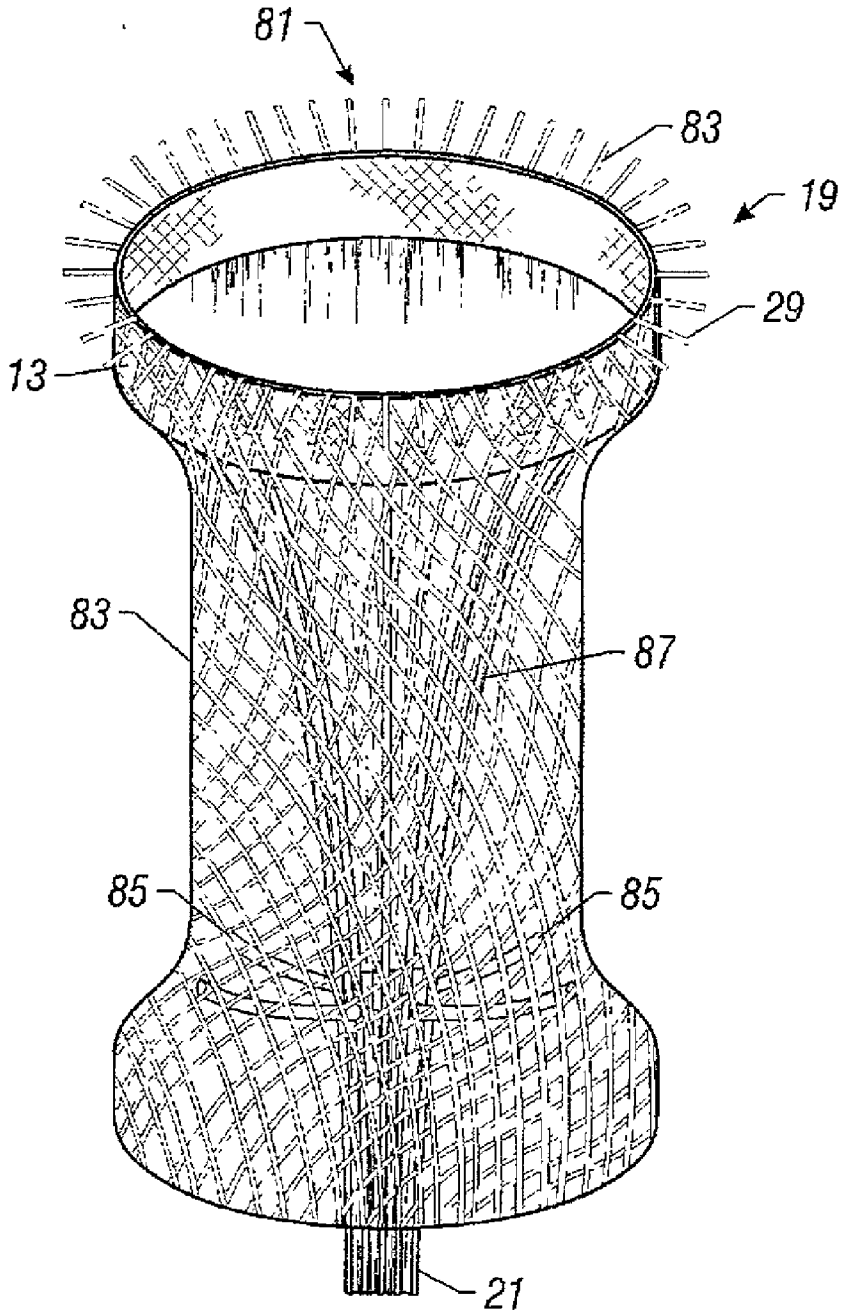


FIG. 6

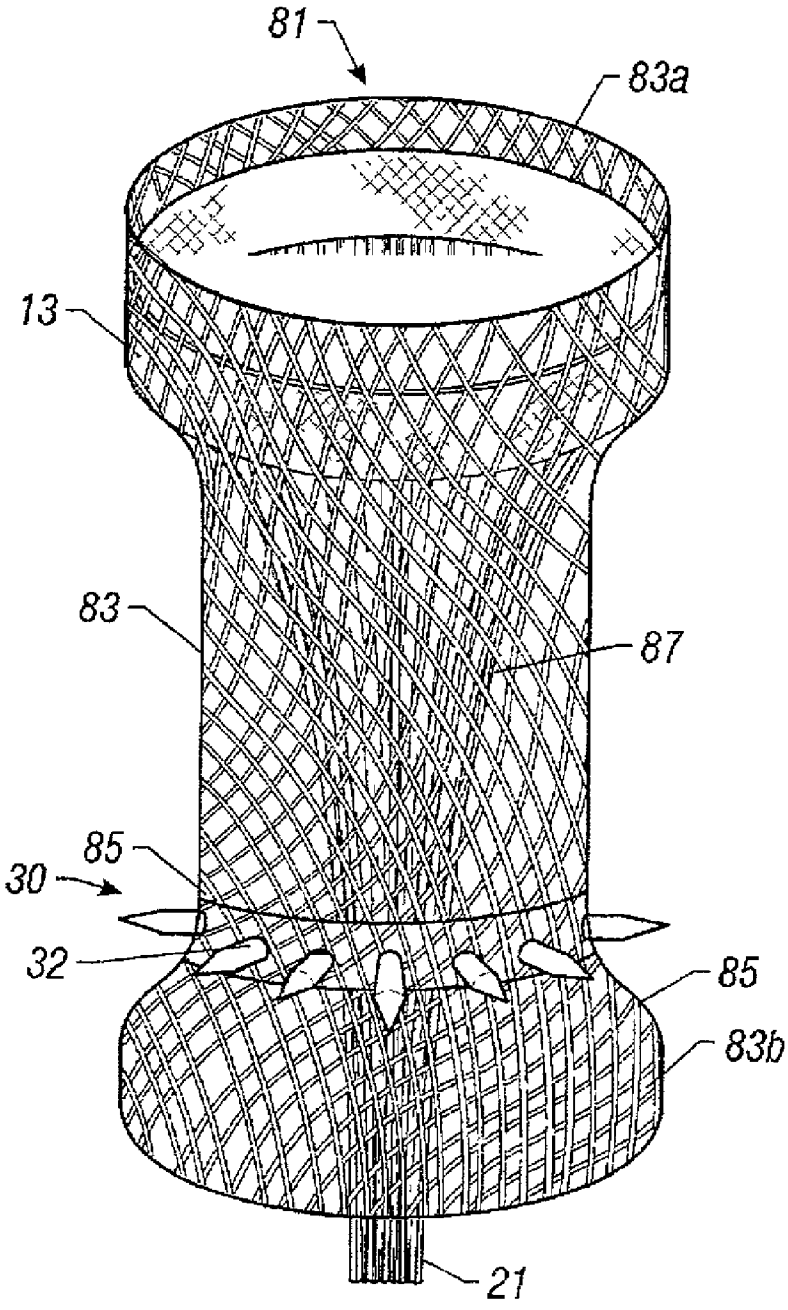


FIG. 7

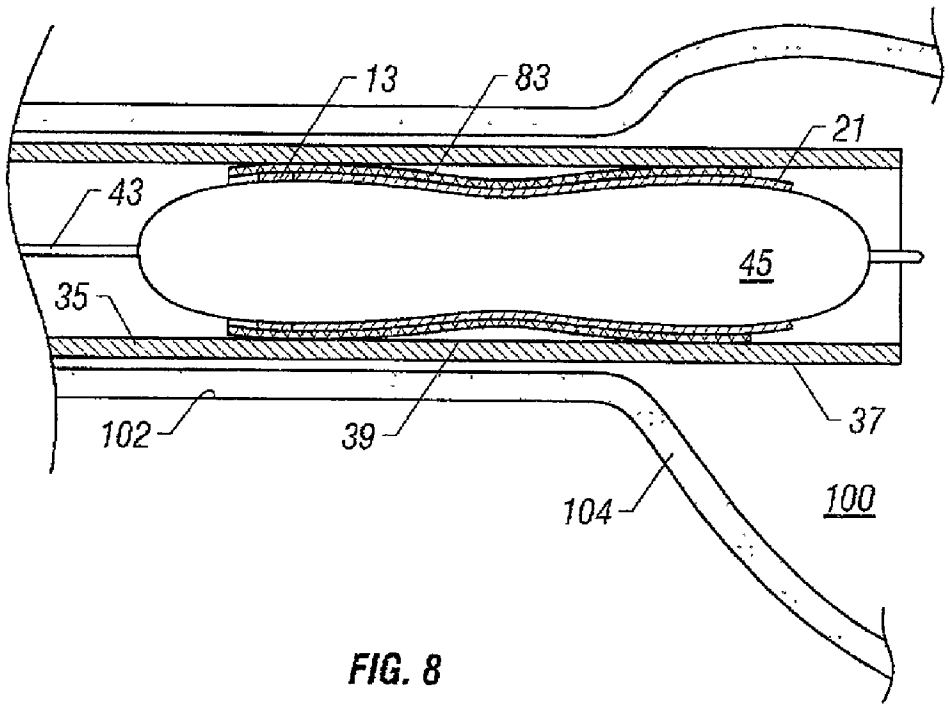


FIG. 8

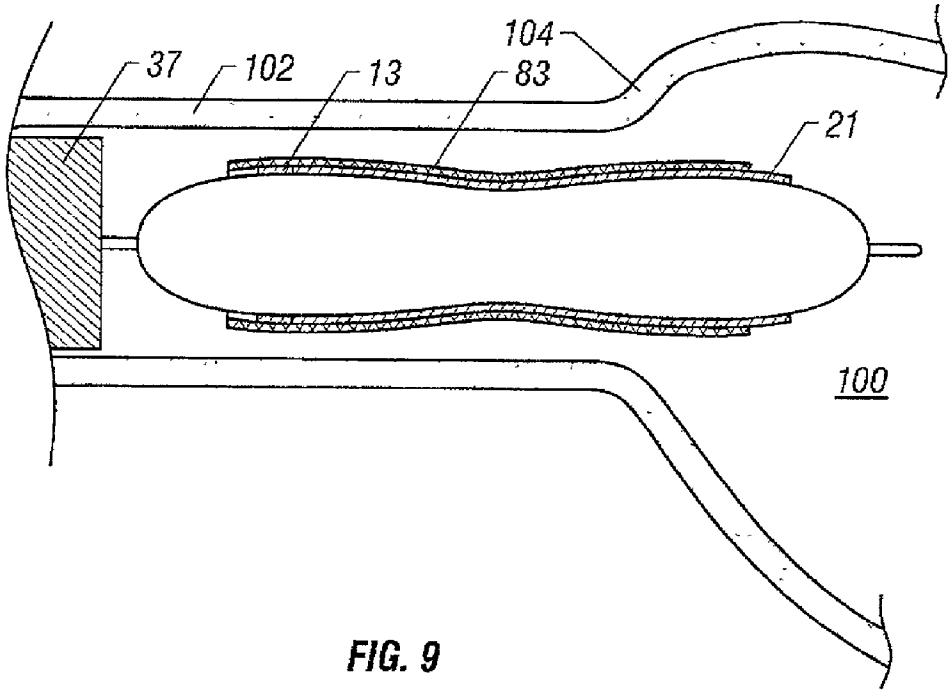


FIG. 9

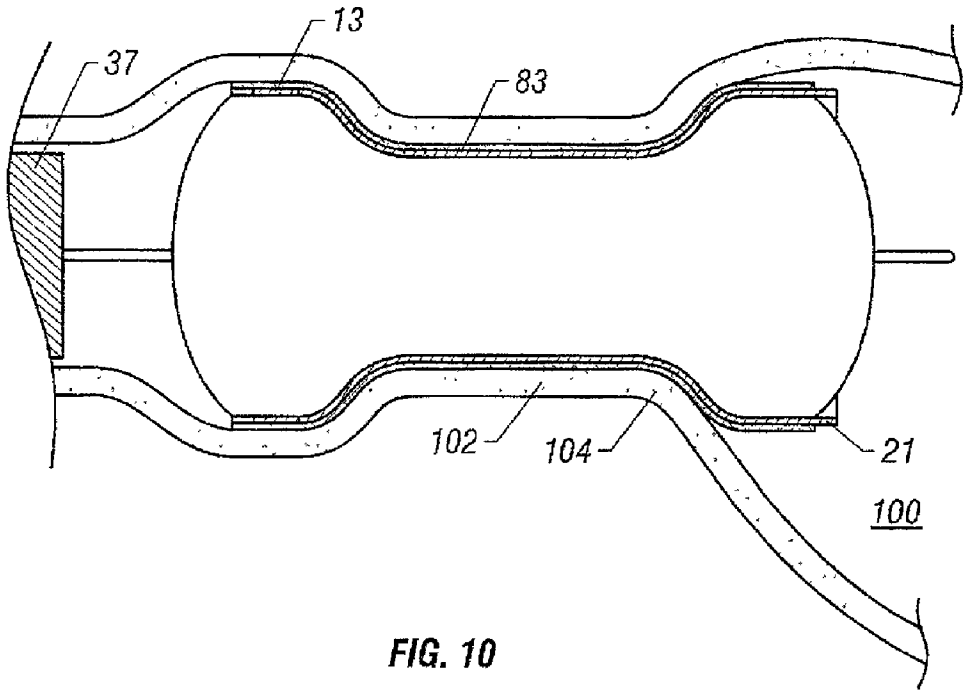


FIG. 10

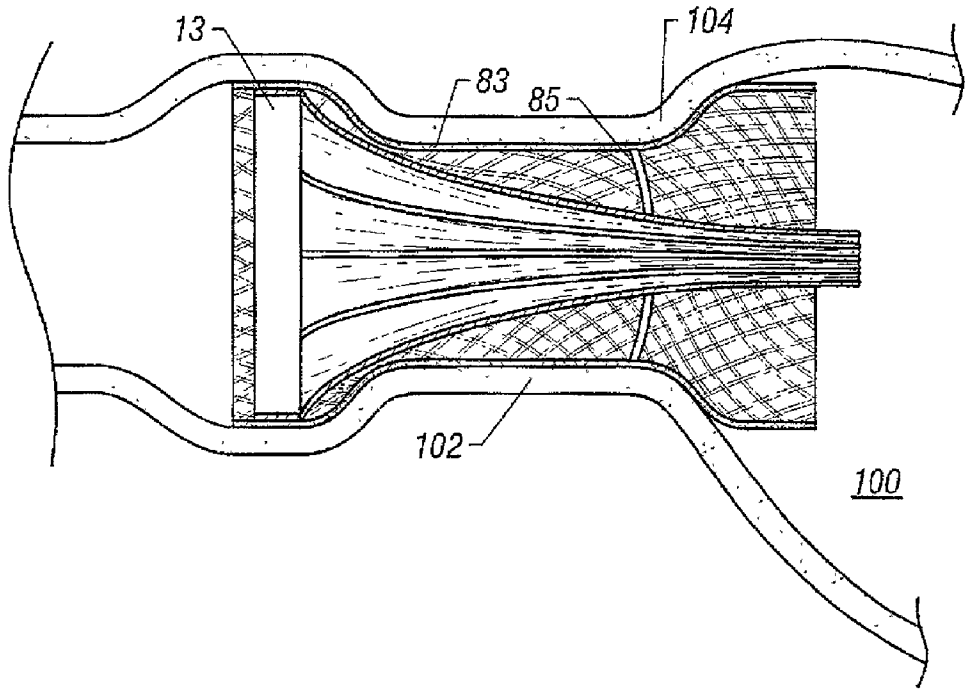


FIG. 11

SUTURELESS GASTROESOPHAGEAL ANTI-REFLUX VALVE PROSTHESIS AND TOOL FOR PERORAL IMPLANTATION THEREOF

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This is a division/continuation-in-part of my earlier copending application Ser. No. 08/987,693, filed Dec. 9, 1997, now U.S. Pat. No. _____, which is hereby incorporated herein by reference in its entirety.

BACKGROUND OF INVENTION

[0002] This invention relates to a device and non-invasive surgical method for treating gastroesophageal reflux disease. More specifically, it relates to an anti-reflux valve prosthesis and associated instrumentation for its peroral placement and in situ fixing at the gastroesophageal junction, to prevent the reflux of gastric contents into the esophagus in the treatment of gastroesophageal reflux disease in a patient.

[0003] Gastroesophageal reflux disease (GERD) is the commonest cause of dyspepsia, affecting some 30% of the United States adult population intermittently and some 10% on a continuous and troublesome basis. Gastroesophageal reflux disease produces heartburn, abdominal pain and regurgitation of acid-containing gastric contents into the esophagus and pharynx. It may also lead to alteration of the lining of the esophagus (Barrett's Esophagus), which may go on to produce esophageal cancer. Current methods of treating GERD include powerful antacid medication therapies and surgical interventions.

[0004] Medication therapy with powerful antacids is directed at treating the symptoms of GERD, and is necessarily not curative. Furthermore, medication-based therapies are not always fully effective, as reflux is not prevented and the esophagus may continue to be exposed to gastric content.

[0005] Surgical intervention typically involves either open surgery (performed through the abdomen or the chest) or laparoscopic surgery (performed through one or more incision access ports inserted through the abdominal wall), and the re-sectioning of tissue or the implanting of a prosthetic device. Although surgical interventions can be curative, these treatments are seriously invasive and have the attendant risk of such procedures. Despite the risk, the field has been motivated to provide solutions to the GERD problem, which has resulted in the development of a number of surgically implantable anti-reflux valve prosthetic devices. Prior anti-reflux valve prostheses are essentially one-way valves implanted at the gastroesophageal junction using open or laparoscopic surgery. The implanted prosthesis allows normal swallowing to take place in an orthograde manner while preventing the reflux of gastric contents from the stomach into the esophagus.

[0006] Examples of surgically implanted esophageal anti-reflux valve prostheses include the devices of: Godin (U.S. Pat. No. 5,314,473) which discloses a one-way, antivalve comprising a flattened tubular part associated with an annular fixing element; and Reich (U.S. Pat. No. 4,846,836) which discloses a bi-directional valve and housing for similar purposes. These devices were developed to be inserted into the gastro-esophageal junction via open or laparoscopic surgery and fixed there. The purpose was to permit the unidirectional passage of ingested materials into the stomach while preventing the reflux of gastric content of the stomach into the esophagus. Typically, these devices require suturing or other means to fix them to the tissue of the esophagus.

[0007] Generally, all of these prior devices and methods require surgical invasion of a body cavity and breach of the body membrane in some fashion (e.g., open surgery or laparoscopy) in order to accomplish their utility. However, such invasive surgical interventions are too frequently complicated by problems such as stricture formation, "gas bloat," or recurrent symptoms of reflux disease. Additionally, the results obtained by gross surgical treatment can be technique-dependent and vary significantly from surgeon to surgeon.

[0008] In view of the preference for minimally invasive forms of surgery there is a need in the art for GERD treatments that can be fully accomplished without surgically compromising the integrity of a patient's body membrane. Applicant has invented a peroral procedure for the insertion and implantation of a sutureless anti-reflux valve prosthesis that can address this need. It benefits the field to have an alternative prosthetic device and method that can be practiced to position and fix an anti-reflux prosthesis in place in the esophagus without resort to surgical incision or laparoscopy.

SUMMARY OF INVENTION

[0009] The present invention relates to an anti-reflux valve prosthesis system for treating gastroesophageal reflux disease (GERD) in a patient, which does not require open or laparoscopic surgery to implant. The present invention provides for perorally inserting a sutureless anti-reflux valve prosthesis down the lumen of the esophagus, to the gastroesophageal junction, where it is fixed in place. The advantage of this system is that peroral insertion of such a valve eliminates the need for either open formal laparotomy, thoracotomy or a laparoscopic approach using multiple access ports. Peroral installation of an anti-reflux prosthesis has the potential benefit of reducing the trauma, morbidity and hospital stay associated with implantation of anti-reflux valve prostheses relative to other surgical techniques. Furthermore, a system permitting the implantation of a standardized anti-reflux valve in an accurate and reproducible manner has the potential for providing more consistent clinical results than can be achieved with other techniquemethods of treatment.

[0010] A preferred embodiment of the present invention provides a prosthesis comprising a cylindrical housing, a mounting ring and a one-way anti-reflux valve. The cylindrical housing is constructed of a memory material that can be fixed in the distal esophagus. The mounting ring and the anti-reflux valve are fixed within the housing.

[0011] Similar cylindrical devices have been used (without the incorporation of an anti-reflux valve prosthesis) in the treatment of strictures due to esophageal cancer. An example of such a device is the WALLSTENT® esophageal endoprosthesis (Schneider USA, Inc.). These devices typically comprise a cylinder of memory metal in close contact with a sleeve of suitable material, such as silicone. The prosthesis is inserted perorally and positioned using an adaptation of the usual tool used for installing similar

cylindrical devices. The prosthesis is fixed in place by the expansion of the cylindrical device housing the anti-reflux valve.

[0012] Another embodiment of the present invention provides an anti-reflux prosthesis comprising a cylindrical housing having an enlarged upper end, an optionally enlarged or bell-shaped lower end, and an interior defined by an interior wall. The cylindrical housing is constructed of a memory material having a normal cross-section. When a force, applied to the housing to make the cross-section small, is removed, the housing returns to its normal cross-section, or is expandable to its normal cross-section, e.g. by a balloon. A mounting ring is fixed to the interior wall of the upper end of the housing. Depending from the mounting ring within the interior of the cylindrical housing is a one-way valve. The present invention further comprises an optional anti-inversion support having two ends, one end of which is fixed to a lower end of the one-way valve and the other end of which is fixed to the wall of the lower end of the cylindrical housing.

[0013] Another aspect of the invention is the provision of a system for peroral insertion and mounting of the ant-reflux valve prosthesis in the gastroesophageal junction. The system includes an overtube for holding the cylindrical housing in a radially compressed condition at a distal end of the overtube for peroral insertion down an esophageal lumen. A stylet indwelling in the overtube is in releasable operative engagement with the housing to eject the housing from the distal end of the overtube. A balloon is preferably disposed at a distal end of the stylet within the cylindrical housing, wherein the balloon is in fluid communication with a central longitudinal passage in the stylet for introducing fluid into the balloon to facilitate expansion of the housing to its normal cross-section following ejection of the housing from the overtube, and for removing said fluid from the balloon to allow retraction of the balloon from the housing into the overtube.

[0014] In a further aspect, the invention provides a method for perorally implanting an anti-reflux valve prosthesis. The method comprises: (a) perorally inserting the anti-reflux valve prosthesis described above in a radially compressed condition down the esophageal lumen; (b) positioning the compressed anti-reflux valve prosthesis near the esophageal junction; and (c) expanding the anti-reflux valve prosthesis to normal cross-section to implant said prosthesis in the esophageal junction. The insertion is preferably effected with the valve prosthesis in an overtube, the positioning preferably includes ejecting the valve prosthesis from the overtube, and the expanding optionally comprises inflating a balloon inside the valve prosthesis.

BRIEF DESCRIPTION OF DRAWINGS

[0015] **FIG. 1** is a perspective view of a preferred embodiment of the self-anchoring valve prosthesis showing a metal mesh memory material housing containing an antivalve.

[0016] **FIG. 2** is a perspective view of the one-way valve from **FIG. 1** as seen from the lower end thereof along the lines **2-2**.

[0017] **FIG. 3** is a perspective view of the valve used in the prosthesis of **FIG. 2** as seen from the side.

[0018] **FIG. 4** is a perspective view of an alternate embodiment of the self-anchoring valve prosthesis of **FIG. 1**, further showing a series of barbed spikes attached to a mounting ring.

[0019] **FIG. 5** is a perspective view of another alternate embodiment of the self-anchoring valve prosthesis of **FIG. 1**, further showing a series of uniform spikes attached to a mounting ring.

[0020] **FIG. 6** is a perspective view of a further alternate embodiment of the self-anchoring valve prosthesis of **FIG. 1**, showing the wire mesh bent into a series of radially extending wires that function as anchoring spikes.

[0021] **FIG. 7** is a perspective view of yet another alternate embodiment of the self-anchoring valve prosthesis of **FIG. 1**, further showing a series of spikes affixed to the lower end of the prosthesis.

[0022] **FIG. 8** is a cross-sectional view showing the valve prosthesis of **FIG. 1** in an insertion tool disposed in the lumen of a patient's esophagus in an initial implantation step.

[0023] **FIG. 9** is a cross-sectional view showing the valve prosthesis of **FIG. 8** ejected from the distal end of the insertion tool and disposed in the lumen of a patient's esophagus at the gastroesophageal junction in a first intermediate implantation step.

[0024] **FIG. 10** is a cross-sectional view showing the valve prosthesis of **FIG. 9** positioned in the gastroesophageal junction and being expanded with an inflated expansion balloon in a second intermediate implantation step.

[0025] **FIG. 11** is a cross-sectional view showing the valve prosthesis of **FIG. 1** implanted in the gastroesophageal junction.

DETAILED DESCRIPTION

[0026] As exemplified by the figures, the present invention provides a peroral prosthesis system for treatment of gastroesophageal reflux disease (GERD) in a patient comprising an anti-reflux valve prosthesis, and a peroral implantation tool for perorally inserting and positioning the valve prosthesis at the distal end of the lumen of the esophagus, and implanting or fixing the valve prosthesis to the lumen wall.

[0027] Referring to **FIG. 1**, in a preferred embodiment, the present invention provides a valve prosthesis **81** comprising a generally cylindrical housing **83** having a bell-shaped upper end **83***a*, a bell-shaped lower end **83***b*, and a central bore **83***c*. The upper end **83***a* and the lower end **83***b* of the cylindrical housing **83** are used by the prosthesis **81** to engage the lumen of the esophagus (see **FIG. 11**), and the inner diameter or central bore **83***c* of the cylindrical housing **83** is compatible with orthograde passage of ingested (or swallowed) material through the lumen of the esophagus.

[0028] The cylindrical housing **83** is constructed of a memory material that allows the cylindrical housing **83** to be acted upon and deformed, but to return to its original shape when the deformation force is removed. The cylindrical housing **83** is deformed during installation of the prosthesis **81** (see **FIG. 8**), but returns to its original shape upon release, or is expandable by a balloon, for example, to its original shape (see FIGS. **9-10**). In a preferred embodiment

of the present invention, the memory material comprises a metal wire mesh. The exterior surface of the metal mesh facing the esophageal wall preferably has a textured surface to promote adhesion and facilitate anchoring of the prosthesis **81** to the adjacent esophageal wall, while the interior surfaces are preferably smooth and/or hydrophobic to facilitate the orthograde passage of food and liquids therethrough. Thus, the exterior of the metal mesh can be made of or coated with microporous ceramic such as apatite, for example, hydroxyapatite, open- or closed-cell elastomer foams such as polyurethane, for example, or the like. Smooth materials for the interior surfaces of the metal mesh generally include silicone, polytetrafluoroethylene and the like.

[**0029**] A mounting ring **13** is fixed to the interior wall of the upper end **83***a* of the cylindrical housing **83**. Preferably, the mounting ring **13** is constructed of the inner coating material (such as silicone) or encased or encapsulated in a suitable biologically and chemically compatible or inert material such as silicone or the like. Suspended from the mounting ring **13** within the interior of the cylindrical housing **83** is a one-way valve **21**. The one-way anti-reflux valve **21** permits the easy passage of ingested material through the bore of the cylindrical housing **83** in one direction, while impeding the reflux of stomach content through the bore of the cylindrical housing **83** in the other direction.

[**0030**] In the embodiment seen in **FIGS. 2 and 3**, the valve **21** includes a sleeve **89** depending from the mounting ring **13**. The sleeve **89** can be made of a biologically compatible rubber or silicone material, and preferably includes a plurality of rigid or semi-rigid longitudinal stays **87** longitudinally embedded within the material of the sleeve **89** or securely fixed on either the interior or exterior surface thereof. The stays **87** can be comprise metal wires or polymeric members, having a suitable spring-like quality to urge the sleeve **89** to close, particularly under slight gastric pressure in the stomach **100**. The stays **87** can have a proximal end embedded within the mounting ring **3** to help hold the shape of the valve **21**, and also serve to inhibit inversion of the sleeve **89**.

[**0031**] The valve **21** is normally closed, and the pressure differential between the stomach **100** and the esophagus **102**, and between the abdominal and thoracic cavities, act to maintain closure of the valve **21**. A suitable anti-reflux valve **21** for practicing the present invention is a typical mitral or bicuspid type valve of a half-flattened cylindrical shape. Such a shape is easily suspended from the mounting ring **13** by its cylindrical end. Other valves, such as sleeve valves, monocuspid valves, hinged disk valves and double hinged valves, are practicable in the present invention by the ordinarily skilled artisan.

[**0032**] The bell-shaped upper end **83***a* and lower end **83***b* of the cylindrical housing **83** are used to advantage to engage the esophageal lumen **102** and the lining of the stomach **100** adjacent the gastroesophageal junction **104**, respectively. Such engagement aids the mounting ring **13** in securing the prosthesis **81** within the esophagus. However, one skilled in the art will recognize that the engagement of the lumen wall **102** of the esophagus by the housing **83** in the vicinity of the mounting ring **13** alone generally provides enough resistance such that the contribution of the bell-shaped lower end **83***b* is merely for an additional safeguard against the prosthesis **81** being inadvertently dislocated from the esophagus.

[**0033**] A feature of this embodiment is the optional anti-inversion supports **85**, one end of which is fixed to the lower portion of the valve **21** and the other end of which is fixed to the wall of the lower end **83***b* of the cylindrical housing **83** . The supports **85** prevent the valve **21** from inverting. In the preferred embodiment shown in **FIG. 1**, the anti-inversion supports are biologically compatible ties affixed within the circumference of the interior wall of the cylindrical housing **83**.

[**0034**] Referring to **FIG. 4**, the prosthesis **81** in this embodiment also includes a tissue anchor array **19** for fixing the prosthesis **81** to the lumen **100** of the esophagus. The tissue anchor array **19** extends radially outward away from the axis of the ring **13**. In this embodiment, the tissue anchor array **19** is comprised of barbed spikes **25** for piercing and engaging the lumen wall of the esophagus. The tissue anchor array **19** can be comprised of at least eight spikes or points **25**, but can have as many as forty or more spikes or points **25** arrayed in a plurality of rows. Each of the points **25** preferably has a laterally extending head **26** that can be fixed within the mounting ring **13**, for example, by casting or curing the ring **13** with the heads **26** embedded therein so that when cured, the material of the ring **13** completely covers the heads **26**. The points **25** are aligned to pass between the adjacent wires in the memory metal mesh of the upper end **83***a* of the housing **83**, and if desired, the memory metal mesh can also be embedded in the ring **13** material prior to curing or casting so that the ring **13** is securely fixed to the housing **83** .

[**0035**] **FIG. 5** illustrates another embodiment of the tissue anchor array **19**. In this embodiment, the tissue anchor array **19** is comprised of straight spikes **27**. The straight spikes **27** engage the lumen wall of the esophagus to secure the mounting ring **13** of the prosthesis **81**, but offer the advantage of easier removal than the barbed spikes **25** of the **FIG. 4** embodiment. It may be desirable or necessary at times subsequent to insertion of the prosthesis **81** to remove the prosthesis **81** from the esophagus wall. Barbed spikes **25** cause heightened resistance to removal and act to tear the esophagus wall upon removal. Thus, the uniform spikes **27** of this embodiment can be advantageously used where removal of the prosthesis **81** can be more likely.

[**0036**] It should be noted that in **FIG. 5** the end points **29** of the wire mesh that forms the cylindrical housing **83** are affixed to the mounting ring **13** by being inserted in the mounting ring **13**. However, one skilled in the art will recognize that the end points **29** can be folded over the mounting ring **13**, they can be configured as shown in **FIGS. 1 and 4-5**, or they can be affixed to the mounting ring **13** by adhesives, etc. and remain within the purview of the invention.

[**0037**] Yet another embodiment of the tissue anchor array **19** is illustrated in **FIG. 6**. In this embodiment, the tissue anchor array **19** is comprised of the end points **29** of the wire mesh that forms the cylindrical housing **83**. The end points **29** of the wire mesh are bent outward such that they are pointing outwardly from the surface of the mounting ring **13**.

Sets of adjacent end points **29** can also be integrally wrapped together to form less flexible spikes that can penetrate the lumen wall without deformation (not shown). One skilled in the art will recognize that the end points **29** can similarly be reinforced at their tips to ensure that they can penetrate the lumen wall without deformation.

[**0038**] **FIG. 7** illustrates an embodiment of the valve prosthesis **81** having a tissue anchor array **30** adjacent to the bell-shaped lower end **83***b* of the cylindrical housing **83**. In this embodiment, the tissue anchor array **30** extends radially outward from the valve prosthesis **81**. The tissue anchor array **30**, in combination with the inherent anchoring features of the bell shapes, provides additional safeguard that the prosthesis **81** remains secure within the esophagus. In this embodiment, the tissue anchor array **30** is comprised of points or spikes **32** for piercing and engaging the esophageal junction **104**. The tissue anchor array **30** can be comprised of at least eight points or spikes **32**, but can have as many as forty or more points or spikes **32** arrayed in one or a plurality of rows.

[**0039**] Referring to FIGS. **8-11**, in one preferred embodiment, the prosthesis system of the present invention includes an implantation tool **35** for holding and perorally inserting a prosthesis **81** down the lumen of a patient's esophagus to a position proximate the gastroesophageal junction, and fixing the prosthesis **81** to the lumen wall. The tool **35** comprises a flexible overtube **37**, of a construction and length suitable for peroral insertion into the esophagus. At one end, the overtube **37** has an integral compression collar **39** and at the other end a conventional handle (not shown) for manipulation. The compression collar **39** provides a means for releasably receiving the housing **83** of the prosthesis **81** in a compressed configuration. A hollow stylet **43** is slidably contained (or indwelling) in the length of the overtube **37** from end to end. At the collar **39** of the overtube **37**, the stylet **43** has a balloon **45** attached. The bladder of the balloon **45** communicates with the hollow (not shown) of the stylet **43**, and the balloon **45** is inflatable by pressurizing the hollow of the stylet **43** with a gas or liquid inserted into the hollow from the handle end of the tool **35**.

[**0040**] It should be noted that because the cylindrical housing **83** of the prosthesis **81** is comprised of a memory material, depending upon the application environment, the balloon **45** within the overtube **37** may not be necessary for secure engagement of the mounting ring **31** to the esophagus. The prosthesis **81** can be secured within the esophagus by placing the compressed prosthesis **81** within the overtube **37**, positioning the overtube **37** within the esophagus, and releasing the prosthesis **81** from the overtube **37** in or near the gastroesophageal junction **104** . Once released, the cylindrical housing **83** springs back or is expanded by inflation of the balloon **45** to its initial form, thereby engaging the lumen wall **102** of the esophagus. The balloon **45** is then deflated for removal of the tool **35**.

[**0041**] While the above description contains many specifics, these should not be construed as limitations on the scope of the invention, but rather as exemplifications of preferred embodiments thereof. Many other variations are possible, which would be obvious to one skilled in the art. Accordingly, the scope of the invention should be determined by the scope of the appended claims and their equivalents, and not just by the illustrative embodiments.

1. a sutureless, perorally insertable anti-reflux valve prosthesis, comprising:

a cylindrical housing constructed of a memory material;

a mounting ring fixed to the housing; and

a one-way valve depending from the mounting ring within the cylindrical housing.

2. The anti-reflux valve prosthesis of claim 1 wherein the memory material is a metal mesh.

3. The anti-reflux valve prosthesis of claim 2 wherein the metal mesh further comprises an interior surface and an exterior surface, the exterior surface being textured to facilitate anchoring of the prosthesis, and the interior surface being smooth to facilitate orthograde passage of foods and liquids therethrough.

4. The anti-reflux valve prosthesis of claim 1 wherein the memory material is selected from the group consisting of nickel, titanium alloy, spring steel, and plastic.

5. The anti-reflux valve prosthesis of claim 1 wherein the memory material is encased in silicone.

6. The anti-reflux valve prosthesis of claim 1 wherein the cylindrical housing has an enlarged upper end.

7. The anti-reflux valve prosthesis of claim 6 wherein the cylindrical housing further comprises an enlarged lower end.

8. The anti-reflux valve prosthesis of claim 1 wherein the valve is selected from the group consisting of sleeve valves, monocuspid valves, bicuspid valves, tricuspid valves, hinged disc valves, and double hinged valves.

9. The anti-reflux valve prosthesis of claim 1 further comprising an anti-inversion support having two ends, one end of which is fixed to the one way-valve and the other end of which is fixed to the wall of the lower end of the cylindrical housing to prevent the valve from inverting.

10. The anti-reflux valve prosthesis of claim 1 wherein the valve comprises a sleeve and a plurality of longitudinally aligned stays operatively associated with the sleeve.

11. An anti-reflux valve prosthesis comprising:

a cylindrical housing having an enlarged upper end, a lower end, and an interior defined by an interior wall, the cylindrical housing constructed of a memory material having a normal cross-section, such that when a force, applied to the housing to make the cross-section smaller, is removed, the housing returns to its normal cross-section or is expandable to its normal cross-section;

a mounting ring fixed to the wall of the upper end of the housing;

a one-way valve depending from the mounting ring within the interior of the cylindrical housing comprising a sleeve and a plurality of longitudinal stays associated therewith; and

an optional anti-inversion support having two ends, one end of which is fixed to a lower end of the one-way valve and the other end of which is fixed to the wall of the lower end of the cylindrical housing.

12. The anti-reflux valve prosthesis of claim 11 wherein the memory material is a metal mesh.

13. The anti-reflux valve prosthesis of claim 11 wherein the metal mesh further comprises an interior surface and an exterior surface, the exterior surface being textured to facili-

tate anchoring of the prosthesis, and the interior surface being smooth to facilitate orthograde passage of foods and liquids therethrough.

14. The anti-reflux valve prosthesis of claim 11 wherein the memory material is selected from the group consisting of nickel, titanium alloy, spring steel, and plastic.

15. The anti-reflux valve prosthesis of claim 11 wherein the memory material is encased in silicone.

16. The anti-reflux valve prosthesis of claim 11 wherein the housing further comprises a tissue anchor array.

17. The anti-reflux valve prosthesis of claim 11 comprising a plurality of the anti-inversion supports.

18. The invention of claim 11 wherein the lower end of the cylindrical housing comprises a bell shaped lower end.

19. The invention of claim 18 further comprising a tissue anchor array adjacent the lower end of the cylindrical housing.

20. A method for implanting an anti-reflux valve prosthesis adjacent the esophageal junction, comprising:

perorally inserting the anti-reflux valve prosthesis of claim 1 in a radially compressed condition down the esophageal lumen;

positioning the compressed anti-reflux valve prosthesis near the esophageal junction;

expanding the anti-reflux valve prosthesis to normal cross-section to implant said prosthesis in the esophageal junction.

21. The method of claim 20 wherein the insertion is effected with the valve prosthesis in an overtube, the positioning includes ejecting the valve prosthesis from the overtube, and the expanding optionally comprises inflating a balloon inside the valve prosthesis.

22. The anti-reflux valve prosthesis of claim 1, further comprising:

an overtube for holding the cylindrical housing in a radially compressed condition at a distal end of the overtube for peroral insertion down an esophageal lumen;

a stylet indwelling in the overtube in releasable operative engagement with the housing to eject the housing from the distal end of the overtube.

23. The anti-reflux valve prosthesis of claim 22 further comprising a balloon at a distal end of the stylet in the cylindrical housing, wherein the balloon is in fluid communication with a central longitudinal passage in the stylet for introducing fluid into the balloon to facilitate expansion of the housing to its normal cross-section following ejection of the housing from the overtube, and for removing said fluid from the balloon to allow retraction of the balloon from the housing into the overtube.

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