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(54) **ANTI-REFLUX STENT**

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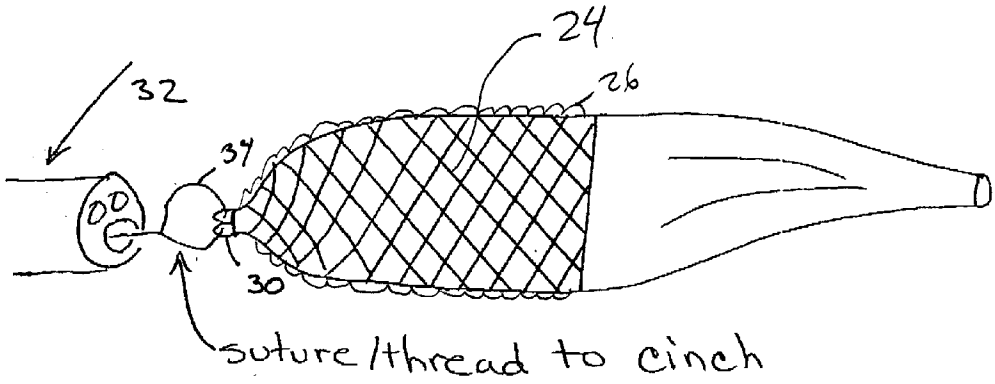
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(57) **ABSTRACT**

An anti-reflux stent includes an extended inner sleeve, a stent surrounding at least a portion of the inner sleeve and a coating that bonds the stent to the inner sleeve whereby the extended inner sleeve can have a cross-sectional thickness that varies along the length of the inner sleeve. The inner sleeve is made of a material having a thickness and/or flexibility such that the distal end not surrounded by the stent collapses under gastric pressure to prevent the contents of the stomach from flowing into an esophagus. Food and liquid can pass through an inner lumen of the inner sleeve to enter a stomach when desired.



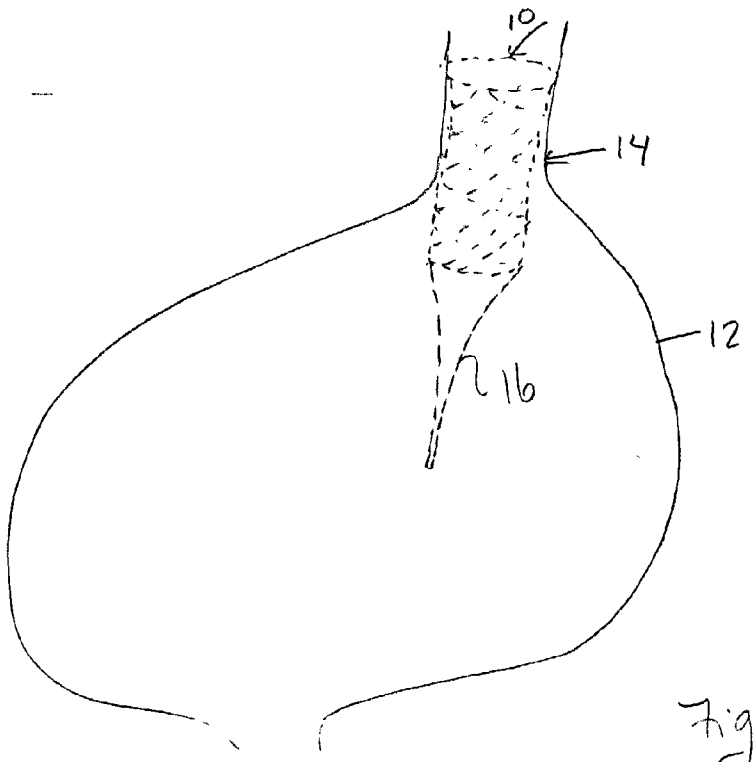


Fig 1
(prior art)

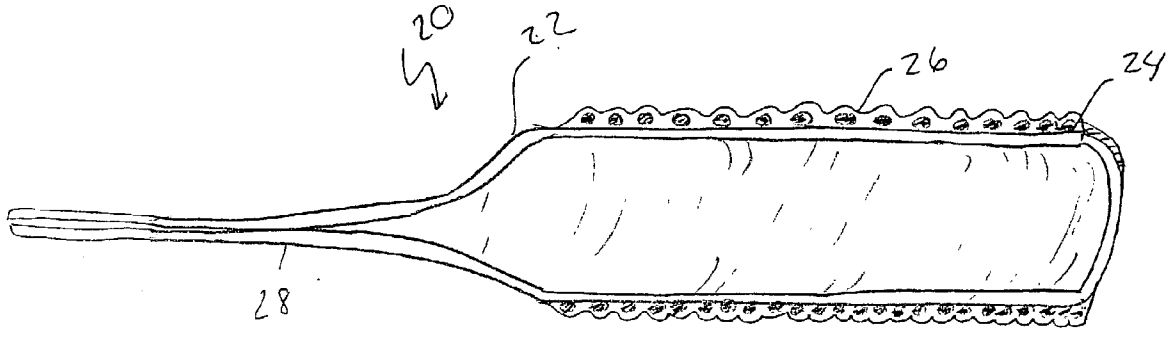


Fig 2

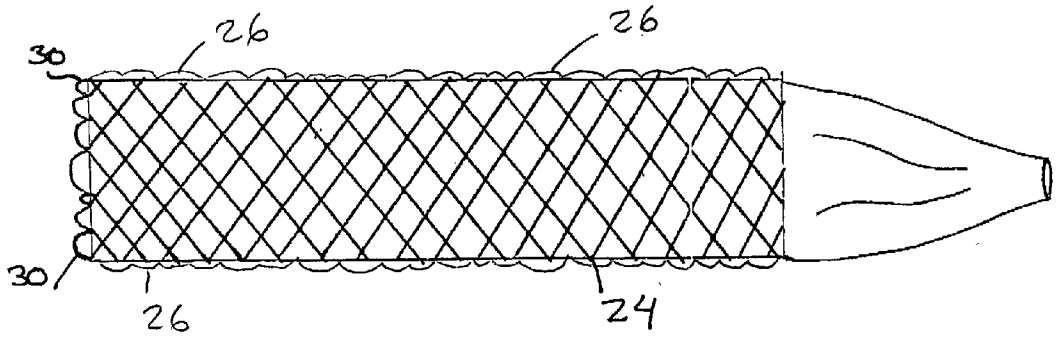


Fig2A

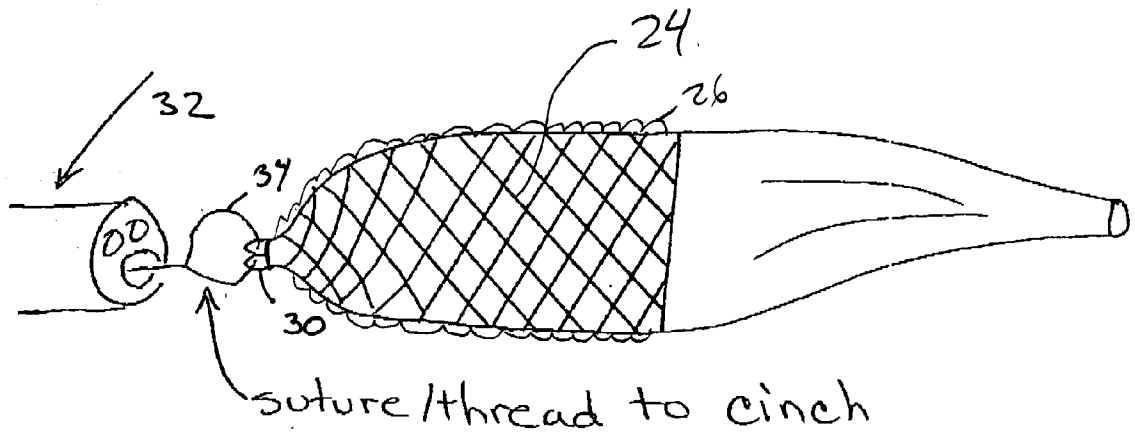


Fig. 2B

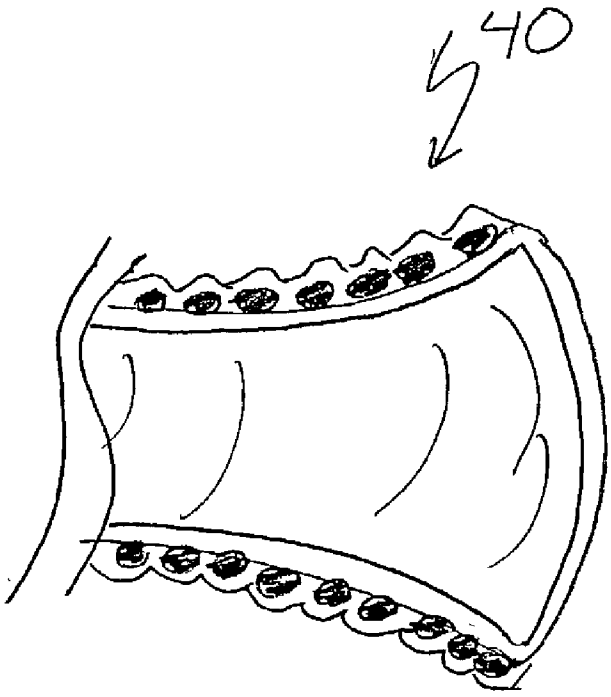


Fig 3

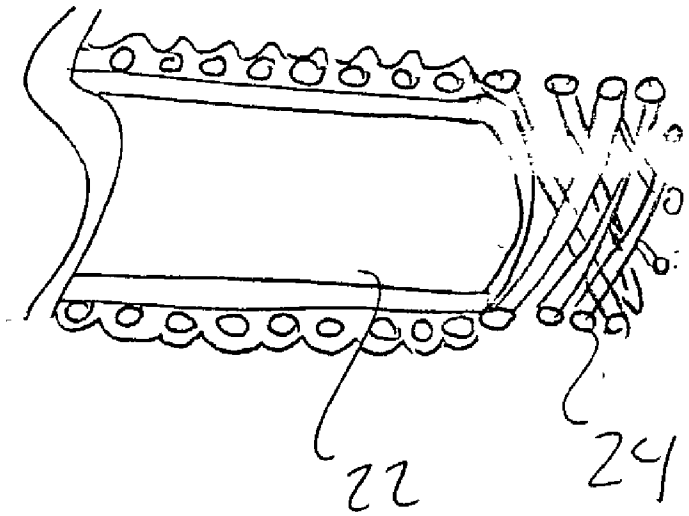


Fig 4

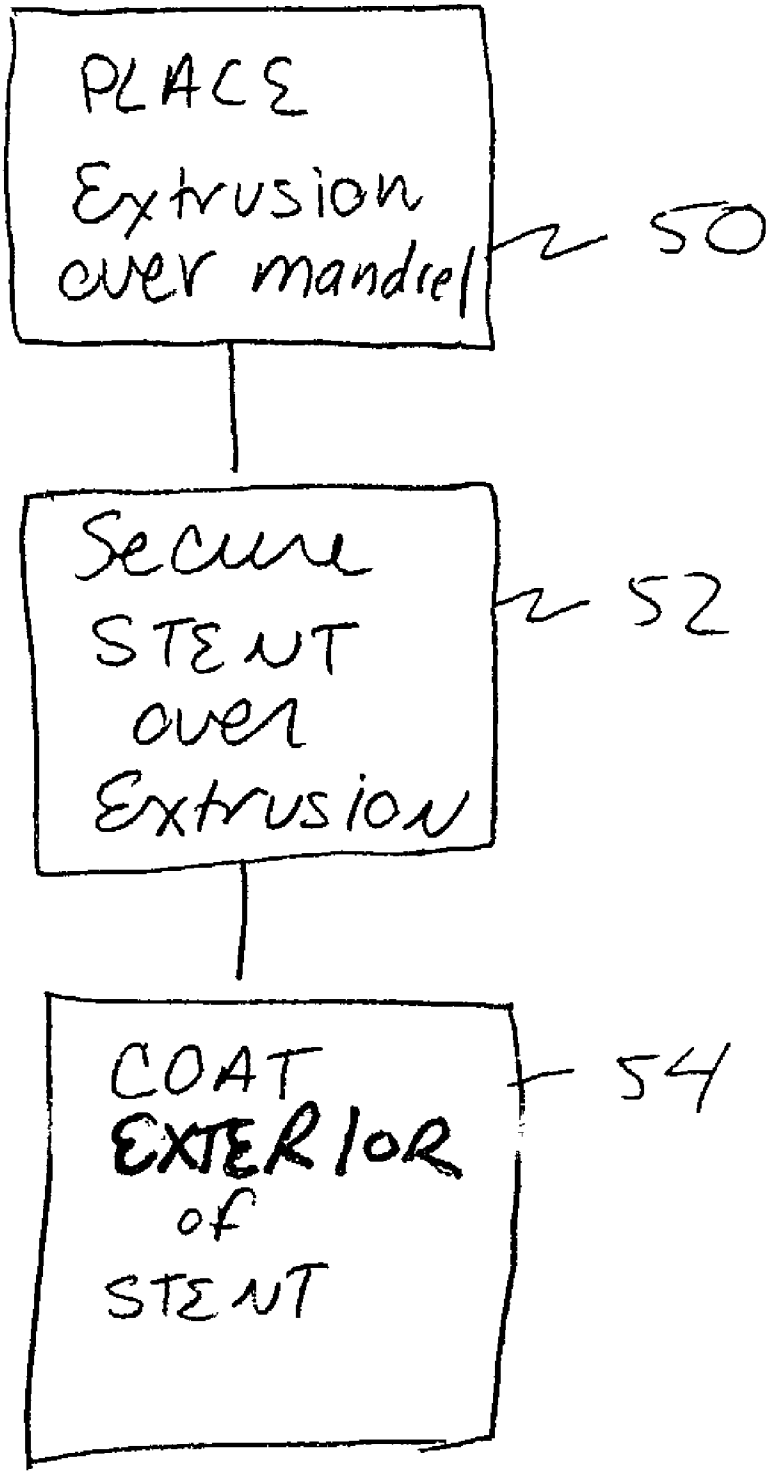

PLACE
Extrusion
over mandrel
50
Secure
STENT
over
Extrusion
52
COAT
EXTERIOR
of
STENT
54

Fig 5

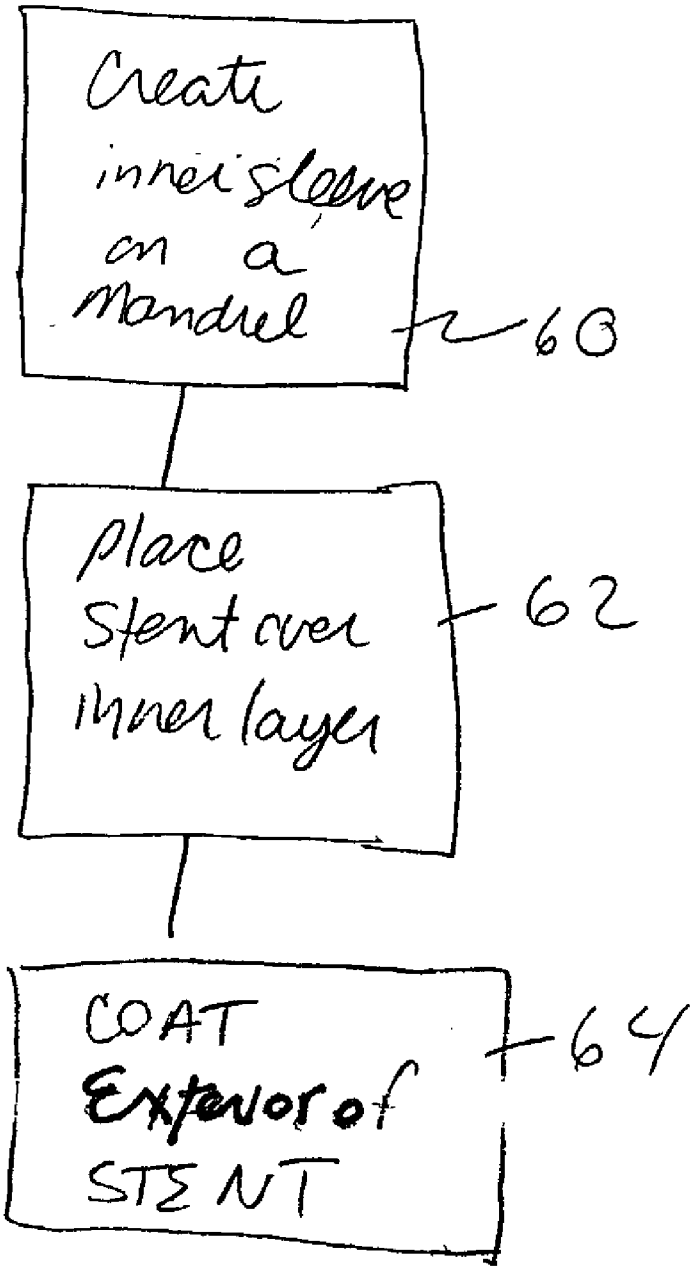

Create inner sleeve on a mandrel
60
Place Stent over inner layer
62
COAT Exterior of STENT
64

Fig 6

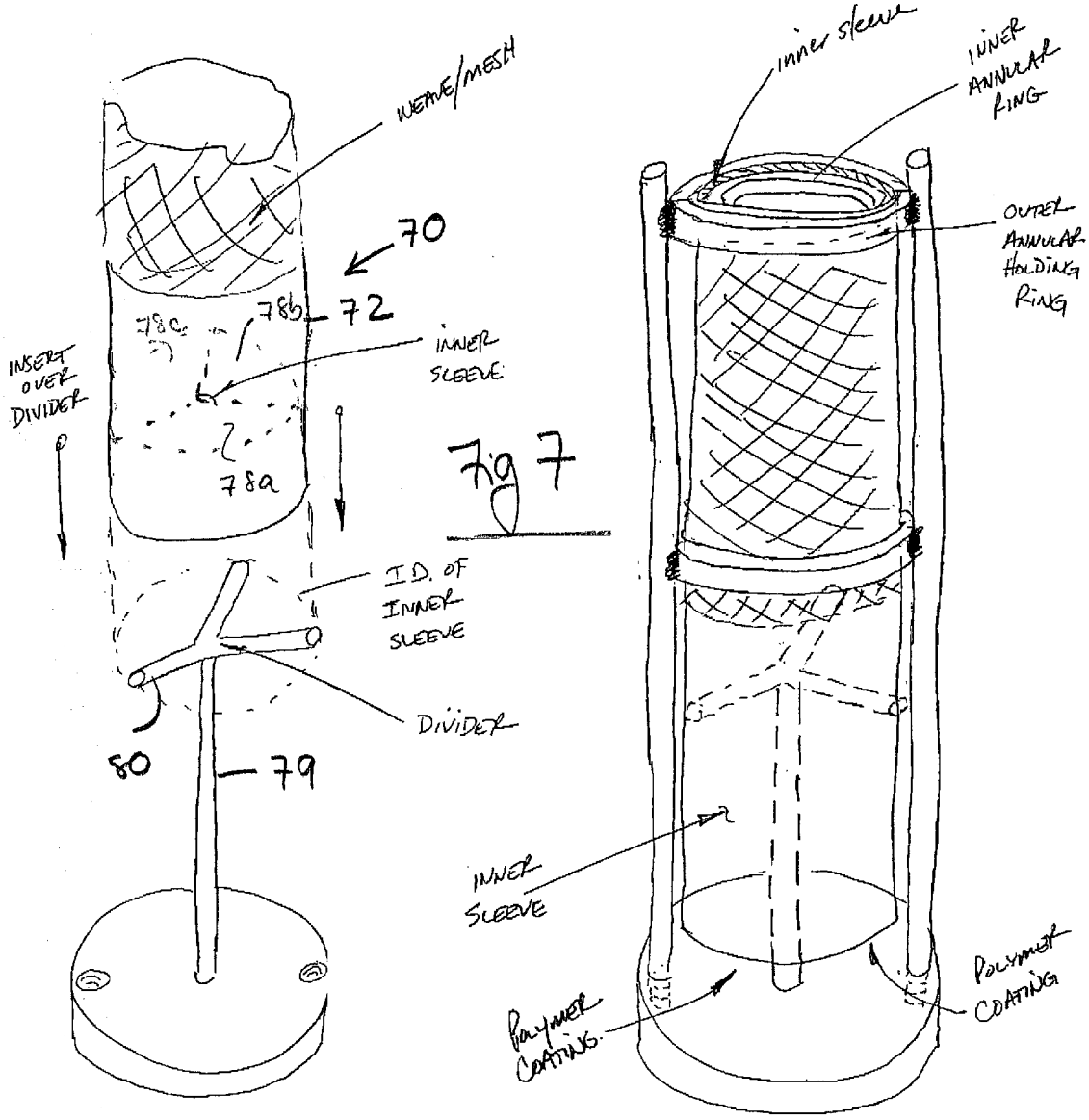

WEAVE/MESH
70
72
78c
78b
INNER SLEEVE
INSERT OVER DIVIDER
78a
I.D. OF INNER SLEEVE
DIVIDER
80
79
inner sleeve
INNER ANNULAR RING
OUTER ANNULAR HOLDING RING
INNER SLEEVE
POLYMER COATING
POLYMER COATING

Fig 7

Fig. 8a

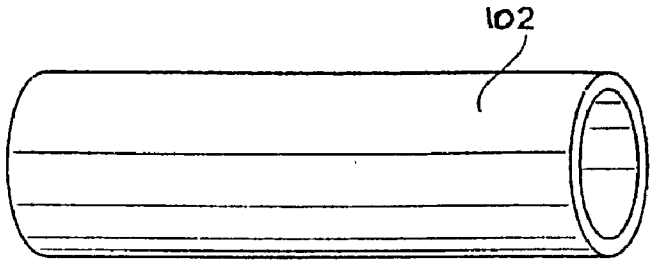


Fig. 8b

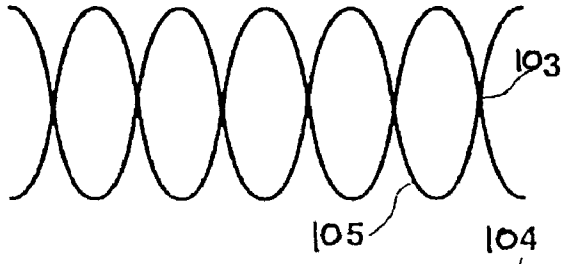


Fig. 8c

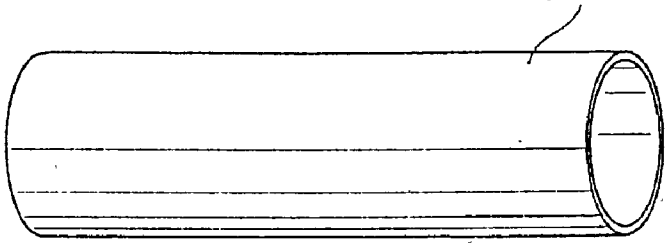


Fig. 8d

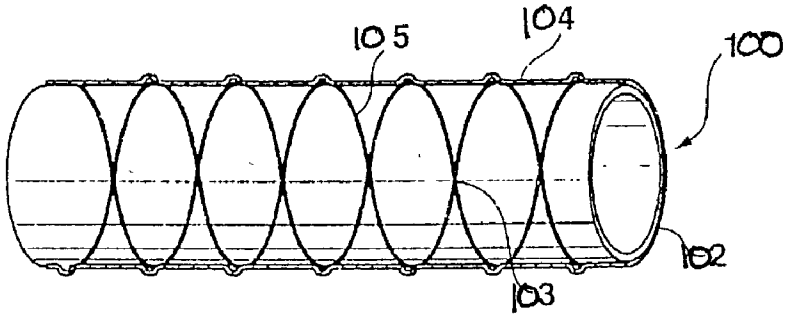


Fig. 9

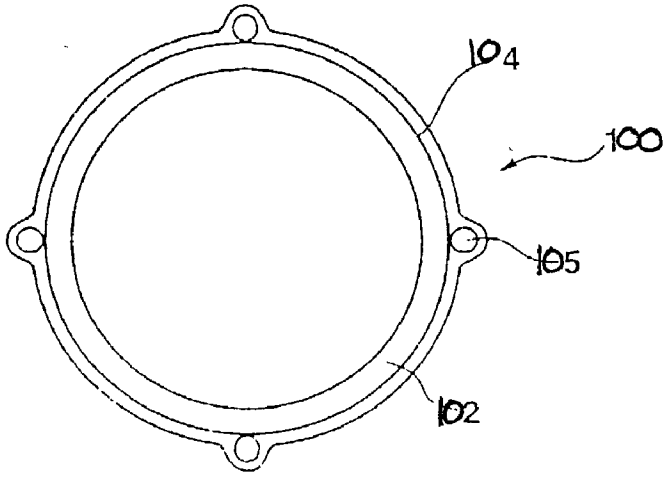


Fig. 10a

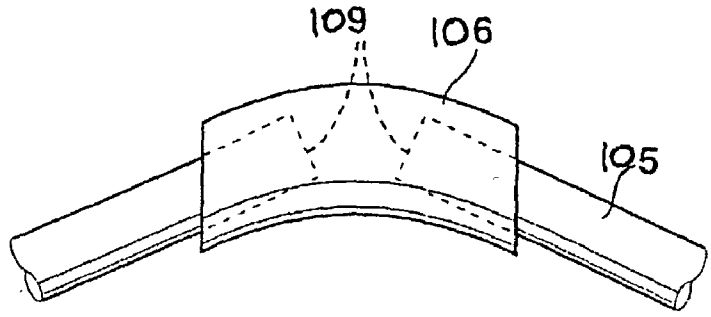


Fig. 10b

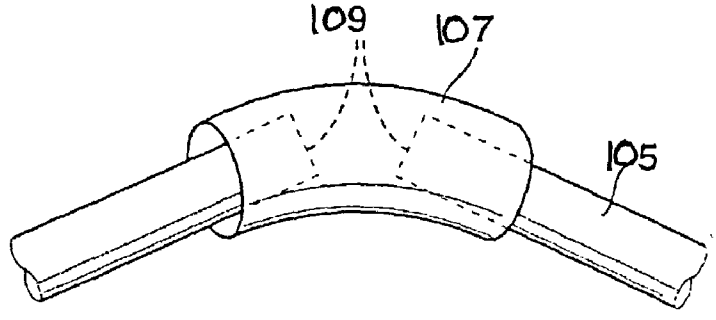


Fig. 10c

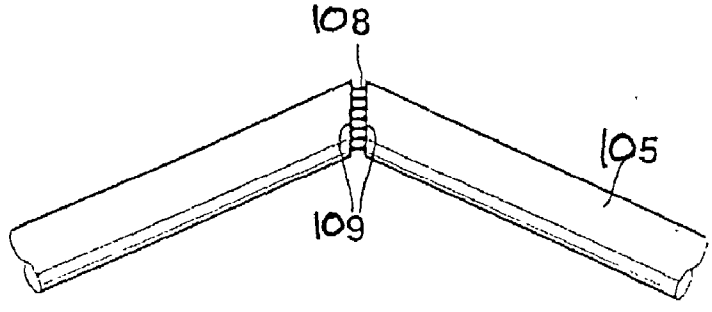


Fig. 10d

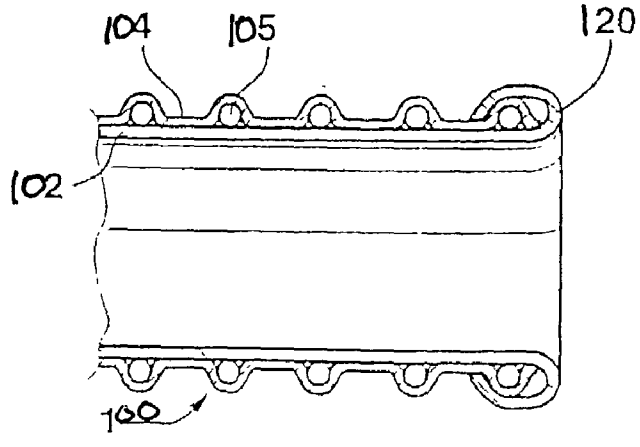


Fig. 11a

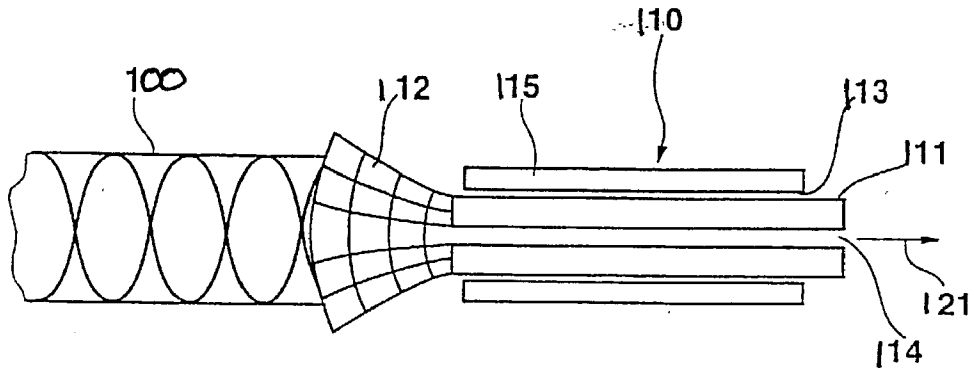


Fig. 11b

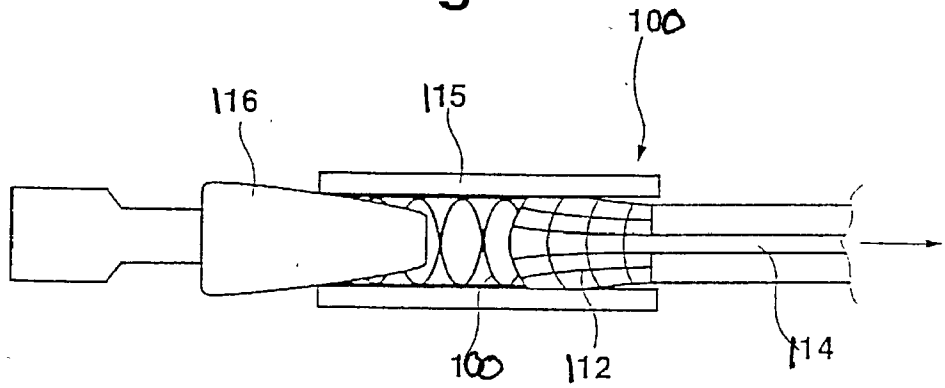


Fig. 11c

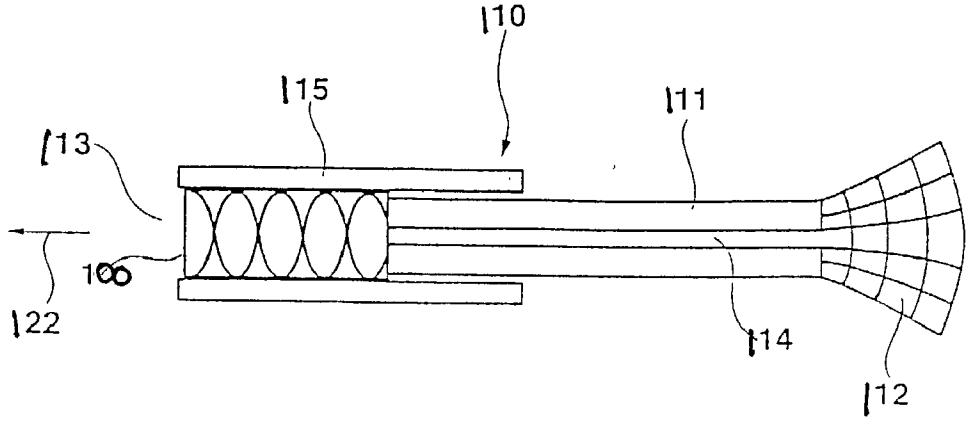


Fig. 12

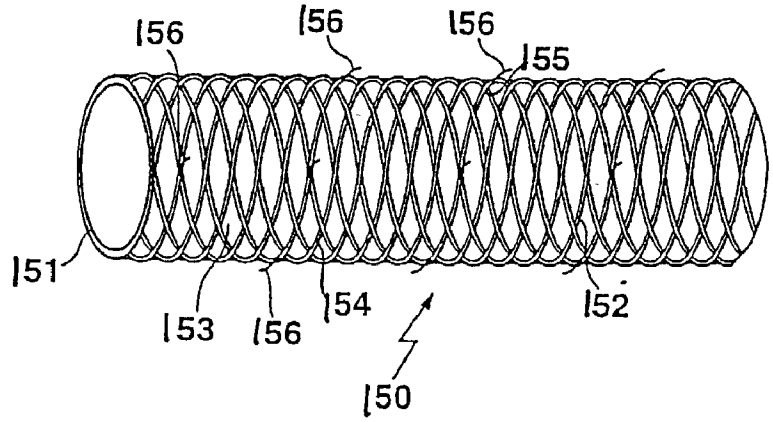


Fig. 13

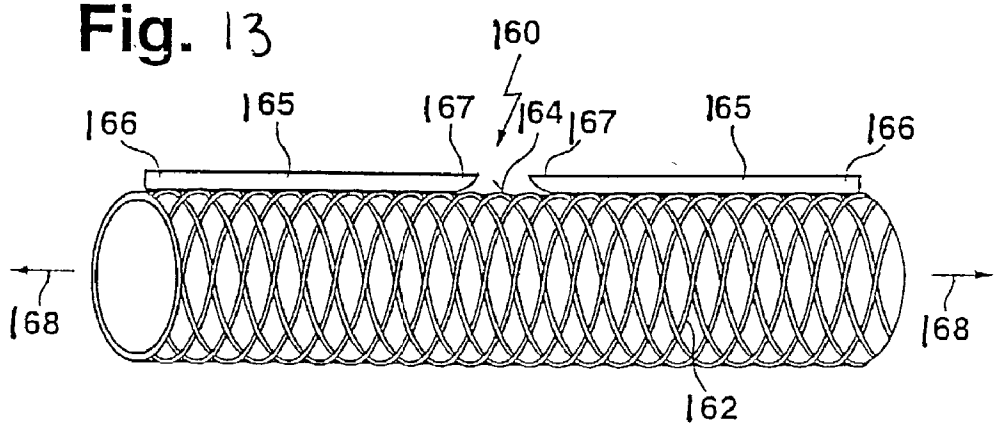


Fig. 14

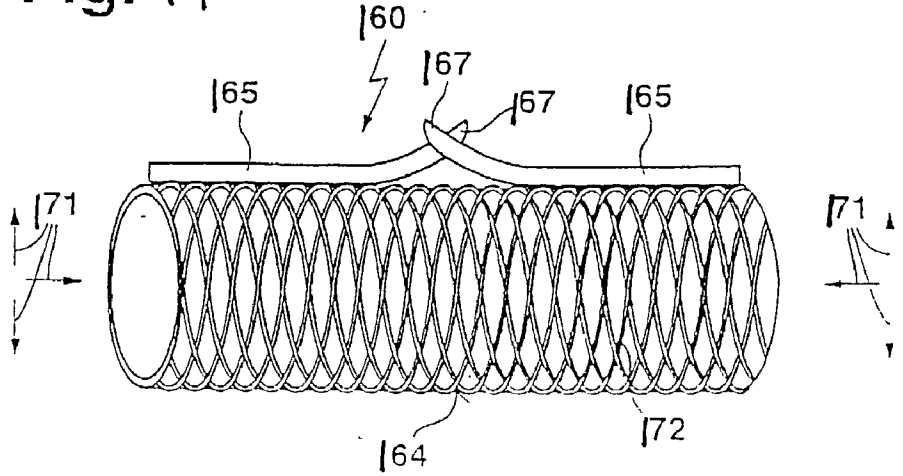


Fig. 15

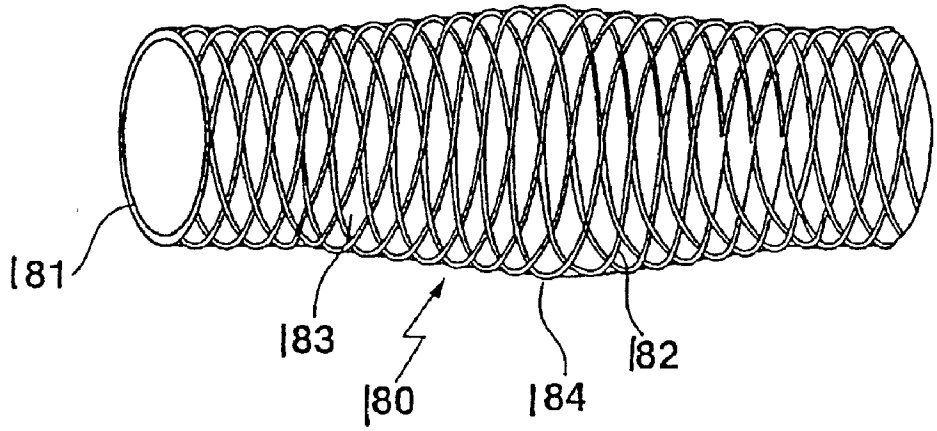
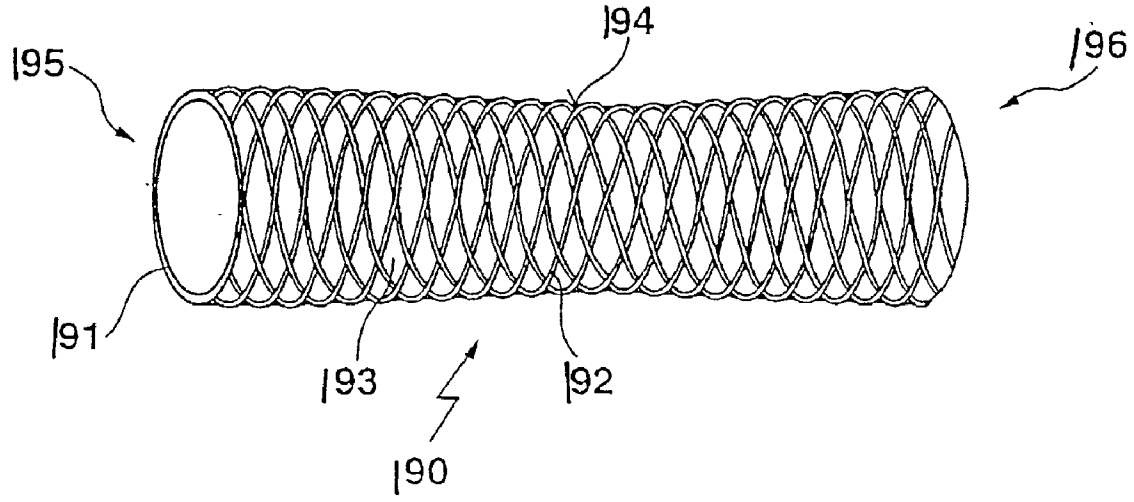


Fig. 16



ANTI-REFLUX STENT

FIELD OF THE INVENTION

[0001] The present invention relates to medical devices in general, and to anti-reflux stents in particular.

BACKGROUND OF THE INVENTION

[0002] Gastroespohageal reflux disease (GERD) is a medical condition whereby stomach acids repeatedly enter the lower portion of the esophagus because the lower esophageal sphincter (LES) at the entrance of the stomach fails to close properly. The LES may fail to close because it is diseased or has atrophied. Alternatively, patients having cancer or a tumor in the esophagus may have the LES forced open by a stent so that food and liquids can be ingested. The reflux of stomach acids into the esophagus causes severe heartburn and may contribute to the onset of other diseases.

[0003] One method of relieving GERD is to place an anti-reflux stent into the entrance of the stomach. An anti-reflux stent is a device that has a one-way valve to allow food and liquid to enter the stomach but prevents liquids from passing back through the valve. Examples of anti-reflux stents can be found in J. Valbuena, "Palliation of Gastroesophageal Carcinoma with Endoscopic Insertion of a New Anti-reflux Prosthesis," Gastrointestinal Endoscopy, Vol. 30, No. 4 pp. 241-243 (August 1994) and U.S. Pat. No. 6,302,917.

[0004] A conventional anti-reflux stent has a tubular sleeve that hangs into the stomach and a stent that surrounds a portion of the sleeve to provide a lumen through which food and liquids may pass.

[0005] In general it is desirable that an anti-reflux stent provide a smooth lumen opening into the stomach and an outer surface that will limit tissue growth into the stent such that it remains open and could be removed if desired. In addition, it is desirable that the valve characteristics that are provided by the sleeve can be easily selected during manufacture.

SUMMARY OF THE INVENTION

[0006] The present invention is an anti-reflux stent that is placed into the opening of a stomach by a physician. The anti-reflux stent includes an extended inner sleeve, a stent surrounding a portion of the inner sleeve, and a coating over the stent such that the stent is bonded to the inner sleeve. The distal end of the inner sleeve is flexible such that it compresses under normal gastric pressure in the stomach to prevent stomach contents from flowing back into the esophagus. However, under increased esophageal pressure and peristaltic action, food and liquid can pass through the sleeve in its collapsed state to enter the stomach.

[0007] In one embodiment of the invention, the inner sleeve has thickness and flexibility such that it inverts into the stent with sufficient gastric pressure. The proximal end of the stent may be coated to allow the stent to be removed or may be free of coating to aid in stent retention. The proximal end of the stent may be cylindrical or flared radially outward such that the stent can be embedded in or secured to an esophageal lining.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

[0009] **FIG. 1** illustrates a conventional anti-reflux esophageal stent in place in an opening of a stomach;

[0010] **FIG. 2** is a cross-sectional view of an anti-reflux esophageal stent in a pressurized or closed position in accordance with one embodiment of the present invention;

[0011] **FIGS. 2A, 2B** illustrate one technique for removing an anti-reflux stent in accordance with the present invention;

[0012] **FIG. 3** illustrates the proximal end of an anti-reflux esophageal stent having a flared end;

[0013] **FIG. 4** illustrates an anti-reflux esophageal stent having a non-coated portion;

[0014] **FIG. 5** is a flow chart showing a series of process steps used to make an anti-reflux esophageal stent in accordance with one embodiment of the invention;

[0015] **FIG. 6** is a flow chart showing a series of process steps used to make an anti-reflux esophageal stent in accordance with another embodiment of the present invention;

[0016] **FIG. 7** shows one embodiment of a form that creates a valve within an anti-reflux stent in accordance with another embodiment of the present invention;

[0017] **FIG. 8***a* shows a tube forming the basis of the stent;

[0018] **FIG. 8***b* shows a weave forming the basis of the stent;

[0019] **FIG. 8***c* shows a layer forming the basis of the stent in accordance with the invention;

[0020] **FIG. 8***d* is a schematic representation of the composition forming the stent in accordance with the invention comprising a tube, a weave and a coating;

[0021] **FIG. 9** shows a schematic cross section or end view of the stent of the invention in accordance with **FIG. 8***d;*

[0022] **FIG. 10***a* shows an embodiment in accordance with the invention of capturing free filament ends using a cover cap;

[0023] **FIG. 10***b* shows an additional embodiment in accordance with the invention of captured filament ends using a filament tube;

[0024] **FIG. 10***c* shows an embodiment having welded filament ends;

[0025] **FIG. 10***d* shows a folding-over of the tube to effect capture of the filament ends;

[0026] **FIG. 11***a* shows an application device for placing the stent in accordance with the invention;

[0027] **FIG. 11***b* shows an application device in accordance with **FIG. 11***a* having an inserted stent and conical plug;

[0028] **FIG. 11***c* shows an application device having a capture and displacement device turned with respect to **FIG. 11***a;*

[0029] **FIG. 12** shows a stent having raised portions on the outer peripheral surface formed by free ends of filament pieces;

[0030] **FIG. 13** shows a stent having anchors introduced on the outer surface in the extended state;

[0031] **FIG. 14** shows a stent in accordance with **FIG. 13** in an expanded state.

[0032] **FIG. 15** shows a stent having differing surface contours in dependence on axial and radial directions; and

[0033] **FIG. 16** shows a stent in an expanded state having widened lumens at each free end region.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0034] As indicated above, the present invention is an anti-reflux esophageal stent that allows a patient to ingest food or other liquid while preventing stomach acids from flowing back into the esophagus. **FIG. 1** illustrates a conventional anti-reflux stent **10** that is placed at the entrance of a stomach **12** in the area of the lower esophageal sphincter (LES) **14**. With the anti-reflux stent **10** in place, the proximal end of the stent forms a lumen into the opening of the stomach while the distal end acts to prevent the contents of the stomach **12** from entering the esophagus. The anti-reflux stent **10** comprises a flexible polymeric sleeve that collapses under the gastric pressure of the stomach **12** thereby forming a one-way valve. Food and liquid can pass in the distal direction through the collapsed sleeve but stomach acids do not flow in the proximal direction through the collapsed sleeve. However, the one-way valve can invert if the stomach pressure is sufficient to force the distal end **16** of the sleeve into the stent such as during vomiting or if the patient needs to belch. Details of the anti-reflux stent **10** are considered known to those of ordinary skill in the art and are for example disclosed in U.S. Pat. Nos. 6,302,917 and 6,162,244, which are herein incorporated by reference.

[0035] **FIG. 2** is a cross-section view of an anti-reflux esophageal stent in accordance with one embodiment of the present invention. The anti-reflux stent **20** has an inner sleeve **22**, a stent **24** surrounding a portion of the inner sleeve **22** at the proximal end, and a coating **26** over the stent **24** that bonds the stent **24** to the inner sleeve **22**. The inner sleeve **22** is preferably a polymeric tube that can be manufactured in a variety of manners including extrusion, molding, or forming the sleeve on a mandrel that is dipped into a polymeric solution. The materials and dimensions of the inner sleeve **22** are selected such that it will collapse in the area where it is not supported by the stent **24**. Therefore, the sleeve **22** forms a one-way valve for passage of food or liquids into the stomach of a patient. Representative materials for the inner sleeve **22** include silicone, urethane or other flexible, bio-compatible materials.

[0036] In accordance with the present invention, the closure characteristics of the one-way valve can be tailored by the selection of the materials and/or dimensions of the inner sleeve. The sleeve may have different dimensions or thicknesses along its length. For example, the sleeve might be thicker in the portion that is covered by the stent and thinner at the portion that is not covered by the stent. In yet another embodiment, the inner sleeve may be made of different layers along its length by coating the inner sleeve with different materials such as silicone, polyurethane, or other surface enhancing, friction reducing or other modifying coatings. Furthermore, the sleeve could be extruded using two or more different materials in order to tailor the characteristics of the inner sleeve along its length.

[0037] The stent **24** bonded to the inner sleeve **22** may be a braided or knitted stent made from a variety of materials including polyester, nylon, stainless steel, Nitinol™ brand metal alloy, Kevlar™ or other materials that provide sufficient rigidity and strength. The stent is preferably self expanding but could be expandable by a balloon or other device. Examples of particular stents that could be used in an anti-reflux stent of the present invention are set forth in U.S. Pat. Nos. 4,954,126 and 4,655,771, which are herein incorporated by reference.

[0038] To bond the stent **24** to the inner sleeve **22**, a coating **26** covers the stent **24**. The coating covers the fibers that comprise the stent thereby sealing it to the inner sleeve **22**. To obtain the best possible adhesion, it is believed that the coating **26** should be made of the same material as the inner sleeve **22**. Therefore, if the inner sleeve **22** is made of a silicone material, then the coating **26** should be similarly made of a silicone material. Alternatively, if the inner tube **22** is made from a urethane material, then the coating **26** should also be made of a urethane-type material. While the use of similar materials is believed to be preferred, other materials may provide sufficient strength and bonding properties to coat the stent and adhere it to the outer surface of the inner sleeve **22**. Various thicknesses of the outer coating can be made by varying the dipping rate or building up a coating as a number of different layers.

[0039] As shown in **FIG. 2**A, the majority of the stent **24** is covered by a coating **26**. At the proximal end of the stent are a number of bare wire or thread loops **30** that allow the anti-reflux stent to be retrieved from the patient.

[0040] As shown in **FIG. 2**B, to retrieve the stent, a catheter **32** is inserted into the esophagus and a suture is passed through a lumen of the catheter and through a number of the loops **30** to cinch the proximal end of the stent closed. With the proximal end of the stent **24** cinched, its diameter is decreased and the endoscope and anti-reflux stent can be withdrawn from the patient's esophagus. Alternatively, the cinched anti-reflux stent may be fully or partially retracted into a retrieval tube prior to being withdrawn from the patient. The coating **26** over the stent **24** limits the ingrowth of tissue into the stent and may be lubricous to aid in its removal.

[0041] In the example shown in **FIG. 2**, the proximal end of the stent **24** has a generally cylindrical cross-section. However the diameter of the stent may vary along its length. For example, the proximal end of the stent may be flared radially outward such as that shown in **FIG. 3**. The flared proximal end **40** extends radially outward and may provide additional ability to hold the stent in place within the esophagus.

[0042] In yet another embodiment of the invention, the proximal end of the stent **24** does not overlap with the inner sleeve **22**. That is, the proximal end of the stent **24** comprises a length of bare mesh. If the proximal end of the stent is not coated, tissue may grow into the interstitial spaces between the fibers or wires that comprise the stent thereby acting to

secure the stent within the esophagus if desired. Alternatively, the physician can put a suture or other attachment mechanisms through the exposed portion of the stent to help maintain its position within the esophagus.

[0043] **FIG. 5** shows a series of process steps that can be used to manufacture an anti-reflux stent in accordance with one embodiment of the invention.

[0044] Beginning at a block **50**, an extrusion that forms the inner sleeve is placed over a mandrel. At a block **52**, a stent is placed over the proximal end of the extrusion. At a block **54**, a coating is formed over the stent to secure it to the extruded inner sleeve. The coating may be formed by dipping the portion of the mandrel including the stent into a 2-part silicone bath or other coating material. Alternatively, the coating may be formed by spraying it or molding it over the stent. The mandrel is then removed from the inner diameter of the inner sleeve.

[0045] **FIG. 6** shows an alternate series of process steps that can be used to make an anti-reflux stent in accordance with the present invention. Beginning at a block **60**, an inner sleeve is created on a mandrel by dipping it in a material such as silicone or urethane bath. With the inner sleeve created on the mandrel, a stent is placed over the proximal end of the inner sleeve at a block **62**. The exterior of the stent is then coated at a block **64** by dipping the mandrel including the stent into a material such as 2-part silicone or urethane bath. Alternatively, the coating can be applied by spraying or molding it over the stent. The mandrel is then removed from the inner sleeve.

[0046] In some embodiments, it may be desirable to add one or more valves to the anti-reflux stent. **FIG. 7** illustrates one method of creating a set of valves in an anti-reflux stent **70**. The anti-reflux stent has an inner sleeve **72**, a stent **74** covering a portion of the inner sleeve **72** and a coating **76** that bonds the stent **74** to the inner sleeve **72**. A set of valve flaps **78***a*, **78***b*, **78***c* can be formed in an inner lumen of the inner sleeve **72** by inserting a form **79** into the inner lumen. The form has a divider **80** that divides the area of the lumen into sections. With the form **79** in place, the anti-reflux stent is dipped into a polymeric solution and the divider **80** creates valve flaps that are bonded to the interior lumen of the inner sleeve. The one or more valve flaps created when the form **79** is removed from the stent **70** further prevent the reflux of stomach acids into the esophagus. The valve flaps can be positioned anywhere along the length of the stent but may be advantageously positioned to align with an LES when the stent is installed.

[0047] **FIGS. 8***a*-**8***d* illustrate the construction of a stent **100** in accordance with the invention. The stent **100** consists essentially of an inner sleeve **102** (see **FIG. 8***a*) made from elastic material, a tubular weave **103** tightly seating on the outer surface of the inner sleeve **102** (see **FIG. 8***b*) and woven together from a plurality of filaments **105**, as well as a coating **104** (**FIG. 8***c*) introduced onto the outer surface of the inner sleeve **102**. **FIG. 8***d* shows the stent **100** in the constructed state. The inner sleeve **102** has a smooth inner surface and is strengthened through integration with the weaving **103** comprising the filaments **105**, wherein the tubular weaving **103** and the inner sleeve **102** are joined by means of the coating **104**. In accordance with **FIG. 8***d*, the coating **104** is constructed in such a fashion that the prominent structure caused by the filaments **105** on the outer surface of the tube **102** projects through the coating **104** to lead to a structured outer surface of the coating **104**.

[0048] **FIG. 9** shows a schematic cross-section or end view of the stent in accordance with the invention. The inner sleeve **102** as well as the weave **103**, comprising the filaments **105** and tightly seating on the outer surface of the inner sleeve **102**, are bonded together by means of the relatively thin coating **104**. In the embodiment in accordance with **FIG. 9**, the stent **100** has a structured outer surface dominated by the filaments **105** of rounded cross-section on the outer surface of the inner sleeve **102**. The coating **104** is thereby sufficiently thin that the spaces between the filaments **105** are not completely filled up, wherein the structure dominated by the filaments **105** at the outer surface of the inner sleeve **102** is simply covered in a sealed fashion using the coating **104**.

[0049] The embodiments in accordance with **FIGS. 10***a*-**10***d* show different ways of holding the filament ends **109** together. In **FIG. 10***a*, the ends **109** of the filaments **105** are connected to each other in a protected fashion using a cover cap **106**. In accordance with **FIG. 10***b*, the ends **109** of the filaments **105** are each connected to each other by means of a common filament tube **107**. The free ends **109** of the filament **105** in accordance with **FIG. 10***c* are held together and captured by means of a weldment **108**. In accordance with **FIG. 10***d*, it is also possible to capture the free ends of the filament **105** by means of a folding-over **120** of the inner sleeve **102**.

[0050] **FIGS. 11***a* and **11***b* show an application device **110** which is suitable for introducing the stent **100** into a body cavity. The application device **110** in accordance with **FIGS. 11***a* and **11***b* consists essentially of an outer application bushing **115** as well as an inner capture and displacement device **111**. The inner capture and displacement device **111** has a spread-out capture device **112** at one end and is configured smoothly at the end opposite to the capture device **112**. In addition, the capture and displacement device **111** has a lumen **114**. In **FIG. 11***a*, the stent **100** is pulled into the application device **110** in the direction of arrow **121** using the spread-out end of the capture device **112**. The outer diameter of the capture and displacement device **111** is thereby dimensioned in such a fashion that it can be displaced within a lumen **113** of the application bushing **115**. In accordance with **FIG. 11***c*, a stent **100** which is already captured using the capture and displacement device **111** is displaced in the direction of arrow **122** out of the application bushing **115** and positioned within a body cavity.

[0051] In order to utilize the application device in accordance with **FIGS. 11***a*, **11***b* and **11***c*, the stent is initially pulled into the application bushing **115** in accordance with **FIG. 11***a* by means of the spread-out end **112** of the capture and displacement device **111**. After the stent **100** is completely within the application bushing **115** in accordance with **FIG. 11***b* the stent **100** is positioned within the lumen **113** of the application bushing **115** by means of the conical plug **116**. A guided motion of the capture device **112** in the direction of arrow **121** then frees the stent **100**. The conical plug **116** is removed from the application bushing **115** and the capture and displacement device **111** is pulled out of the application bushing **115**, turned around and once more inserted into the application bushing **115** at its other end (see **FIG. 11***c*). Optical observation of the placing of the stent

100 is facilitated by an instrument which can be guided through a lumen **114**. The application device **110** is subsequently placed and situated within the body cavity through displacement of the capture and displacement device **111**.

[**0052**] **FIG. 12** shows a stent **150** which is formed from a tube **151**, a weave **152** and a coating **153**. In addition to filament threads **154** from which the weave **152** is produced, a second filament thread **155** is adjacent to the threads **154** and is interrupted in sections, the free ends **156** of which protrude above the weave **152** and the coating **153**. The free ends **156** build hooks for tissue adjacent to the outer surface of the stent.

[**0053**] **FIG. 13** shows another embodiment of a stent **160**, in the elongated state, which has a weave **162**. Anchors **165** are introduced on a flat section of outer surface **164** of the stent **166**. Each anchor **165** is connected to the outer surface **164** of the stent **160** in a position-stable manner via first end **166**. A second end **167** seats on the outer surface **164** of the stent **160**. The stent **160** is elongated in the direction of arrow **168**.

[**0054**] **FIG. 14** shows the stent **160** of **FIG. 13** in an expanded state. The stent **160** expands in the direction of arrow **171** so that an increased lumen **172** results. During expansion, the second ends **167** of the anchors **165**"stand up" and become separated from the outer surface **164**. The second ends **167** facilitate the hooking or digging of the anchors **165** of the stent **160** into an adjacent surface.

[**0055**] **FIG. 15** shows a stent **180** which likewise consists essentially of a tube **181**, a weave **182** and a coating **183**. The shape of the stent **180** differs in dependence on its axial and radial dimensions. The stent **180** assumes a distended shape **184** in an expanded state. The distended shape **184** is effected by weaving the weave **182** over a mould having this distended contour **184**. The shape can be arbitrary and can be adjusted to the application. The distended shape **164** shown in **FIG. 11** can be fashioned in a permanent manner using thermal shaping techniques.

[**0056**] **FIG. 16** shows an additional embodiment of a stent **190**, consisting essentially of a tube **191** supporting a weave **192** covered by a coating **193**. As seen from the side, the outer shape of the stent **190** has a concave dependence **194** along its axial extent so that the stent **190** has free ends **195**, **196** which define a wider lumen in both end regions of the stent **190**. The free ends **195**, **196** can be reinforced by means of ring structures on the outer surface of the stent **190**. These ring structures can also be introduced on arbitrary sections of the stent at the outer surface thereof independent of the embodiment of **FIG. 16**.

[**0057**] The invention concerns a stent **100** for the bracing and/or holding-open of a body cavity having a tube **102** made from an elastic material, a tubular weave **113** comprising filaments **105** seating in close adjacency to the outer surface of the inner sleeve **102** as well as a coating **104** applied to the outer surface of the inner sleeve **102** which attaches the weave **103** to the outer surface of the inner sleeve **102**. The coating **104** is adapted to have a structured outer surface dominated by the weave **103**. The stent **100** in accordance with the invention can be produced economically with adjustable restoring forces and facilitates a secure placing within a body cavity. Means for preventing drifting within the body cavity can also be introduced onto the outer surface of the stent. In each of the FIGS. **8-16**, an anti-reflux stent is created by lengthening the inner sleeve such that it is longer than the stent. With the sleeve sufficiently long, it will collapse in the stomach thereby forming a one-way valve to allow the passage of food and fluids into the stomach but prevent stomach acids from flowing back into the esophagus.

[**0058**] While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. An anti-reflux stent, comprising:

an inner sleeve;

a stent covering at least a portion of the inner sleeve;

a coating on the stent to bond the stent to an exterior of the inner sleeve;

wherein said inner sleeve includes a lumen through which food and liquid may pass and wherein at least a portion of the inner sleeve has a flexibility such that it collapses where the inner sleeve is not covered by the stent.

2. The anti-reflux stent of claim 1, wherein all the stent is coated.

3. The anti-reflux stent of claim 1, wherein a portion of the stent is not coated.

4. The anti-reflux stent of claim 1, wherein the proximal end of the stent is flared radially outwards.

5. An anti-reflux stent for deployment in an opening of a patient's stomach, comprising:

an inner sleeve having a proximal end, a distal end and a lumen extending therethrough;

a stent covering at least a portion of the proximal end of the inner sleeve and not covering the distal end of the inner sleeve;

a coating that bonds the stent to the inner sleeve;

wherein the anti-reflux stent is adapted to be deployed in an entrance to the stomach such that the stent maintains the lumen of the inner sleeve open so food and liquid can pass into the stomach and the distal end of the sleeve collapses due to pressure in the stomach to prevent reflux into the esophagus.

6. An anti-reflux stent, comprising:

an inner sleeve having a proximal end, a distal end and a lumen extending therethrough;

a stent that covers a proximal portion of the inner sleeve and does not cover a distal portion of the inner sleeve; and

a coating that bonds the stent to the inner sleeve, wherein the portion of the inner sleeve that is not covered collapses to form a one-way valve.

7. The anti-reflux stent of claim 6, wherein the inner sleeve includes one or more valve flaps formed in a lumen of the inner sleeve.

8. The anti-reflux stent of claim 6, wherein the inner sleeve has different flexibility characteristics along its length.

9. The anti-reflux stent of claim 6, wherein the inner sleeve has a varying thickness along its length.

10. The anti-reflux system of claim 6 wherein the inner sleeve is made of different materials along its length.

11. The anti-reflux stent of claim 6, wherein the anti-reflux stent is removable.

12. The anti-reflux stent of claim 6, wherein the proximal end of the stent has a mechanism for allowing the stent to be grasped and removed from a patient.

13. The anti-reflux of claim 12, wherein the mechanism for allowing a stent to be grasped includes a number of exposed loops at the proximal end of the stent.

14. The anti-reflux stent of claim 11, wherein the coating that covers the stent is lubricous.

15. In a stent system for splitting and holding open a body cavity of the type having:

a tube made from an elastic material;

a tubular weave seating firmly on an outer surface of said tube, said weave having a filament with a diameter and;

a coating covering said tube and said weave to hold said weave on said tube, said coating having a thickness less than said filament diameter, said coating consisting essentially of a self-solidifying fluid into which said tube and said weave are dipped, whereby the stent has a structured outer surface defined by said weave, and further having an application device for introducing the stent into a body cavity, said application device including a capture and a displacement device, an application bushing, and a conical plug, the improvement comprising: a one-way valve formed by the tube having a length that extends beyond the tubular weave such that a portion of the tube that extends beyond the tubular weave collapses on itself due to pressure in the body cavity.

16. In a stent system for splitting and holding open a body cavity of the type having:

a tube made from an elastic material;

a tubular weave seating firmly on an outer surface of said tube, said weave having a filament with a diameter and;

a coating covering said tube and said weave to hold said weave on said tube, said coating having a thickness less than said filament diameter, said coating consisting essentially of a self-solidifying fluid into which said tube and said weave are dipped, whereby the stent has a structured outer surface defined by said weave, wherein said filament has a fixed end, and wherein said filament comprises a plurality of threads having neighboring ends pair-wises connected to each other and further comprising a covering element for pair-wise connecting said neighboring ends, the improvement comprising: a valve formed by the tube extending beyond the tubular weave such that the tube is collapsible in the body cavity.

17. In a stent system for splitting and holding open a body cavity of the type including:

a tube made from an elastic material;

a tubular weave seating firmly on an outer surface of said tube, said weave having a filament with a diameter and;

a coating covering said tube and said weave to hold said weave on said tube, said coating having a thickness less than said filament diameter, said coating consisting essentially of a self-solidifying fluid into which said tube and said weave are dipped, whereby the stent has a structured outer surface defined by said weave, and further comprising raised portions protruding beyond said structured outer surface, the improvement comprising: a valve formed by the tube having a length extending beyond the tubular weave and a flexibility such that the tube is compressible in the body cavity.

18. In a stent system for splitting and holding open a body cavity of the type including:

a tube made from an elastic material;

a tubular weave seating firmly on an outer surface of said tube, said weave having a filament with a diameter and;

a coating covering said tube and said weave to hold said weave on said tube, said coating having a thickness less than said filament diameter, said coating consisting essentially of a self-solidifying fluid into which said tube and said weave are dipped, whereby the stent has a structured outer surface defined by said weave, wherein said weave has shapes differing in at least one of an axial and a radial direction, the improvement comprising: an anti-reflux valve formed by the tube having a length that is longer than the tube and a flexibility that allows the tube to collapse in the body cavity.

19. In a stent system for splitting and holding open a body cavity of the type including:

a tube made from an elastic material;

a tubular weave seating firmly on an outer surface of said tube, said weave having a filament with a diameter and;

a coating covering said tube and said weave to hold said weave on said tube, said coating having a thickness less than said filament diameter, said coating consisting essentially of a self-solidifying fluid into which said tube and said weave are dipped, whereby the stent has a structured outer surface defined by said weave, wherein said tube has fold-over covering an end of said filament, the improvement comprising: an anti-reflux valve formed by the tube having a length that is longer than the tubular weave and a flexibility that allows a portion of the tube not covered by the tubular weave to collapse in the body cavity.

20. In a stent system for splitting and holding open a body cavity of the type including:

a tube made from an elastic material;

a tubular weave seating firmly on an outer surface of said tube, said weave having a filament with a diameter and;

a coating covering said tube and said weave to hold said weave on said tube, said coating having a thickness less than said filament diameter, said coating consisting essentially of a self-solidifying fluid into which said tube and said weave are dipped, whereby the stent has a structured outer surface defined by said weave, wherein said filament comprises a plurality of threads having at least one of differing separations with respect to each other and differing diameters, the improvement comprising: an anti-reflux valve formed by the tube having a length that is longer than the tubular weave and a flexibility that allows a portion of the tube not covered by the tubular weave to collapse in the body cavity.

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