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(71) Applicant (for all designated States except US): **THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA** [US/US]; 3160 Chestnut Street, Suite 200, Philadelphia, PA 19104 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **FRIEDBERG, Joseph** [US/US]; 2109 Lombard Street, Philadelphia, PA 19146 (US).

(74) Agent: **COHEN, Joshua, L.**; RatnerPrestia, P.O. Box 980, Valley Forge, PA 19482 (US).

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(54) Title: DEVICE FOR PREVENTING GASTRO-ESOPHAGEAL REFLUX

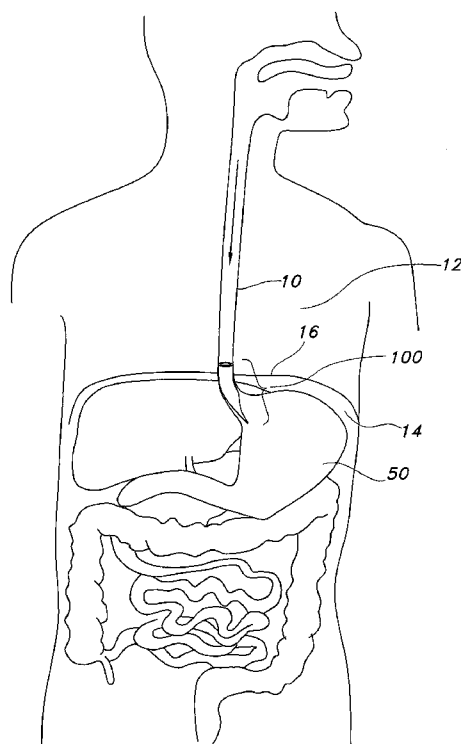


FIG. 1A

(57) Abstract: An apparatus and method for inhibiting gastro-esophageal reflux is provided. The device includes a flexible conduit having an inlet opening, an outlet opening, and a flow passage defined there between. The conduit is eversible between an extended condition and an everted condition. In the extended condition, inlet opening is proximal to the outlet opening such that the inlet opening is positioned within a portion of the esophagus proximal to a diaphragm and the outlet opening is positioned within a portion of the stomach distal to the diaphragm. The conduit is collapsible in the extended condition to partially restrict flow up from the outlet opening. In the everted condition, such as when one vomits, the outlet opening is proximal to the inlet opening and is positioned within the esophagus proximal to the diaphragm. The apparatus also includes a means for inhibiting distal migration of the inlet opening of conduit with respect to the esophagus.



GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

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— *with international search report (Art. 21(3))*

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DEVICE FOR PREVENTING GASTRO-ESOPHAGEAL REFLUX

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application No. 61/026,598, filed February 6, 2008, the contents of which are herein incorporated by
5 reference in their entirety.

FIELD OF INVENTION

This invention relates to apparatus and methods for inhibiting or preventing or otherwise managing gastro-esophageal reflux.

BACKGROUND OF THE INVENTION

10 Gastroesophageal reflux affects millions of people. The significance of this condition ranges from none to minor intermittent "heartburn" to fatal aspiration pneumonia to causation of terminal esophageal cancer. It is possible to reestablish an anatomic configuration that prevents reflux, but this requires an operation with the attendant risks and failure rate. As a result, medical antacid therapy remains the
15 prevalent treatment for symptomatic gastro-esophageal reflux. These medications do not, however, address the underlying anatomic defect responsible for reflux, but they do neutralize stomach acid and relieve the symptoms resulting from acidic irritation of the esophagus during reflux. In short, reflux can be prevented, but typically requires an operation. Medications that neutralize gastric pH relieve symptoms, but do not
20 prevent reflux. As a result, the current treatment options for gastroesophageal reflux leave room for improvement, and a need exists for an improved way to manage or prevent reflux. The present invention addresses this need, among others.

SUMMARY OF THE INVENTION

In one aspect, an apparatus for inhibiting gastro-esophageal reflux is provided.
25 The apparatus includes a flexible conduit having an inlet opening configured to be positioned within the esophagus, an outlet opening configured to extend into a portion of the stomach that extends distal to the diaphragm, and a flow passage defined there between. The conduit is eversible between an extended condition and an everted condition. In the extended condition, the inlet opening is proximal to the outlet
30 opening such that the inlet opening is positioned within the esophagus and the outlet opening is positioned within a portion of the stomach that extends distal to the diaphragm. In the everted condition (e.g., a configuration in which a portion of the conduit is folded inside itself), the outlet opening is proximal to the inlet opening and is positioned within the esophagus. The conduit is collapsible in the extended condition,
35 with the portion that resides below or distal to the diaphragm being exposed to positive pressure, to at least partially restrict flow through the flow passage from the outlet

opening that is positioned within the stomach to the inlet opening that is positioned in the esophagus. The flow passage of the conduit in the everted condition allows flow through the flow passage and outlet opening. The apparatus also includes means for inhibiting distal migration of the inlet opening of the conduit with respect to the esophagus.

According to another aspect, a method of inhibiting gastro-esophageal reflux from a stomach to an esophagus is provided. The method includes the step of positioning a flexible conduit such that in an extended condition of the conduit, an inlet opening of the conduit is proximal to an outlet opening of the conduit and positive pressure within the stomach at least partially collapses a portion of the conduit that is positioned distal to the diaphragm. In an everted condition, such as it exists during vomiting, the portion of the conduit that is positioned distal to the diaphragm everts on itself from the stomach back into the esophagus so the outlet opening of the conduit is proximal to the inlet opening and vomiting opens the flexible conduit to allow egress of stomach contents. The flexible conduit is engaged to a portion of the esophagus at or proximal to the diaphragm to inhibit distal migration of at least a portion of the conduit with respect to the esophagus.

According to yet another aspect, a method of inhibiting gastro-esophageal reflux from a stomach to an esophagus is provided. The method includes the step of defining a passage through a flexible conduit for flow from the esophagus into the stomach. The flexible conduit is collapsed under influence of pressure in the stomach to at least partially block flow from the stomach into the esophagus. The flexible conduit is everted under the influence of the vomiting reflex for flow from the stomach into the esophagus.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is best understood from the following detailed description when read in connection with the accompanying drawings, with like elements having the same reference numerals. This emphasizes that according to common practice, the various features of the drawings are not drawn to scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawings are the following figures:

FIG. 1A is a schematic anatomical view of a human body showing placement of an embodiment of an apparatus for preventing gastro-esophageal reflux with a portion of the apparatus being shown asymmetrically collapsed according to an exemplary aspect of this invention;

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FIG. 1B is a schematic anatomical view of a human body showing flow through the apparatus in FIG. 1A during eating or drinking according to an exemplary aspect of this invention;

FIG. 1C is a schematic anatomical view of a human body showing the apparatus in FIG. 1A in an everted condition during vomiting according to an exemplary aspect of this invention;

FIG. 1D is a schematic anatomical view of a human body showing the apparatus in FIG. 1C collapsing asymmetrically upon itself after vomiting according to an exemplary aspect of this invention;

FIG. 2A is a schematic view of an apparatus for preventing gastro-esophageal reflux in the position shown in FIG. 1A, according to an exemplary aspect of this invention;

FIG. 2B is a schematic view of the apparatus shown in FIG. 2A with a portion of the apparatus being symmetrically collapsed according to an exemplary aspect of this invention;

FIG. 2C is a schematic view of an apparatus for preventing gastro-esophageal reflux in the position shown in FIG. 1B, according to an exemplary aspect of this invention;

FIG. 2D is a schematic view of an apparatus for preventing gastro-esophageal reflux in the position shown in FIG. 1C, according to an exemplary aspect of this invention;

FIG. 2E is a schematic view of an apparatus for preventing gastro-esophageal reflux in the position shown in FIG. 1D, according to an exemplary aspect of this invention; and

FIG. 3 is a perspective view of an apparatus for preventing gastro-esophageal reflux according to another embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring generally to the figures (FIGs. 1A-3), in accordance with an exemplary embodiment, the invention provides an apparatus 100, 200 for preventing gastro-esophageal reflux. Apparatus 100, 200 includes a flexible conduit 20, 20a having an inlet opening 21, 21a configured to be positioned within the esophagus 10, an outlet opening 22, 22a configured to extend into a portion of the stomach 50 distal to the diaphragm 16 where there is positive pressure, and a flow passage 23 defined between inlet opening 21, 21a and outlet opening 22, 22a. Conduit 20, 20a is eversible between an extended condition (FIGs. 1A, 1B, 2A, 2B, 2C) and an everted condition (FIGs. 1C, 1D, 2D, 2E). In the extended condition, inlet opening 21, 21a is proximal to the outlet opening 22, 22a such that inlet opening 21, 21a is positioned within a

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portion of the esophagus 10 and outlet opening 22, 22a is positioned within a portion of the stomach 50 that extends distal to the diaphragm 16. Thus, the flexible conduit functionally extends the esophagus 10 distal to the diaphragm 16. The conduit 20, 20a is collapsible in at least the extended condition to partially restrict flow F up from the outlet opening 22, 22a through flow passage 23. In the everted condition, such as when one vomits, outlet opening 22, 22a is proximal to the inlet opening 21, 21a and is positioned within a portion of the esophagus 10 proximal to the diaphragm 16 (e.g., in the chest cavity 12 where there is negative pressure). Apparatus 100, 200 also includes a means for inhibiting distal migration 30, 30a of the inlet opening 21, 21a of the conduit 20, 20a with respect to the esophagus 10.

In a further embodiment of the present invention, a method for preventing gastro-esophageal reflux is provided. The method includes the step of positioning a flexible conduit 20, 20a in an extended condition such that inlet opening 21, 21a of conduit 23 is proximal to outlet opening 22, 22a. Flexible conduit 20, 20a is then engaged to a portion of the esophagus 10 at or proximal to the diaphragm 16 to inhibit distal migration of at least a portion of the conduit with respect to the esophagus 10.

In some cases, acid reflux is so severe that a valve can be inserted in the gastro-esophageal junction. For example, a one way valve is optionally inserted to allow food to enter into the stomach. However, this option is sometimes less preferred because such a valve does not allow acids and other gastro intestinal fluids to flow back into the esophagus so as to permit a patient to vomit. Accordingly, it is preferred to provide apparatus and methods for preventing acid reflux yet, at the same time, allow the patient to vomit when necessary by using the body's normal pressure differential between the negative pressure in the chest cavity 12 and the positive pressure in the abdominal cavity 14, thereby causing the flexible conduit 20a to act like a valve.

Referring now to the individual drawings in detail, FIG. 1A illustrates schematically an anatomical view of a human body torso having an apparatus 100 for preventing gastro-esophageal reflux attached to a bottom portion of esophagus 10. Apparatus 100 may be attached, for example, at the gastroesophageal junction into stomach 50 such that portion of apparatus 100 extends distal to the diaphragm 16 between the chest cavity 12 and abdominal cavity 14. Alternatively, apparatus 100 may be attached to the esophagus 10 at a location above or proximal to the diaphragm 16 which separates the chest cavity 12 and abdominal cavity 14, so a portion of apparatus 100 extends below or distal to the diaphragm 16 and into the stomach 50. Under normal physiological conditions, chest cavity 12 is typically under negative pressure and abdominal cavity 14 is under positive pressure. The pressure differential

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between the negative pressure in the chest cavity 12 and the positive pressure in the abdominal cavity 14 is used for the normal functioning of apparatus 100.

In certain cases, patients with acid reflux may be diagnosed with hiatal hernia, meaning that the gastroesophageal junction of the stomach 50 (e.g., the junction
5 between the esophagus and entrance into the stomach) extends proximal to the diaphragm 16 and into the chest 12. For these types of patients, a proximal portion of apparatus 100 may be attached to the esophagus 10 at a location sufficiently proximal to the diaphragm 16 and a distal portion of apparatus 100 extends distal to the diaphragm 16, thereby functionally extending and restoring the distal portion of the
10 esophagus to an intra-abdominal location where there is positive pressure. Thus, according to an embodiment, during normal conditions, when one is not vomiting, apparatus 100 extends down into the stomach 50. The positive pressure from the abdomen collapses apparatus 100, either asymmetrically as shown or symmetrically, thereby substantially or completely "sealing" itself and restricting stomach 50 contents
15 from moving back up into the esophagus 10. Upon eating or drinking as shown in FIG. 1B, however, the apparatus 100 opens to allow flow into stomach 50.

In FIG. 1C, upon the sudden and severe pressure increase associated with vomiting, apparatus 100 everts and is expelled up into the esophagus 10 along with any contents that may be in the stomach 50. In the everted condition or position,
20 apparatus 100 may protect the esophageal tissue lining and minimize tissue damage from the acidic contents of the stomach 50. In another position shown in FIG. 1D, upon drinking, eating or passage of time, apparatus 100 may collapse upon itself and "slide" back down into the stomach 50, once again sealing the esophagus 10 from contents of the stomach 50. For example, normal peristaltic waves in the esophagus
25 and simply swallowing saliva may be sufficient to cause apparatus 100 to return to its normal position.

Referring now to FIG. 2A, a schematic view of apparatus 100 shown in FIG. 1A is illustrated. Apparatus 100 includes a flexible conduit 20 having an inlet opening 21 and an outlet opening 22. Flow passage 23 provides a passageway through which fluid
30 or food may pass through inlet opening 21 and outlet opening 22.

In an exemplary embodiment, conduit 20 is constructed of a thin flexible material that is thin enough and/or long enough to enable it to collapse upon itself as it extends down into the stomach 50. The thin material may be formed, for example, in a substantially cylindrical or tubular shape that may be collapsible under positive
35 pressure from the abdominal cavity 14. Although conduit 20 is illustrated as a substantially asymmetrical "duckbill" shape when collapsed, other shapes and dimensions may be used as long as conduit 20 is elastic enough to fold back into itself.

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For example, as shown in FIG. 2B, conduit 20 may collapse symmetrically upon itself due to positive pressure in stomach 50 under normal non-vomiting conditions. As illustrated in FIGs. 2A and 2B, the distal opening 22 is collapsed under positive pressure of the abdominal cavity under normal conditions, such that flow F is substantially or completely prevented from traveling up into the flow passage 23 and into esophagus 10.

Conduit 20 may be made of flexible polymers such as polypropylene, silicone, or other biocompatible materials. In an exemplary embodiment, conduit 20 may be made of a tissue engineered material such as from the patient's own tissue or other biocompatible tissue. The thickness of the material used for conduit 20 may depend on the type and strength of the material. For example, conduit 20 which is made of a material with high strength may be thinner than a conduit 20 made of a material with lower strength so that conduit 20 is flexible and collapsible. According to an exemplary embodiment, conduit 20 may be stretchable or distensible so the diameter of conduit 20 may accommodate boluses of food that pass down the esophagus 10. Since conduit 20 is aperistaltic, in order to avoid food impaction, conduit 20 may be stretchable to a diameter greater than the esophagus 10 to allow food to enter stomach 50.

Conduit 20 may have various lengths and diameters depending on factors such as the type and thickness of the material and the size of the patient, the patient's stomach 50, and/or size of the patient's esophagus 10. In an exemplary embodiment, conduit 20 may have a length that ranges from about 25 mm to about 100 mm, and in some cases from about 40 mm to about 60 mm. Other lengths and diameters may be used to accommodate different patients so that in the extended position, a portion of conduit 20 extends distal to the diaphragm 16 and into the region of positive pressure. Additionally, conduit 20 extends into stomach 50 at a sufficient length so the conduit 20 may evert upon itself during vomiting.

As described above, apparatus 100 may be coupled to the bottom or near the bottom of esophagus 10 such that a portion of conduit 20 remains fixed in the esophagus 10 when one vomits. For example, apparatus 100 may include means for inhibiting distal migration 30 of at least a portion of conduit 20 with respect to esophagus 10. Attaching apparatus 100 to the esophagus 10 or to the gastro-esophageal junction may be accomplished by any means known or developed in the art. For example, apparatus may be attached by a ring, a cuff, or a stent placed inside esophagus 10. Other possibilities include endoscopically clipping, stapling, gluing, or sewing a portion of apparatus 100 to esophagus 10.

Referring now to FIG. 2C, a schematic view of apparatus 100 shown in FIG. 1B is illustrated. Under normal conditions, inlet opening 21 of conduit 20 is proximal to

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outlet opening 22 and is attached at or near the bottom of esophagus 10 so that outlet opening 21 extends downward into stomach 50. When one ingests food or fluids, flow F passes through the inlet opening 21 and into flow passage 23. Force of the food or fluid flow F downwards towards the stomach 50 opens the outlet opening 22 of flexible conduit 20. After one has finished eating or drinking, positive pressure of the abdominal cavity 14 and/or positive pressure in the stomach 50 collapses conduit 20 back into the configuration shown in FIGs. 2A, 2B. As described above, conduit 20 may be collapsed symmetrically or asymmetrically.

Referring now to FIG. 2D, a schematic view of apparatus 100 shown in FIG. 1C is illustrated. When one vomits, the sudden and severe pressure increase causes flow F of stomach contents to evert flexible conduit 20 into esophagus 10. In the everted condition, outlet opening 22 of conduit 20 is proximal to inlet opening 21 so that outlet opening 22 is positioned in the esophagus 10 proximal to the diaphragm 16. Accordingly, in the everted condition, a substantial portion of conduit 20 protects esophagus 10 from damage.

In FIG. 2E, a schematic view of apparatus 100 shown in FIG. 1D is illustrated. After one has vomited, upon drinking, eating or passage of time, flexible conduit 20 collapses and "slides" back down in the direction of flow F into the stomach 50. Accordingly, apparatus 100 reverts back to the extended condition to at least partially restrict flow F through the flow passage 23 from the outlet opening 22 to the inlet opening 21.

As shown FIG. 3, according to another embodiment, apparatus 200 includes conduit 20a having an inlet opening 21a and an outlet opening 22a. Apparatus 200 also includes means for inhibiting distal migration of at least a portion of conduit 20a with respect to esophagus 10. For example, apparatus may be attached by a stent 30a placed inside esophagus 10. Stent 30a may be made of a polymer material or any biocompatible material known or developed in the art. For example, stent 30a may be made from silicone, nitinol, a metal or a combination of metals such as a nickel-titanium alloy, etc. As will be described in detail below, stent 30a may also be made of a bioabsorbable material.

Stent 30a is not limited to any one particular structure and can include a mesh or mesh-like structure. Other fixation devices for inhibiting distal migration of at least a portion of conduit 20a may include a suspension system similar to aortic stents which have prongs or hooks to keep the stent 30a in place. Another way to fix apparatus 200 near the base of the esophagus 10 includes scarifying a ring in the distal portion of esophagus 10 and placing an absorbable ring or teflon cuff into which tissue would grow and serve as an infection barrier and as a fixation device.

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According to another exemplary embodiment, the entire apparatus 200 may be made of an absorbable scaffolding that would employ tissue engineering technology and capitalize on the fact that the esophagus is lined with high turnover simple squamous cell mucosa and could be used to make a "skin" valve, instead of a prosthetic. For example, it may also be possible to make the entire conduit 20a, including a stent suspension system, from absorbable polymer. This could be used to prevent reflux for a temporary period of time. Applications for this may include patients who have a condition causing obesity that is expected to reverse – like someone being treated for morbid obesity. Or someone with esophageal cancer who is being treated preoperatively with chemotherapy and/or radiation in preparation for esophagectomy. Another application for an absorbable apparatus 200 might be for a diagnostic test to consider an operation or in situations where it is unclear that reflux is the cause of a symptom – as with some cases of adult onset asthma that can be caused by reflux and aspiration into the lungs. In these cases, using an absorbable apparatus 200 could be like a diagnostic test to see if eliminating reflux eliminates the symptoms.

Although apparatus 100, 200 has been described for preventing gastro-esophageal reflux, apparatus 100, 200 may be used in other embodiments in which a flexible two way valve is needed. For example, apparatus 100, 200 may be used for urethral reflux, stool continence, heart valves, etc.

While the invention has been described in detail and with reference to specific examples thereof, it will be apparent to one skilled in the art that various changes and modifications can be made therein without departing from the spirit and scope thereof.

What is Claimed:

1. An apparatus for inhibiting gastro-esophageal reflux from a stomach to an esophagus comprising:

a flexible conduit having an inlet opening configured to be positioned within the esophagus, an outlet opening configured to extend into the stomach, and a flow passage defined there between, the conduit being eversible between

(a) an extended condition in which the inlet opening is proximal to the outlet opening such that the inlet opening is positioned within the esophagus proximal to a diaphragm and the outlet opening is positioned within a portion of the stomach distal to the diaphragm, and

(b) an everted condition in which the outlet opening is proximal to the inlet opening and is positioned within the esophagus proximal to the diaphragm;

said conduit being collapsible in the extended condition to at least partially restrict flow through the flow passage from the outlet opening positioned within the stomach to the inlet opening positioned in the esophagus;

said flow passage of the conduit in the everted condition allowing flow through the flow passage and the outlet opening; and

means for inhibiting distal migration of the inlet opening of the conduit with respect to the esophagus.

2. The apparatus of claim 1, wherein the conduit comprises tissue.

3. The apparatus of claim 1, wherein the conduit comprises a polymer material.

4. The apparatus of claim 1, wherein the conduit comprises a biocompatible material.

5. The apparatus of claim 1, wherein the means for inhibiting distal migration comprises a stent.

6. The apparatus of claim 5, wherein the stent comprises a metal.

7. The apparatus of claim 5, wherein the stent comprises a polymer material.

8. The apparatus of claim 5, wherein the stent comprises a biocompatible material.

9. The apparatus of claim 1, wherein the means for inhibiting distal migration comprises one or more hooks.

10. The apparatus of claim 1, wherein the means for inhibiting distal migration comprises a cuff.

11. A method of inhibiting gastro-esophageal reflux from a stomach to an esophagus comprising:

positioning a flexible conduit such that:

(a) in an extended condition of the conduit, an inlet opening of the conduit is positioned proximal to a diaphragm and proximal to an outlet opening of the conduit and pressure within the stomach at least partially collapses a portion of the conduit distal to the diaphragm;

(b) in an everted condition of the conduit, the outlet opening is proximal to the inlet opening proximal to the diaphragm and vomiting opens the flexible conduit; and

engaging the flexible conduit to a portion of the esophagus so as to inhibit distal migration of at least a portion of the conduit with respect to the esophagus.

12. The method of claim 11, comprising engaging a portion of the flexible conduit to the esophagus when the flexible conduit is in the extended condition.

13. The method of claim 11, comprising tissue engineering the flexible conduit.

14. A method of inhibiting gastro-esophageal reflux from a stomach to an esophagus comprising:

defining a passage through a flexible conduit for flow from the esophagus into the stomach;

collapsing a portion of the flexible conduit at a location distal to a diaphragm under influence of pressure in the stomach to at least partially block flow from the stomach into the esophagus; and

everting a portion of the flexible conduit to a location proximal to the diaphragm under the influence of a vomiting reflex for flow from the stomach into the esophagus.

15. The method of claim 14, wherein the defining step includes defining the passage from an inlet of the conduit positioned in the esophagus to an outlet of the conduit positioned in the stomach.

16. The method of claim 14, wherein the collapsing step includes collapsing an outlet of the conduit to substantially close the outlet.

17. The method of claim 14, wherein the everting step includes everting the conduit such that an outlet of the conduit is positioned within the esophagus and proximal to an inlet of the conduit.

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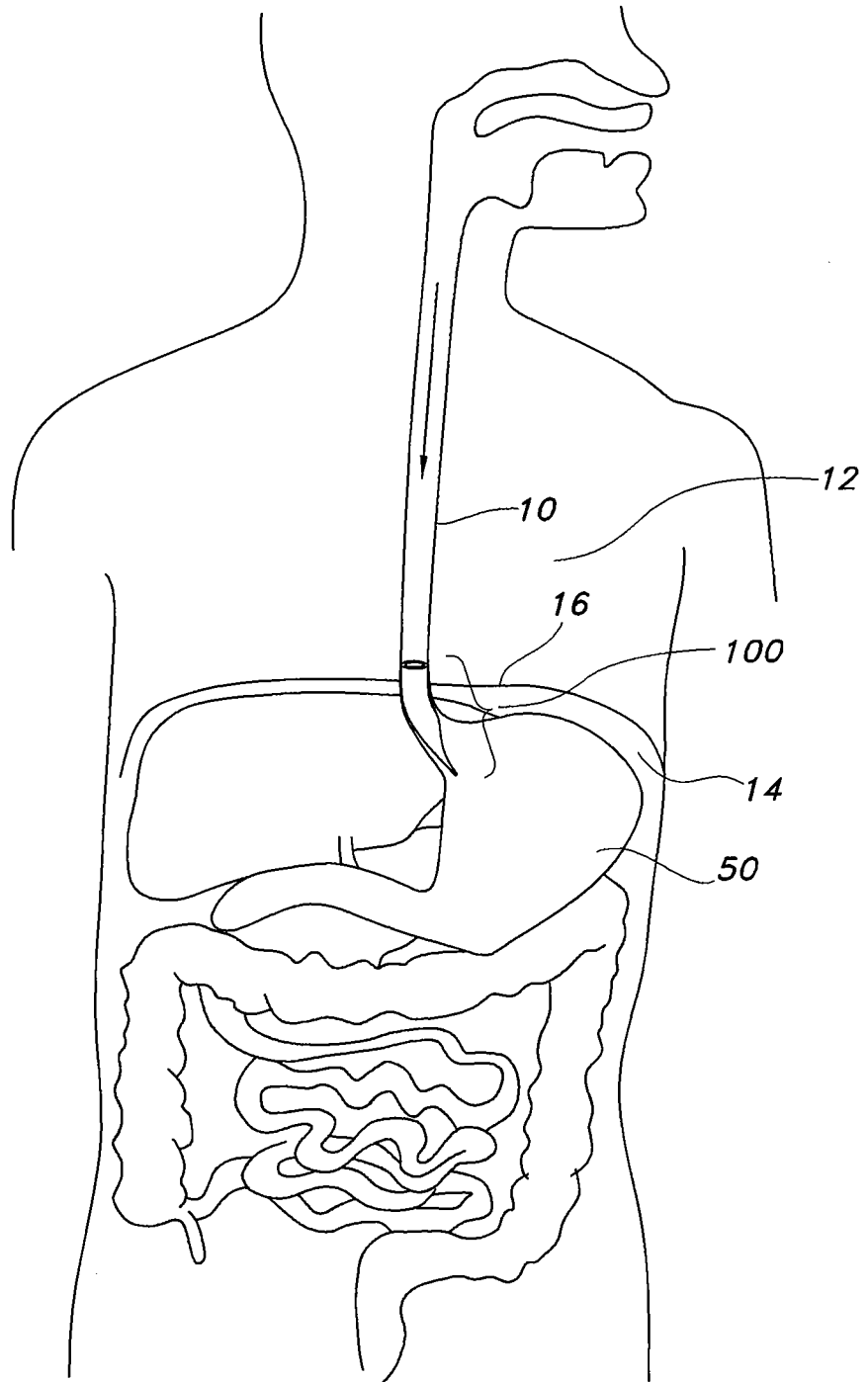


FIG. 1A

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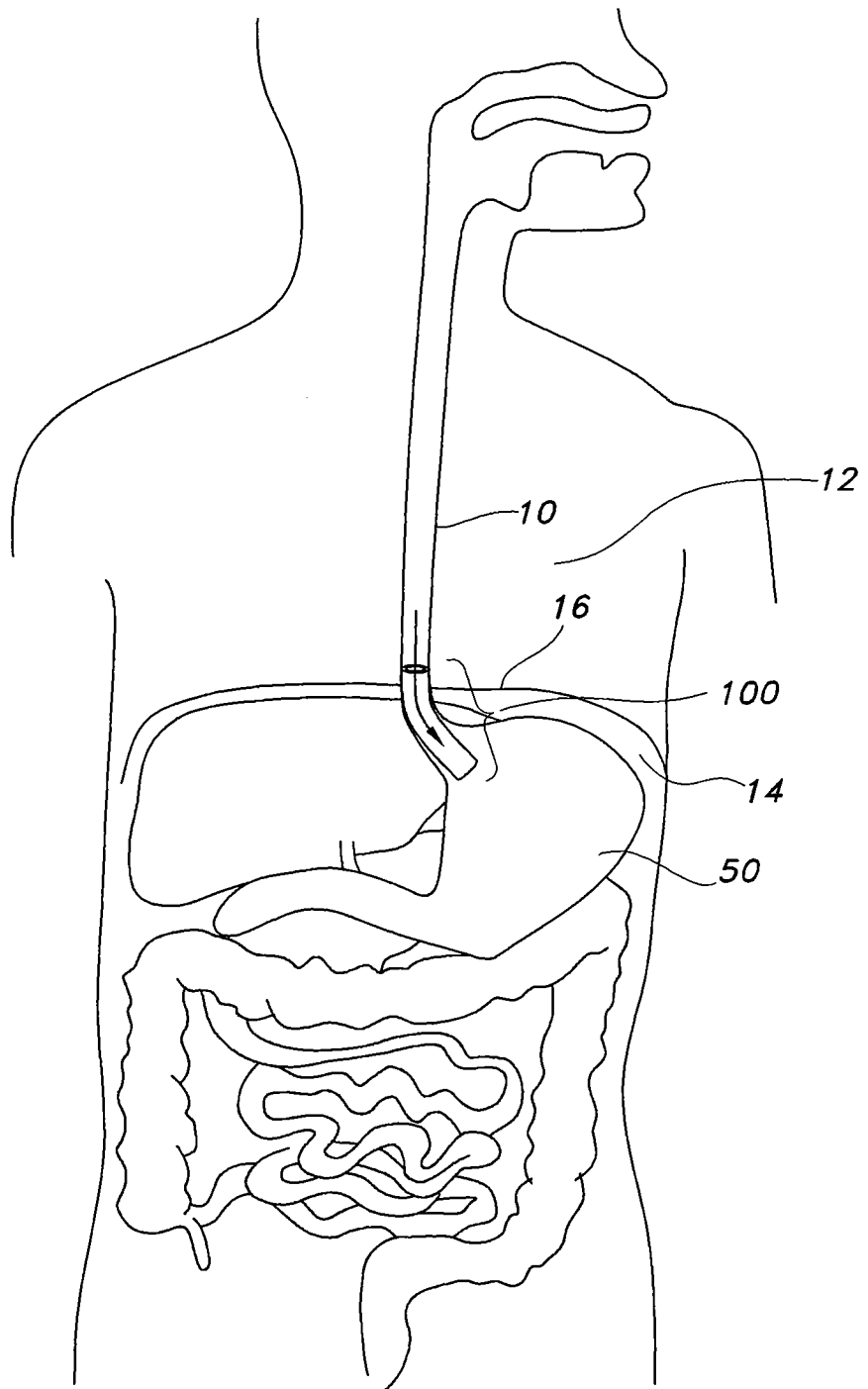


FIG. 1B

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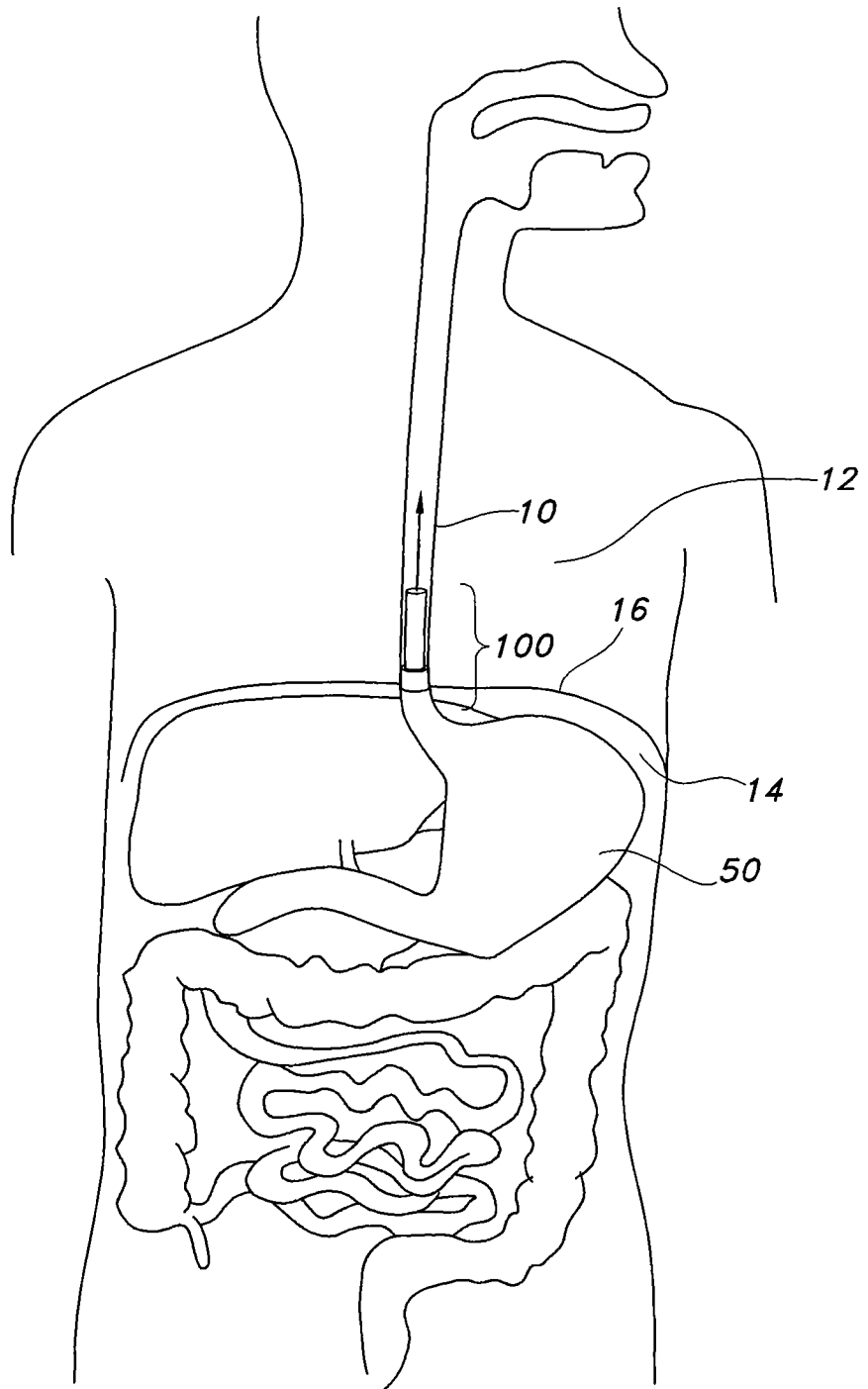


FIG. 1C

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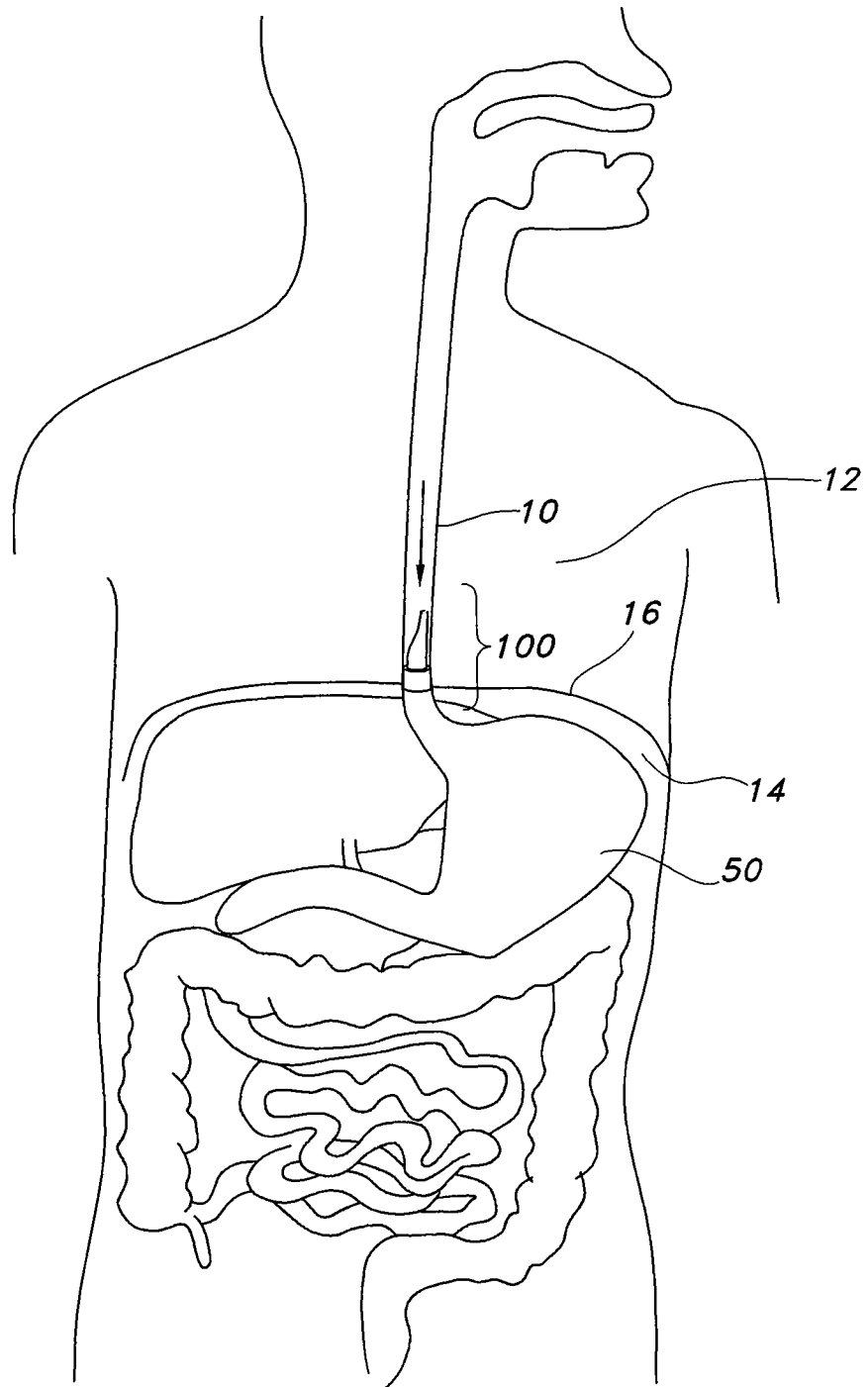
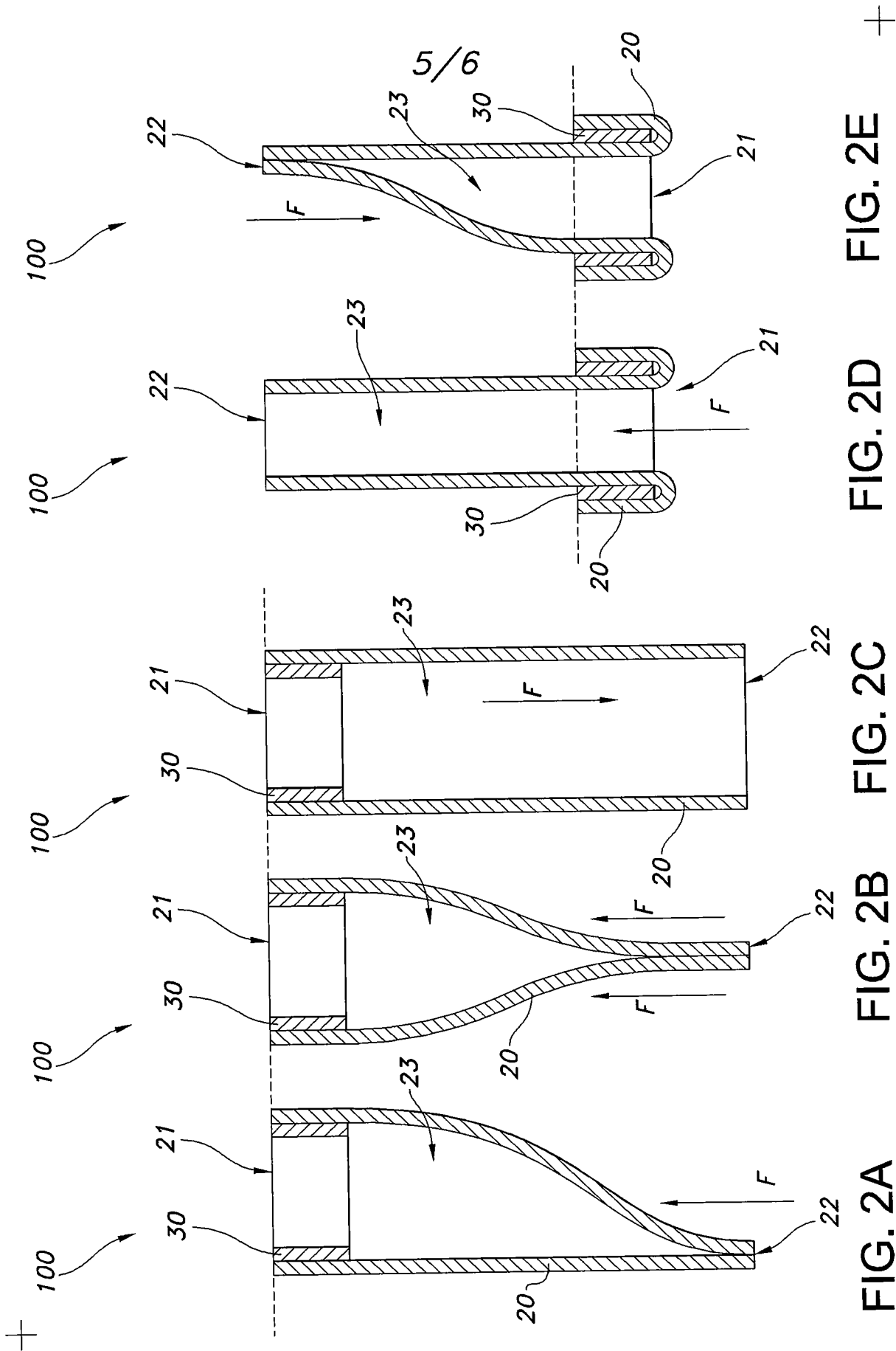


FIG. 1D



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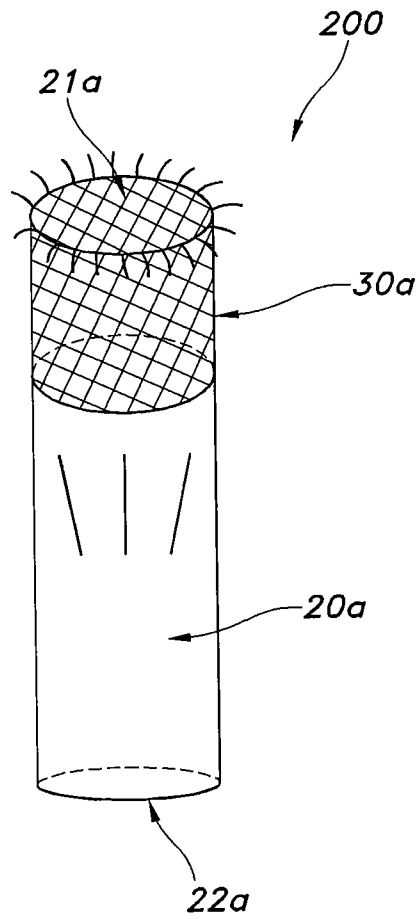


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2009/033362

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/04; A61M 25/00 (2009.01)

USPC - 623/23.64; 604/523

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61M 5/00, 25/00, 31/00; A61B 17/08; A61F 2/04 (2009.01)

USPC - 600/30; 604/8, 57, 264, 523; 606/153, 155; 623/23.64

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase, Google Search

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0032487 A1 (DUA et al) 14 March 2002 (14.03.2002) entire document	1-17
A	US 4,846,836 A (REICH) 11 July 1989 (11.07.1989) entire document	1-17
A	US 5,993,427 A (ROLLAND et al) 30 November 1999 (30.11.1999) entire document	1-17

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Further documents are listed in the continuation of Box C.

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* Special categories of cited documents:

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Date of the actual completion of the international search

06 March 2009

Date of mailing of the international search report

27 MAR 2009

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