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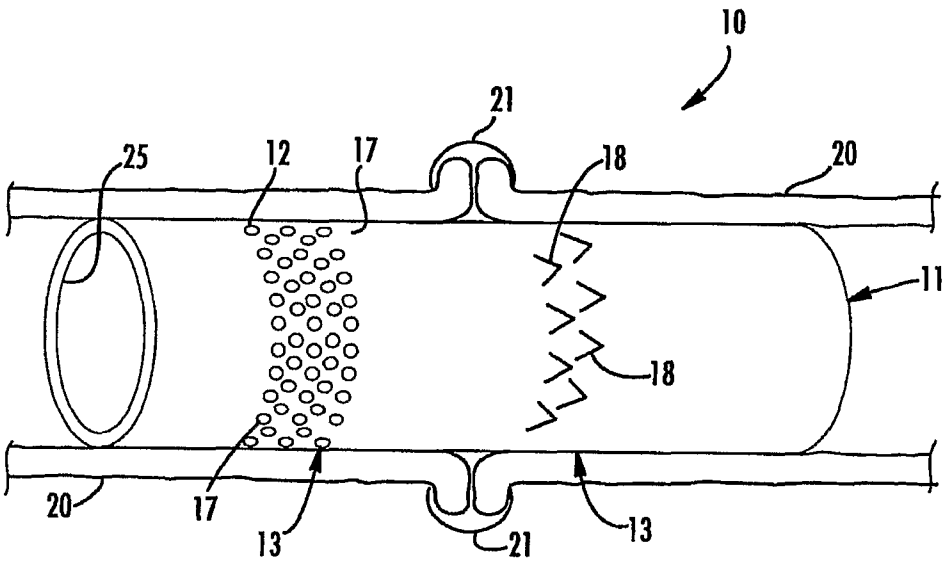
(54) **Title:** GASTRO-INTESTINAL THERAPEUTIC DEVICE AND METHOD



(57) **Abstract:** A gastro-intestinal therapeutic device and method includes providing a therapeutic device having a body and an anchoring mechanism. The anchoring mechanism is adapted to resist distal migration of said body in a gastro-intestinal tract. The body is generally configured to a portion of the gastro-intestinal tract and has a first wall portion and a second wall portion. The first wall portion defines a generally sealed membrane. The second wall portion has a scar forming area.

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GASTRO-INTESTINAL THERAPEUTIC DEVICE AND METHOD

BACKGROUND OF THE INVENTION

The present invention is directed to a therapeutic method and apparatus for the gastro-intesfinal tract. While it may have other applications, the therapeutic device may be used as therapy for an anastomosis, a fistula, diverticular disease, an incision or a stricture. Also, the therapeutic device may be used in forming a stomal opening.

Anastomoses have an unacceptably high rate of leakage. This is especially the case for the anastomosis of the esophagus and bowel. Various anastomotic devices have been proposed. Such prior devices have been more concerned with the mechanical joining of the portions of the ligated luminal viscus and not with leakage thereof. Moreover, prior devices often require complex procedures for joining the portions. For example, many require specialized tools to apply the device. The complexity imposed by the separate joining means and specialized tools increases the time required to make the anastomosis and limits the applications for which the prior devices may be used.

Also, prior devices are capable of being applied only at the time of the anastomosis. Should a leak develop at an anastomosis after it is completed, the prior devices are not configured to be applied at a later time. Also, prior devices are not capable of being applied to both anastomosis and fistulas.

Over 250,000 gastric bypass surgeries are performed each year in the United States. Patients typically lose up to 60 percent of their excess body weight over approximately 18 months. At least 10 percent of the patients will begin to gain weight back. The weight gain is often due to stomal dilation, or enlargement, over time. The stoma is the anastomosis site where the pouch opens to the small bowel. Such enlargement leads to the loss of satiety as the pouch empties too early. The stomal enlargement occurs irrespective of techniques used to form the stoma, such as linear staple, hand sown, EEA, or the like.

Diverticular disease, which may include an out pouching or even a perforation of the diverticula, may require a resection of the bowel. Leaks and fistulas of the bowel are typically treated by withholding oral intake while treating the patient with various medications. Both procedures have obvious risks. The resection of the bowel is intrusive and can cause abdominal infection. Withholding

oral intake is uncomfortable to the patient and risks weakening the patient. Also, some patients require parenteral feeding which further increases risks.

Transgastric surgery, whereby the peritoneal cavity is accessed through the stomach wall for visualization and/or therapeutic intervention, is recognized as having potential for reducing trauma to the patient. However, intentional or accidental incisions in the bowel made during such intervention may be difficult to repair transgastrically. This may result in the need for conventional or laparoscopic surgery, which is what transgastric surgery is intending to avoid.

SUMMARY OF THE INVENTION

A gastro-intestinal therapeutic device and method according to an aspect of the invention includes providing a therapeutic device having a body and an anchoring mechanism. The anchoring mechanism is adapted to resist distal migration of said body in a gastro-intestinal tract. The body is generally configured to a portion of the gastro-intestinal tract and has a first wall portion and a second wall portion. The first wall portion defines a generally sealed membrane. The second wall portion has a scar forming area. The body is bioabsorbable in a patient. The therapeutic device is positioned at a portion of the gastro-intestinal tract and the scar forming area causes scar tissue to form at the portion of the gastro-intestinal tract. The body is absorbed in the patient. The device may be used, for example, for stricture amelioration, leak and fistula control and decrease in the risk of stomal dilation.

The therapeutic device may be positioned at a portion of the gastro-intestinal tract having at least one chosen from (i) an anastomosis, (ii) a fistula, (iii) diverticular disease, (iv) a stomal opening, (v) an incision, and (vi) a stricture. The therapeutic device may be deployed endoscopically through the esophagus or the colon.

The therapeutic device may be used in performing transgastric surgery. The device may be positioned at an incision in the bowel formed during the transgastric surgery.

The therapeutic device may be used in creating a stomach pouch having a stomal site that is adapted to restrict the passage of food. The therapeutic device is positioned at said stomal site. The through-opening in the body may have a diameter that is in the range of from approximately 0.5 centimeters to approximately 1.5 centimeters. The body may be positioned at a stomal site that is formed using at

least one chosen from linear stapling, hand suturing and EEA. The stomal site may be formed laparoscopically. The stomal site may be formed in a gastric bypass procedure. The body may be positioned during the same procedure as forming a stoma or after the procedure forming a stoma.

The therapeutic device may be used to repair an anastomosis post-operatively.

The anchoring mechanism may include an annular flange around said body. The anchoring mechanism may include the outer layer being of a material having tissue in-growth fenestrations. The anchoring mechanism may include anti-migration tines. The tines may be deployed *in situ* such as with a deployment device. The deployment device may include a balloon and the tines may be deployed by inflating the balloon.

Radiopaque markers may be provided on the body. The markers may be used to monitor for distal migration of the body as well as the absorption of the body in the patient.

These and other objects, advantages and features of this invention will become apparent upon review of the following specification in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a sectional view of a gastro-intestinal therapeutic device, according to an aspect of the invention;

Fig. 2 is a sectional view of a deployment device;

Fig. 3 is the same view as Fig. 1 of an alternative embodiment thereof;

Fig. 4 is an illustration of a gastric bypass surgical procedure utilizing a gastro-intestinal therapeutic device and method according to an aspect of the invention; and

Fig. 5 is a perspective view of the therapeutic device in Fig. 4.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now specifically to the drawings, and the illustrative embodiments depicted therein, a therapeutic device 10 is shown applied to a portion 21 of the gastro-intestinal tract 20, such as in the esophagus, colon, stomach, or the like (Fig. 1). Portion 21 may be, for example, an anastomosis and may be made in a conventional fashion according to the preferences of the surgeon, such as by sutures, staples, circular stapler, linear stapler, or the like. Therapeutic device 10 includes

body 11 having a wall 12 that forms an interference fit with portion 21 of the gastro-intestinal tract, such as at the anastomosis. The interference fit may be created by making wall 12 from a self-expanding material. The self-expanding material may be bio-absorbable. Examples of suitable materials include ePTFE, silicone, or the like. Also, bio-absorbable metal-based materials are also known, as would be within the knowledge of the skilled artisan. The wall may include a plastic expandable coil in order to impart the self-expanding nature of the wall. The wall may be formed of a mesh with a sealed layer. Alternatively, the interference fit may be formed by over-sizing the diameter of wall 2 with respect to the organ, such as to form flared ends to the body and temporarily reducing the diameter of the wall to fit within the organ.

Wall 12 includes a first portion 14, which may be an inner layer, which forms a generally sealed membrane. Inner layer 14 defines a through-opening 25 in the device. This facilitates passage of food and other materials through the gastro-intestinal tract while resisting leakage to the site where therapy is occurring. Wall 12 further includes a second portion 15, which may be an outer layer, which causes formation of scar tissue in the patient at a scar forming area 16. The scar forming area may be the entire extent of second portion 15, running the length of body 11, or may be discrete section(s), such as at the ends or in the middle. The scar tissue provides therapeutic affects on the patient. For example, the scar tissue strengthens the wall of the gastro-intestinal tract as well as fills in fistulas, voids, and the like. Inner layer 14 may be a rigid or semi-rigid material. In this manner, first portion 14 provides a form, or backing, that supports the portion of the site of the gastro-intestinal tract at which the device is positioned in order to resist any shrinkage resulting from the formation of scar tissue. Once the scar tissue forms, body 11 can be removed, such as by absorption in the patient, with the opening of the site maintained generally at its desired size without significant dilation or shrinkage thereof. This is because scar tissue does not readily dilate or shrink, once formed.

In one embodiment, the scar forming area includes a sclerosant agent that is applied to the second portion 15. Alternatively, the sclerosant agent may be applied between therapeutic device 10 and the wall of the gastro-intestinal tract. Alternatively, the sclerosant agent may be incorporated into the material forming second portion 15 of sidewall 12. The sclerosant agent may be incorporated into the sidewall 12 in a manner that the absorption of the therapeutic device 10 causes release of the sclerosant agent to the site in the gastro-intestinal tract to cause the

scaring. Once scar tissue has formed, sidewall 12 is no longer necessary to maintain the size of the opening in the gastro-intestinal tract. Sclerosant agents are known in the art. An example is sodium morrhuate, although any known sclerosant agent may be used.

Scar forming area 16 may, alternatively, be formed by the physical characteristics of second portion 15 or wall 12. For example, second portion may be formed of a copolymer glycolide and trimethylene carbonate micro porous structure, of the type that is commercially available from W.L. Gore & Associates under the SeamGuard brand. In yet an additional alternative embodiment, scar forming area 16 may include an osteosynthesis material of the type available from Stryker Corporation. Such osteosynthesis material forms bone tissue locally thereby producing scarring at the site.

Therapeutic device 10 includes a fixation system, or anchoring mechanism, generally shown as 13 to resist distal migration of the device with respect to the gastro-intestinal tract where peristalsis tends to cause distal migration of any object in the track. Fixation system 13 may include a pattern of holes, or fenestrations, 17 for the purpose of promoting ingrowth of tissue through wall 12. The tissue provides fixation from distal migration. If wall 12 is made from a bioabsorbable material, then the ingrown tissue will dissipate when the body is absorbed in the patient. Fixation system 13 may include a series of projections 18 from wall 12. Projections 18 may include barbs, V-shaped appendages, metal anchors, and the like. The projections are oriented to resist migration distally. Additionally, the fixation may be in the form of stapling, or suturing, of the device to the organ. It should be clear that more than one fixation system may be used. For example, V-shaped appendages may be utilized to temporarily fix the device while tissue is growing through the pattern of holes 7.

In an embodiment illustrated in Fig. 2, fixation system 113 may be balloon-deployed *in situ* upon placement of the therapeutic device at the site. Fixation system 113 includes a series of tines 118 that are positioned in the wall 119 of a deployment device 120. A balloon inside of wall 119 is inflatable in order to expand wall 119 thus thrusting the tines through the wall of body 11 and into the wall of the gastro-intestinal tract. If the first portion is made from a self-sealing material, the tines will not create a significant leak. Alternatively, tines 118 may be formed in the

wall of body 11 and projecting into opening 21 of body 11. The balloon, upon expansion, will drive the tines outwardly into the wall of the gastro-intestinal tract.

Therapeutic device 10 may be used in making an anastomosis, such as in the esophagus, bowel, or the like. In use, at the time of making anastomosis, the surgeon inserts one end of device 10 into one portion 20 of the organ and inserts the other end of device 10 into the other portion 20 of the organ. If fixation system 13 is unidirectional in operation, then care should be taken to position the device with the fixation system oriented to resist distal migration. The anastomosis is then made by the surgeon using the preferred technique of the surgeon. If it is discovered that an anastomosis is leaking, therapeutic device 10 may be positioned at the anastomosis site post-operatively. Dependent upon the location of the anastomosis site with respect to the organ, the therapeutic device 10 may be inserted, by way of example, endoscopically, colonoscopically, or the like. In order to accomplish such insertion through a natural orifice of the body, a conventional deployment device (not shown) may be positioned over the leak protection device in order to compress wall 12. When the device is positioned at the anastomosis site, the deployment device is retracted from the leak protection device to deploy the leak protection device at the anastomosis site.

By providing the ability to apply therapeutic device 10 subsequent in time to performing the anastomosis, leak protection can be provided to an anastomosis that subsequently leaks. This is especially useful because it is not always possible to predict when an anastomosis may leak and, therefore, the leak protection device may not have been inserted at the time of anastomosis. Also, where the surgeon is called upon to repair a leaking anastomosis, therapeutic device 10 may be readily deployed in a minimally invasive manner. Device 10 may also be configured with a side appendage from wall 12 to fit within the fistula to further promote scar formation.

Although illustrated in the context of an anastomosis, it should be apparent to the skilled artisan that therapeutic device 10 is also useful for sealing fistulas. The scar forming area of therapeutic device 10 forms scar tissue to close the fistula while the characteristics of wall 12 resist structuring of the gastro-intestinal wall. Once body 11 is absorbed in the patient, the fistula is repaired. The fistula site is sealed immediately upon deployment of device 10 at the site. Device 10 is particularly useful because it can be deployed through a natural orifice of the body, such as through the mouth or the anus. Therefore, fistulas resulting from surgery,

such as gastric bypass surgery, and the like, may be readily repaired when discovered in a minimally invasive manner.

An alternative embodiment of a therapeutic device 110 includes a wall 112 in a generally cylindrical shape (Fig. 3). Wall 112 may be semi-rigid and is self-expanding. Wall 112 has an outer surface 15 that is configured to form an interference fit with the lumen of the luminal viscus. Thus, device 110 may be positioned within the ends of the ligated luminal viscus with wall 12 in a non-expanded form. This may be accomplished by a delivery mechanism (not shown) that fits over the wall and compresses the wall. After the device is properly positioned, the device is deployed from the delivery mechanism. This allows the self-expanding wall to expand into an interference fit with the lumen of the luminal viscus.

In order to assist in providing leak protection and to resist distal migration, a flange 126 may be defined by wall 112. With the ends of the organ passing over flange 126, leakage of bowel material from the lumen will be further impeded. Also, flange 126 provides anti-migration to prevent distal migration of device 10 within the viscus. In the embodiment illustrated in Fig. 3, body 112 has opposite end portions 18. Each end portion 18 receives and forms an interference fit with one of the ligated luminal viscus portions 20. In addition to this interference fit and the function performed by flange 126, reinforcement may be provided to the anastomosis by suturing, stapling, or the like, used by the surgeon to join organ portions 20 together. Device 110 may be deployed at the time of making the anastomosis. Alternatively, it may be deployed later, such as when a leak occurs, by compressing wall 12 and positioning the device through a natural orifice of the body.

A roux-en-y gastric bypass procedure is illustrated in Fig. 4. Such procedure, which is known in the art, uses stapling shown at S to create a small, upper stomach pouch P, which restricts the amount of food which is able to be consumed. A portion of the small bowel may also be bypassed, thus delaying food from mixing with the digestive enzymes to avoid complete caloric absorption. The purpose is to experience an early sense of fullness, combined with a sense of satisfaction that reduces the desire to eat. One difficulty with known stomach pouches, or stomas, is that the opening to the jujunal of the small intestine may dilate which decreases the restrictive component of the stoma. Existing solutions,

such as an outer band, may result in erosion to the conduit. Also, in certain circumstances, the opening from the stoma may experience stricture thereby requiring intervention to dilate the opening.

To overcome these difficulties, a therapeutic method of maintaining a stomal size includes providing a therapeutic device 210 having a body 212 including a first wall portion 214 defining a generally sealed membrane (Fig. 5). Sidewall portion 214 defines a through-opening 226 which extends the entire length of body 212, such that food passes through opening 226. Opening 226 is sized to have a cross-sectional area A that is selected in order to control the rate of ingested food passing through body 212. Therapeutic device 210 additionally includes an anchoring mechanism, such as flared end portions 218 which are sized to form a tight fit with the esophagus.

A scar forming area 215, such as by a scleroscant agent, or the like, applied to an outer portion of wall 212 causes scaring of the stomal site. The scar tissue tends to contract the stomal to the shape of sidewall 212. Because sidewall portion 214 is at least semi-rigid, it resists further contraction of the stomal. Once the scar tissue forms, body 212 can be removed by absorption in the patient. The sclerosant agent may be applied directly to body 212 either by applying a coating to the outside of sidewall 14 or by incorporating the sclerosant agent into the material forming sidewall portion 214.

In the illustrative embodiment, opening 226 has a cross-sectional area A of a diameter that is sized to the patient and may range from approximately 0.5 cm to approximately 1.5 cm with approximately 1.2 cm being a nominal diameter.

The benefit of having a combination of therapeutic agent 210 and a sclerosant agent is that the therapeutic device additionally assists in preventing leaks at the jujunal junction. However, once the scar tissue is formed and any leaks healed, the stomal-sizing device can be dissolved, thereby allowing the body to function without further use of an external device. While the amount of time that the stomal-sizing device is present in the patient may vary from patient to patient, a period of approximately six weeks may be used. Because of the scar tissue, once the therapeutic device is removed, the stoma opening should not experience significant dilation.

Other applications may be found for the therapeutic devices and methods disclosed herein. For example, they can be used to repair strictures by providing a

mechanical form to keep the stricture open while the scar forming process more permanently retains the size of the opening. It may also be used with diverticular disease in the bowel. The placement of the therapeutic device at the site of the put-pouching or fistula formed with the diverticular disease will seal the pouched area or fistula thereby allowing food to be taken orally without causing further difficulties. The scar forming area will produce scar tissue to close the out-pouching or fistula. Any abscess already present can be drained such as by percutaneous drain placed with a computed axial tomography scan.

The therapeutic devices and methods disclosed herein can also be used with transgastric surgery. Should the surgeon perform an incision in the bowel, either intentionally or unintentionally, a therapeutic device can be deployed using colonoscopy in order to heal the incision without formation of infection. Other applications will be apparent to the skilled artisan. Also, although illustrated as made from bioabsorbable material, in certain applications, the body of the therapeutic device can be made from a non-absorbable material and removed, such as endoscopically, upon completion of scar formation.

Changes and modifications in the specifically described embodiments can be carried out without departing from the principles of the invention which is intended to be limited only by the scope of the appended claims, as interpreted according to the principles of patent law including the doctrine of equivalents.

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

1. A gastro-intestinal therapeutic device, comprising:

a body generally configured to a portion of the gastro-intestinal tract, said body having a wall including a first wall portion and a second wall portion, said first wall portion defining a generally sealed membrane;

an anchoring mechanism, said anchoring mechanism resisting distal migration of said body in a gastro-intestinal tract;

said second portion having a scar forming area, said scar forming area adapted to causing formation of scar tissue in a patient; and

said body being bioabsorbable in a patient.

2. The therapeutic device as claimed in claim 1 wherein said scar forming area includes a sclerosant agent.

3. The device as claimed in claim 2 wherein said sclerosant agent comprises a coating applied to said scar forming area.

4. The device as claimed in claim 2 wherein said sclerosant agent is integral with said scar forming area.

5. The device as claimed in any of the preceding claims wherein said second portion includes an osteosynthetic material.

6. The device as claimed in any of the preceding claims wherein said second portion has a physical configuration that is adapted to causing formation of scar tissue in a patient.

7. The device as claimed in any of the preceding claims wherein said anchoring mechanism includes an annular flange around said body.

8. The device as claimed in any of the preceding claims wherein said anchoring mechanism includes said outer layer of a material having tissue in-growth fenestrations.

9. The device as claimed in any of the preceding claims wherein said anchoring mechanism comprises anti-migration tines.

10. The device as claimed in claim 9 wherein said tines are adapted to be deployed *in situ*.

11. The device as claimed in claim 9 or claim 10 including a deployment device, said deployment device adapted to deploying said tines.

12. The device as claimed in claim 11 wherein said deployment device comprises a balloon, said balloon adapted to deploying said tines when inflated.

13. The device as claimed in any of the preceding claims including a through-opening defined in said body, said through-opening having a cross-sectional area adapted to controlling the rate of ingested food passing through said body.

14. The device as claimed in claim 13 wherein said through-opening has a cross-sectional diameter that is in the range of from approximately 0.5 centimeters to approximately 1.5 centimeters.

15. The device as claimed in any of the preceding claims wherein said scar forming area comprises a portion of the length of said wall.

16. The device as claimed in any of the preceding claims including radiopaque markers on said body.

17. The device as claimed in any of the preceding claims wherein said body is adapted to be deployed endoscopically.

18. The device as claimed in any of the preceding claims wherein said body is adapted to be positioned at a site of diverticular disease.

19. The device as claimed in any of claims 1 through 17 wherein said body is adapted to be positioned at a stomal site.

20. The device as claimed in any of claims 1 through 17 wherein said body is adapted to be positioned at a bowel incision site.

21. The device as claimed in any of claims 1 through 17 wherein said body is adapted to be positioned at a fistula.

22. The device as claimed in any of claims 1 through 17 wherein said body is adapted to be positioned at a stricture.

23. The device as claimed in any of the preceding claims wherein said inner layer is rigid or semi-rigid.

24. A gastro-intestinal therapeutic method, comprising:

providing a therapeutic device having a body and an anchoring mechanism, said mechanism adapted to resist distal migration of said body in a gastro-intestinal tract, said body having a wall generally configured to a portion of the gastro-intestinal tract and having a first wall portion and a second wall portion, said first wall portion defining a generally sealed membrane, said second wall portion having a scar forming area, and said body being bioabsorbable in a patient;

positioning said therapeutic device at a portion of the gastro-intestinal tract;

causing formation of scar tissue at the portion of the gastro-intestinal tract with said scar forming area; and

absorbing said body in the patient.

25. The method as claimed in claim 24 including positioning said therapeutic device endoscopically.

26. The method as claimed in claim 24 or claim 25 including positioning the therapeutic device at a portion of the gastro-intestinal tract having at least one chosen from (i) an anastomosis, (ii) a fistula, (iii) diverticular disease, (iv) a stomal opening, (v) an incision, and (vi) a stricture.

27. The method as claimed in any of claims 24 through 26 including performing transgastric surgery and further including positioning said therapeutic device at an incision in the bowel formed during the transgastric surgery.

28. The method as claimed in any of claims 24 through 26 including creating a stomach pouch having a stomal site that is adapted to restrict the passage of food and further including positioning said therapeutic device at said stomal site.

29. The method as claimed in claim 28 wherein said opening has a diameter that is in the range of from approximately 0.5 centimeters to approximately 1.5 centimeters.

30. The method as claimed in claim 28 or claim 29 including positioning said body at a stomal site that is formed using at least one chosen from linear stapling, hand suturing and EEA.

31. The method as claimed in any of claims 28 through 30 including forming a stomal site laparoscopically.

32. The method as claimed in any of claims 28 through 31 including forming a stomal site in a gastric bypass procedure.

33. The method as claimed in any of claims 28 through 32 including positioning said body during the same procedure as forming a stoma.

34. The method as claimed in any of claims 28 through 32 including positioning said body after the procedure forming a stoma.

35. The method as claimed in any of claims 24 through 26 used to repair an anastomosis post-operatively.

36. The method as claimed in any of claims 24 through 35 wherein said anchoring mechanism includes an annular flange around said body.

37. The method as claimed in any of claims 24 through 36 wherein said anchoring mechanism includes said outer layer of a material having tissue in-growth fenestrations.

38. The method as claimed in any of claims 24 through 37 wherein said anchoring mechanism comprises anti-migration tines.

39. The method as claimed in claim 38 including deploying said tines *in situ*.

40. The method as claimed in claim 39 including providing a deployment device and deploying said tines with said deployment device.

41. The method as claimed in claim 40 wherein said deployment device comprises a balloon and including deploying said tines by inflating said balloon.

42. The method as claimed in any of claims 24 through 41 including providing radiopaque markers on said body.

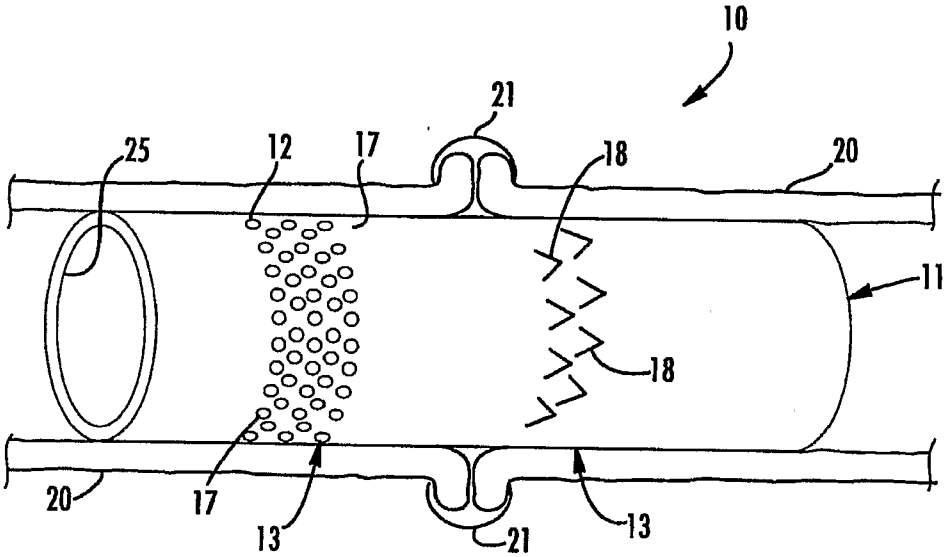

FIG. 1.

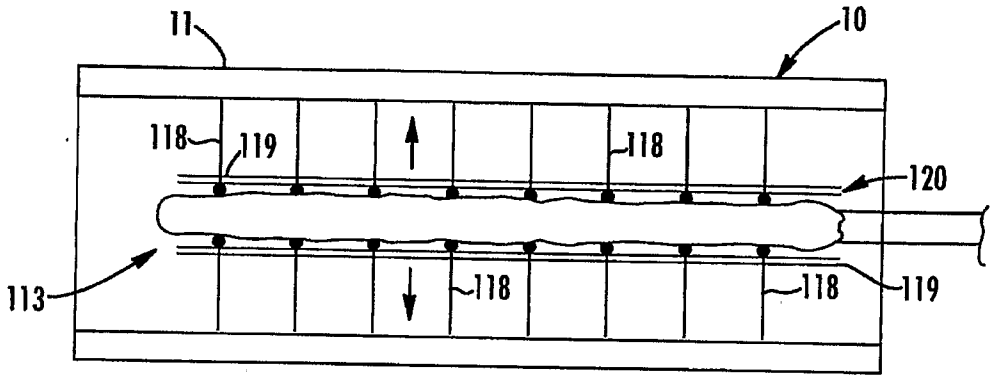

FIG. 2.

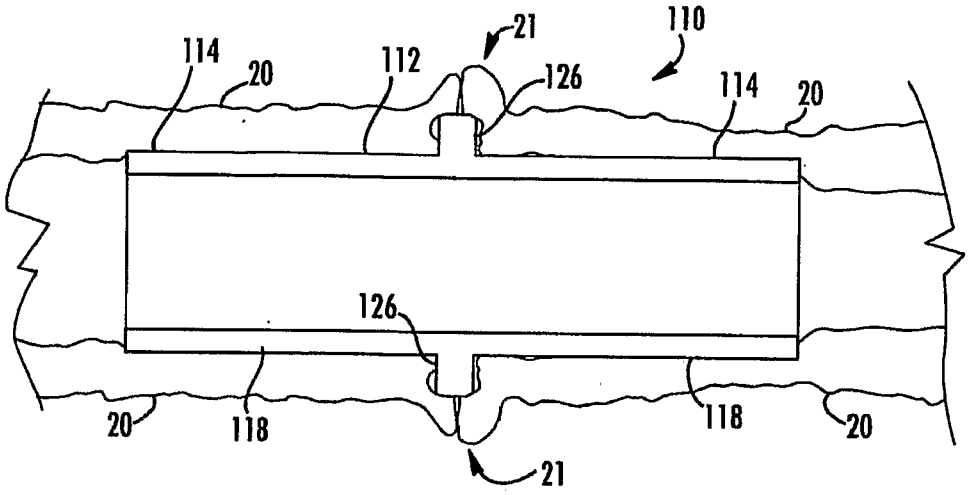

FIG. 3.

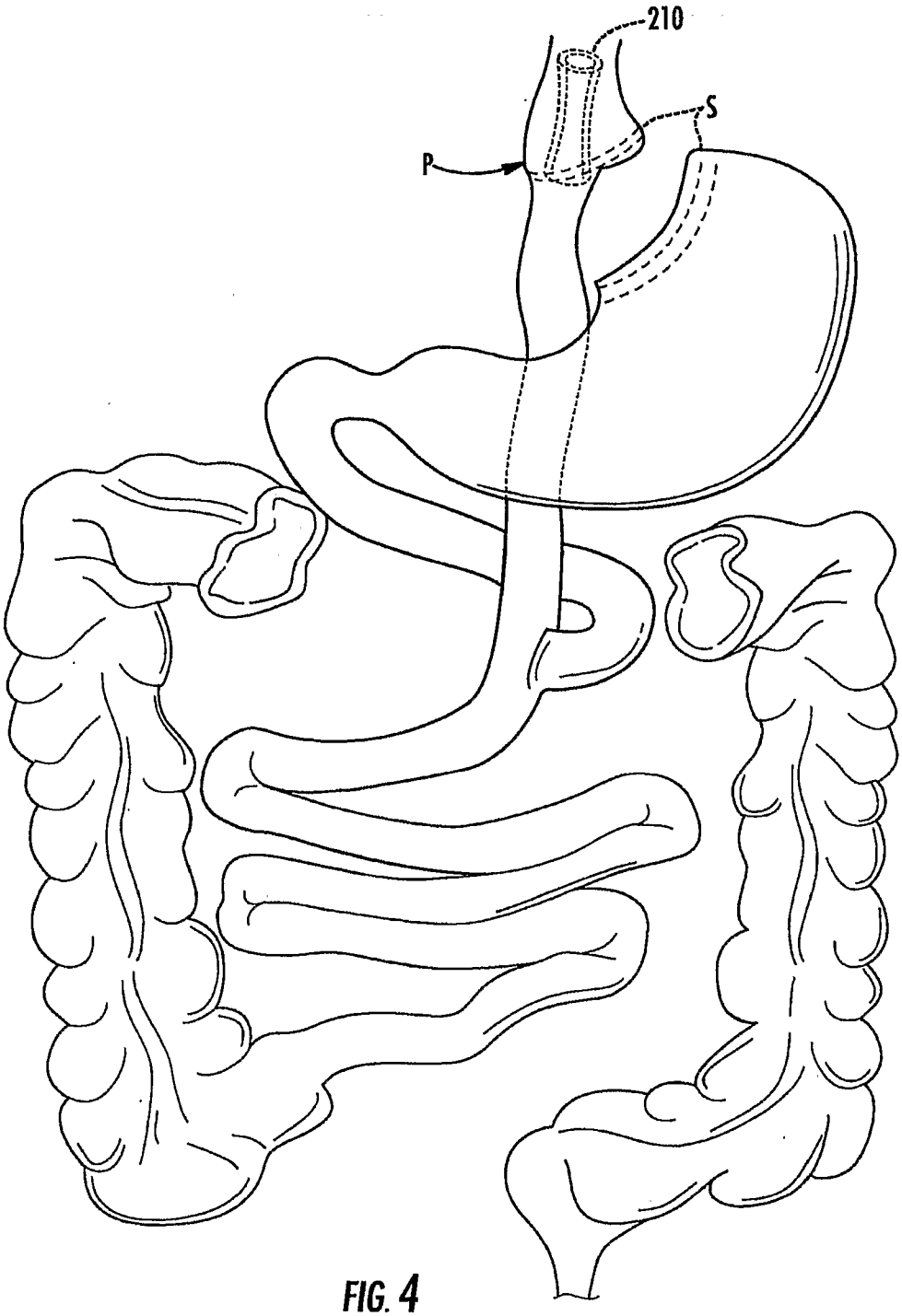

FIG. 4

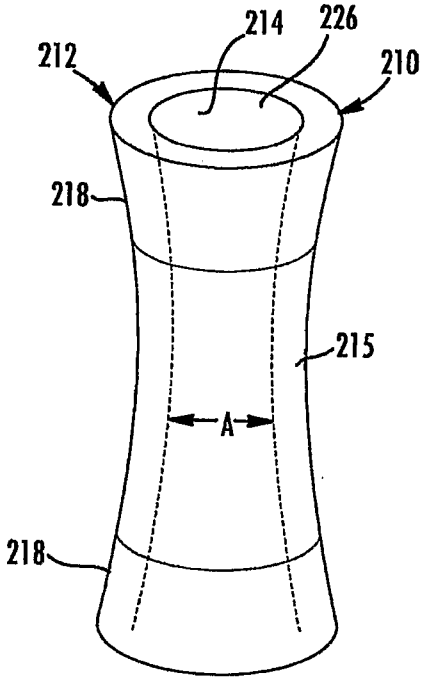

FIG. 5