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(54) Title: APPARATUS AND METHOD FOR CREATING A LUMEN OF A DESIRED SHAPE AND SIZE IN A HOLLOW VISCUS ORGAN FROM TISSUE OF THE ORGAN

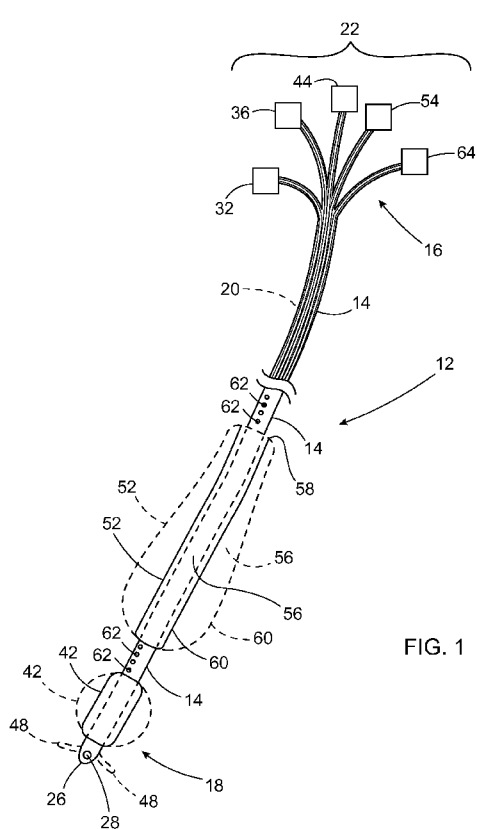


FIG. 1

(57) Abstract: An apparatus is positioned in a hollow viscus organ and functions as a template for creating a lumen of a desired shape and size in the organ from the tissue of the organ. The apparatus is comprised of an elongate, flexible tube having opposite proximal and distal ends. The tube has several lumens or pathways that extend through the interior of the tube between the proximal and distal ends of the tube. A directional, steerable feature extends through one of the lumens of the tube. An anchor feature is provided at the tube distal end and is manually operable from the tube proximal end. An exterior surface dimension adjustable feature is provided adjacent the tube distal end. A suction communication feature is provided along at least a portion of the tube length.

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**APPARATUS AND METHOD FOR CREATING A LUMEN OF A DESIRED SHAPE
AND SIZE IN A HOLLOW VISCUS ORGAN FROM TISSUE OF THE ORGAN**

This patent application claims the benefit of the filing date of the provisional patent application Serial No. 61/471,454, which was filed on April 4, 2011.

BACKGROUND OF THE INVENTION

[0001] The present invention pertains to an apparatus that is positioned in a hollow viscus organ and functions as a template for creating a lumen of a desired shape and size in the organ from the tissue of the organ, and the method of using the apparatus in creating the lumen.

SUMMARY

[0002] The apparatus of the invention is employed in creating a lumen of a desired shape and size in a hollow viscus organ from tissue of the organ. In particular, the present invention is employed in creating a tubular gastric sleeve from the tissue of a patient's stomach.

[0003] The apparatus is comprised of an elongate, flexible tube having opposite proximal and distal ends. The tube has several lumens or pathways that extend through the interior of the tube between the proximal and distal ends of the tube.

[0004] A directional, steerable feature extends through one of the lumens of the tube. The directional, steerable feature is manually operable at the tube proximal end to direct and steer the tube distal end in different directions relative to the length of the tube.

[0005] An anchor feature is provided at the tube distal end and is manually operable from the tube proximal end. The anchor feature selectively anchors or secures the tube distal end to tissue of a hollow viscus organ. In particular, the anchor feature can be selectively operated to secure the tube distal end in the beginning of the small intestine or duodenum of a patient.

[0006] An exterior surface dimension adjustable feature is provided adjacent the tube distal end. The adjustable feature is also manually operable at the tube proximal end. The adjustable feature can be selectively enlarged and reduced in shape configuration and circumferential dimensions. When enlarged, the exterior surface of the adjustable feature has its largest circumferential dimension at the end of the adjustable feature that is adjacent the tube distal end. From this end of the enlarged adjustable feature the circumferential dimension of the feature gradually decreases as the adjustable feature extends toward the tube proximal end.

[0007] A suction communication feature is provided along at least a portion of the tube length. The suction feature is also operable at the tube proximal end. Manual operation of the suction feature supplies suction pressure along at least a portion of the tube length that draws the tissue of the hollow viscus organ toward the exterior surface of the tube.

[0008] In use of the apparatus the tube distal end is first inserted through the patient's esophagus and then into the patient's stomach. The anchor feature at the tube distal end is guided from the stomach interior past the patient's pyloric valve and into the beginning of the small intestine or duodenum. The anchor feature is then operated to secure the tube distal end in its position. The length of the tube is then manually pulled from the proximal end to position the tube, and in particular the exterior surface dimension adjustable feature along the lesser curvature of the

stomach and adjacent the stomach incisura. The exterior surface dimension adjustable feature is then enlarged. The suction communication feature is then operated, causing portions of the stomach wall to be drawn to and wrapped around the exterior surface dimension adjustable feature. The position of the adjustable feature along the stomach lesser curvature is then demarcated on the stomach exterior. Opposing portions of the stomach wall are then affixed together along the side portion of the enlarged dimension adjustable feature that is opposite the stomach lesser curvature, thereby creating a tubular gastric sleeve from the patient's stomach. The exterior surface dimension adjustable feature is then reduced in size, and the anchor feature is disengaged from the stomach. The apparatus is then removed from the patient's stomach leaving the gastric sleeve. The gastric sleeve will then function as a new gastric reservoir with an interior configuration that is without any significant, limiting constriction in the sleeve interior configuration in the area of the stomach incisura or other tenuous area of the reservoir after the apparatus has been removed.

DESCRIPTION OF THE DRAWINGS

[0009] Further features of the apparatus and its method of use are set forth in the following detailed description of the apparatus and method and in the drawing figures.

[0010] Figure 1 is a representation of one embodiment of the apparatus of the invention.

[0011] Figure 2 is a representation of the apparatus being inserted into a hollow viscus organ with the stomach being shown as one example of a hollow viscus organ.

[0012] Figure 3 is a representation of the apparatus being anchored to stomach tissue.

[0013] Figure 4 is a representation of the apparatus being positioned against the lesser curvature of the stomach wall.

[0014] Figure 5 is a representation of the apparatus in which a portion of the apparatus exterior surface has had its circumferential dimension increased.

[0015] Figure 6 is a representation of the apparatus functioning as a template in creating a lumen of a desired shape and size in a hollow viscus organ from the tissue of the organ, i.e., in the stomach from the tissue of the stomach.

[0016] Figure 7 is a representation of the apparatus after the lumen of the desired shape and size has been created in the stomach and the apparatus is being removed from the stomach.

DESCRIPTION OF THE APPARATUS OF THE INVENTION AND ITS METHOD OF USE

[0017] The apparatus of the invention 12 is designed for use in surgical procedures in creating a lumen of a desired shape and size in a hollow viscus organ from the tissue of the organ. In one example of the method of using the apparatus disclosed herein, the apparatus is designed to be introduced through the esophagus of a human patient and into the patient's stomach. The apparatus is then positioned along the lesser curvature of the stomach and is used as a template or guide in creating a lumen of a desired shape and size in the stomach from stomach tissue wrapped around the apparatus. The apparatus 12 is therefore constructed of biocompatible materials typically employed in the constructions of surgery devices.

[0018] Although the apparatus 12 of the invention and its method of use are described herein as creating a lumen of a desired shape and size in the stomach from the tissue of the stomach, it should be understood that the apparatus 12 of the invention is designed to be used as a template or guide in creating a lumen of a desired shape and size in a hollow viscus organ, not necessarily the stomach.

[0019] The apparatus 12 is basically constructed as a bougie having an elongate flexible, tube 14 with opposite proximal 16 and distal 18 ends. A plurality of separate bores or lumens represented by dashed lines 20 in Figure 1 extend through the interior of the tube 14 from the tube proximal end 16 toward the tube distal end 18. The lumens provide separate paths of communication through the interior of the tube 14 that communicate a plurality of manually operable controls 22 at the tube proximal end 16 with a plurality of features of the apparatus 12 that are positioned along portions of the tube length adjacent the tube distal end 18.

[0020] The extreme distal end of the apparatus tube length is formed as a blunt tip 26 having a smooth exterior surface. This enables the distal end tip 26 to easily pass over or through body tissue without causing damage to the tissue. If desired, an illumination light and/or endoscope opening 28 could be provided in the distal end tip 26 of the tube. The light and/or endoscope would be connected by any known appropriate communication means through one of the lumens 20 extending through the length of the tube 14 with a manually operable control 32 provided for the light or endoscope at the tube 14 proximal end 16. In this manner, illumination light could be provided at the tube distal end tip 26. This enables the location of the tip 26 in the stomach to be identified through the stomach wall from the abdominal cavity. Additionally, an endoscope visual image could be provided at the tube distal end tip.

[0021] The apparatus tube 14 is also provided with a directional or steerable feature that extends from the distal end 18 through one of the lumens 20 to a manually operable control 36 of the feature at the tube proximal end 16. Any conventional or known directional or steerable feature could be employed in the construction of the apparatus 12 for this purpose. The directional/steerable feature would be operable at the proximal end 16 of the tube 14 to direct and steer the distal end 18 of the tube in different directions relative to the length of the tube 14. Examples of known directional/steerable features include those that employ wires that extend along different sides of the tube length that are pulled in tension to curve and direct the different sides of the tube length. Additionally, shape memory wires or other equivalent means could be employed as the directional/steerable feature of the apparatus 12.

[0022] The apparatus 12 is also provided with an anchor feature 42 at the tube distal end 18. In the embodiment of the apparatus 12 shown in Figure 1, the anchor feature 42 is an inflatable balloon that communicates through one of the lumens 20 with a control 44 at the tube proximal end 16. The balloon anchor feature 42 is shown in solid lines in its deflated condition in Figure 1, and in dashed lines in its inflated condition in Figure 1. The manually operable control 44 provided at the tube length proximal end 16 controls the selective inflation and deflation of the balloon 42. In its deflated condition the balloon 42 is dimensioned to enable it to be inserted through the esophagus and into the stomach interior and from the stomach interior past the pyloric valve or sphincter and into the beginning of the small intestine or duodenum. With the balloon 42 so positioned, inflating the balloon 42 anchors the distal end portion 18 of the apparatus 12 in the duodenum. In this manner, the apparatus distal end 18 is securely anchored to the stomach tissue. In addition, the

anchor feature 42 could be provided with an illuminating light that is controllable at the manual control 44. The anchor feature light would enable identifying the location of the anchor feature inside the stomach by viewing the light through the stomach well from inside the abdominal cavity.

[0023] In different embodiments of the apparatus 12, the balloon anchor feature 42 could be replaced with other equivalent types of anchors. For example, the balloon anchor feature 24 could be replaced with selectively extendable hooks or prongs 48 shown in dash lines in Figure 1 that would also function to anchor the apparatus distal end 18 to the stomach tissue.

[0024] An exterior surface dimension adjustable feature 52 is also provided on the apparatus 12 along a portion of the tube 14. As shown in Figure 1, the exterior surface adjustable feature 52 extends completely around the tube and along a significant portion of the tube 14 length adjacent the distal end 19 of the tube, but is spaced along the tube length and is separate from the anchor feature 42. The exterior surface adjustable feature 52 communicates through one of the lumens 20 with a manual control 54 provided for the feature at the tube proximal end 16. The control 54 is manually operated to selectively move the adjustable feature 52 between a retracted condition shown in solid lines in Figure 1 and an extended or enlarged condition shown in dashed lines in Figure 1. In the retracted condition the circumferential dimension of the adjustable feature 52 enables insertion of the feature through the esophagus of a patient and into the stomach of the patient. When manually operated to move to its enlarged condition in dashed lines in Figure 1, the exterior surface 56 of the adjustable feature 52 has a shape configuration and circumferential dimensions along the length of the feature that enable it to be used as a template in creating a lumen of a desired shape and size in a hollow viscus

organ from the tissue of the organ. In the example of Figure 1, the adjustable feature 52 is used as a template for creating a lumen of a desired shape and size in the stomach tissue surrounding the adjustable feature 52 in performing the desired method of the invention that will be later described. One example of the desired shape configuration and circumferential dimensions of the exterior surface 56 of the adjustable feature 52 in its enlarged condition is shown in dashed lines in Figure 1. The adjustable feature has a generally annular cross-section configuration defined by the circular cross-section of the tube 14 at its center and the exterior surface 56 of the adjustable feature 52. The exterior surface 56 extends around an interior volume of the adjustable feature 52 with the tube 14 at the center of the volume. The length of the adjustable feature 52 extends from a proximal end 58 of the exterior surface 56 to a distal end 60 of the exterior surface. As seen in Figure 1, the circumferential dimension of the enlarged exterior surface 56 increases as it extends from adjacent the proximal end 58 to adjacent the distal end 60. It should be understood that the exterior surface adjustable feature 52 in its enlarged condition could have other desired shape configurations and size dimensions depending on its intended use. As shown in Figure 1, the exterior surface circumferential dimensions of the enlarged feature 52 are largest toward the distal end 18 of the tube 14. The exterior surface circumferential dimensions of the enlarged feature 52 gradually become smaller as the adjustable feature 52 extends along the portion of the tube length toward the proximal end 16 of the tube 14.

[0025] An example of an exterior surface adjustable feature 52 that could be employed on the apparatus 12 is an inflatable balloon having a desired exterior configuration with desired circumferential dimensions when in the enlarged or inflated condition of the balloon, and when deflated the balloon returns to the

retracted condition of the feature 52 represented by the solid lines in Figure 1. The adjustable feature would communicate through one of the lumens 20 through the tube to a manual control 54 to selectively inflate and deflate the adjustable feature 52. As an alternative to an inflatable balloon, the exterior surface adjustable feature 52 could be a mechanical linkage system that enlarges and retracts in the same manner as an inflatable balloon, or other equivalent means of performing the functions of the exterior surface adjustable feature 52.

[0026] The apparatus of the invention 12 is also provided with a suction pressure communication feature 62 that communicates through one of the lumens 20 with a manual control 64. The suction feature 62 enables suction pressure to be delivered to a portion or portions of the apparatus tube 14 length in response to the manual operation of the control 64 at the tube proximal end 16. Figure 1 shows suction holes 62 provided in portions of the apparatus tube 14 length that function as the suction pressure communication feature 62. The holes 62 deliver suction pressure to the exterior surface of the tube 14 length in the areas of the holes 62. In other examples of the apparatus 12, the holes 62 could be replaced by slits in the exterior surface of the tube length or other equivalent means of delivering suction pressure to desired areas of the exterior surface of a tube length. The suction pressure delivered to the holes 62 by manual operation of the control 64 causes the stomach or other hollow viscus organ to contract around the apparatus in the areas of the holes. The portions of the stomach tissue or organ tissue are drawn or wrapped around the exterior surface of the adjustable feature 52 and around the portions of the apparatus tube length having the suction holes 62.

[0027] The use of the apparatus of the invention 12 according to the method of the invention is shown in the drawing Figures 2-7. In Figures 2-7 the apparatus 12 is

shown being used as a template or guide in creating a lumen of a desired shape and size in the stomach from the tissue of the stomach. It should be understood that this is only one example of a use of the apparatus and the apparatus is not limited to use in the stomach. The apparatus of the invention 12 is designed to be used as a template or guide for creating a lumen of a desired shape and size in a hollow viscus organ (not necessarily the stomach) from the tissue of the organ.

[0028] Figure 2 shows the apparatus 12 being inserted distal end 18 first through the patient's esophagus 72 and into the interior 74 of the patient's stomach 76. As the apparatus 12 is moved through the stomach interior 74 by manually operating the steerable feature control 36, the apparatus distal end 18 is directed toward the pylorus 78 and is inserted through the pyloric valve 82. The illumination light and/or endoscope 28 may be employed in directing the apparatus distal end 18 through the valve. Additionally, the illuminating light of the anchor feature 42 may be used in identifying the location of the apparatus distal end 18 inside the stomach by viewing the light through the stomach wall from the abdominal cavity.

[0029] With the apparatus distal end 18 inserted through the pyloric valve 82 and position in the pylorus 78, the anchor feature control 44 is then manually operated to cause the anchor feature 42 to secure the apparatus' distal end 18 to the stomach tissue. Figure 3 shows the balloon anchor feature 42 being inflated in the pylorus 78 and thereby securing the apparatus distal end 18 to the stomach tissue in the pylorus 78.

[0030] The tube 14 of the apparatus 12 is then manipulated from the apparatus proximal end 16 to position a portion of the tube length and in particular to position the external surface adjustment feature 52 against the lesser curvature wall 84 of the stomach 76 as shown in Figure 4. With the exterior surface adjustment feature 52

so positioned, the control 54 for the feature 52 is then manually operated to cause the feature 52 to enlarge to its desired shape configuration and circumferential dimensions as shown in Figure 5.

[0031] The suction pressure feature 62 of the apparatus 12 is then activated by manual operation of its associated control 64. This evacuates the stomach interior 74 through the suction pressure feature 62 and causes the stomach to contract around the apparatus and in particular around the exterior surface adjustment feature 52. The contraction of the stomach causes portions of the stomach tissue along the stomach lesser curvature 84 to wrap around and envelop the exterior surface adjustment feature 52. With portions of the stomach wall along the lesser curvature 84 wrapped over the exterior surface adjustment feature 52, the template configuration of the exterior surface adjustment feature 52 is demarcated on the stomach wall outside the stomach, making it easier to discern the position of the exterior surface adjustment feature 52 from outside the stomach.

[0032] Opposing portions of the stomach wall are then affixed 86 together along the side of the exterior surface adjustment feature 52 that is opposite the stomach lesser curvature 84. The opposing portions of the stomach wall can be affixed 86 together by conventional means such as stapling, suturing, etc. Plication could also be used to reduce the size of the stomach and secure the opposing portions of the stomach wall together along the side of the exterior surface adjustment feature 52 that is opposite the stomach lesser curvature 84. This creates a lumen 88 of a desired shape and size in the stomach from the opposing portions of the stomach wall wrapped around the exterior surface adjustment feature 52. The lumen 88 created has an interior configuration of a desired shape and size that conforms to the shape configuration and the circumferential size dimensions of the exterior surface

adjustment feature 52 inside the just created lumen 88. Due to the shape of the adjustment feature 52 and in particular the circumferential dimension of the adjustment feature 52 being larger adjacent the tube distal end 18 and becoming smaller as it extends toward the tube proximal end 16, the interior configuration of the lumen 88 created is without any significant, limiting constriction in the lumen interior in the area of the stomach incisura or other tenuous area of the lumen interior.

[0033] With the lumen 88 created, the exterior surface adjustment feature 52 is controlled by its associated control 54 to return to its retracted condition on the apparatus tube 14 as shown in Figure 6. The anchor feature 42 is also controlled by its associated control 44 to disengage from the stomach tissue as shown in Figure 7. The apparatus 12 can then be removed from the lumen 88. The lumen 88 then functions as a new gastric reservoir with an interior configuration that is without any significant, limiting constriction in the interior configuration of the lumen 88 in the area of the stomach incisura 92 or other tenuous interior area of the created lumen 88 after the apparatus 12 has been removed.

CLAIMS

1. A method of creating a lumen of a desired shape and size in a hollow viscus organ of a patient from tissue of the organ, the method comprising:

providing a template having a flexible tube length with opposite proximal and distal ends;

inserting the template distal end first into the patient's hollow viscus organ;

positioning a portion of the template length against an interior wall of the organ;

demarcating the template's configuration so as to make it easily discernable from outside the organ;

affixing together opposing portions of the organ wall, along a side of the portion of the template length that is opposite the portion of the template length positioned against the organ interior wall, thereby creating a lumen of a desired shape and size in the organ from the tissue of the organ, the lumen having an interior configuration that conforms to the portion of the template length with in the portion of the organ wall;

removing the template from the lumen whereby the lumen has an interior configuration that is without any significant, limiting constriction in the lumen interior configuration or other tenuous area of the lumen interior after the template has been removed.

2. The method of claim 1, further comprising:

creating the lumen as a tubular gastric sleeve from the patient's stomach.

3. The method of claim 2, further comprising:
inserting the template distal end first through the esophagus of the patient and then into the patient's stomach.
4. The method of claim 3, further comprising:
positioning the portion of the template length against the patient's stomach wall, along the stomach lesser curvature.
5. The method of claim 4, further comprising:
affixing together opposing portions of the stomach wall, along a side of the portion of the template length that is opposite the stomach lesser curvature, thereby creating the lumen as a tubular sleeve of the stomach having an interior configuration that conforms to the portion of the template length within the portion of the stomach wall.
6. The method of claim 5, further comprising:
removing the template from the gastric sleeve whereby the sleeve will function as a new gastric reservoir with an interior configuration that is without any significant, limiting constriction in the sleeve interior configuration in the area of the stomach incisura or other tenuous area of the reservoir after the template has been removed.
7. The method of claim 1, further comprising:
enlarging a portion of an exterior surface of the template before demarcating the template's configuration.
8. The method of claim 7, further comprising:

enlarging the portion of the exterior surface of the template with the enlarged portion of the exterior surface having a larger circumferential dimension adjacent the template distal end and the circumferential dimension of the enlarged portion of the exterior surface becoming smaller as it extends toward the template proximal end.

9. An apparatus for creating a lumen of a desired shape and size in a hollow viscus organ from tissue of the organ, the apparatus comprising:
- an elongate, flexible tube with opposite proximal and distal ends;
 - an anchor feature at the tube distal end that is selectively operable at the tube proximal end to selectively anchor the tube distal end to tissue of the hollow viscus organ; and
 - an exterior surface dimension adjustable feature positioned on the tube between the anchor feature and the tube proximal end, the exterior surface dimension adjustable feature being operable to selectively enlarge and reduce a shape configuration of the adjustable feature and circumferential dimensions of the adjustable feature.

10. The apparatus of claim 9, further comprising:
- a directional, steerable feature along the tube length that is operable at the tube proximal end to direct and steer the tube distal end in different directions relative to the tube length.

11. The apparatus of claim 9, further comprising:

a suction communication feature along at least a portion of the tube length, the suction communication feature being operable at the tube proximal end to supply suction pressure along at least the portion of the tube length.

12. The apparatus of claim 9, further comprising:

the anchor feature being operable at the tube proximal end to selectively anchor the tube distal end to stomach tissue.

13. The apparatus of claim 9, further comprising:

the circumferential dimension of the exterior surface dimension adjustable feature adjacent the tube distal end when enlarged being larger than the circumferential dimension of the exterior surface dimension adjustable feature adjacent the tube proximal end.

14. The apparatus of claim 9, further comprising:

the circumferential dimension of the exterior surface dimension adjustable feature when enlarged gradually becomes smaller as the enlarged exterior surface dimension adjustable feature extends from adjacent the distal end toward the tube proximal end.

15. The apparatus of claim 9, further comprising:

the tube having a plurality of lumens extending through an interior of the tube from the tube proximal end toward the tube distal end.

16. The apparatus of claim 15, further comprising:

the circumferential dimension of the exterior surface dimension adjustable feature adjacent the tube distal end when enlarged being larger than the circumferential dimension of the exterior surface dimension adjustable feature adjacent the tube proximal end.

17. The apparatus of claim 16, further comprising:

a suction communication feature along at least a portion of the tube length, the suction communication feature being operable at the tube proximal end to supply suction pressure along at least the portion of the tube length.

18. The apparatus of claim 17, further comprising:

the suction communication feature having suction openings on the tube on opposite sides of the exterior surface dimension adjustable feature.

19. The apparatus of claim 18, further comprising:

the anchor feature and the exterior surface dimension adjustable feature being separated by a portion of the tube.

20. The apparatus of claim 19, further comprising:

a directional, steerable feature along the tube length that is operable at the tube proximal end to direct and steer the tube distal end in different directions relative to the tube length.

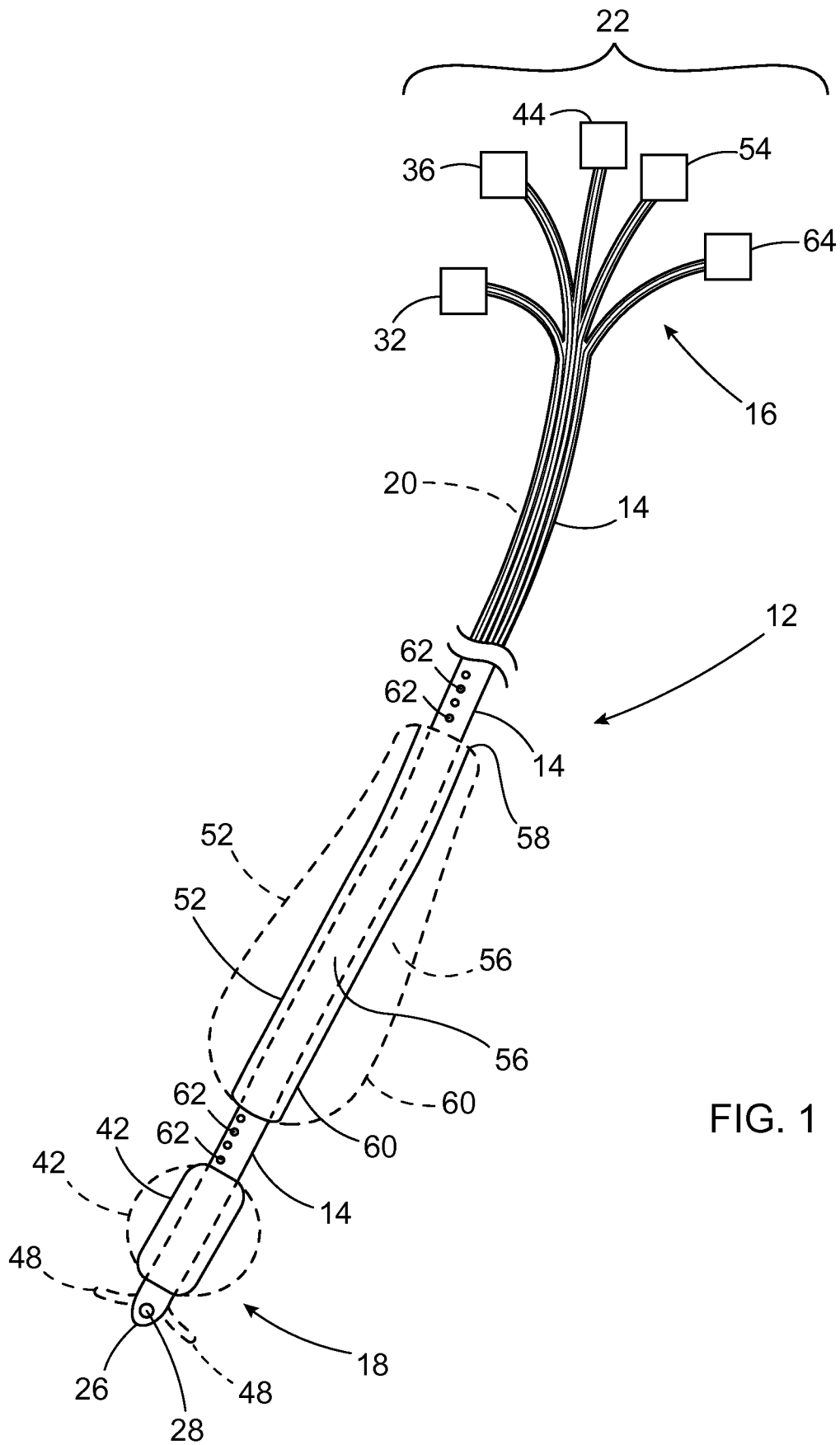


FIG. 1

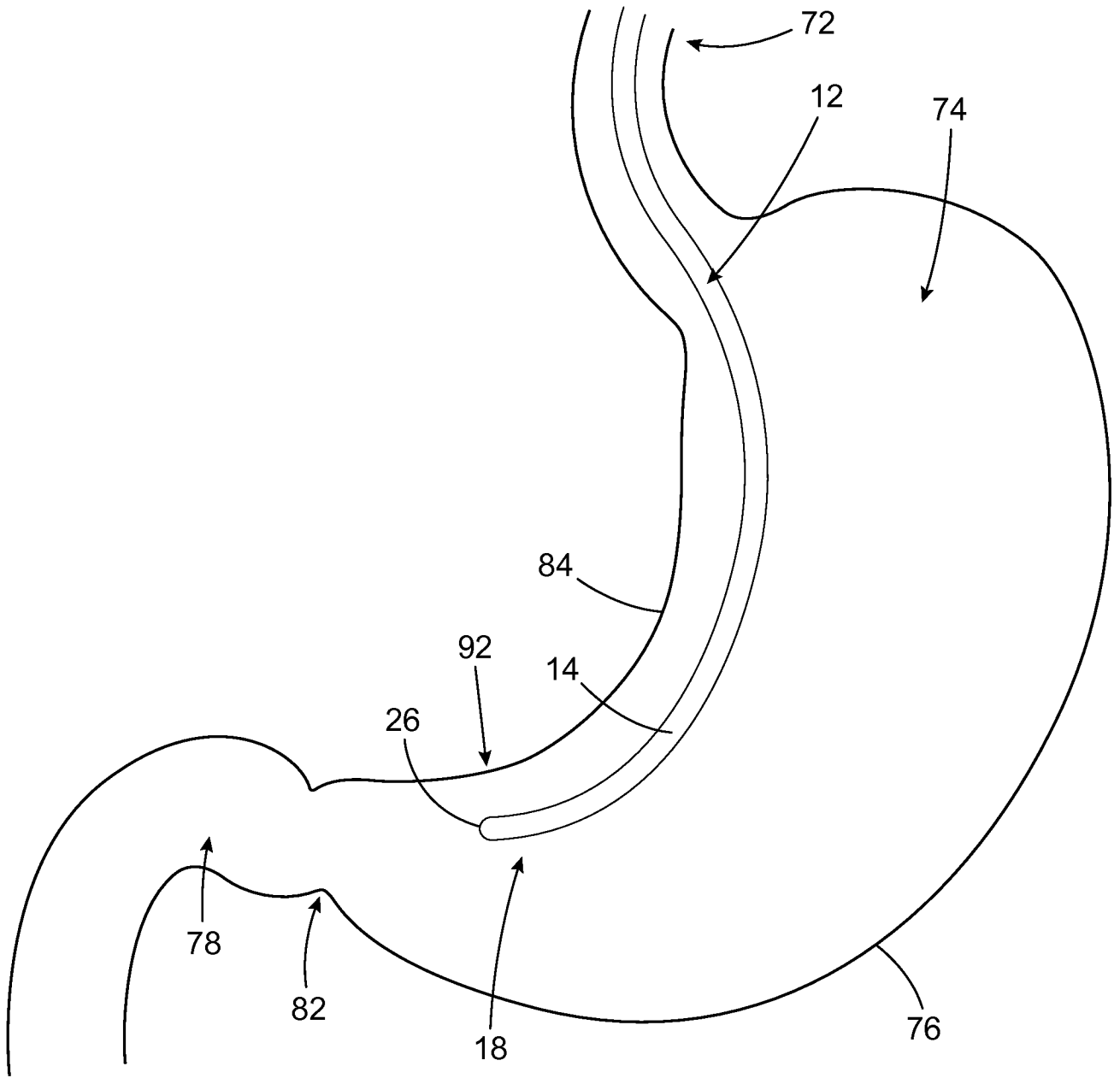


FIG. 2

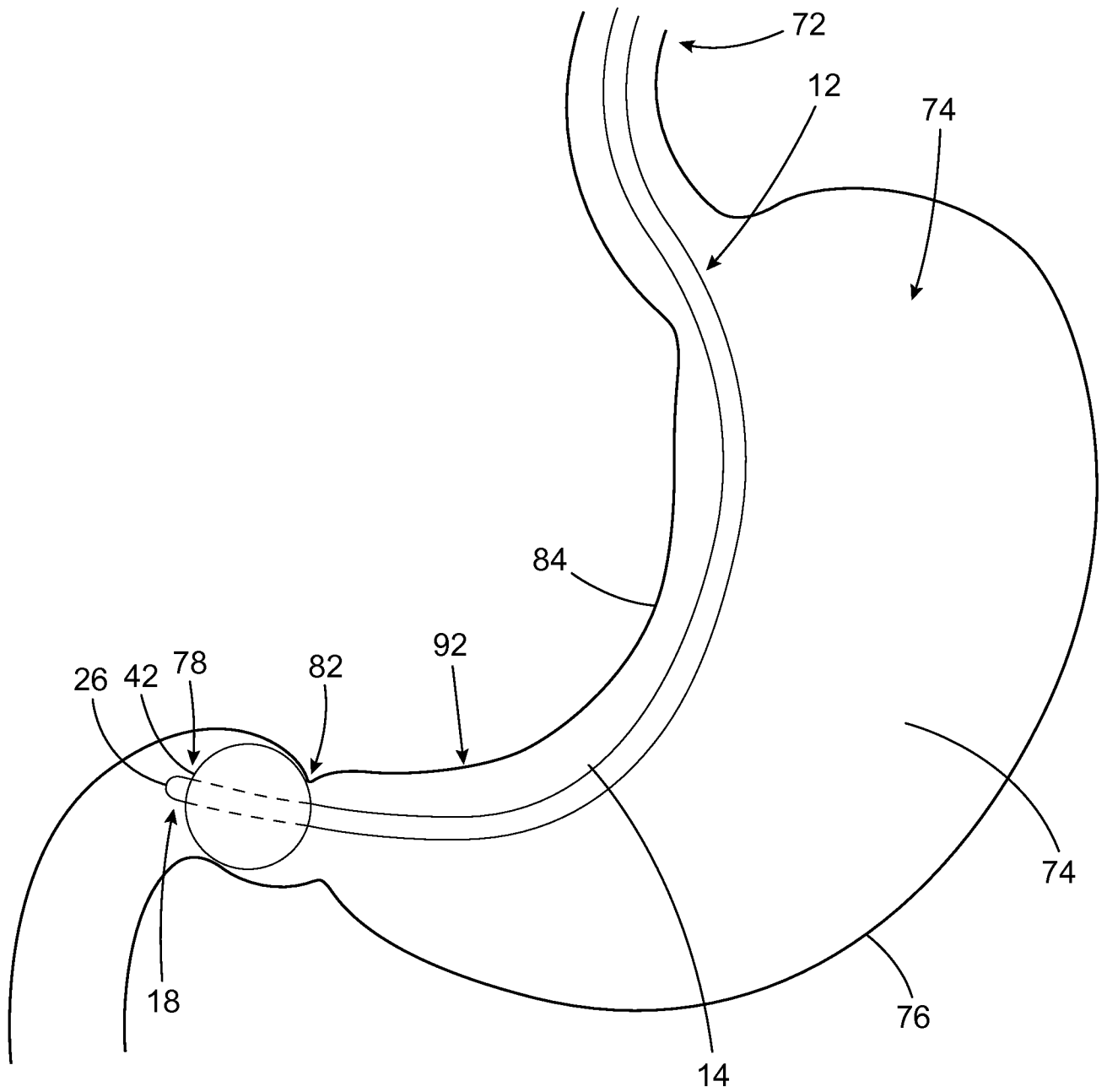


FIG. 3

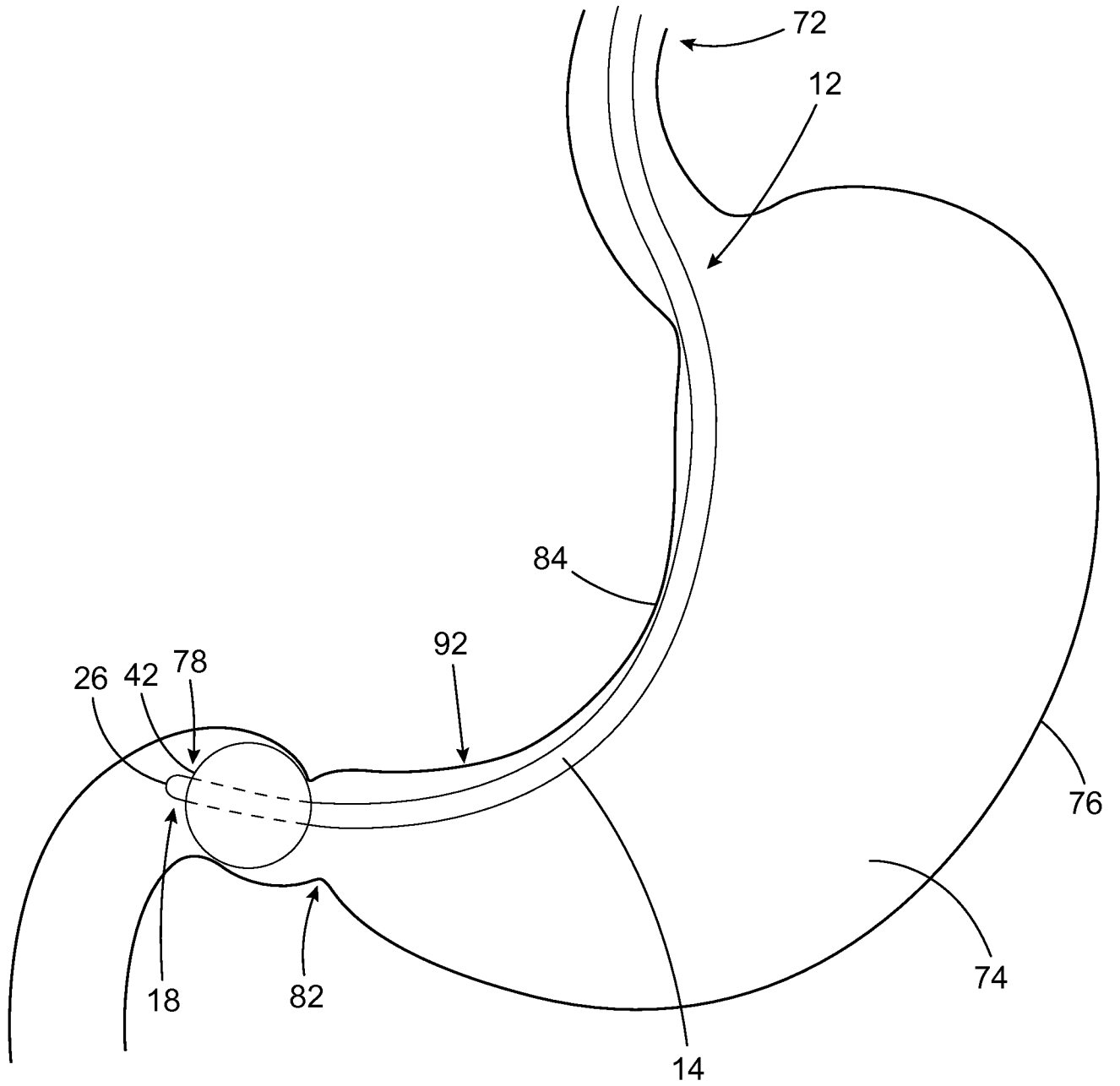


FIG. 4

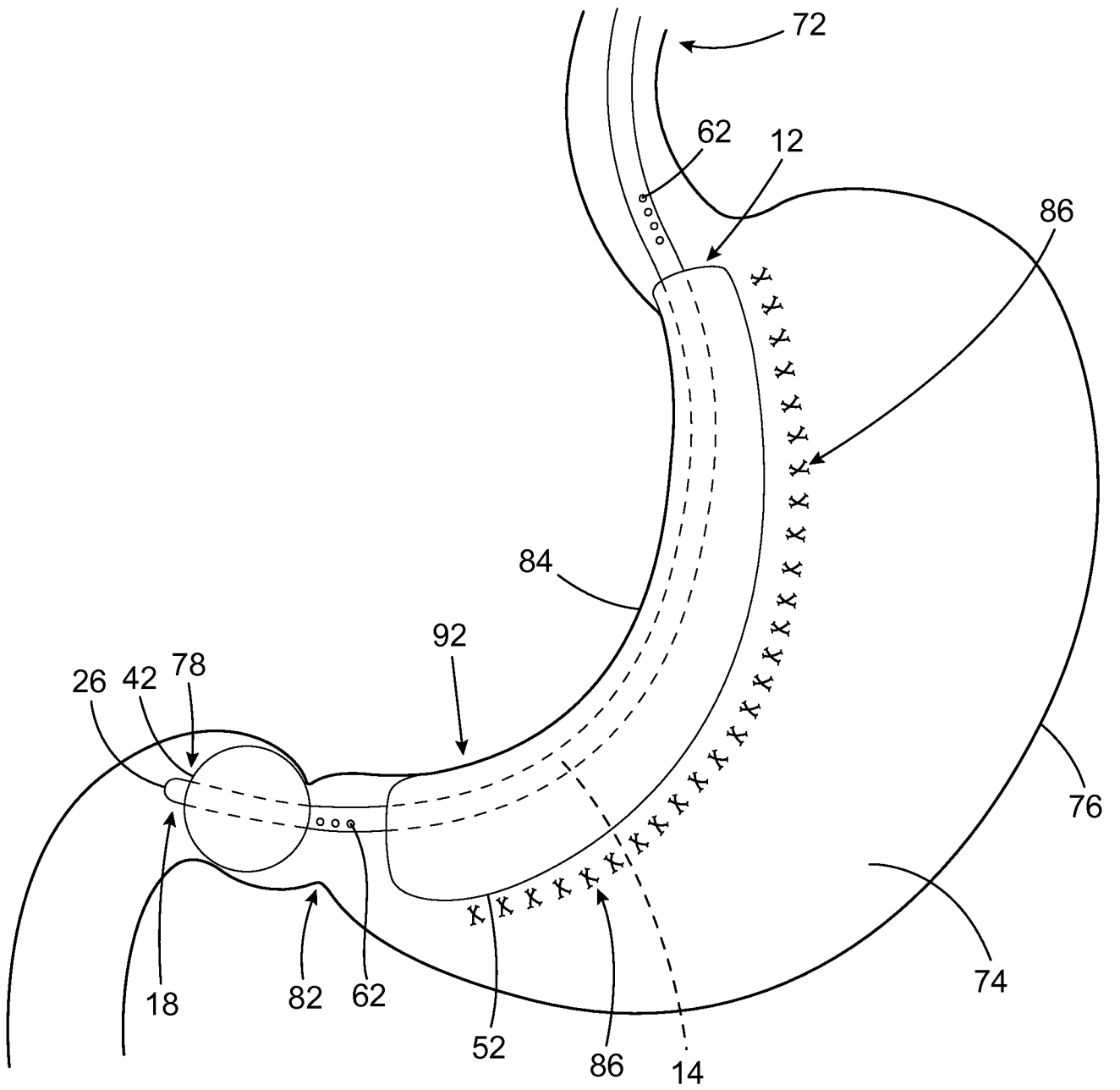


FIG. 5

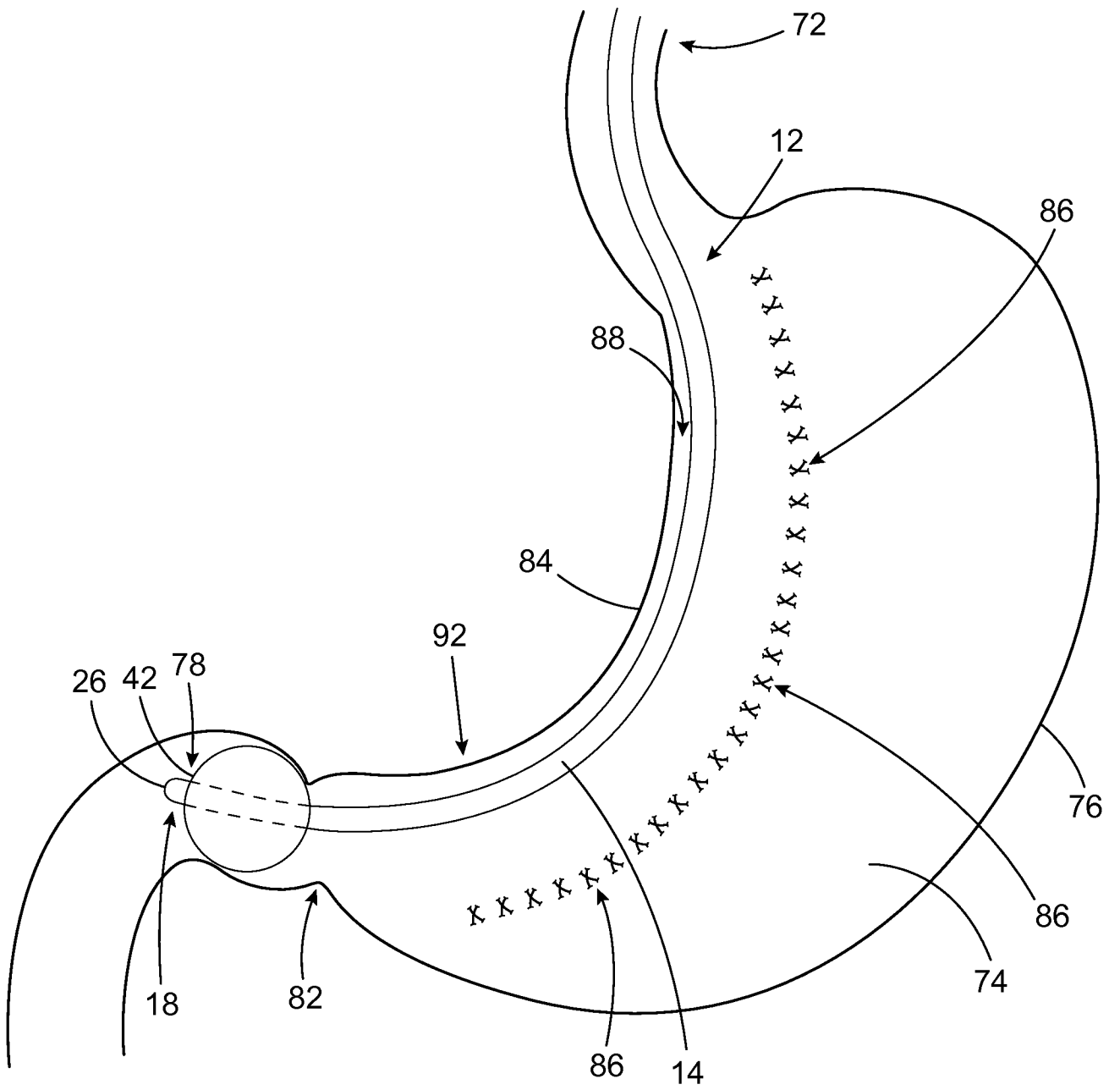


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2012/032138

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61B 17/138 (2012.01) USPC - 606/145 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) - A61B 17/08, 17/138; A61F 2/04; A61M 29/00 (2012.01) USPC - 606/144, 145, 151, 191; 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 Scholar		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0275473 A1 (FILIPPI et al) 06 November 2008 (06.11.2008) entire document	1-20
A	US 2010/0114125 A1 (ALBRECHT et al) 06 May 2010 (06.05.2010) entire document	1-20
P, A	US 2011/0257760 A1 (WALDREP) 20 October 2011 (20.10.2011) entire document	1-20
A	SEAMAN et al. Tissue anchors for transmural gut-wall apposition. Gastrointestinal Endoscopy Volume 64, Issue 4, Pages 577-581, 22 May 2006 entire document	1-20
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
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Date of the actual completion of the international search 12 July 2012		Date of mailing of the international search report 26 JUL 2012
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