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(54) **Title:** SYSTEM AND METHOD FOR ESOPHAGEAL SPHINCTER REPAIR

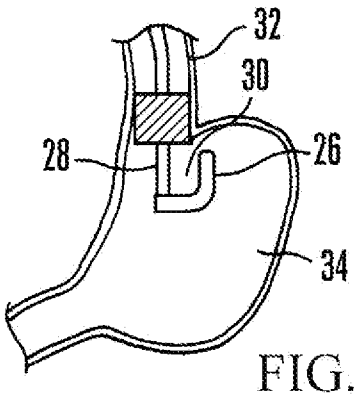

FIG. 7

(57) **Abstract:** An arcuate nitinol splint (10, 40, 50) with a rounded cross-section has two ends facing each other and spaced from each other. The splint is advanced through the mouth into the esophagus by an introducer device. By means of the device the splint is implanted completely into the wall of the esophageal sphincter to strengthen the sphincter. Materials other than Nitinol may be used.

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SYSTEM AND METHOD FOR ESOPHAGEAL SPHINCTER REPAIR

I. Field of the Invention

The application relates generally to repairing the esophageal or cardiac sphincter located at the gastroesophageal junction.

II. Background of the Invention

Gastro esophageal reflux disease (GERD), in which contents in the stomach pass back ("reflux") into the esophagus, is primarily caused by a weakened esophageal sphincter. The esophageal sphincter is a circular muscle, essentially a one-way valve, at the bottom end of the esophagus that, when functioning properly in the absence of nausea, allows food to pass from the esophagus into the stomach while preventing stomach contents from passing back into the esophagus.

GERD can be treated by dietary changes, medicine, and when these treatments are insufficient, by surgery. For example, a procedure known as "fundoplication" has been introduced in which the upper curve of the stomach (the fundus) is wrapped around the esophagus and sewn into place so that the lower portion of the esophagus passes through a small tunnel of stomach muscle. This surgery strengthens the esophageal sphincter, which stops acid from backing up into the esophagus as easily. However, as understood herein the surgery is invasive even when executed laparoscopically, raising the risk of complications including infection by resistant strains of bacteria that attend all invasive procedures.

Implants have been introduced that surround the esophagus from the outside to grip it. As understood by present principles, not only does placement of such implants entail

invasive surgery, but such implants can cause the swallowing disorder known as "dysphagia". Moreover, the external implants typically can move on the esophagus, eroding tissue and in extreme cases causing death.

SUMMARY OF THE INVENTION

A device includes an arcuate non-flaccid splint formed with two ends facing each other. The splint is configured for advancement through a patient's mouth into the esophagus by an introducer device. The splint is configured for implantation completely into the wall of the esophageal sphincter to strengthen the sphincter (intramural implantation). To this end, the splint is biased toward a narrow configuration, wherein the splint urges the wall of the sphincter inwardly. However, the splint can be moved by food passing from the esophagus into the stomach to a wide configuration wherein the ends are spaced from each other such that the sphincter can open sufficiently to allow the food to enter the stomach. This mimics and reinforces the natural tendency of the sphincter, resulting in both an anatomic and physiologic repair.

The splint may be made of Nitinol or other material, e.g., polyolefin, acetal, or teflon. If desired, the splint can be drug-eluting. Also, the splint can be hollow and can be formed with at least one opening. In example embodiments the splint has a rounded cross-section, and the splint may have a smooth exterior or an externally barbed or textured exterior for enhancing tissue engagement.

In another aspect, an introducer device includes a device body advanceable through the mouth of a patient into the esophagus. The body is configured to hold at least one esophageal sphincter splint. The device with splint is configured for forming a passage in the

wall of the esophageal sphincter for placement of the splint therein. A stop member is positioned on the body a predetermined distance from the splint. The stop member is configured for abutting the esophagus-stomach fundus junction to thereby securely locate the splint at the esophageal sphincter.

In one example, the stop member is an inflatable balloon juxtaposed with a distal end of the device body. In another example, the stop member is a distal L-shaped member forming a bight with the device body. The device can be advanced into the stomach and retracted to trap a portion of the fundus and esophagus in the bight.

In another aspect, a method includes advancing a tightening element, such as a splint or an elastic suture thread, through the mouth of a patient to the esophageal sphincter. The method then includes implanting the tightening element inside the wall of the esophageal sphincter to urge the sphincter closed. The tightening element is sufficiently flexible to permit the sphincter to open when food passes through the sphincter into the stomach.

The details of the present invention, both as to its structure and operation, can best be understood in reference to the accompanying drawings, in which like reference numerals refer to like parts, and in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of an example esophageal sphincter splint in the narrow (biased) configuration;

Figure 2 is a side view of the splint in the wide configuration;

Figure 3 is a cross-sectional view of the splint as seen along the line 3-3 in Figure 1;

Figure 4 is a cross-sectional view of an alternate hollow splint as would be seen along the line 3-3 in Figure 1;

Figure 5 is a cross-sectional view of the splint embedded within the esophageal sphincter;

Figure 6 is a perspective view of a first introducer device for implanting the splint in the esophageal sphincter;

Figure 7 is a side view in partial cross-section showing the device of Figure 6 advanced through the mouth and esophagus into the stomach;

Figure 8 is a side view in partial cross-section showing the device of Figure 6 pulled back up to trap the fundus against the esophagus;

Figure 9 is a larger side view showing the stop member of the device in Figure 6 abutting the esophagus-stomach fundus junction to thereby securely locate the tunneler element at the esophageal sphincter;

Figure 10 is a side view of a hollow splint;

Figure 11 is a side view of a barbed splint;

Figure 12 is a schematic view of an alternate introducer device for implanting the splint, with both positioning balloons inflated at the desired locations to position the splint at the esophageal sphincter;

Figure 13 is a top plan view of the tunneler element of the device of Figure 12 in the housed configuration, with the catheter body omitted for clarity;

Figures 14-16 are top plan views of the tunneler element shown in Figure 13 in progressive stages of operation;

Figure 17 is a perspective view of the tunneler element with push rod, showing the push rod in the vertical plane and the tunneler element in the horizontal plane.

Figure 18 is a schematic view of an alternate deployment mechanism with alternate tightening element that is established by suture thread; and

Figure 19 is a schematic view of the assembly shown in Figure 18, with the suture thread cinched.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring initially to Figures 1 and 2, an arcuate non-flaccid splint 10 is shown that is formed with two ends 12, 14 facing each other. The arcuate shape of the splint 10 in its biased configuration may define a U-shape or it may define an arc of a circle greater than 180 degrees and less than 360 degrees, although it may be coiled inside the below-described introducer device in more than 360 degrees. As described in greater detail below, the splint 10 is configured for advancement through a patient's mouth into the esophagus by an introducer device for implantation completely into the wall of the esophageal sphincter to strengthen the sphincter.

As shown in cross-reference to Figures 1 and 2, the splint 10 is biased toward a narrow configuration (Figure 1) in which the ends 12, 14 are spaced from each other a first distance, with the splint 10 being movable to a wide configuration (Figure 2) in which the ends 12, 14 are spaced from each other by a greater distance than in the narrow configuration. With this structure, owing to its material bias the splint, when horizontally implanted into the wall of the esophageal sphincter, urges the wall of the sphincter inwardly. However, because the splint 10 can be moved relatively easily to the wide configuration by food passing from

the esophagus into the stomach, the sphincter can open sufficiently to allow the food to enter the stomach. This sphincter opening is a result of pressure created by peristalsis of the esophagus which forces food against the sphincter.

In an example embodiment the splint 10 advantageously is made of shape memory metal such as Nitinol. Other materials may be used, e.g., polyolefin, acetal, or teflon. Furthermore, the splint 10 may be coated with a drug or otherwise be drug-eluting for delivering, e.g., anti-inflammatory drugs.

As shown in Figure 3, the splint 10 may have a round (circular) cross-section and may be solid. Or, as shown in Figure 4 a splint 16 that is in all substantial respects identical to the splint 10 shown in Figures 1-3 may be hollow.

Accordingly and turning to Figure 5, the splint 10 may be advanced through the mouth of a patient to the esophageal sphincter 18 and then implanted entirely ("intramurally") into the wall of the sphincter as shown. The splint 10 can be implanted horizontally inside the wall of the esophageal sphincter 18. Owing to the above-described material bias the splint 10 urges the sphincter 18 closed, but is sufficiently flexible to permit the sphincter to open when food passes through the sphincter into the stomach.

Figures 6-9 illustrate an example introducer device 20 for implanting the splint 10. In the example implementation shown in Figure 6, the device 20 includes a device body 22 that is advanceable through the mouth of a patient into the esophagus. A preferably arcuate tunneler element 24 that may be established by the splint 10 itself or that may be separate from the splint 10 and hold or otherwise be juxtaposed with the splint 10 is configured for forming a round, generally horizontal passage in the wall of the esophageal sphincter for

placement of the splint. When provided as an element separate from the splint the tunneler element 24 shown in Figure 6 may be affixed at its center point to the body 22. Also, if desired the tunneler element 24 may be coated with or otherwise elude an analgesic drug.

When the splint 10 is used as the tunneling element, the splint 10, which is biased to its preset curved shape, can be loaded in the device in a more open configuration, indeed in an almost a straight configuration. As the splint 10 is driven out by a rod pusher or other mechanism, e.g., small rollers, the splint 10 starts to curve assume its biased (non-constrained) configuration. In such an embodiment the splint can have a sharpened or pointed distal tip.

Furthermore, the thermal setting characteristics of Nitinol may be used to load the splint in one shape then cause it to assume another shape upon application of heat.

The body 22 is formed with or attached to a distal L-shaped stop member 26. The distance between the stop member 26 and the tunneling element 24 is established to approximate the distance between the esophageal sphincter and the junction of the fundus and esophagus as will be illustrated further below.

A pin 28 or other vertical support may extend proximally from the L-shaped stop member 26 as shown. Accordingly, as perhaps best shown in Figure 7 a bight 30 is established between the pin 28 and L-shaped stop member 26.

With the above in mind, as shown in Figure 7 the stop member 26 can be advanced entirely through the esophagus 32 into the stomach 34, with or without visualization. When visualization is desired, an endoscope may be provided on the device 20. Alternatively, ultrasound imaging or fluoroscopy or other visualization modality can be used.

The device 20 may then be retracted proximally as shown in Figures 8 and 9 until the bottom of the "L" abuts the junction of the esophagus with the fundus, trapping a portion of the fundus and esophagus in the bight 30. The tunneler 24 is then rotated by, e.g., rotating the device 20 to pierce the wall of the esophagus, in effect to form a passage in the wall. One or more splints, which may be housed within the tunneler 24, can then be advanced out of the tunneler 24 by, e.g., pushing the splints out or reversing rotation of the tunneler 24 once an end of a protruding splint has gripped the tissue.

It may now be appreciated that by establishing the distance between the tunneler 24 and stop member 26, and by causing the stop member 26 to abut the esophagus-stomach fundus junction, the tunneler element 24 is securely located at the esophageal sphincter. Furthermore, by appropriately establishing the depth of the bight 30, the depth into the sphincter wall at which the splint is implanted is established.

As mentioned above, a hollow splint 40 may be provided, in which case a fluid infusion opening 42 may be formed in the splint to infuse fluid into the hollow core of the splint. One or more fluid exhaust ports 44 may also be formed in the splint. With this structure fluid can be infused into the splint and the pressure monitored to determine proper splint placement, with a slowly decaying pressure indicating proper placement and with a quickly decaying pressure indicating improper placement (i.e., not entirely intramurally into the wall of the sphincter). Alternatively, radiological contrast media may be used as the fluid and visualized radiologically to determine leakage and, hence, proper splint placement. Methyl blue can alternatively be used to visually look for leaks.

Figure 11 shows that if desired, a splint 50 may be formed with small external barbs 52 for gripping tissue. The barbs may be established by a textured surface of the splint 50 effected using, e.g., a diamond cut.

Figures 12-17 show an alternate introducer device that includes a delivery catheter 60 to which a proximal and distal balloon 62, 64 may be attached. The balloons 62, 64 are inflatable through the catheter 60. Between the balloons 62, 64 a hollow tunneler element 66 can be disposed and can protrude outside the catheter 60 as shown.

With this structure, the balloons 62, 64 can be deflated and then the device advanced through the mouth and esophagus 32 until the distal balloon 64 clears the esophagus and is disposed in the stomach 34. The distal balloon 64 can then be inflated and the device retracted proximally until the distal balloon 64 abuts the junction of the esophagus and fundus as shown in Figure 12. When a proximal balloon 62 is provided, it may then be inflated to anchor the device at the appropriate location in the esophagus.

Figures 13-16 illustrate how the splint 10 shown in Figures 1-3 may be deployed into the wall of esophageal sphincter using the device shown in Figures 12-17. The tunneler element 66 can be a resilient flexible tubular device that is trapped in the catheter 60 in a coil-like configuration. In the example non-limiting embodiment shown, the tunneler 66 is joined to a horizontal arm 68 of a vertical rotatable hollow shaft 70 within the catheter at a pivot point 72. As the shaft 70 is rotated as indicated by the arrow 74 in Figure 14, the tunneler 66, which protrudes from the catheter 60 as described above, is pushed from the configuration shown in phantom in Figure 14 to the configuration shown in solid. As the tunneler 66

emerges from the catheter, owing to its material bias it uncoils (Figure 15), piercing the wall of the sphincter. To this end, the tunneler 66 may be formed with a sharpened distal tip 76.

Then, in cross-reference to Figures 16 and 17 a flexible push rod 78 that may be made of nitinol can be advanced through the shaft 70 against one or more splints 10 (shown in phantom in Figure 17) that are housed within the tunneler 66. With the push rod 78 against the splint 10, the tunneler 66 may be rotated in the reverse direction as shown in Figure 16, leaving the splint 10 in place inside the wall of the sphincter. Once the splint completely clears the tunneler 66, the introducer device may be retracted from the patient.

Figures 18 and 19 show that instead of a non-flaccid splint, a tightening element according to present principles may be established by an elastic suture thread 100. To deploy the thread 100 within the wall of the esophageal sphincter 32, the thread 100 can be loaded into a hollow tunneler 102, with an end of the thread extending back through the introducer device and out of the patient's mouth. The tunneler 102 may function in accordance with above principles to pierce the wall of the sphincter, leading the suture thread through the wall until the suture thread 100 generally forms a circle inside the wall. As shown in Figure 19, the device is then retracted back through the patient's mouth such that both ends 104, 106 of the thread 100 extend outside the patient's mouth. The ends 104, 106 can be tensioned and knotted by advancing an extracorporeal knot down into the sphincter in accordance with suture knotting principles known in the art. Owing to its elasticity, the thread 100 can expand within the wall to allow food to pass from the esophagus into the stomach.

While the particular SYSTEM AND METHOD FOR ESOPHAGEAL SPHINCTER REPAIR is herein shown and described in detail, it is to be understood that the subject matter

which is encompassed by the present invention is limited only by the claims. For example, while natural orifice placement of the splint is envisioned, the splint alternatively may be placed laparoscopically.

WHAT IS CLAIMED IS:

1. Device, comprising:

an arcuate non-flaccid splint (10, 40, 50) formed with two ends facing each other, the splint configured for advancement through a patient's mouth into the esophagus by an introducer device, the splint configured for implantation completely into the wall of the esophageal sphincter to strengthen the sphincter, the splint being biased toward a narrow configuration, wherein the splint urges the wall of the sphincter inwardly, the splint being movable by food passing from the esophagus into the stomach to a wide configuration wherein the ends are spaced from each other such that the sphincter can open sufficiently to allow the food to enter the stomach.

2. The device of Claim 1, wherein the splint (10, 40, 50) is made of Nitinol.

3. The device of Claim 1, wherein the splint (10, 40, 50) is made of polyolefin, acetal, or teflon.

4. The device of Claim 1, wherein the splint (10, 40, 50) is drug-eluting.

5. The device of Claim 1, wherein the splint (40) is hollow and is formed with at least one opening (42).

6. The device of claim 1, wherein the splint (10, 40, 50) has a rounded cross-section.

7. The device of Claim 1, wherein the splint (50) includes external barbs (52) for enhancing tissue engagement.

8. An introducer device (20, 60) comprising:

a device body (22) advanceable through the mouth of a patient into the esophagus, the body configured to hold at least one esophageal sphincter splint (10, 40, 50);

the device with splint configured for forming a passage in the wall of the esophageal sphincter for placement of the splint therein; and

at least one stop member (26, 64) positioned on the body a predetermined distance from the splint and configured for abutting the esophagus-stomach fundus junction to thereby securely locate the splint at the esophageal sphincter.

9. The device of Claim 8, wherein the stop member (64) is an inflatable balloon juxtaposed with a distal end of the device body.

10. The device of Claim 8, wherein the stop member (26) is a distal L-shaped member forming a bight (30) with the device body, the device being advanceable into the stomach and retractable to trap a portion of the fundus and esophagus in the bight, a depth of the bight being established to establish a depth into the sphincter wall at which the splint is implanted.

11. The device of Claim 8, comprising a tunneler element (24, 66) separate from the splint and holding the splint, wherein the tunneler element is rotatable to pierce the wall of the esophagus.

FIG. 1

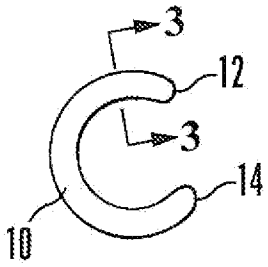
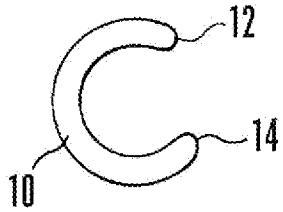


FIG. 2



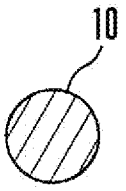


FIG. 3

FIG. 4

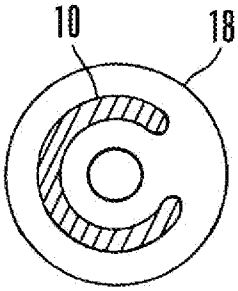


FIG. 5

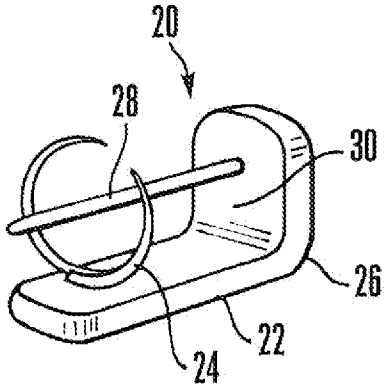


FIG. 6

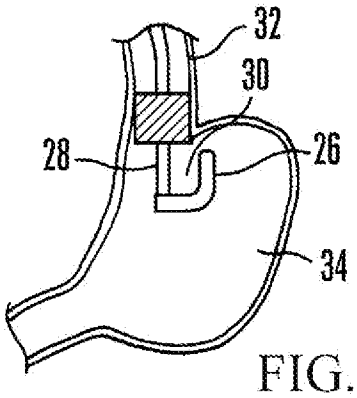


FIG. 7

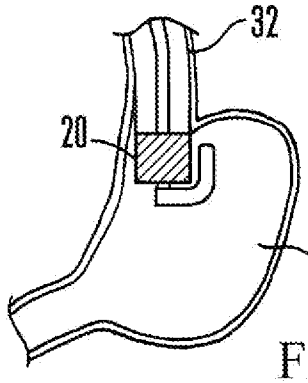


FIG. 8

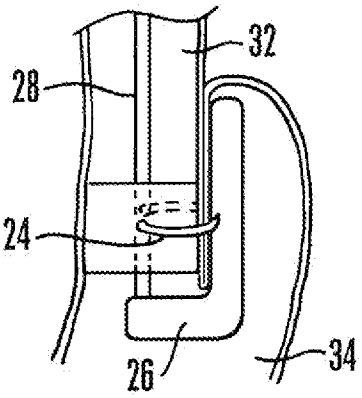


FIG. 9

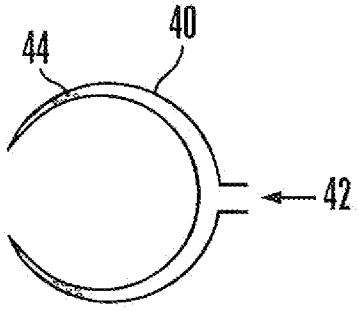


FIG. 10

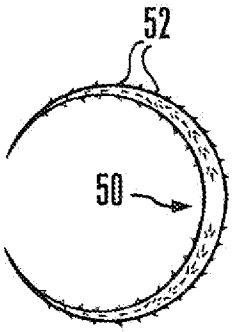


FIG. 11

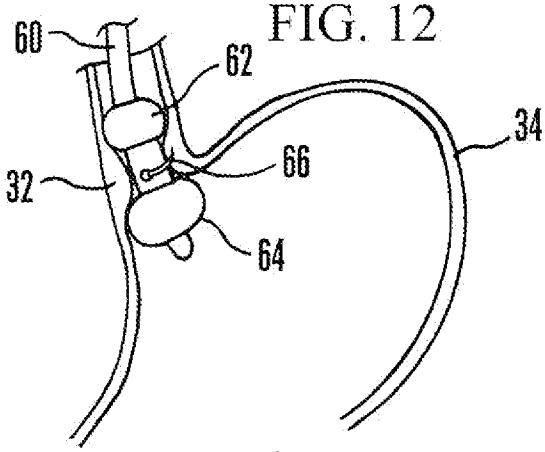


FIG. 12

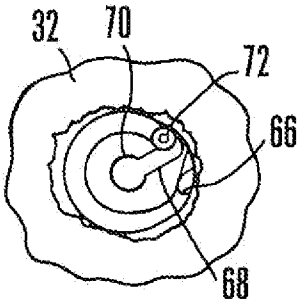


FIG. 13

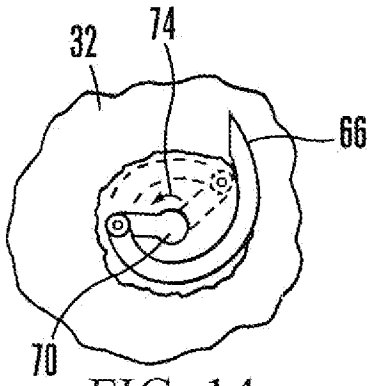


FIG. 14

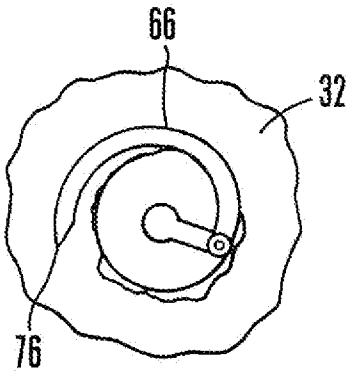


FIG. 15

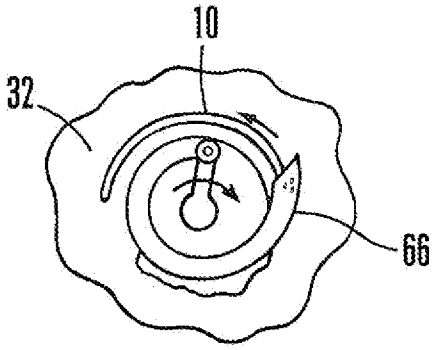


FIG. 16

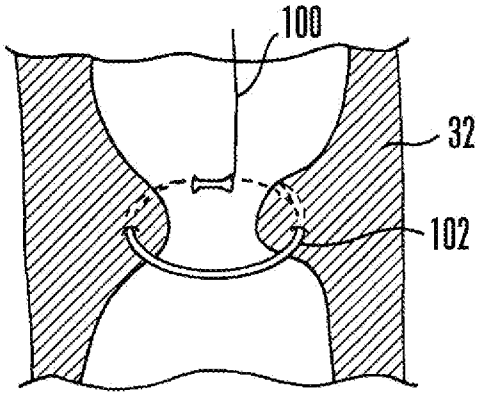


FIG. 18

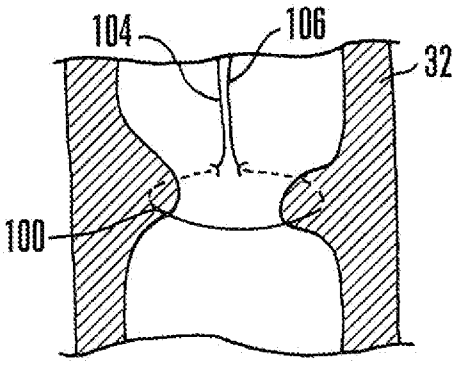


FIG. 19

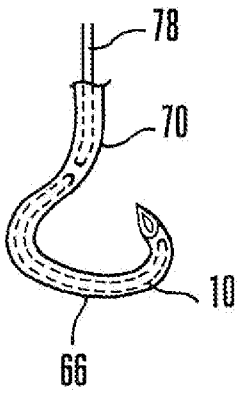


FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/084492

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/04 (2009.01)
USPC - 623/23.7
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) - A61F 2/04 (2009.01)
USPC - 606/213; 623/23.7

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/0198048 A1 (BEHAN et al) 23 August 2007 (23.08.2007) entire document	1-7
Y	US 5,006,106 A (ANGELCHIK) 09 April 1991 (09.04.1991) entire document	1-7
A	US 6,790,237 B2 (STINSON) 14 September 2004 (14.09.2004) entire document	1-7
A	US 7,118,600 B2 (DUA et al) 10 October 2006 (10.10.2006) entire document	1-7

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04 March 2009	17 MAR 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/084492

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-7

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/084492

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees need to be paid.

Group I, claims 1-7 are drawn to a splint device.
Group II, claims 8-11 are drawn to an introducer device.

The inventions listed in Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons:

The special technical features of Group I, a splint biased toward a narrow configuration to urge the wall of the esophageal sphincter inwardly and moveable by the passage of food therethrough, are not present in Group II; and the special technical features of Group II, an introducer device for positioning a splint therein including a stop member that may be an inflatable balloon, are not present in Group I.

Since none of the special technical features of the Group I and II inventions are found in more than one of the inventions, unity is lacking.