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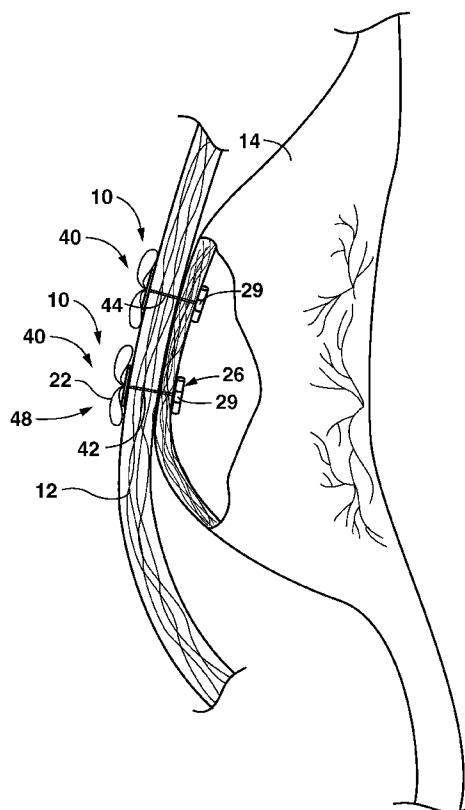
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(54) Title: A SEGMENTED TISSUE-TO-TISSUE ANCHORING DEVICE AND METHOD OF USING THE SAME



(57) Abstract: The invention describes an apparatus and method of use for anchoring two or more body tissue layers to one another. The apparatus includes a plurality of individual anchor segments (28) that are placeable within a body cavity. The segments may assume a first relaxed state wherein the segments are movable relative to each other and alignable along an initial longitudinal axis (20) for initial placement of the apparatus through the body tissue layers. Once placed within the body cavity, the anchor segments are manipulated into a second rigid state with an actuator wherein the segments assume a rigid configuration at a transverse angle relative to the initial longitudinal axis.



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A SEGMENTED TISSUE-TO-TISSUE ANCHORING DEVICE AND METHOD OF USING THE SAME

FIELD OF THE INVENTION

5 The present invention relates to a device for anchoring a first body tissue to one or more additional body tissue layers. Such a device may be used, for example, to anchor a patient's stomach wall to the abdominal wall prior to use of a gastronomy feeding tube used in the direct feeding of a patient's stomach. More particularly, the present invention may be used in procedures related to
10 percutaneously placing various gastric catheters, forming artificial stomas capable of accessing the gastrointestinal tract, and otherwise securing two or more tissue layers to one another until such time as the tissue layers fuse to one another.

BACKGROUND OF THE INVENTION

It is recognized that numerous medical conditions exist in which it becomes
15 necessary to gain percutaneous access to viscera such as the stomach or small intestines. Situations where a patient has lost the ability to swallow and will require long term nutritional support may dictate feeding directly into the stomach or jejunum. Feeding in this manner may be accomplished by inserting a feeding tube into the patient's stomach such that one end remains anchored in the stomach,
20 while the other end remains external to the patient's body for connection to a nutrient source. Such feeding tubes may be inserted into a patient's stomach in a number of ways. For example, the feeding tubes may be endoscopically placed, surgically placed through an open incision, laparoscopically placed, or percutaneously placed under endoscopic, fluoroscopic or ultrasonic guidance.
25 different types of feeding tubes may be placed using these procedures, including gastrostomy, jejunostomy or gastro-jejunostomy tubes. These tubes may be retained in the lumen (stomach or intestine) with a variety of retention anchors. These anchoring mechanisms include: inflatable balloons, obturatable domes, fixed dome-type bumpers, or suture wings.
30 Prior to placing the actual enteral feeding device, it is generally necessary to perform a gastropexy procedure wherein the stomach wall is drawn against the abdominal wall at a location where the stoma tract will be eventually defined. This

attachment is critical to prevent inadvertent separation and exposure of the peritoneal cavity to contamination and possible peritonitis.

Initial placement devices are often not readily removable without additional invasive procedures. That is, many initially placed anchoring devices contain rigid retention members that are not readily removable without additional procedures. These retention members are typically rigid T-shaped or H-shaped metal fasteners (collectively referred to as a "T-bar") and are not removable, but are allowed to pass naturally in the patient's stool. In many cases, however, the T-bar is not passed and remains within the body cavity. Moreover, during the six to eight weeks it takes for the fistula's stoma tract to be established, the T-bar of the prior art gastropexy device may embed itself into the gastric or intestinal wall and ultimately lead to infection. Furthermore, the T-bar itself may have sharp edges which can be uncomfortable for the patient.

In many of these procedures, in order to achieve the desired seal between the stomach and the abdominal wall, a traction force must be applied to the anchoring mechanism. The force is applied in such a way as to pull the stomach cavity to the abdominal wall so that the penetration through both may heal together, resulting in the tissue layers essentially adhering to each other. It is necessary to apply this traction force for a period of a couple of days through a couple of weeks until the attachment forms and stoma site adequately heals. During this period the patient has reduced mobility which may lead to additional post-operative complications.

There is thus a need and desire for an improved tissue anchoring device that may be used during initial placement or creation of a stoma site. Such a device would foster the permanent fusion of the stomach wall to the abdomen. This would serve to reduce the invasiveness of the procedure, greatly enhance wound healing, and enable immediate, post-placement gastric access for feeding and drainage, and ultimately allow a traumatic exchange of the low profile device. What is needed is a fixation device that is easy to place within an internal body cavity, allows for the formation of a stoma between the internal body cavity and the external environment, and enables the user to easily remove the fixation device when it is no longer necessary.

SUMMARY OF THE INVENTION

Objects and advantages of the invention will be set forth in part in the following description, or may be obvious from the description, or may be learned through practice of the invention.

5 The present invention is directed toward an apparatus for insertion into a body orifice for anchoring a first body tissue layer to a second body tissue layer. In a particular embodiment, the apparatus includes a plurality of individual substantially rigid anchor segments that are designed for insertion through at least two body tissue layers and into a body orifice from a point exterior to the body

10 10 The anchor segments may be introduced through the tissue layers and into the body cavity through a hollow needle or trocar-type introducer wherein the anchor segments are longitudinally aligned in a first relaxed state and are movable relative to each other. The anchor segments can be manipulated into a second rigid state within the body cavity wherein the segments assume a rigid

15 15 configuration relative to each other and extend at a transverse angle relative to their initial aligned longitudinal axis. For example, at least two transverse branches of anchor segments may extend perpendicular from the initial longitudinal axis, with at least one anchor segment in each branch. The branches may extend from a central anchor segment, with one or more segments in each

20 20 branch.

The anchor segments may take on any suitable shape and configuration, and are desirably void of sharp angles or corners to minimize any discomfort to the patient. In a particular embodiment, the anchor segments are substantially cylindrical elements with a passage therethrough.

25 25 An actuator is connected to the anchor segments and extends through central anchor segment to the distal end of the last anchor segment in each branch. The actuator provides a means for a clinician to externally manipulate the anchor segments from their first relaxed state to the second rigid state. In a particular embodiment, the actuator includes a respective filament that extends

30 30 through the central anchor segment shaft to each branch of anchor segments, and is fixed to an end of the last anchor segment in each transverse branch. The filaments extend through the tissue layers, with the opposite ends of the filaments extend externally from the body. These ends are pulled or otherwise tensioned by

the clinician to draw the anchor segments against into the second rigid state. It should be appreciated that "filament" is used herein to refer to any flexible elongated member that is connected to the anchor segments and extends through the tissue layers to actuate the apparatus.

5 In a particular embodiment, the apparatus may include two transverse anchor segments and a central anchor segment, with each transverse anchor segment extending in a transverse direction relative to central anchor segment. The transverse anchor segments may extend in opposite directions (i.e., 180 degrees apart) or in less than opposite directions (i.e., an angle less than 180
10 degrees).

In an alternate embodiment, a plurality of anchor segments are included within each transversely extending branch. For example, the apparatus may include at least two anchor segments extending in each transverse direction from a central anchor segment. In this embodiment, the individual anchor segments are
15 disconnected and movable relative to each other in the first relaxed state of the apparatus. The actuator runs through all of the anchor segments within an individual branch and draws the segments together into a rigid configuration upon being tensioned in the second rigid state.

The anchor segments may have relatively flat adjacent faces that are
20 brought into abutting axial alignment upon a sufficient tension being applied to the actuator. In an alternative embodiment, the end faces of the anchor segments may contain inter-engaging structure, such as any male/female engagement, that aids in aligning and maintaining the anchor members in the second rigid state. This structure may include, for example, a tapered protrusion defined on an end
25 face of one anchor segment that engages into a correspondingly shaped slot in the adjacent end face of another anchor segment.

The anchor segments may be maintained in the second rigid state by a constant external tensioning force applied to the actuator, whereupon the anchor segments assume the first relaxed state upon release of the tensioning force.

30 The apparatus may further include any manner of low profile external fixing member that receives and maintains the actuator filaments in their tensioned or drawn state. This device may be a simple plate-like member with a slot or hole through which the filaments are threaded and tied off.

It may be desirable that at least one of the components of the apparatus is made from a resorbable material that breaks down over time in the patient. For example, any combination of the actuator and anchor segments may be made from such a material. The resorbable materials aid in collapsing and passing the apparatus components through the patient's digestive tract after the stoma has formed and the apparatus is no longer needed. The resorbable components break down into even smaller pieces and are readily passed through the digestive tract with less chance of becoming lodged .

5 The present invention also encompasses any manner of surgical method or procedure for anchoring a first body tissue layer to a second body tissue layer using aspects of the apparatus described herein. Such a method may be particularly well suited for use in performing a gastropexy procedure wherein one of the body tissue layers comprises the abdominal wall and the other layer comprises the stomach.

10 15 Other objects, advantages and applications of the present invention will be made clear by the following detailed description of a preferred embodiment of the invention and the accompanying drawings wherein reference numerals refer to like or equivalent structures.

BRIEF DESCRIPTION OF THE DRAWINGS

20 Figure 1 depicts an illustrative view of one embodiment of the present invention inserted through a patient's abdominal wall and stomach.

Figure 2 is a perspective view of an embodiment of an anchoring apparatus in accordance with the invention inserted into an introducer for placement in a patient.

25 Figure 3 is a perspective view of the apparatus of Fig. 2 with the anchor segments in their second rigid state.

Figure 4 is a partial cross-sectional view of an alternative embodiment of an anchoring apparatus with a single anchoring segment extending in opposite transverse directions.

30 Figure 5 is a partial cross-sectional view of an embodiment of the anchoring segments incorporating multiple anchor segments extending in opposite transverse directions with alignment structure between the individual segments.

Figures 6A through 6C are various views of an alternative embodiment of an anchoring apparatus with anchor segments having alignment structure in the end faces thereof.

5 Figures 7A and 7B are perspective views of embodiments of anchor segments that incorporate a resorbable material in accordance with aspects of the invention.

Figure 8 is a perspective view of an embodiment of a fixing device that may be used to secure actuator filaments external to the patient.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

10 Reference will now be made in detail to embodiments of the invention, one or more examples of which are illustrated in the drawings. Each embodiment is presented by way of explanation of aspects of the invention, and not as a limitation of the invention. For example, features illustrated or described as part of one embodiment may be used with another embodiment to yield still a further 15 embodiment. It is intended that the invention include these and other modifications and variations as come within the scope and spirit of the invention.

The present invention is directed toward an apparatus for anchoring a first body tissue to a second body tissue and a method for using such an apparatus. Should such a device be caused to enter a body from an exterior position, traverse 20 two or more body tissue layers, and be situated at a distal end within a suitable body cavity or orifice, the device may be used to pull the two or more tissue layers into contact thereby anchoring one to the other. The apparatus is particularly useful in a gastropexy procedure wherein the stomach wall is drawn against the abdominal wall at a location where a stoma tract will be eventually defined. This 25 attachment is critical to prevent inadvertent separation and exposure of the peritoneal cavity to contamination and possible peritonitis.

Fig. 1 shows an embodiment 10 of an inventive apparatus for insertion into a body orifice or cavity for anchoring a first body tissue layer 12 to at least one other body tissue layer 14. In the illustration, the devices 10 are used to anchor 30 abdominal wall tissue 12 to the stomach wall 14 in a gastropexy procedure for forming a feeding stoma in the patient. Each apparatus 10 includes a plurality of anchor segments 26 that have been placed into the body cavity (e.g., through the stomach wall and into the stomach). An actuator 40 is connected to the anchor

segments 26 and extends through the body tissue layers 12, 14, and is used to draw the anchor segments into a rigid state wherein they extend at a transverse angle from the longitudinal axis of the actuator 40, or from opposite sides of a central anchor segment 29. The actuator 40 is secured externally to an external 5 fixing member 48 placed against the patient, as discussed in greater detail below.

As used herein, distal refers generally to the direction of the patient, while proximal refers to the direction of the user.

The various components of the apparatus 10 may be formed from a biocompatible metal or polymeric material. Such polymeric materials may include 10 polyurethane (PU), low-density polyethylene (LDPE), polyvinyl chloride (PVC), polyamide (PA) or polyethylene teraphthalate (PETP). Copolymer admixtures for modifying the characteristics of the material are also possible, for example a low density polyethylene and ethylene-vinylacetate copolymer (LDPE-EVA), or blends of the above mentioned materials (e.g. PU with PVC or PU with PA) would be 15 considered suitable for such a device.

As discussed in greater detail below, any combination of the components forming the apparatus 10 may be formed partially or wholly of a resorbable material that degrades and breaks down over time. These materials are typically polymers that can be cleaved hydrolytically or by the action of enzymes, and are 20 currently used in medical applications as sealants, sutures, staples, implants, and the like. Examples of such materials include natural or semi-synthetic polymers, including certain bone cements. The materials can be sterilized and have biocompatible (non-toxic) degradation products. A wide class of suitable resorbable materials are known to those skilled in the art. For gastropexy 25 procedures, the resorbable materials must be able to maintain their integrity in the relatively harsh stomach environment of strong acids and enzymes for a time sufficient for the stoma to properly form, ideally about 6 weeks. Presently, it is believed that a copolymer of an aromatic polyester and a lactide; polydioxanones; or polyanhydrides may present optimal resorbable material for use in the 30 apparatus of the present invention for gastropexy procedures.

Fig. 2 illustrates the apparatus 10 loaded into an introducer 56, which may be a trocar or needle having a bore 58 therethrough. The introducer 56 may be used to pierce the body tissue layers and for insertion of the apparatus 10 into the

body cavity. Alternatively, the introducer 56 may be inserted through a previously formed puncture site.

In the particular embodiment illustrated in Figs. 2 and 3, the anchor segments 26 include a plurality of cylindrical segments 28 having a bore therethrough. In Fig. 2, the cylindrical segments 28 are illustrated in their first relaxed state wherein the segments 28 are movable relative to each other and aligned within the introducer 56 along an initial longitudinal axis 20. In this manner, the cylindrical segments 28 are readily insertable into the introducer 56 for initial placement of the apparatus 10 through the body tissue layers.

Referring to Fig. 2, an insertion tool 16 may also be inserted into the introducer 56 to "push" the anchor segments 26 out of the introducer once the distal tip of the introducer has been inserted into the body cavity. This tool 16 may be any rigid rod-like member having a bore 18 through which the actuator 40 runs. After the anchor segments 26 have been pushed from the introducer, the introducer 56 and tool 16 may be removed while maintaining the end of the actuator 40 external to the body, as depicted in Fig. 3. The tool 16 may be removed from the introducer by simply unthreading the tool 16 from the actuator 40.

It should be appreciated that any motive force may be used to push the anchor segments 26 through the introducer 56. For example, a liquid may be injected into the introducer to force the anchor segments through and out of the introducer 56.

Once the apparatus 10 has been properly placed, the anchor segments 26 can be manipulated into a second rigid state as illustrated in Fig. 3 wherein the segments assume a rigid configuration at a transverse angle relative to the initial longitudinal axis 20. In the illustrated embodiment, at least two transverse branches of the anchor segments 26 extend at opposite perpendicular directions from the axis 20.

Referring to Figs. 2 and 3, a plurality of individual cylindrical segments 28 are aligned in each of the branches of anchor segments 26 on opposite sides of a central cylindrical segment 29. The actuator 40 runs through the central segment 28 to each branch of the anchor segments 26 and defines structure wherein an external vertical tensioning force applied to the actuator 40 is converted to a

generally transverse force that pulls the anchor segments together towards the central segment 29. It should be appreciated that any number of the cylindrical segments 28 may be aligned within any individual branch. It should also be understood that each branch may include only a single cylindrical segment 28, as 5 illustrated for example in Fig. 4.

The anchor segments 26 may take on any suitable shape and configuration, but are desirably void of sharp angles or corners to minimize any discomfort to the patient. The cylindrical segments 28 may be desired for this reason.

An actuator 40 is connected to the anchor segments 26 and extends 10 through the central segment 29 to the distal end of the anchor segments 26 in each transverse branch. The actuator 40 provides a means for the clinician to externally manipulate the anchor segments 26 from their first relaxed state illustrated in Fig. 2, to the second rigid state illustrated in Fig. 3. In a particular embodiment, the actuator 40 includes separate filaments 42, 44 that extend 15 through the body tissue layers along the axis 20, into the central segment 29, and through the anchor segments 26 in each transverse branch. The filaments 42, 44 are fixed to the end of the last anchor segment 26 furthest from the central segment 29 in each transverse branch of anchor segments, as illustrated particularly in Figs. 3-5. The filaments may be simply threaded through the bores 20 in the anchor segments 26 and knotted or otherwise secured at the end face 30 of the furthest segment 26.

The opposite end of the actuator 40 extends external to the body tissue layers, as particularly illustrated in Figs. 1 and 3. Once the anchor segments 26 have been pushed through the introducer 56 and into the body cavity, the actuator 25 40 (filaments 42, 44 in the illustrated embodiment) are pulled or otherwise tensioned by a clinician to the draw the anchor segments 26 together against the central segment 29 so that the segments 26 assume the second rigid state as illustrated in Fig. 3. To maintain the anchor segments in the rigid state, the filament actuators 42, 44 may be tied, sutured, or otherwise fixed externally to the 30 body so that tension is maintained on the anchor segments 26.

The anchor segments 26, such as the individual cylindrical segments 28, may have flat end faces 30, 32 that are brought into abutting axial alignment upon a sufficient tension force being applied to the filaments 42, 44. In an alternate

embodiment illustrated, for example in Fig. 5, the end faces of the cylindrical segments 28 include interengaging alignment structure 34 that aids in aligning and maintaining the cylindrical segments 28 in the second rigid state. The alignment structure 34 may include any suitable male/female engagement structure, such as

5 a recess 38 defined in the second end face 32 of one cylindrical segment 28 that is engaged by a protrusion 36 in the first end face 30 of the adjacent cylindrical segment 28. The distal end of the shaft 16 may include protrusions 25 that engage into a recess 38 of the cylindrical segment 28 that is pulled into abutting engagement with the shaft 16, as particularly illustrated in Fig. 5.

10 Figs. 6A through 6C illustrate an alternative embodiment of interengaging structure between adjacent anchor segments 26. In this particular embodiment, the anchor segments 16 include a tapered protrusion 27 extending from the end

face 32 thereof closest to the central segment 29. This protrusion 27 engages into a correspondingly shaped slot 31 formed in the central segment 29, as particularly

15 illustrated in Figs. 6A and 6B. Upon initial tensioning of the actuator filament 44, the end face 32 of the anchor segment 26 is drawn against the central segment 29 such that the protrusion 27 engages and slides into the recess 31. It should be

appreciated that this configuration may be provided between adjacent faces of multiple anchor segments 26 within any branch of the segments. This type of

20 protrusion/recess engagement may be desired in that it requires less tension on the actuator filaments 42, 44 to maintain the segments in the second rigid configuration.

The central segment 29 in the embodiment of Figs. 6A through 6C is a cylindrical segment oriented vertically. It should be appreciated that this segment

25 may be oriented horizontally as well.

The anchor segments 26 may be maintained in their second rigid state by a constant external tensioning force applied to the actuator filaments 42, 44, as with the embodiments of Figs. 3 through 6. Upon release of the tensioning force, for example by cutting or releasing of the filaments 42, 44, the anchor segments 26

30 are free to assume their first relaxed state.

Fig. 7A illustrates an embodiment of cylindrical segments 28 that may be used as anchor segments 26 wherein an outer circumferential portion of resorbable material 54 is formed around a polymeric core member 55 having the

bore defined therethrough. Thus, after the resorbable material 54 breaks down, the central core portion 55 remains, but is relatively small and easily passed by the patient. In the embodiment of Fig. 7B, the entire cylindrical segments 28 are formed from the resorbable material 54. As discussed, the resorbable materials

5 aid in collapsing and passing the apparatus components through the patient's digestive tract after the stoma has been formed in the tissue layers and the apparatus 10 is no longer needed. The resorbable components break down into small pieces that are easily passed through the patient's digestive tract with less chance of becoming lodged.

10 Any manner of low profile external fixing member 48 (Fig. 8) may be used to receive the proximal end of the actuator filaments 42, 44 relative to the patient. In the embodiment of Figs. 1 and 8, the external fixing member 48 is a relatively flat disc shaped member 50 having a slot or hole 52 formed therein through which the filaments 42, 44 are received. The actuator filaments 42, 44 may be tied off in a manner such that they are prevented from being pulled back through the body tissue layers. For example, the filaments 42, 44 may be tied or otherwise attached to the fixing member 48. An advantage of such a device is that the disc 50 can be made as thin as possible, for example on the order of 1 to 2 mm dependent upon the material from which the disc is manufactured. A fixing member 48 of this

15 construction has a very low profile and is thus easily concealed by the application of a bandage over the patient's skin. This enables the apparatus 10 to be in place and performing its function without being noticeable to the public. Also, such a configuration assists in maintaining sterility of the site and minimizes the potential for inadvertent injury to the area.

20 In an alternative embodiment of a fixing member 48 not illustrated in the figures, a multicomponent design may be used wherein a base plate seats against the patient's body and receives the actuator filaments 42, 44 similar to the embodiment illustrated in Fig. 8. A lid or cap may be provided that secures over the base plate, as well as any portion of the shaft 16 protruding from the body.

25 Due to the collapsible nature of the apparatus 10, the removal process of the apparatus is far less traumatic as compared to prior art devices. In a first removal process, the actuator 40 is "released" (i.e. cut or untied from the external fixing member 48) such that the anchor segments 26 are no longer positively held

in the second rigid state. The anchor segments 26 are free to separate and collapse into their first relaxed state wherein they are allowed to remain in the patient and are eventually passed by the patient, particularly in the embodiment wherein the anchor segments 26 are formed by even smaller individual cylindrical segments 28.

5 In still an alternate removal process, the actuator filaments 42, 44 are formed of a resorbable material that essentially disintegrates over time such that the anchor segments 26 are released from their rigid state and are passed by the patient. As mentioned, the segments 26 may also be formed of a resorbable material and allowed to essentially degrade and break into smaller pieces that are passed by the patient.

10 While the invention has been described in detail with respect to specific embodiments thereof, it should be appreciated by those skilled in the art that various alterations, modifications, and other changes may be made to the invention without departing from the scope and spirit of the invention. It is intended that the invention include all such modifications and alterations as encompassed by the appended claims.

WHAT IS CLAIMED IS:

1. An apparatus for insertion into a body orifice for anchoring a first body tissue layer to a second body tissue layer comprising:

a plurality of individual substantially rigid anchor segments for placement in a body cavity, said anchor segments having a first relaxed state wherein said

5 segments are movable relative to each other and alignable along a common initial longitudinal axis for initial placement of said apparatus through the body tissue layers, said anchor segments having a second rigid state wherein said segments assume a rigid configuration relative to each other at a transverse angle relative to said initial longitudinal; and

10 an actuator connected to said anchor segments and configured to extend through the tissue layers to an external location external, said actuator externally manipulated to configure said anchor segments between said first relaxed state and said second rigid state.

2. The apparatus of claim 1, comprising at least two said anchor segments, wherein in said second rigid state at least one said anchor segment extends in opposite transverse directions from said initial longitudinal axis, said actuator comprising a filament associated with said anchor segments extending in each transverse direction.

5 3. The apparatus of claim 2, further comprising a center anchor segment, said at least two anchor segments extending in opposite directions from said center anchor segment.

4. The apparatus of claim 3, wherein said filaments pass through said anchor segments and are fixed to a distal end of a last one of said anchor segments extending in each transverse direction.

5. The apparatus of claim 4, comprising a plurality of said anchor segments extending in each transverse direction, said anchor segments disconnected and movable relative to each other in said first relaxed state.

6. The apparatus of claim 5, wherein said anchor segments comprise engaging alignment structure at end faces thereof.

7. The apparatus of any one of claims 1 through 6, wherein said anchor segments comprise substantially cylindrical segments with said actuator passing

therethrough and anchored to a last one of said anchor segments extending in each transverse direction.

8. The apparatus of any one of claims 1 through 7, wherein said anchor segments are maintained in said second rigid state by an external tensioning force applied to said actuator, and whereupon said anchor segments assume said first relaxed state upon release of said tensioning force.

9. The apparatus of any one of claims 1 through 8, further comprising an external fixing member configured to secure said actuator in position relative to the patient.

10. The apparatus of any one of claims 1 through 9, wherein at least a portion of said anchoring segments are made from a resorbable material such that over time said anchoring segments decrease in size within a patient.

11. The apparatus of claim 10, wherein said anchoring segments are formed substantially entirely from said resorbable material.

12. The apparatus of any one of claims 1 through 11, wherein said actuator is formed from a resorbable material that breaks down over time in a patient, whereupon said anchor segments become disconnected from said actuator.

13. An apparatus for insertion into a body orifice for anchoring a first body tissue layer to a second body tissue layer comprising:

a plurality of individual anchor segments having individual passages therethrough, said anchor segments having a first relaxed state wherein said segments are movable relative to each other and alignable along an initial common longitudinal axis for initial placement of said apparatus through the body tissue layers, said anchor segments having a second rigid state wherein said segments assume a rigid configuration relative to each other at a transverse angle relative to said initial longitudinal axis such that a plurality of said anchor segments extend in generally opposite transverse directions from a central anchor segment, said anchor segments disconnected and movable relative to each other in said first relaxed state; and

a filament actuator connected to each set of said transversely extending anchor segments, said filament actuators extending through said central anchor segment and through said passages in said anchor segments and fixed to a last

one of said anchor segments in each transverse direction, said actuator filaments being externally manipulated to configure said anchor segments between said first relaxed state and said second rigid state.

14. The apparatus of claim 13, wherein said anchor segments comprise engaging alignment structure at end faces thereof.

15. The apparatus of claims 13 or 14, wherein said anchor segments are maintained in said second rigid state by an external tensioning force applied to said actuator, and whereupon said anchor segments assume said first relaxed state upon release of said tensioning force.

16. The apparatus of any one of claims 13 through 15, wherein at least a portion of said anchoring segments are made from a resorbable material that breaks down over time in a patient such that said anchoring segments decrease in size within the patient.

17. The apparatus of any one of claims 13 through 16, wherein said actuator filaments are formed from a resorbable material that breaks down over time in a patient, whereupon said anchor segments become disconnected from said shaft.

18. A method for anchoring a first body tissue layer to a second body tissue layer comprising:

inserting a needle or trocar introducer into a body through at least a first body tissue layer, a second body tissue layer, and into a body cavity, the
5 introducer having a plurality of individual anchor segments longitudinally aligned therein in a first relaxed state wherein the segments are movable relative to each other for initial placement of the apparatus through the body tissue layers, the anchor segments having an actuator associated therewith;

pushing the anchor segments through the introducer so that the anchor
10 segments are disposed within the body cavity and the actuator extends externally from the body;

with the actuator connected to the anchor segments, externally drawing the anchor segments into a second rigid state wherein the anchor segments assume a rigid configuration relative to each other at a transverse angle relative to the
15 actuator; and

maintaining the anchor segments in the second rigid state to secure the apparatus as long as necessary to attach the body tissue layers.

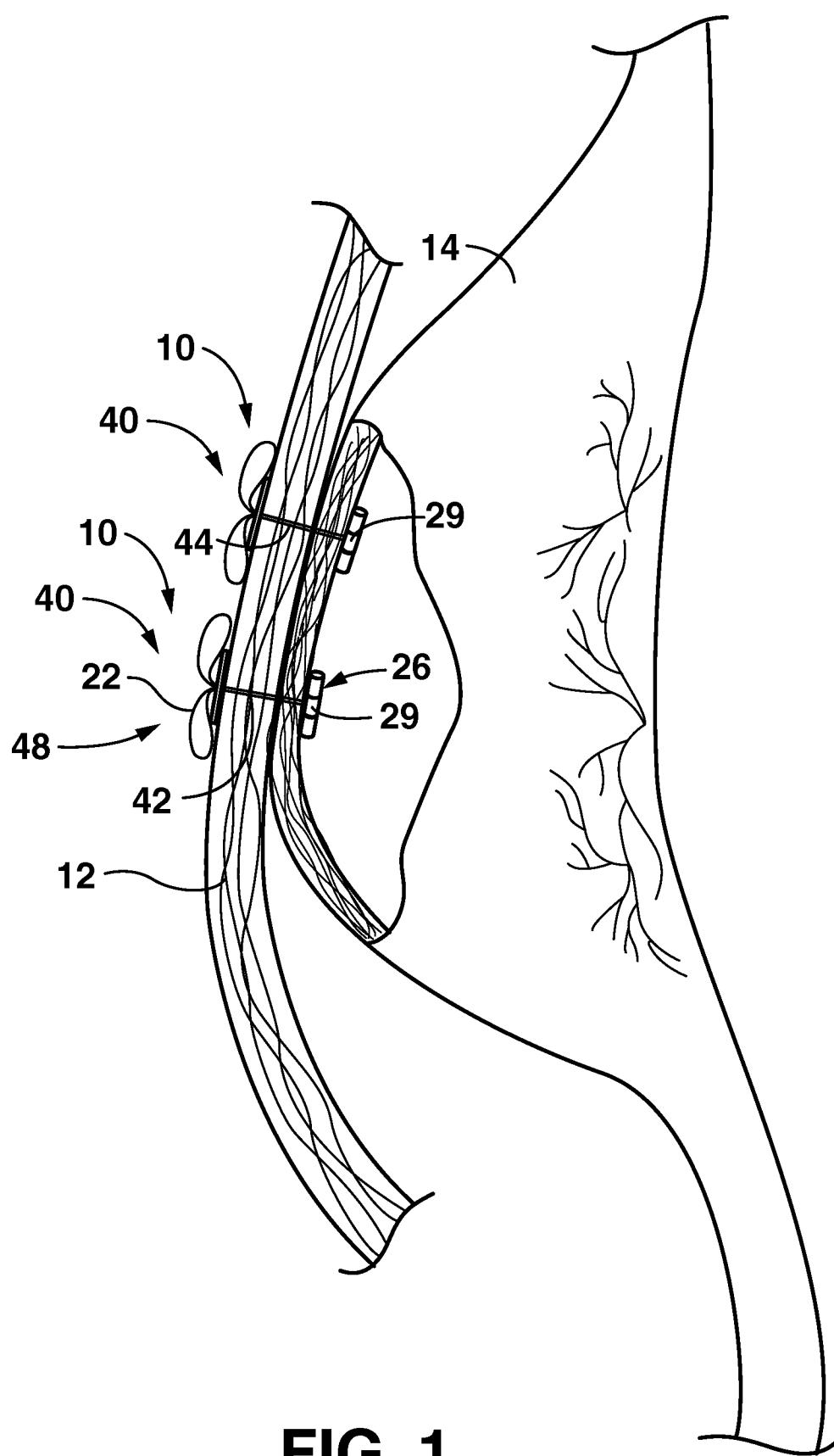
19. The method of claim 18, wherein said method is for performing a gastropexy procedure and the body tissue layers comprises the abdominal wall and the stomach.

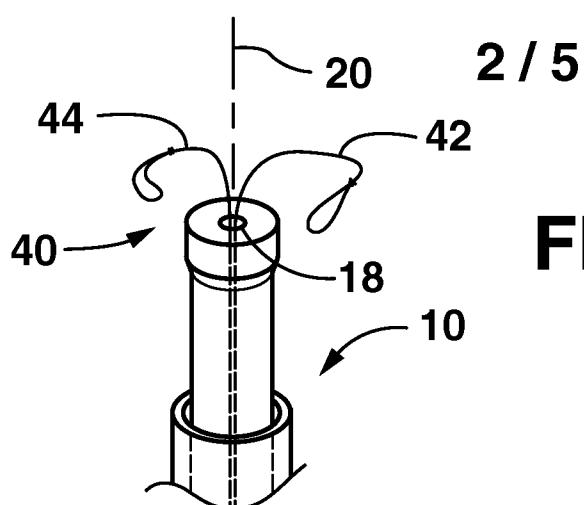
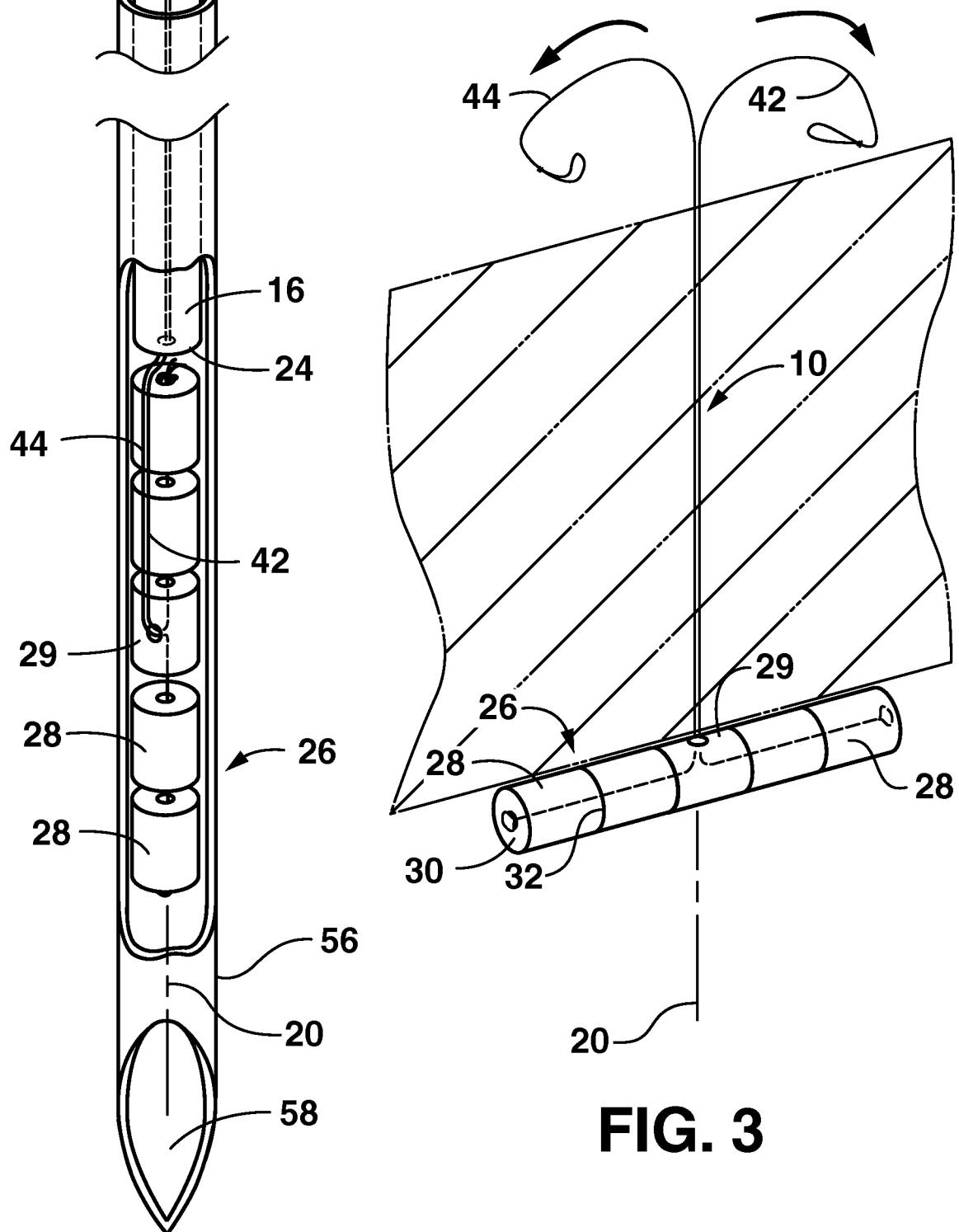
20. The method of claims 18 or 19, comprising configuring multiple anchor segments together in different transverse directions relative to a central anchor segment in the second rigid state of the apparatus and maintaining the anchor segments in the second rigid state by applying an external tensioning force
5 to the actuator.

21. The method of claim 20, further comprising securing the actuator in its tensioned state to a fixing device configured external to the patient.

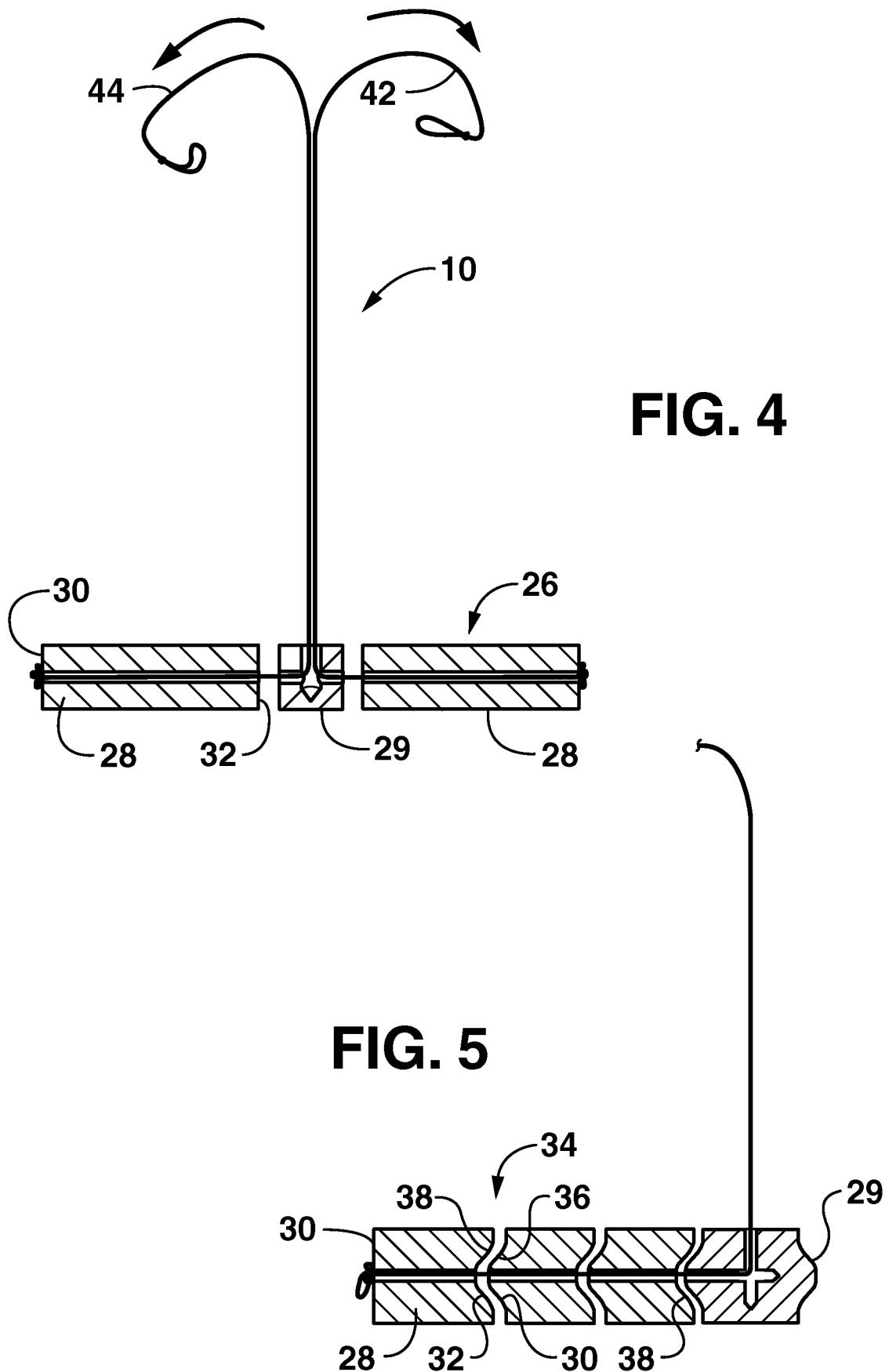
22. The method of any one of claims 18 through 21, further comprising releasing the anchor segments from the second rigid state and allowing the apparatus components to pass through the patient's digestive tract.

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**FIG. 1**

**FIG. 2**

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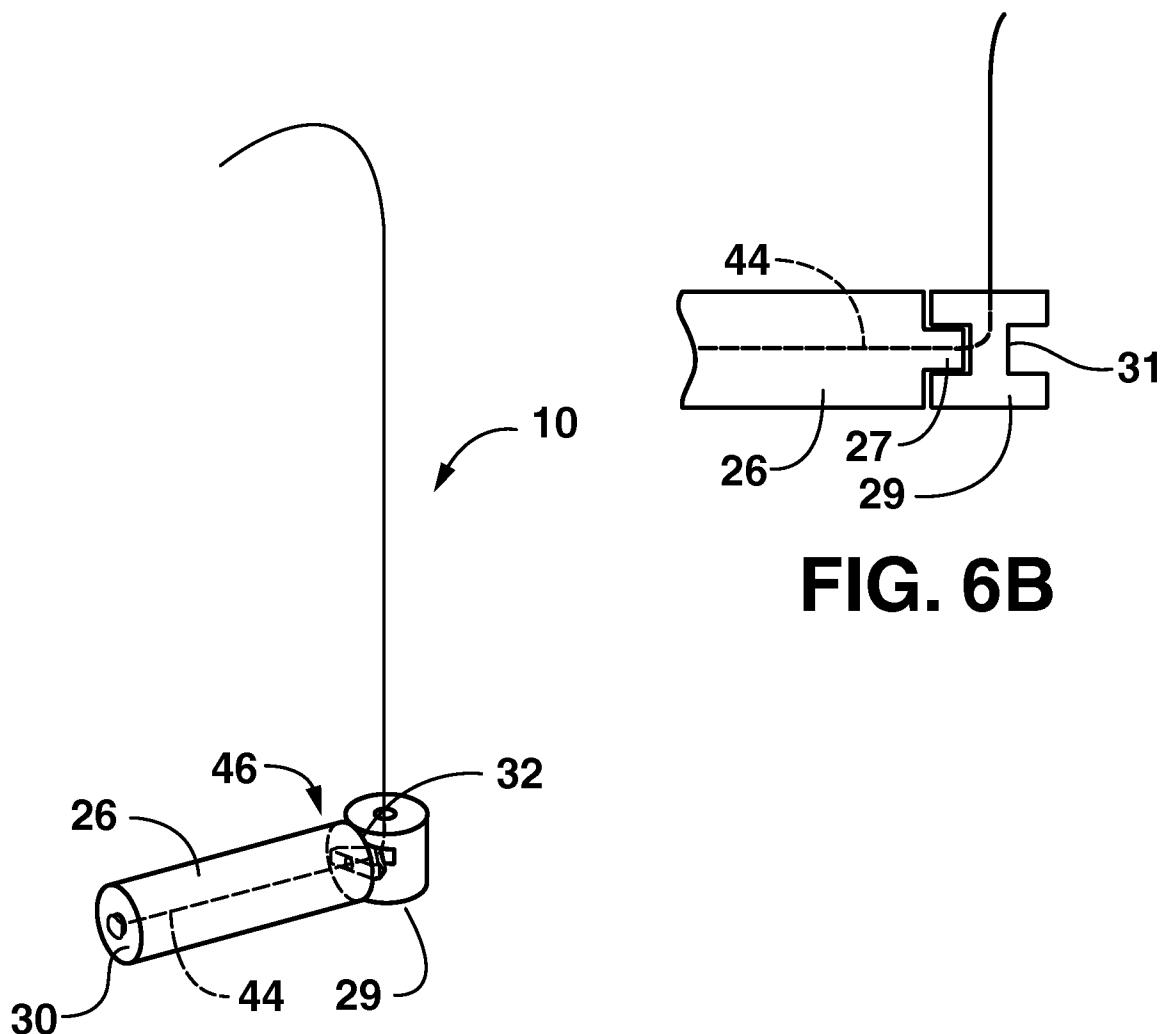
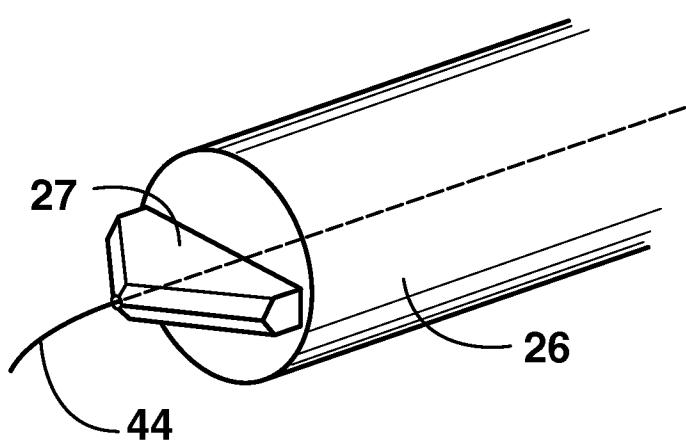


FIG. 6A

FIG. 6C



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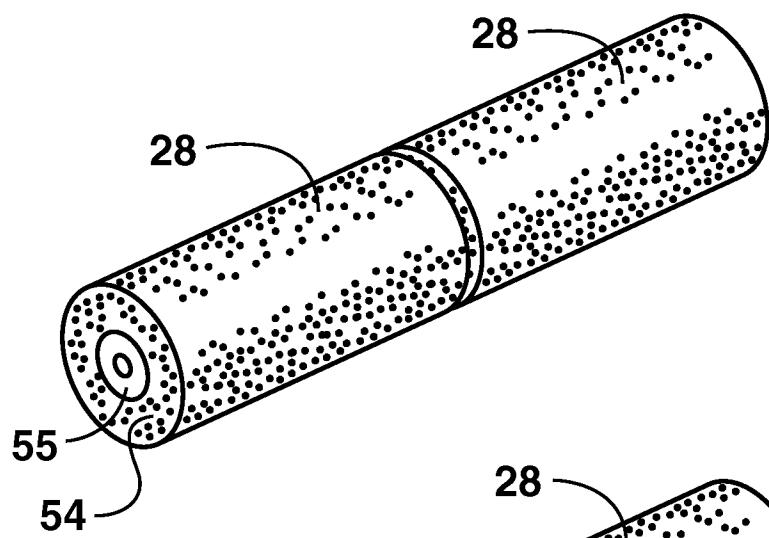


FIG. 7A

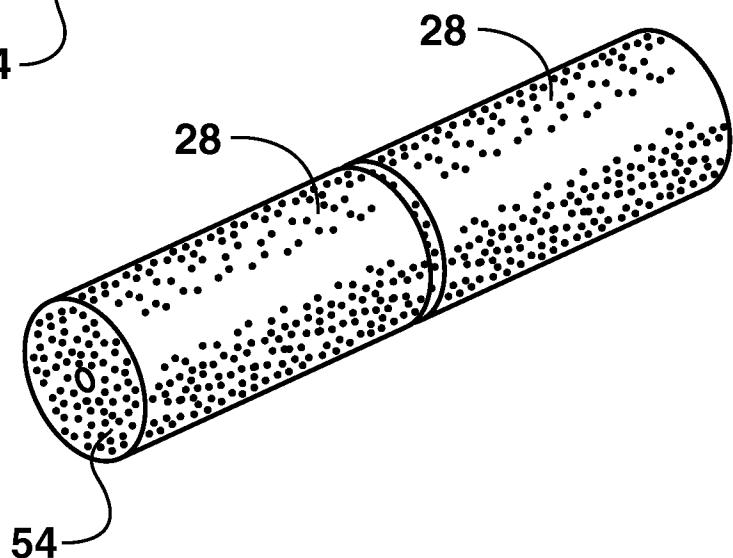


FIG. 7B

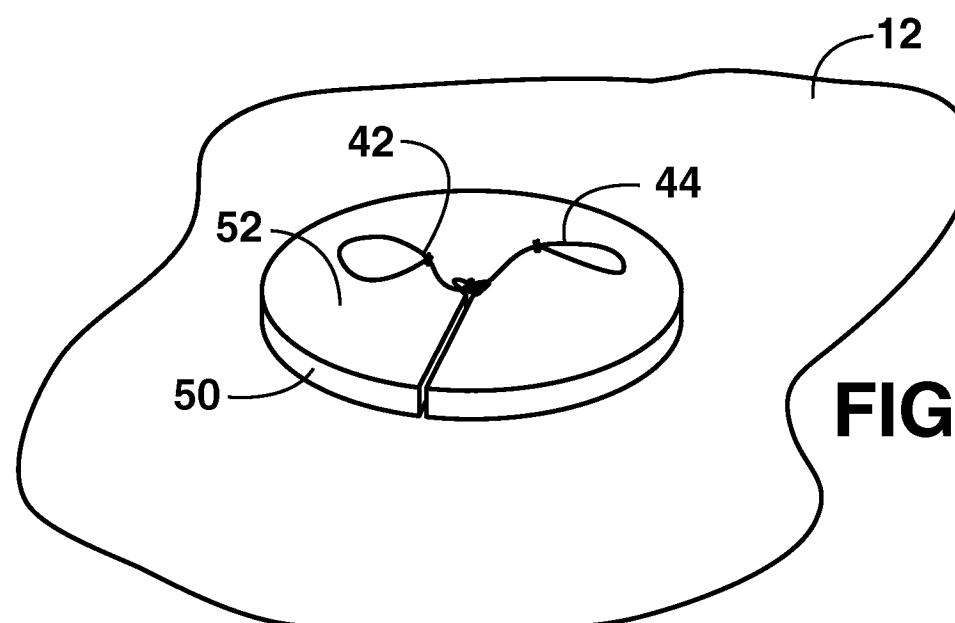


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2007/053196

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04

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)
A61B .

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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/096910 A (UNIV LONDON [GB]; SWAIN CHRISTOPHER PAUL [GB]; MOSSE CHARLES ALEXANDER) 27 November 2003 (2003-11-27) figures 3,4	1-9, 13-15
Y	-----	10-12, 16,17
X	WO 2005/089658 A (SDGI HOLDINGS INC [US]; LEHMANN LI K [US]) 29 September 2005 (2005-09-29) figures 1-9	1-12
Y	page 11, line 2	10-12, 16,17
X	EP 0 699 416 A (BONUTTI PETER M [US]) 6 March 1996 (1996-03-06)	1,2,7,8
Y	figures 13-16	10-12

Further documents are listed in the continuation of Box C.

See patent family annex.

* 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 document 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
28 March 2008	11/04/2008
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Schießl, Werner

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2007/053196

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.: 18-22 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by therapy
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:

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 an 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.:

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

Information on patent family members

International application No

PCT/IB2007/053196

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