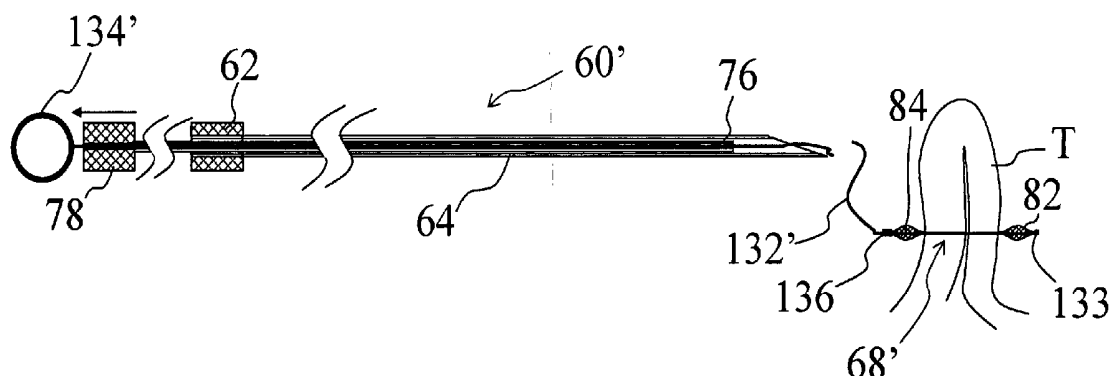


Nov. 30, 2006



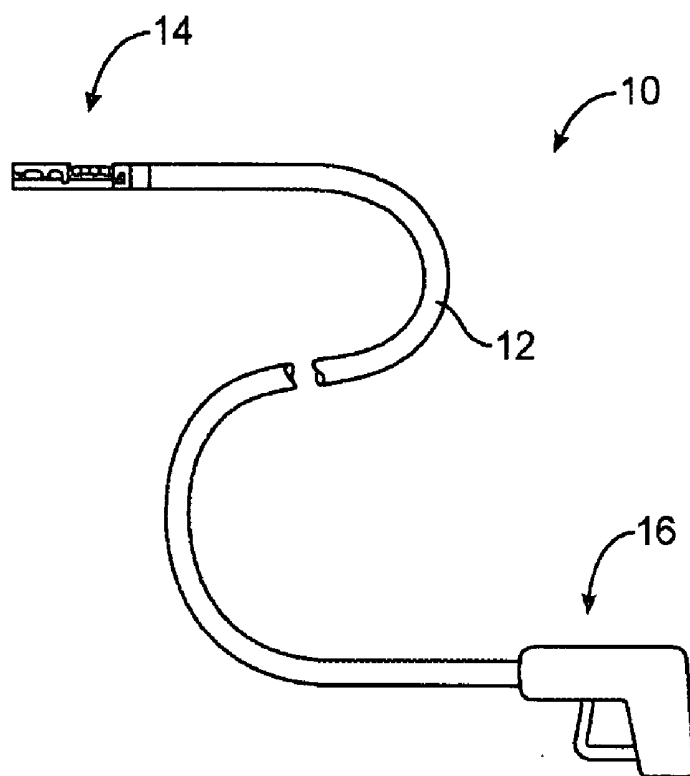


FIG. 1A

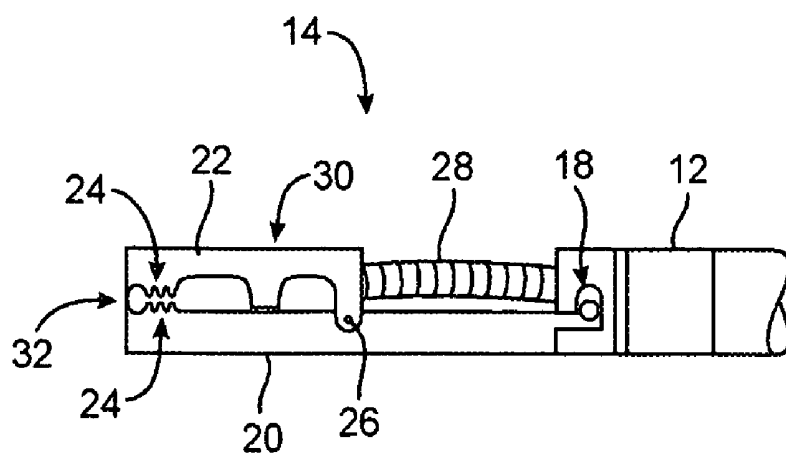


FIG. 1B

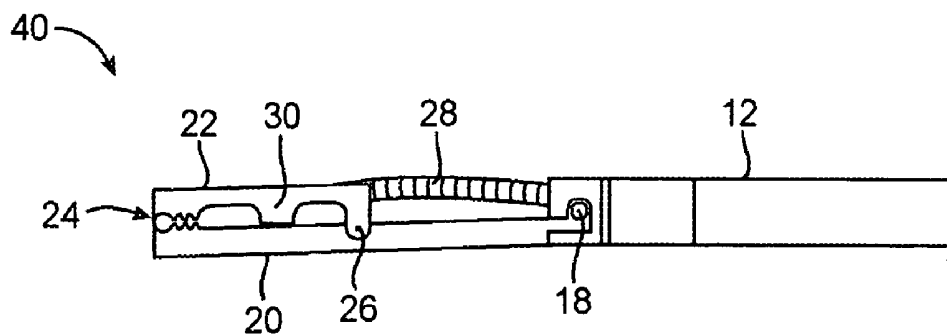


FIG. 2A

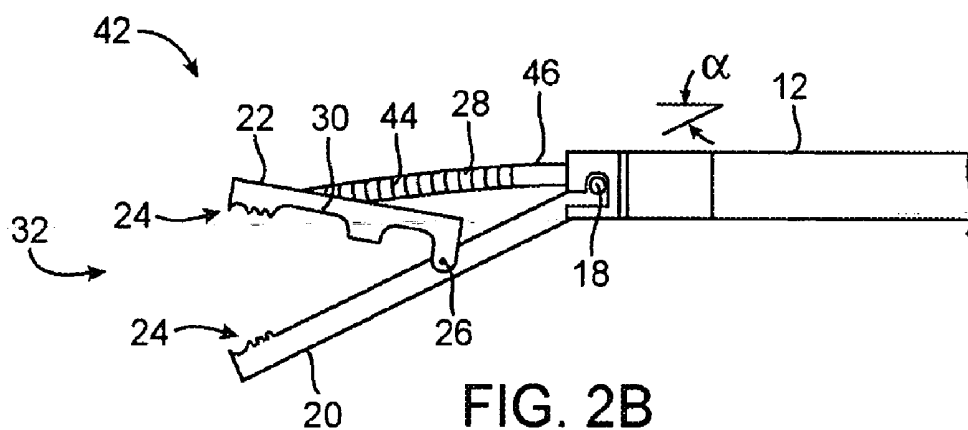


FIG. 2B

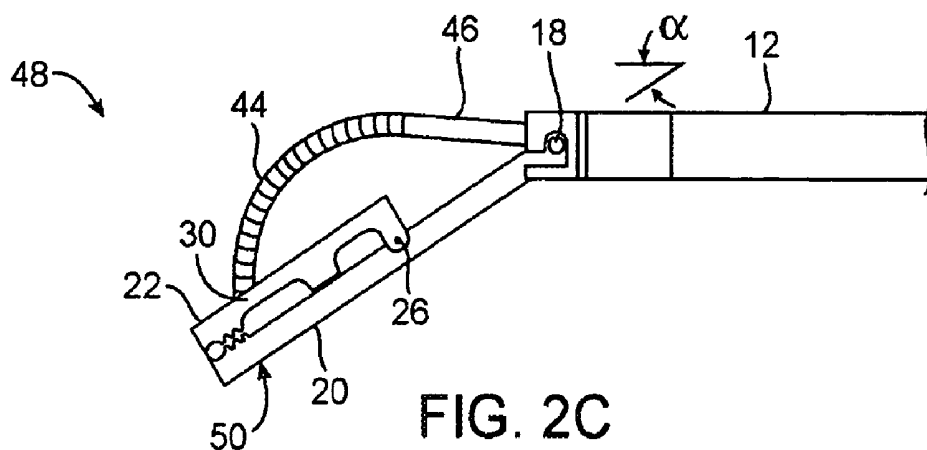


FIG. 2C

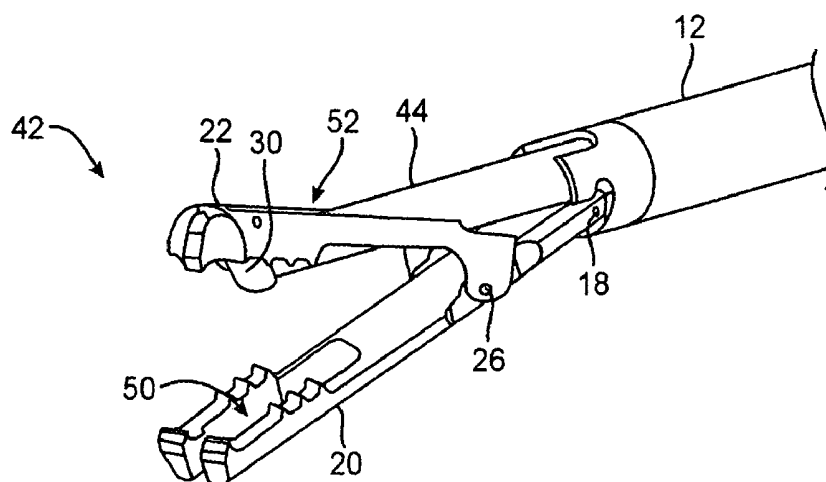


FIG. 3A

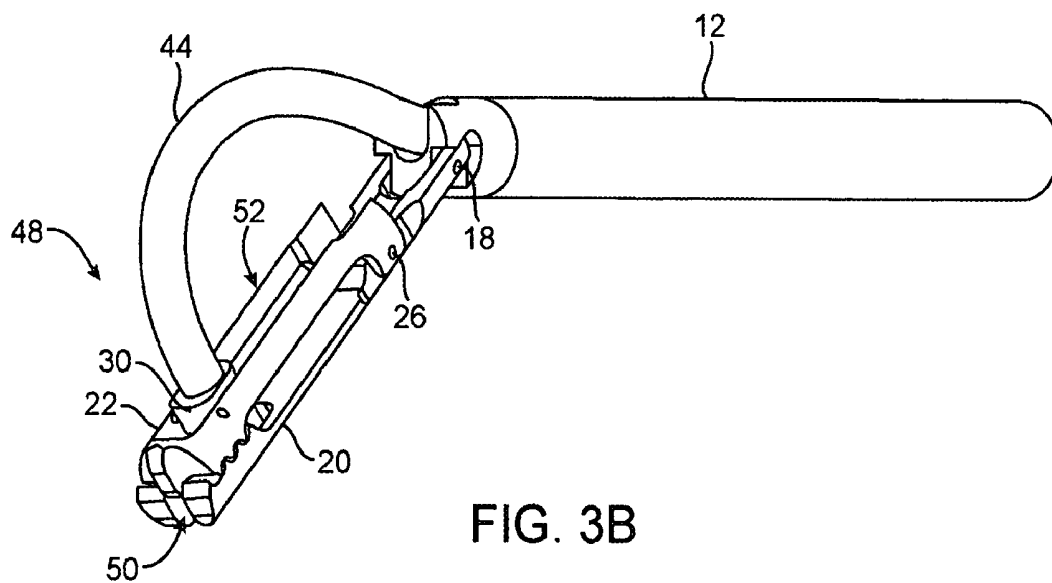


FIG. 3B

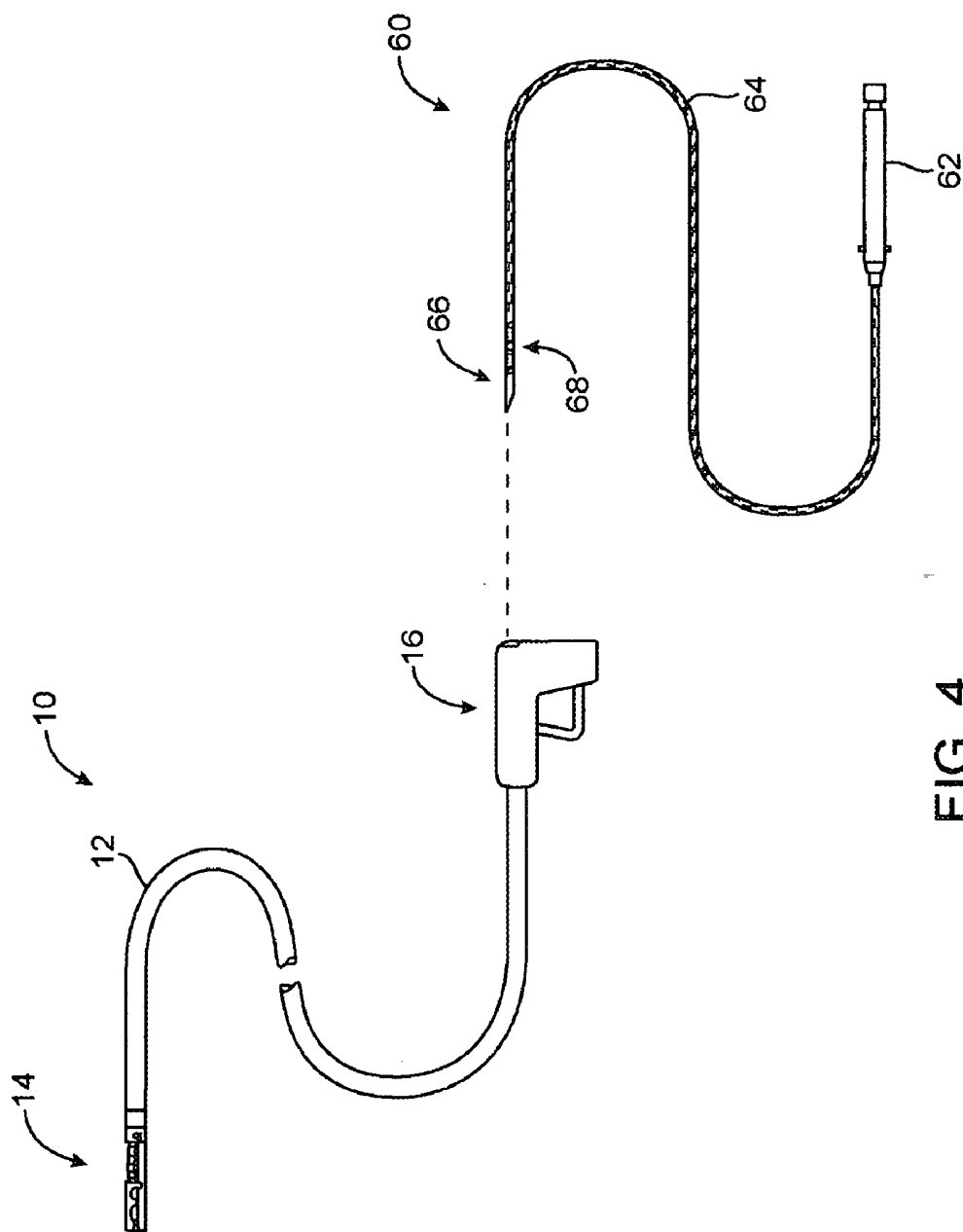


FIG. 4

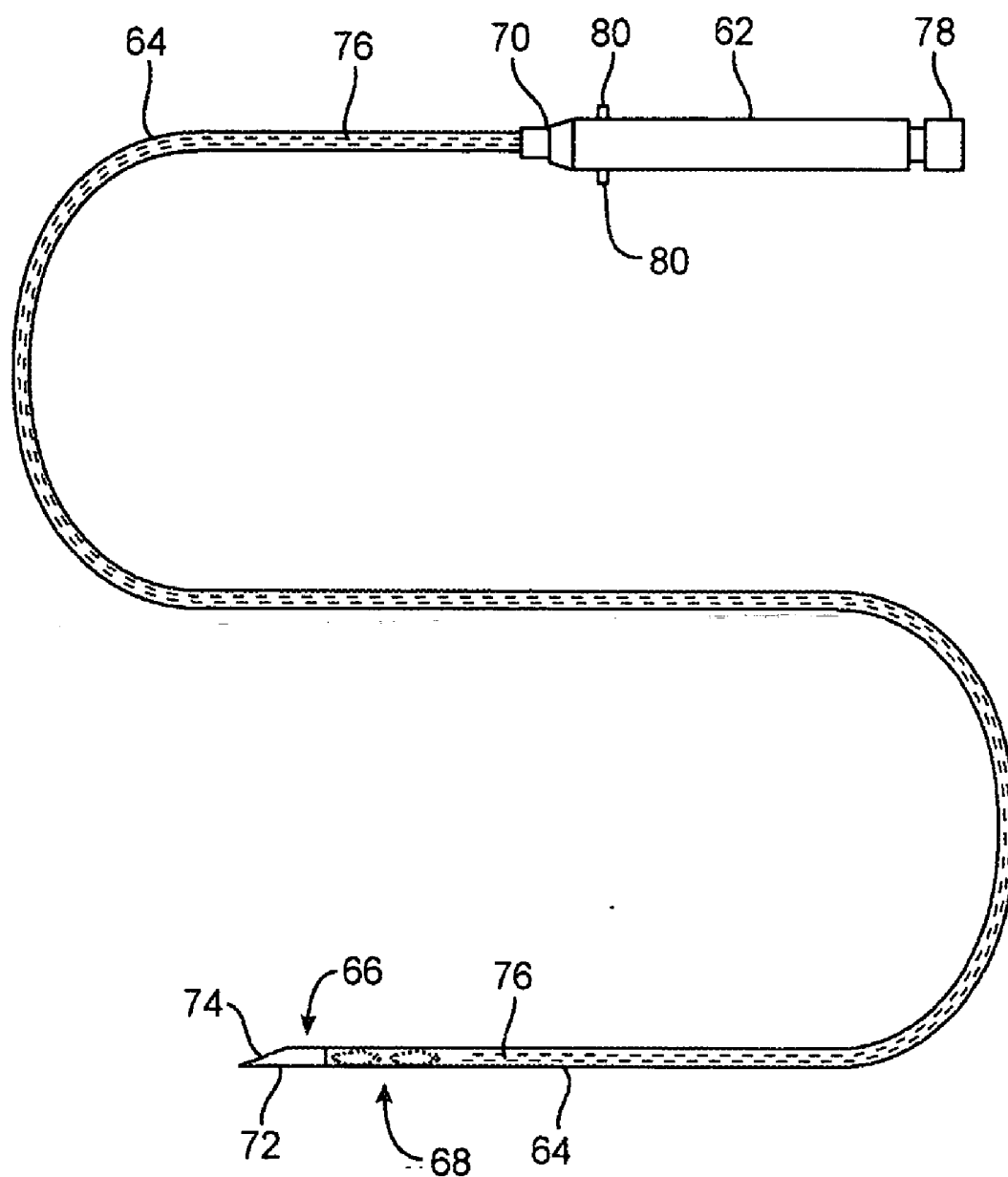


FIG. 5A

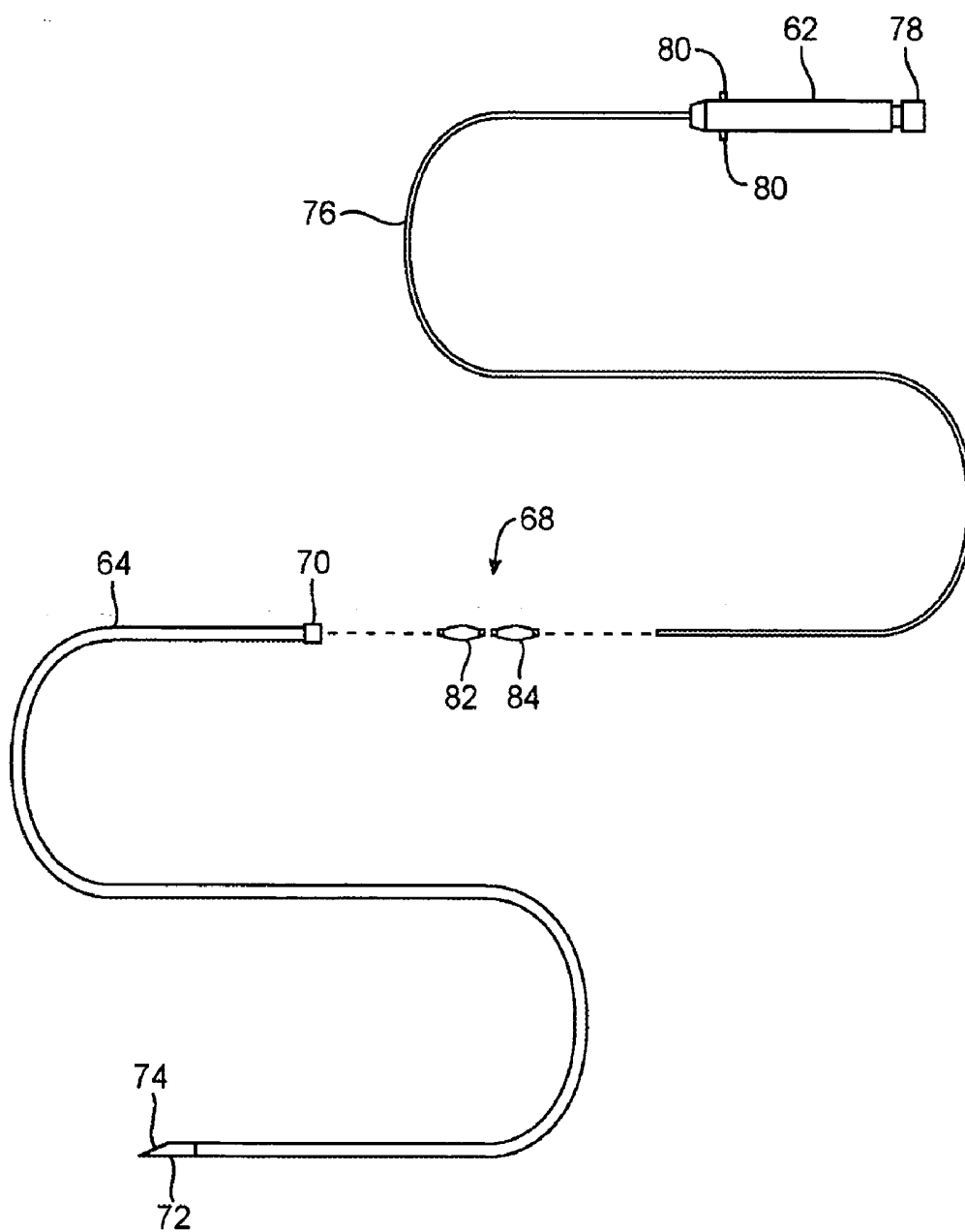


FIG. 5B

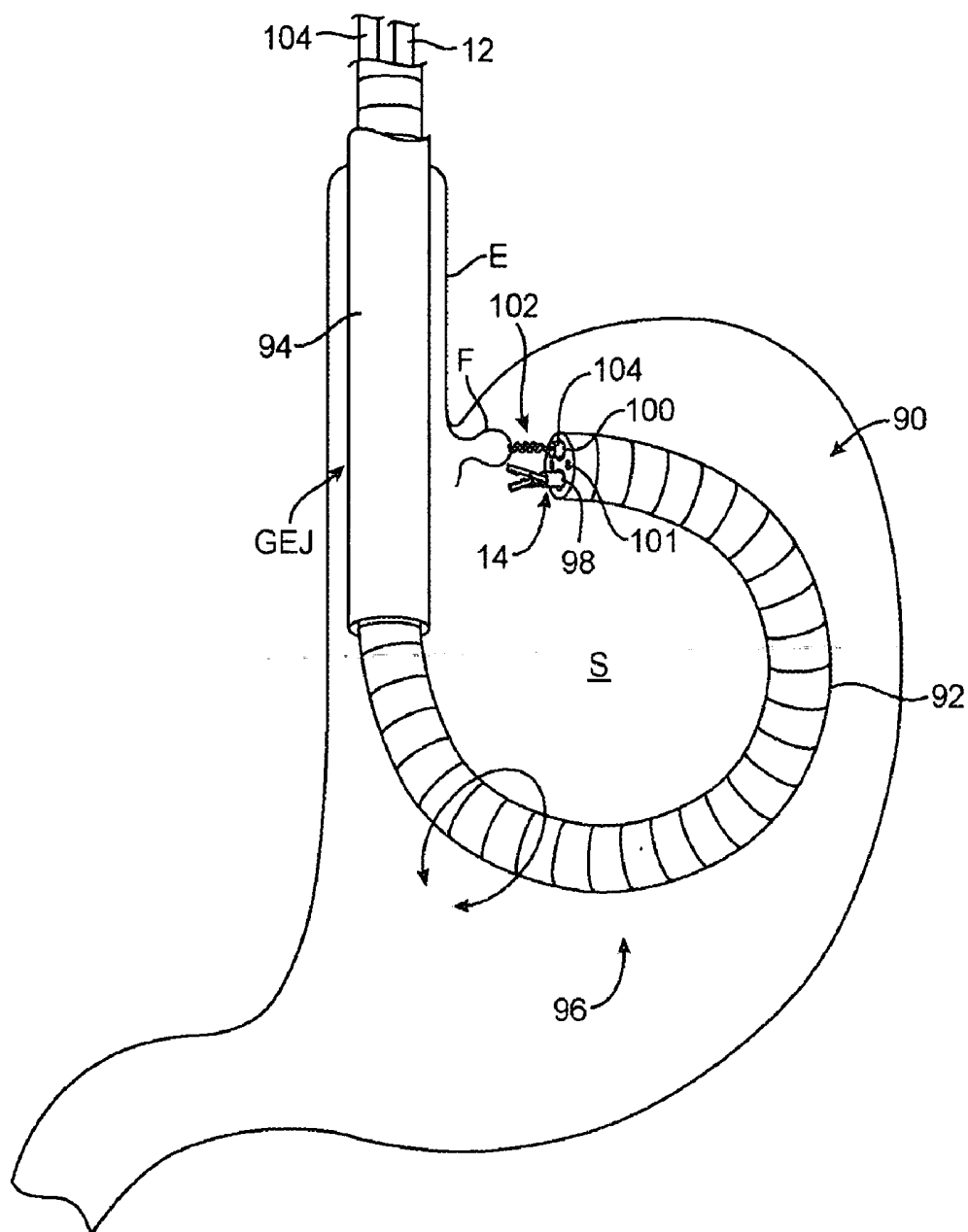


FIG. 6

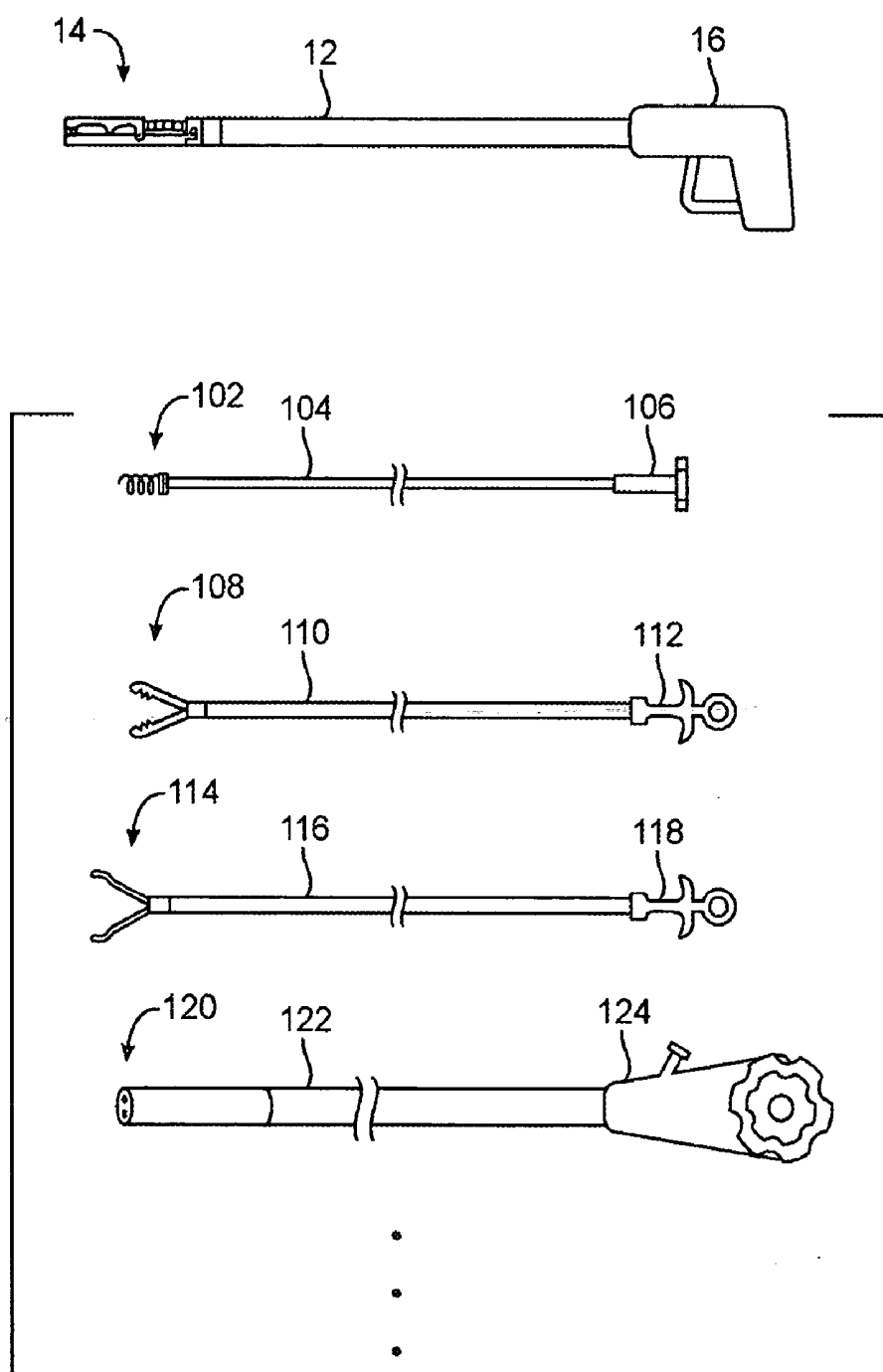


FIG. 7

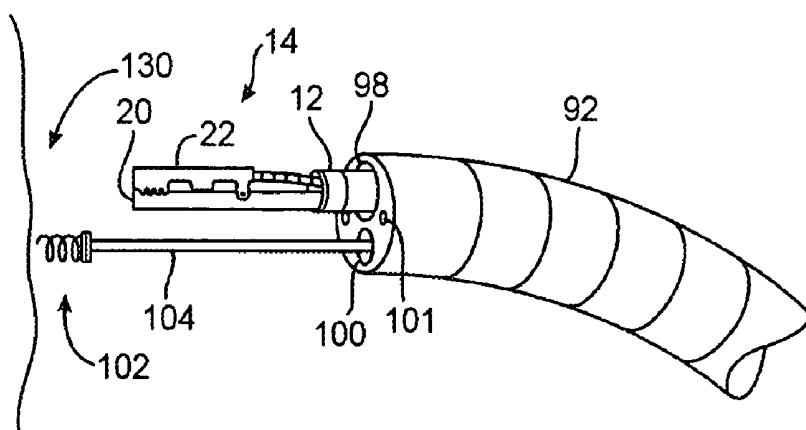


FIG. 8A

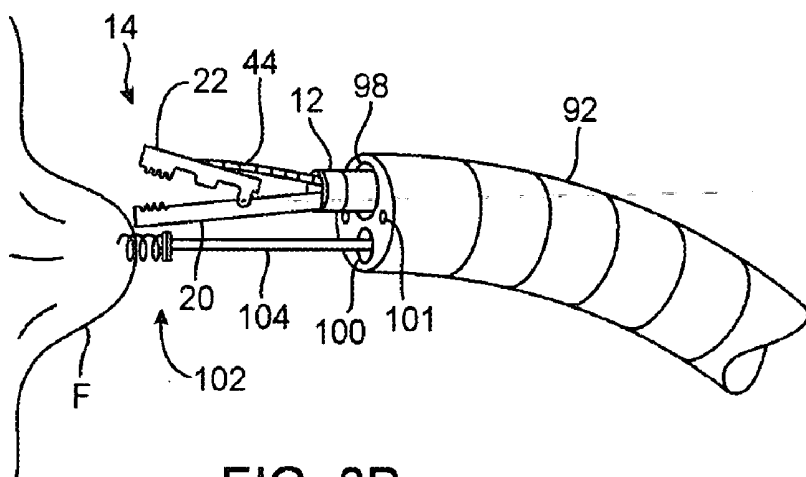


FIG. 8B

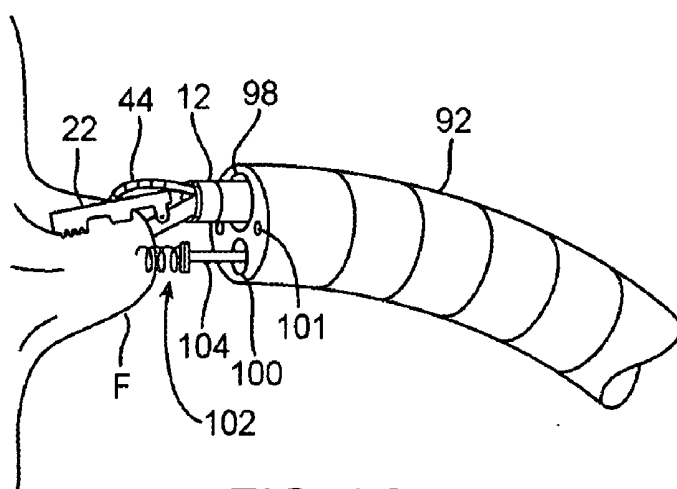


FIG. 8C

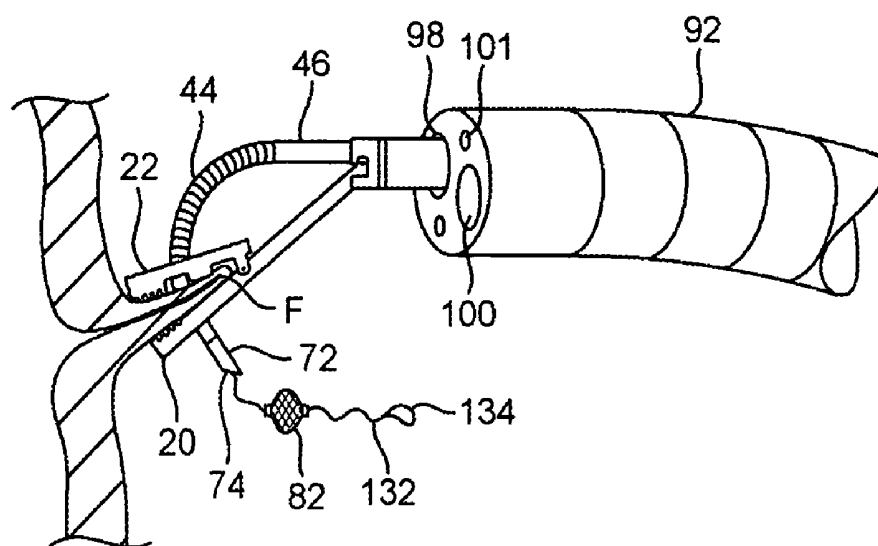


FIG. 8D

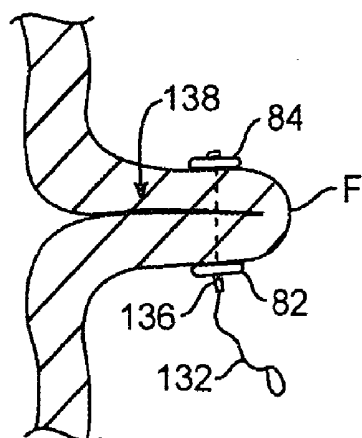


FIG. 9A

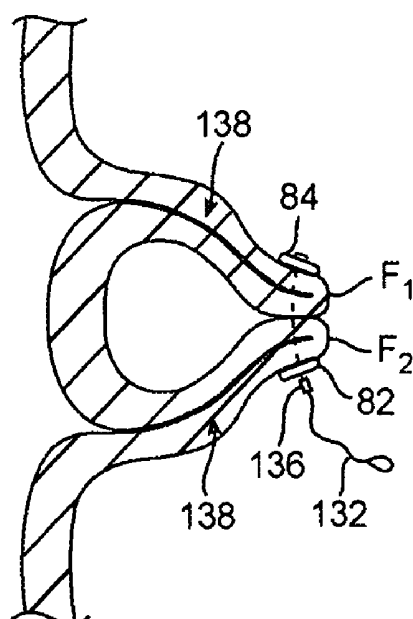
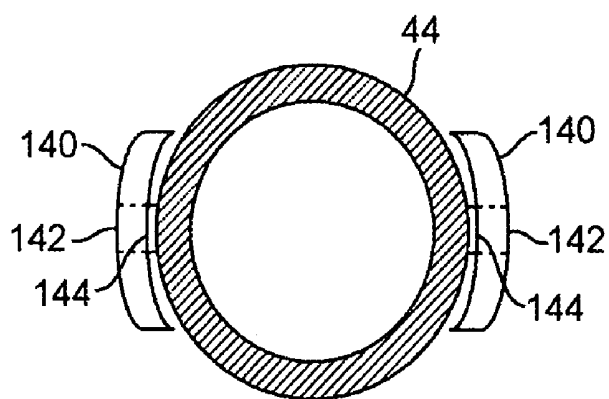
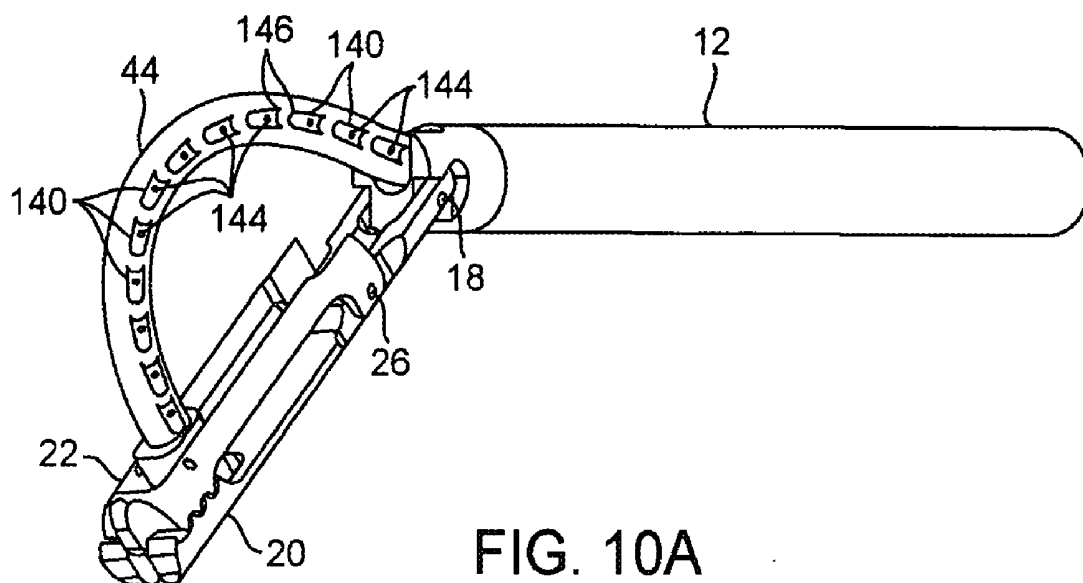
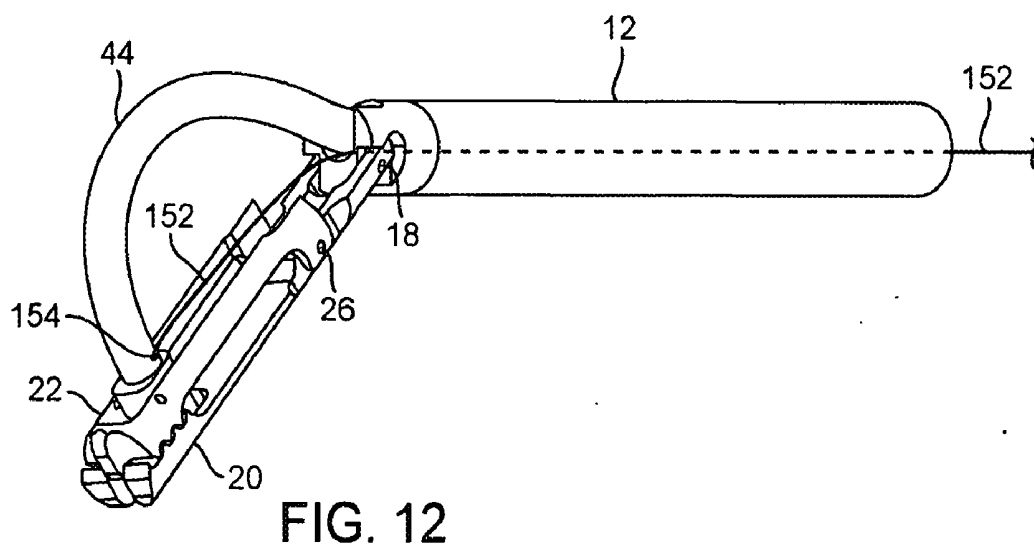
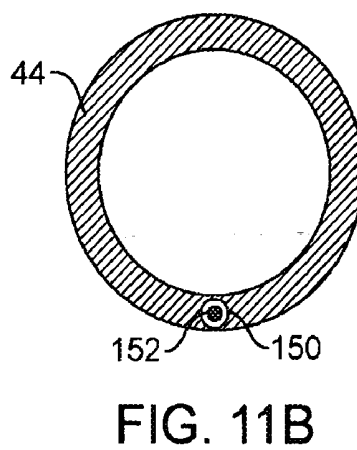
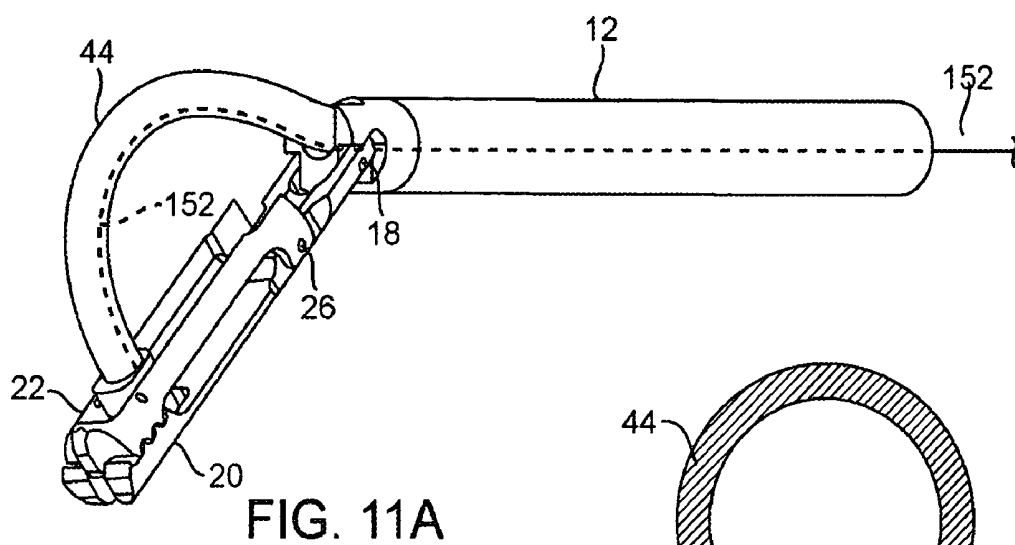


FIG. 9B





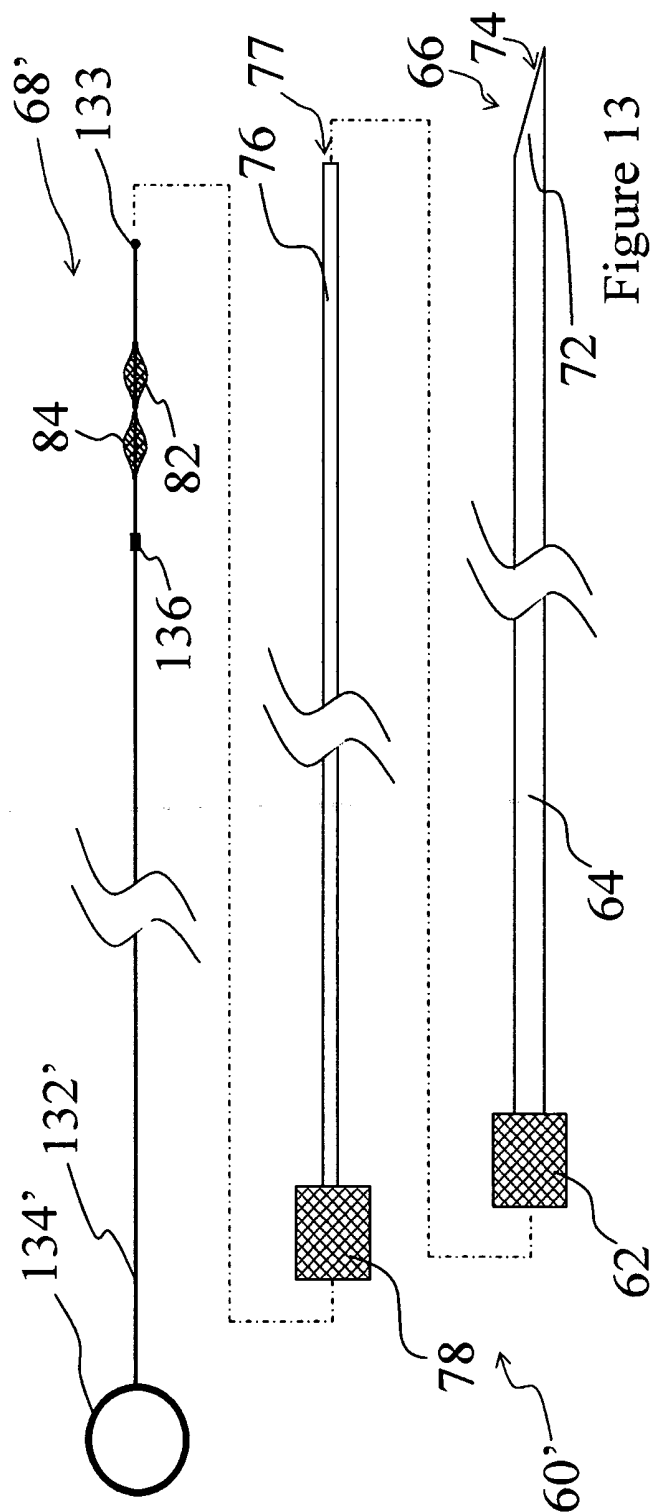


Figure 13

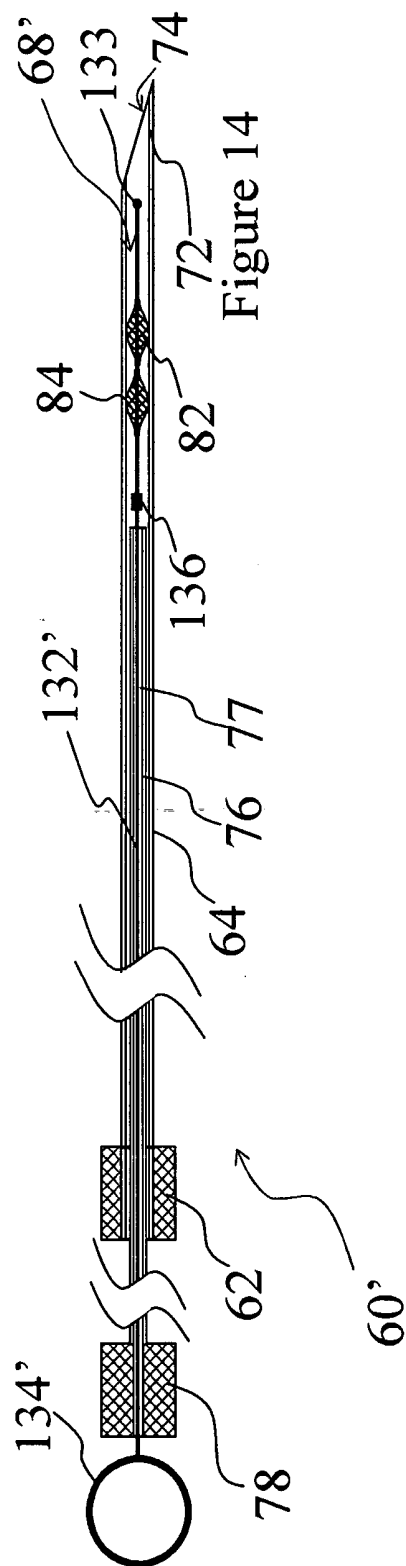
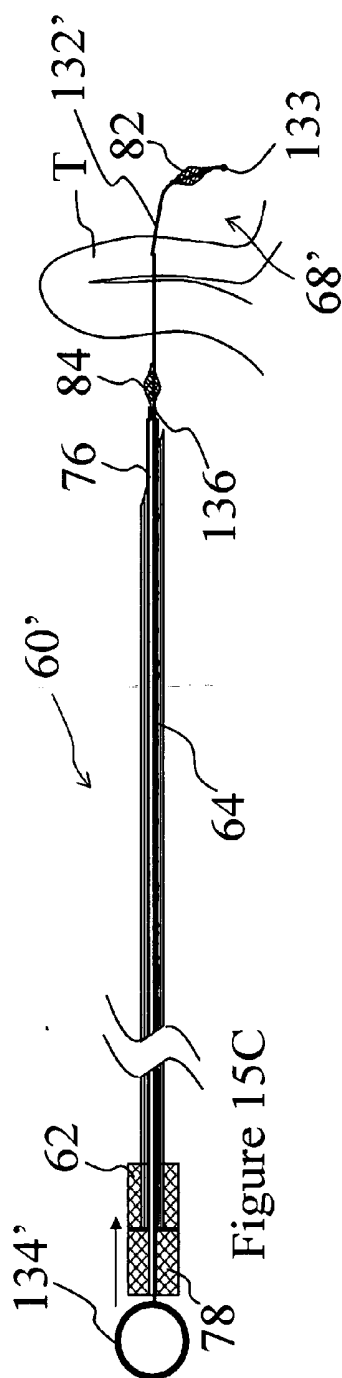
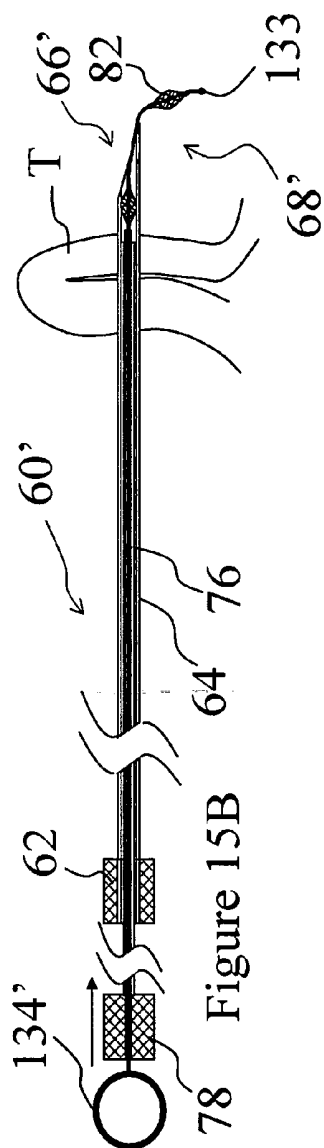
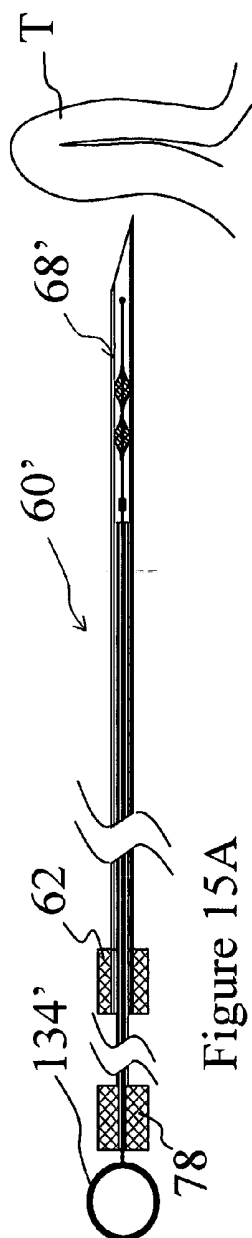
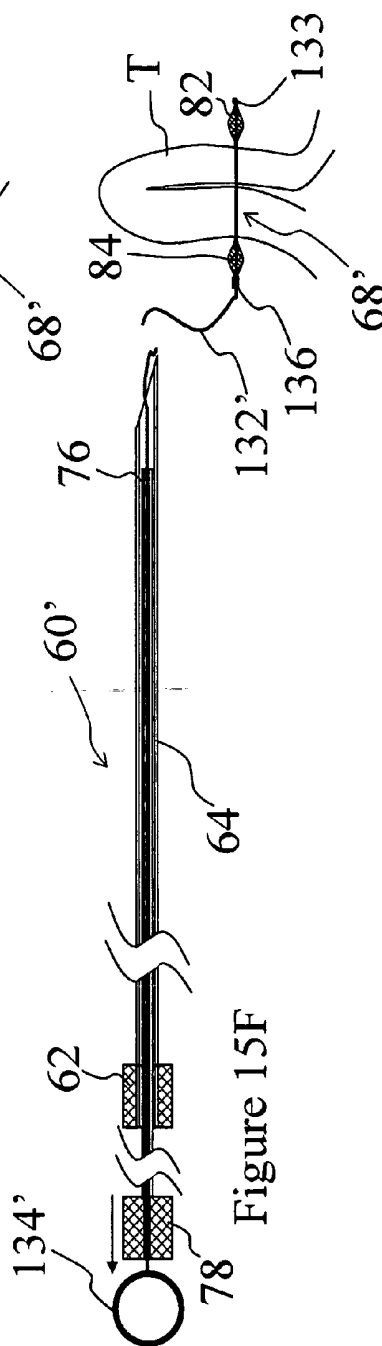
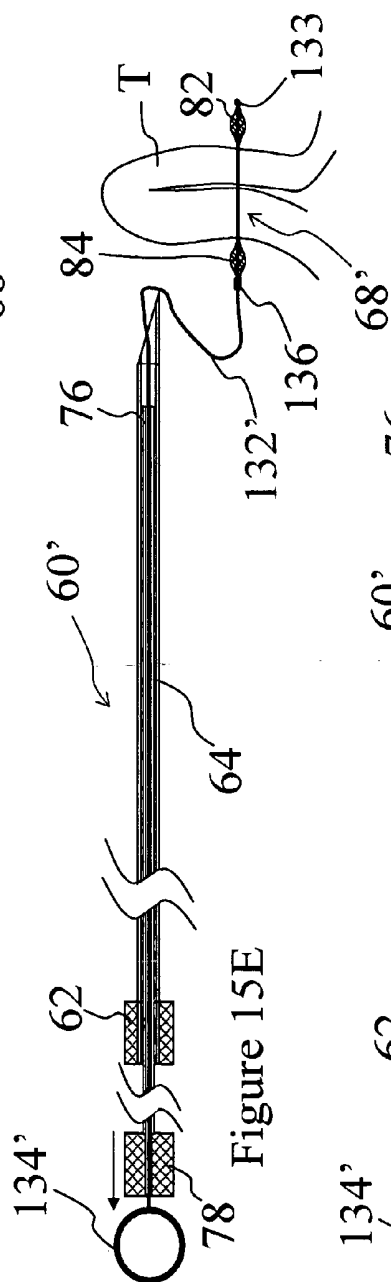
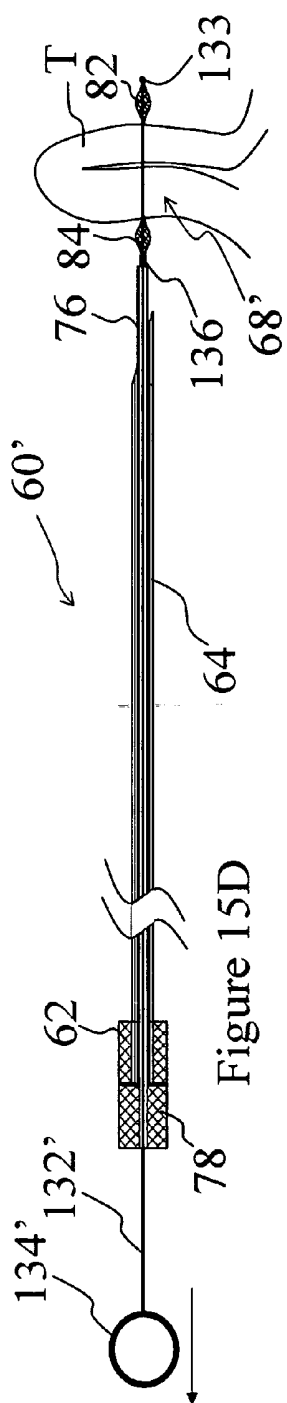
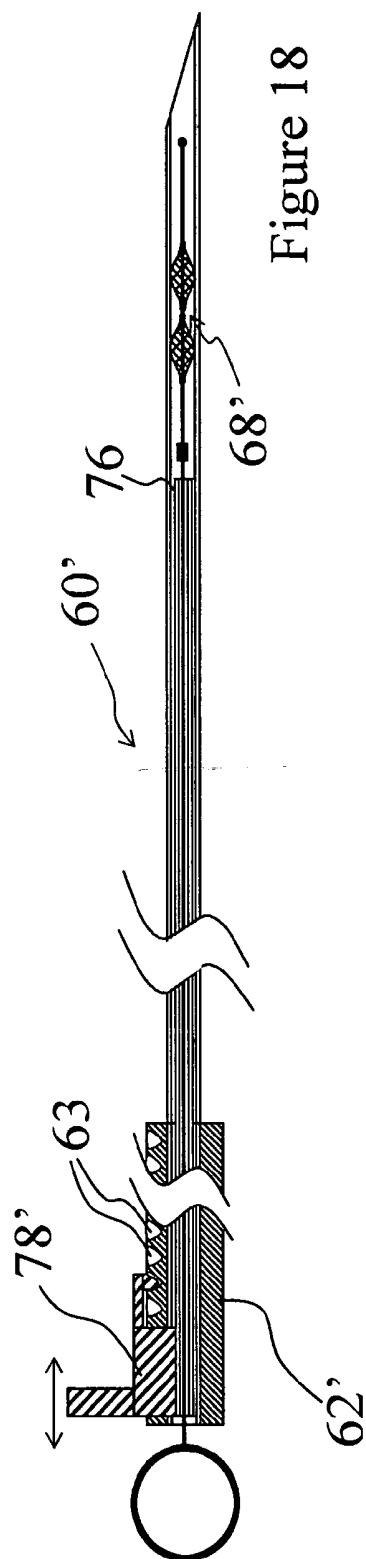
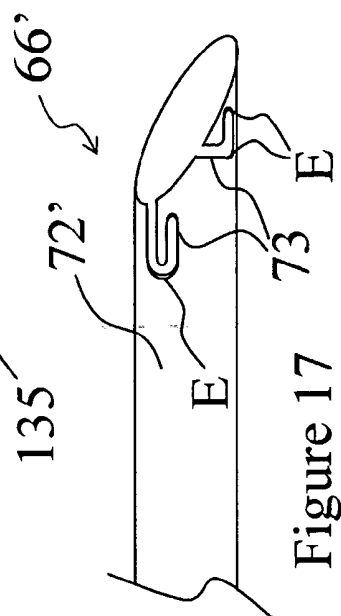
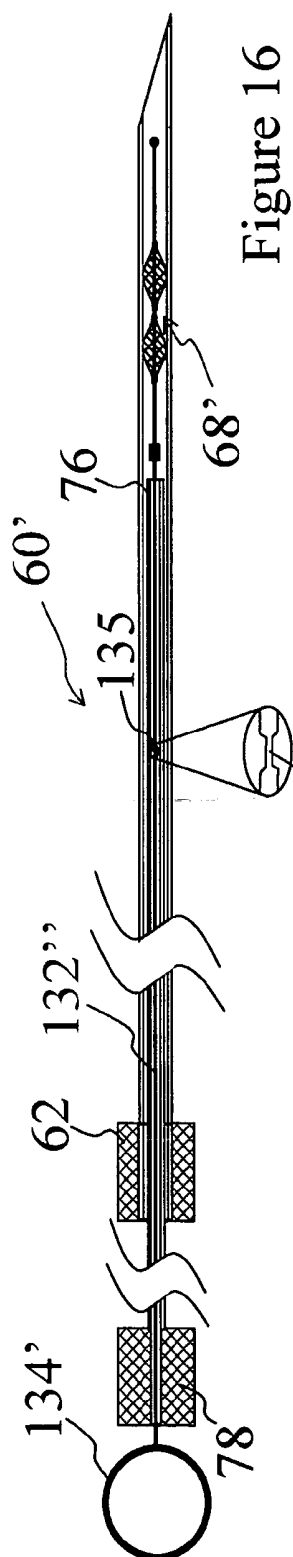
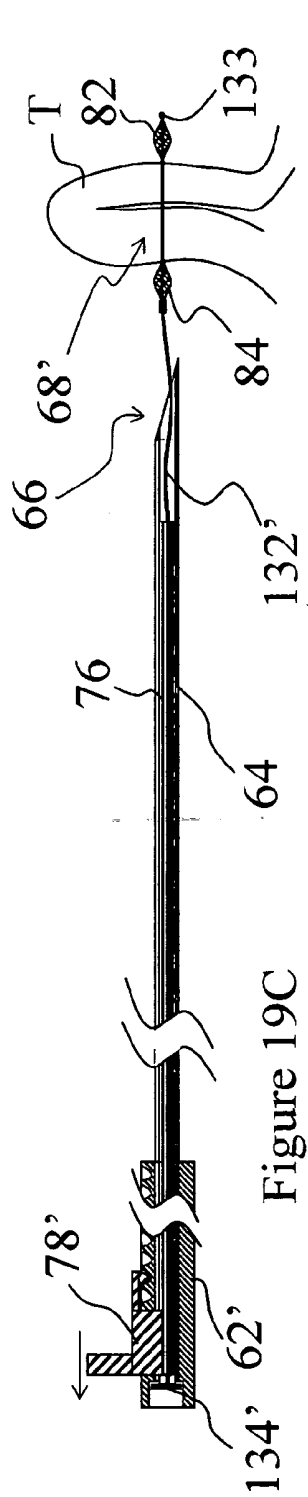
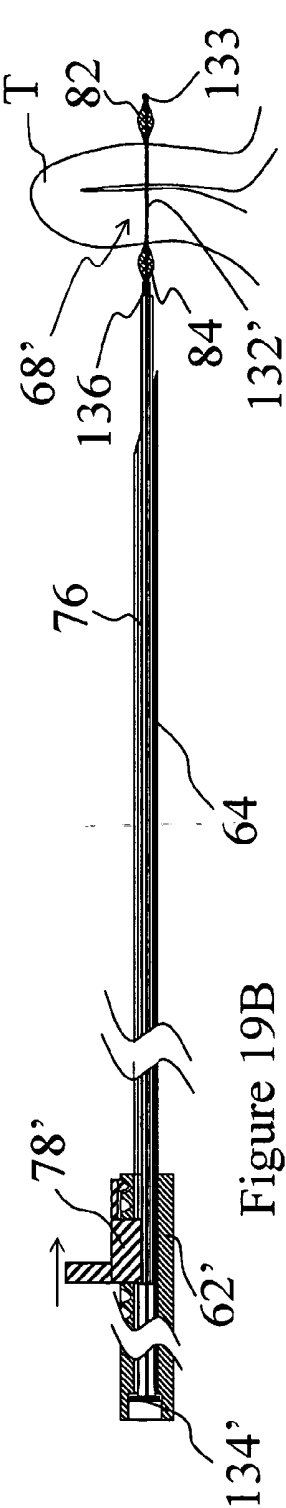
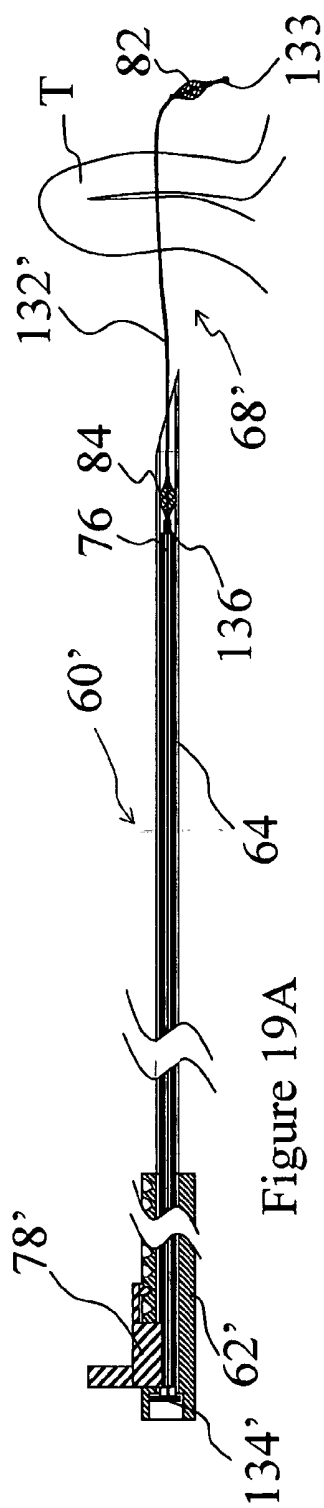


Figure 14









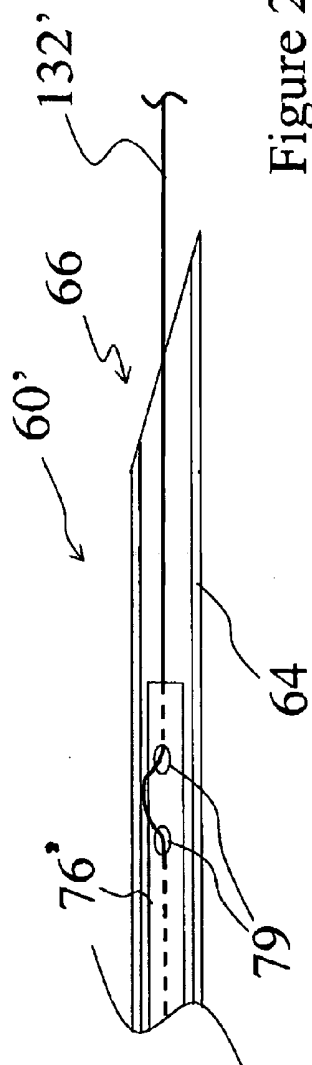


Figure 20A

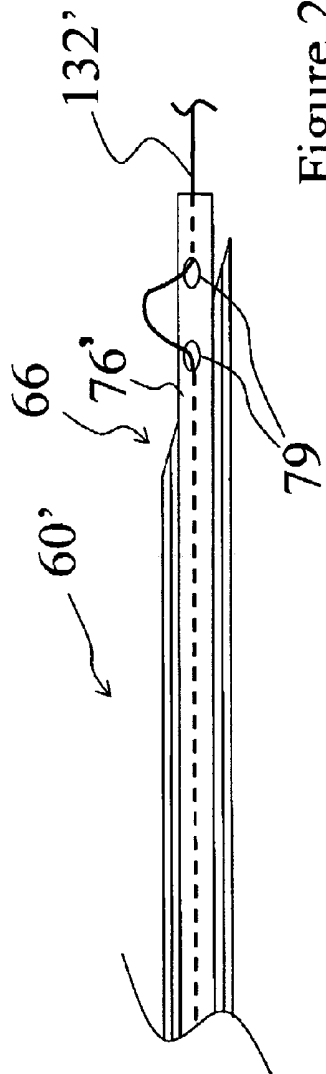


Figure 20B

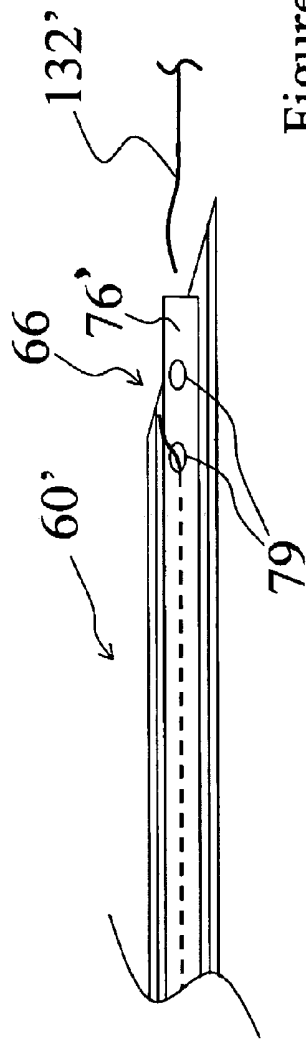
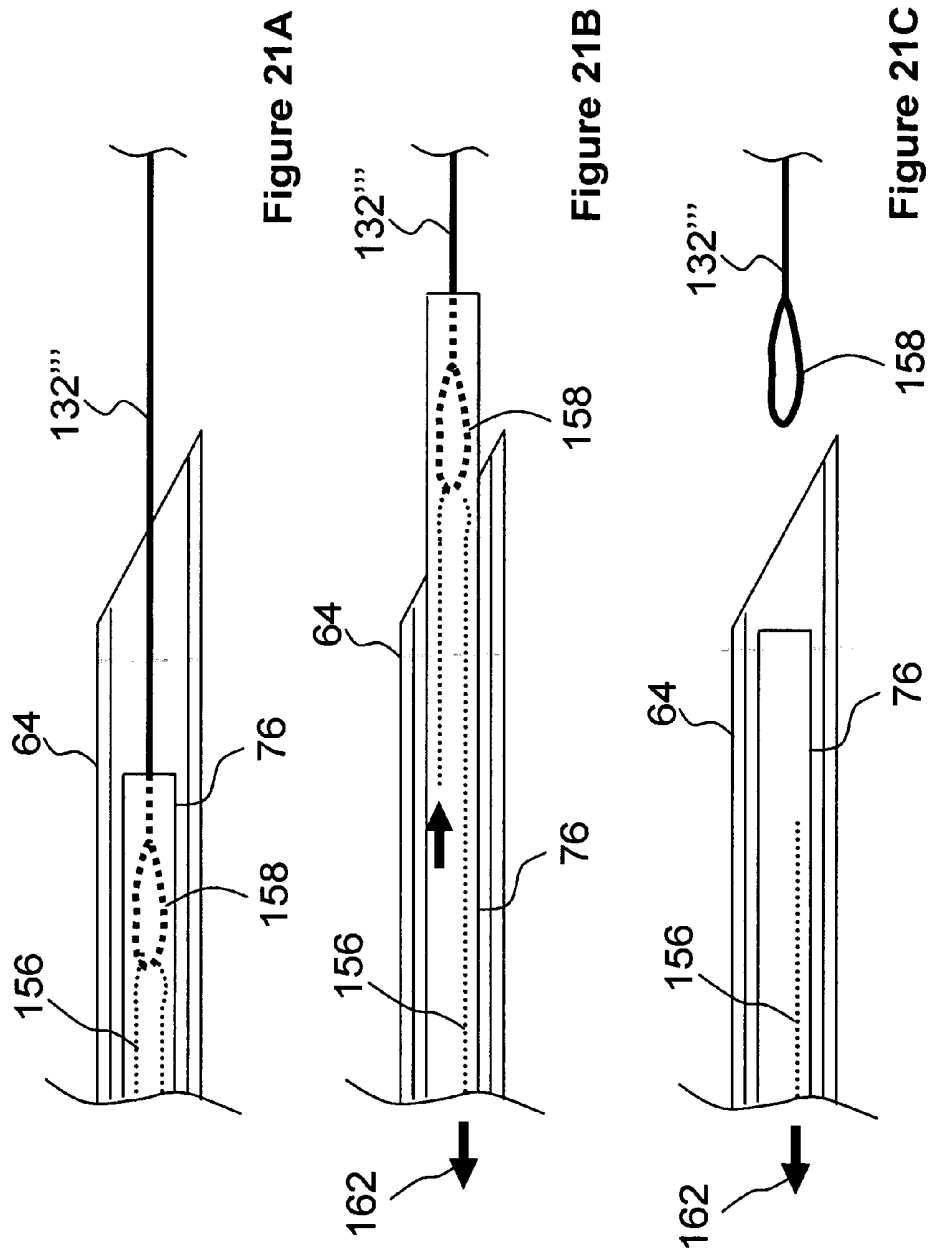


Figure 20C



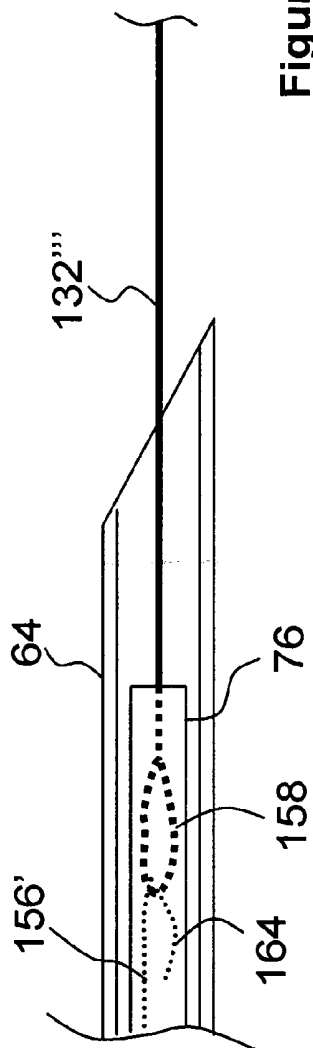


Figure 22A

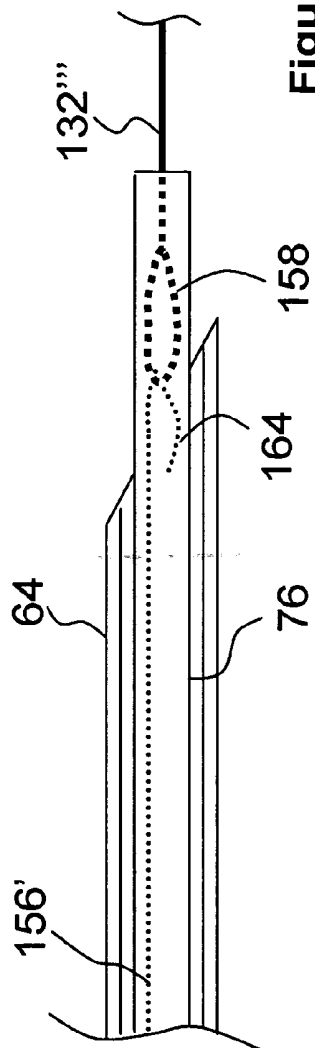


Figure 22B

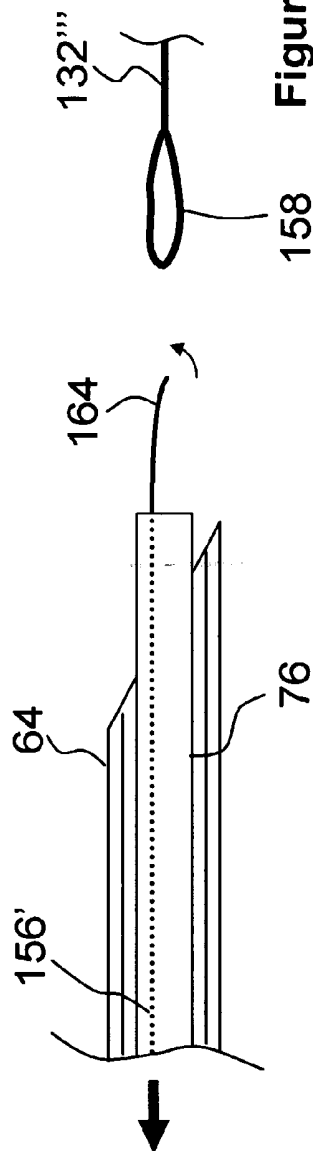
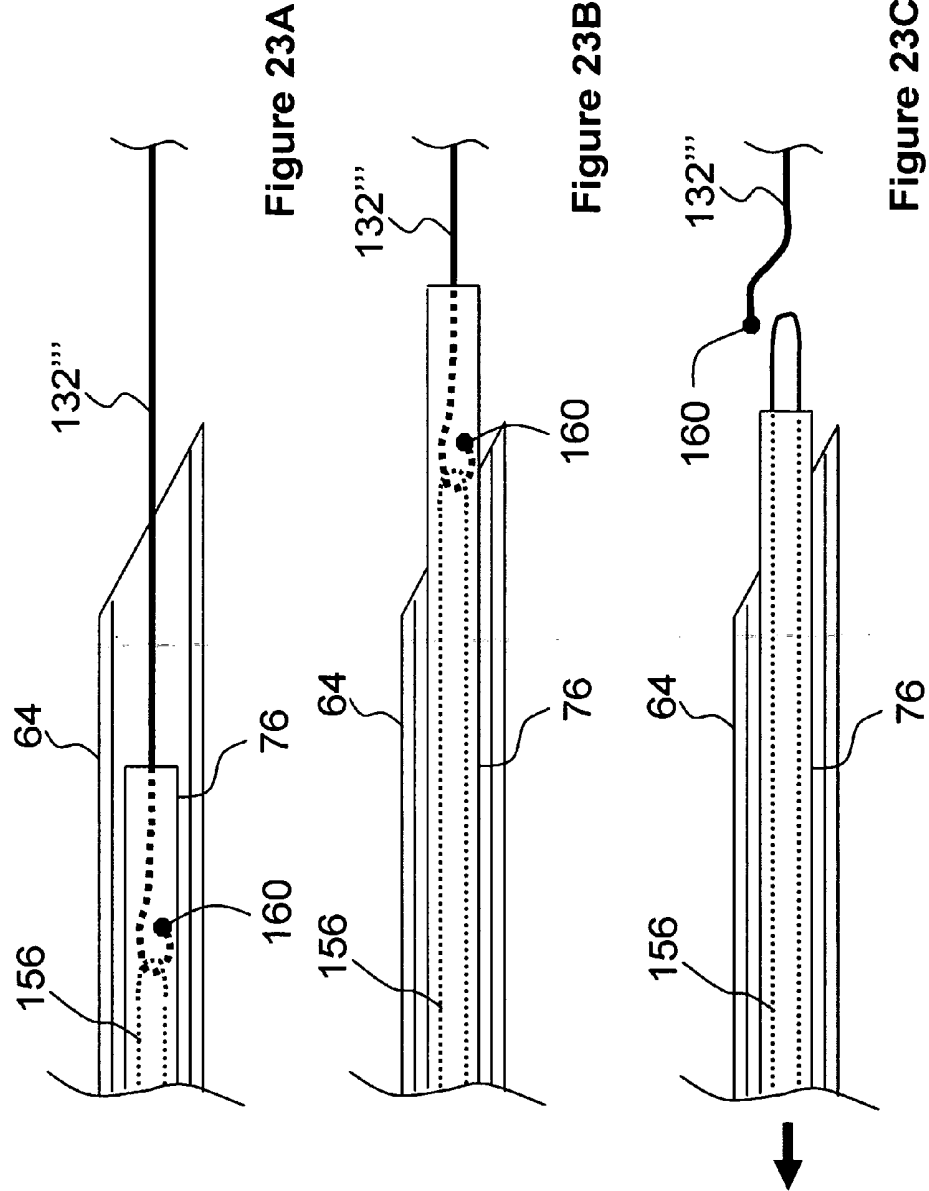


Figure 22C



METHODS AND APPARATUS FOR SECURING AND DEPLOYING TISSUE ANCHORS

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to methods and apparatus for securing and deploying tissue anchors. More particularly, the present invention relates to methods and apparatus for endoluminally or laparoscopically securing and deploying anchors within or against tissue, for instance, to form and/or secure tissue folds or to approximate regions of tissue, etc.

[0002] A number of surgical techniques have been developed to treat various gastrointestinal disorders. One such example of a pervasive disorder is morbid obesity. Conventional surgical treatment for morbid obesity typically includes, e.g., bypassing an absorptive surface of the small intestine, or reducing the stomach size. However, many conventional surgical procedures may present numerous life-threatening post-operative complications, and may cause atypical diarrhea, electrolytic imbalance, unpredictable weight loss and reflux of nutritious chyme proximal to the site of the anastomosis.

[0003] Furthermore, the sutures or staples that are often used in surgical procedures for gastrointestinal disorders typically require extensive training by the clinician to achieve competent use, and may concentrate significant force over a small surface area of the tissue, thereby potentially causing the suture or staple to tear through the tissue. Many of the surgical procedures require regions of tissue within the body to be approximated towards one another and reliably secured. The gastrointestinal lumen, for instance, includes four tissue layers, where the mucosa layer is the inner-most tissue layer followed by connective tissue, the muscularis layer, and where the serosa layer is the outer-most tissue layer.

[0004] One problem with conventional gastrointestinal reduction systems is that the anchors (or staples) should engage at least the muscularis tissue layer in order to provide a proper foundation. In other words, the mucosa and connective tissue layers typically are not strong enough to sustain the tensile loads imposed by normal movement of the stomach wall during ingestion and processing of food. In particular, these layers tend to stretch elastically rather than firmly hold the anchors (or staples) in position, and accordingly, the more rigid muscularis and/or serosa layer should ideally be engaged. This problem of capturing the muscularis or serosa layers becomes particularly acute where it is desired to place an anchor or other apparatus transesophageally rather than intra-operatively, since care must be taken in piercing the tough stomach wall not to inadvertently puncture adjacent tissue or organs.

[0005] One conventional method for securing anchors within a body lumen to the tissue is to utilize sewing devices to suture the stomach wall into folds. This procedure typically involves advancing a sewing instrument through the working channel of an endoscope and into the stomach and against the stomach wall tissue. The contacted tissue is then typically drawn into the sewing instrument where one or more sutures or tags are implanted to hold the suctioned

tissue in a folded condition known as a plication. Another method involves manually creating sutures for securing the plication.

[0006] One of the problems associated with these types of procedures is the time and number of intubations needed to perform the various procedures endoscopically. Another problem is the time required to complete a plication from the surrounding tissue with the body lumen. In the period of time that a patient is anesthetized, procedures such as for the treatment of morbid obesity or for GERD must be performed to completion. Accordingly, the placement and securement of the tissue plication should ideally be relatively quick and performed with a minimal level of confidence.

[0007] Another problem with conventional methods involves ensuring that the staple, knotted suture, or clip is secured tightly against the tissue and that the newly created plication will not relax under any slack which may be created by slipping staples, knots, or clips. Other conventional tissue securement devices such as suture anchors, twist ties, crimps, etc. are also often used to prevent sutures from slipping through tissue. However, many of these types of devices are typically large and unsuitable for low-profile delivery through the body, e.g., transesophageally.

[0008] Moreover, when grasping or clamping onto or upon the layers of tissue with conventional anchors, sutures, staples, clips, etc., many of these devices are configured to be placed only after the tissue has been plicated and not during the actual plication procedure.

BRIEF SUMMARY OF THE INVENTION

[0009] An example of a tool which may be utilized for endoluminally accessing tissue may generally comprise a flexible catheter or tubular body which may be configured to be sufficiently flexible for advancement into a body lumen, e.g., transorally, percutaneously, laparoscopically, etc. The tubular body may be configured to be torqueable such that when a control handle is manipulated and/or rotated by a practitioner from outside the patient's body, the longitudinal and/or torquing force is transmitted along the flexible body such that the distal end of body is advanced, withdrawn, or rotated in a corresponding manner.

[0010] A tissue manipulation assembly may be located at the distal end of the tubular body and is generally used to contact and form tissue folds, as mentioned above. The tissue manipulation assembly may be connected to the distal end of the tubular body via a pivotable coupling, and a lower jaw member may extend distally from the pivotable coupling with an upper jaw member, in this example, pivotably coupled to the lower jaw member via a jaw pivot. The location of the jaw pivot may be positioned at various locations along the lower jaw depending upon a number of factors, e.g., the desired size of the "bite" or opening for accepting tissue between the jaw members, the amount of closing force between the jaw members, etc. One or both jaw members may also have a number of protrusions, projections, grasping teeth, textured surfaces, etc., on the surface or surfaces of the jaw members to facilitate the adherence of tissue therebetween.

[0011] A launch tube may extend from the handle, through tubular body, and distally from the end of tubular body where a distal end of the launch tube is pivotally connected

to the upper jaw member at a pivot. A distal portion of the launch tube may be pivoted into position within a channel or groove defined in upper jaw member to facilitate a low-profile configuration of the tissue manipulation assembly. When articulated, either via the launch tube or other mechanism, the jaw members may be urged into an open configuration to receive tissue in the jaw opening between the jaw members.

[0012] In operation, a shape-lockable endoscopic assembly may be advanced into a patient's stomach per-orally and through the esophagus. Such an endoscopic assembly may generally comprise an endoscopic device, which may have a distal portion that may be articulated and steered to position its distal end anywhere within the stomach. Once desirably configured, the assembly may then be locked or rigidized to maintain its shape or configuration to allow for procedures to be performed on the tissue utilizing any number of tools delivered therethrough.

[0013] The tissue manipulation assembly may be delivered into the patient while in a low-profile configuration, e.g., transorally, through the shape-lockable endoscopic assembly, through an endoscope, an endoscopic device, or directly. Once desirably positioned, the launch tube may be urged proximally via its proximal end at handle. Because the jaw assembly pivot and the relative positioning of the upper jaw pivot along lower jaw member and launch tube pivot along upper jaw member, the proximal movement of the launch tube may effectively articulate upper jaw into an expanded jaw configuration. Proximally urging the launch tube may also urge the lower jaw member to pivot about the assembly pivot and form an angle relative to a longitudinal axis of the tubular body. The opening of the upper jaw relative to the lower jaw creates a jaw opening for grasping or receiving tissue. Moreover, the tissue manipulation assembly may also include a stop located adjacent to the jaw assembly pivot or within the pivot itself.

[0014] A second tool for initially engaging the tissue region of interest may also be deployed and utilized to engage the tissue and to position the engaged tissue between the jaws of the jaw assembly. Any number of tools may be used in combination with the tissue manipulation assembly. Once the tissue has been engaged between the jaw members, a needle assembly may be urged through the launch tube to pierce through the grasped tissue. Once the needle assembly has been passed through the engaged tissue, one or more tissue anchors may be deployed for securing the tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] **FIG. 1A** shows a side view of one variation of a tissue manipulation assembly having a flexible body and a handle.

[0016] **FIG. 1B** illustrates a detail side view of a tissue manipulation assembly in a low-profile configuration connected to the distal end of the tubular body via a pivotable coupling.

[0017] **FIGS. 2A to 2C** illustrate a method for articulating the tissue manipulation assembly from a low-profile configuration to an opened configuration and to a closed jaw configuration for clamping upon tissue, respectively.

[0018] **FIGS. 3A and 3B** show detail perspective views of the tissue manipulation assembly in an open and clamped configuration, respectively.

[0019] **FIG. 4** shows an assembly view of how a needle deployment assembly may be introduced through a handle and tubular body of the tissue manipulation assembly.

[0020] **FIG. 5A** shows a detailed assembly view of the needle deployment assembly from **FIG. 4**.

[0021] **FIG. 5B** shows an exploded assembly view of the needle deployment assembly from **FIG. 5A**.

[0022] **FIG. 6** illustrates one example in which a shape-lockable endoscopic assembly may be advanced into a patient's stomach per-orally and through the esophagus with a tissue manipulation assembly advanced through a first lumen and a tissue engagement member advanced through a second lumen.

[0023] **FIG. 7** illustrates a tissue manipulation assembly and examples of various tools which may be used in combination with the tissue manipulation assembly.

[0024] **FIGS. 8A to 8D** illustrate an example for performing an endoluminal tissue manipulation and securement procedure utilizing a tissue manipulation assembly in combination with a separate tissue grasping tool within, e.g., a patient's stomach.

[0025] **FIG. 9A** shows one variation where a single tissue fold may be secured between tissue anchors using the tissue manipulation assembly.

[0026] **FIG. 9B** shows another variation where two or more tissue folds may be secured between tissue anchors using the tissue manipulation assembly.

[0027] **FIGS. 10A and 10B** illustrate a variation of the tissue manipulation assembly in a perspective and cross-sectional view, respectively, where a number of reinforcement members or bars may be positioned along the launch tube to increase its column strength.

[0028] **FIGS. 11A and 11B** illustrate another variation of the tissue manipulation assembly in a perspective and cross-sectional view, respectively, where a pull wire may be routed through the launch tube to facilitate articulation of the launch tube and/or jaw assembly.

[0029] **FIG. 12** illustrates yet another variation of the tissue manipulation assembly which may also utilize a pull wire connected directly to the launch tube.

[0030] **FIG. 13** illustrates an exploded view of a variation of an anchor assembly and needle deployment assembly.

[0031] **FIG. 14** illustrates an assembly view, partially in section, of the anchor assembly and needle deployment assembly variation of **FIG. 13**.

[0032] **FIGS. 15A to 15F** illustrate an exemplary method of using the anchor assembly and needle deployment assembly variation of **FIGS. 13 and 14**.

[0033] **FIG. 16** illustrates a variation of the suture element for use with the anchor assembly and needle deployment assembly of **FIGS. 13 to 15**.

[0034] **FIG. 17** illustrates a variation of the needle for use with the anchor assembly and needle deployment assembly variation of **FIGS. 13 to 15**.

[0035] **FIG. 18** illustrates a variation of the control mechanisms for use with the needle deployment assemblies of **FIGS. 13 to 17**.

[0036] **FIGS. 19A to 19C** illustrate an exemplary method of using another variation of the anchor assembly and needle deployment assembly.

[0037] **FIGS. 20A to 20C** are schematic views illustrating another variation of the needle deployment assembly.

[0038] **FIGS. 21A to 21C** illustrate another variation of the needle deployment assembly utilizing a release suture or wire which may be routed through a looped terminal end of a suture element.

[0039] **FIGS. 22A to 22C** illustrate yet another variation of the needle deployment assembly utilizing a reconfigurable hook element which may configure itself from a hooked configuration to an open or straightened configuration.

[0040] **FIGS. 23A to 23C** illustrate yet another variation of the needle deployment assembly utilizing a release suture or wire with an obstructive element to be released from the release suture or wire.

DETAILED DESCRIPTION OF THE INVENTION

[0041] In manipulating tissue or creating tissue folds, a having a distal end effector may be advanced endoluminally, e.g., transorally, transgastrically, etc., into the patient's body, e.g., the stomach. The tissue may be engaged or grasped and the engaged tissue may be manipulated by a surgeon or practitioner from outside the patient's body. Examples of creating and forming tissue plications may be seen in further detail in U.S. patent application Ser. No. 10/955,245 filed Sep. 29, 2004, which has been incorporated herein by reference above, as well as U.S. patent application Ser. No. 10/735,030 filed Dec. 12, 2003, which is incorporated herein by reference in its entirety.

[0042] In engaging, manipulating, and/or securing the tissue, various methods and devices may be implemented. For instance, tissue securement devices may be delivered and positioned via an endoscopic apparatus for contacting a tissue wall of the gastrointestinal lumen, creating one or more tissue folds, and deploying one or more tissue anchors through the tissue fold(s). The tissue anchor(s) may be disposed through the muscularis and/or serosa layers of the gastrointestinal lumen.

[0043] An illustrative side view of one example of a tool which may be utilized for endoluminally accessing tissue is shown in **FIG. 1A**, which shows assembly 10. The assembly 10 generally comprises a flexible catheter or tubular body 12 which may be configured to be sufficiently flexible for advancement into a body lumen, e.g., transorally, percutaneously, laparoscopically, etc. Tubular body 12 may be configured to be torqueable through various methods, e.g., utilizing a braided tubular construction, such that when handle 16 is manipulated and/or rotated by a practitioner from outside the patient's body, the longitudinal and/or torquing force is transmitted along body 12 such that the distal end of body 12 is advanced, withdrawn, or rotated in a corresponding manner.

[0044] Tissue manipulation assembly 14 is located at the distal end of tubular body 12 and is generally used to contact and form tissue folds, as mentioned above. **FIG. 1B** shows an illustrative detail side view in which tissue manipulation

assembly 14 may be seen connected to the distal end of tubular body 12 via a pivotable coupling 18. Lower jaw member 20 extends distally from the pivotable coupling 18 and upper jaw member 22, in this example, may be pivotably coupled to lower jaw member 20 via jaw pivot 26. The location of jaw pivot 26 may be positioned at various locations along lower jaw 20 depending upon a number of factors, e.g., the desired size of the "bite" or opening for accepting tissue between the jaw members, the amount of closing force between the jaw members, etc. One or both jaw members 20, 22 may also have a number of protrusions, projections, grasping teeth, textured surfaces, etc., 24 on the surface or surfaces of the jaw members 20, 22 facing one another to facilitate the adherence of tissue between the jaw members 20, 22.

[0045] Launch tube 28 may extend from handle 16, through tubular body 12, and distally from the end of tubular body 12 where a distal end of launch tube 28 is pivotally connected to upper jaw member 22 at launch tube pivot 30. A distal portion of launch tube 28 may be pivoted into position within a channel or groove defined in upper jaw member 22, to facilitate a low-profile configuration of tissue manipulation assembly 14. When articulated, either via launch tube 28 or other mechanism, as described further below, jaw members 20, 22 may be urged into an open configuration to receive tissue in jaw opening 32 between the jaw members 20, 22.

[0046] Launch tube 28 may be advanced from its proximal end at handle 16 such that the portion of launch tube 28, which extends distally from body 12, is forced to rotate at hinge or pivot 30 and reconfigure itself such that the exposed portion forms a curved or arcuate shape that positions the launch tube opening perpendicularly relative to upper jaw member 22. Launch tube 28, or at least the exposed portion of launch tube 28, may be fabricated from a highly flexible material or it may be fabricated, e.g., from Nitinol tubing material which is adapted to flex, e.g., via circumferential slots, to permit bending.

[0047] **FIGS. 2A to 2C** illustrate one method for articulating a tissue manipulation assembly into an opened and closed configuration. As shown in **FIG. 2A**, the assembly may be delivered into a patient while in a low-profile configuration 40, e.g., transorally, through an endoscope, an endoscopic device, or directly. Once desirably positioned, launch tube 28 may be urged proximally via its proximal end at handle 16. Because of jaw assembly pivot 18 and the relative positioning of upper jaw pivot 26 along lower jaw member 20 and launch tube pivot 30 along upper jaw member 22, the proximal movement of launch tube 28 may effectively articulate upper jaw 22 into an expanded jaw configuration 42, as shown in **FIG. 2B**. Proximally urging launch tube 28 may also urge lower jaw member 20 to pivot about assembly pivot 18 and form an angle, α , relative to a longitudinal axis of tubular body 12. The opening of upper jaw 22 relative to lower jaw 20 creates jaw opening 32 for grasping or receiving tissue. Moreover, the tissue manipulation assembly may also include a stop located adjacent to jaw assembly pivot 18 or within the pivot 18 itself.

[0048] Once launch tube 28 has been urged proximally, it may be locked into place thus locking the jaw configuration as well. Moreover, having the launch tube 28 articulate the jaw members 20, 22 in this variation eliminates the need for

a separate jaw articulation and/or locking mechanism. Once the tissue has been pulled or manipulated between jaw members 20, 22, launch tube 28 may be pushed distally to actuate the jaw members 20, 22 into a closed, grasping configuration 48, as shown in FIG. 2C, for engagement with the tissue. As launch tube 28 is urged distally through body 12, lower jaw member 20 may be maintained at the angle, *a*, relative to the tissue to further facilitate manipulation of the grasped tissue.

[0049] Launch tube 28 may further define a flexible portion 44 distally of a rigid portion 46. Although launch tube 28 may be fabricated from different materials having differing flexibilities, it may also be fabricated from a single material, as mentioned above, where the flexible portion 44 may be configured, e.g., by slotting, to allow for bending of the launch tube 28 in a plane to form a single curved or arcuate section while the rigid section 46 may extend at least partially into tubular body 12 to provide column strength to launch tube 28 while it is urged distally upon upper jaw member 22 and upon any tissue engaged thereby, as seen in the FIG. 2C.

[0050] Once the tissue has been engaged between jaw members 20, 22, a needle assembly may be urged through handle 16 and out through launch tube 28. The needle assembly may pass through lower jaw member 20 via needle assembly opening 50 defined in lower jaw member 20 to pierce through the grasped tissue. Once the needle assembly has been passed through the engaged tissue, one or more tissue anchors may be deployed for securing the tissue, as described in further detail in U.S. patent application Ser. No. 10/955,245, which has been incorporated by reference above.

[0051] FIGS. 3A and 3B show detail perspective views of the tissue manipulation assembly. As shown in FIG. 3A, lower jaw member 20 and upper jaw member 22 may be seen in its open configuration 42 when the launch tube has been urged proximally. Launch tube channel 52 may also be seen defined within upper jaw member 22 for providing a space for positioning the launch tube when in the low-profile configuration. Also shown is needle assembly opening 50 defined within lower jaw member 20 for passage of the needle assembly therethrough. FIG. 3B shows the assembly in its closed jaw configuration where the launch tube has been urged distally in which it rotates about launch tube pivot 30 such that the opening the launch tube become perpendicular relative to the jaw members 20, 22.

[0052] Although one particular variation of the jaw members 20, 22 is shown, this is not intended to be limiting in jaw member configuration or operation. Other variations may include various placement of the jaws relative to one another, alternative configurations for articulating the jaw members, alternative configurations for the launch tube placement, etc. Other variations are intended to be within the scope of this disclosure.

[0053] As mentioned above, a needle deployment assembly 60 may be deployed through the assembly 10 by introducing needle deployment assembly 60 into the handle 16 and through tubular body 12, as shown in the assembly view of FIG. 4, such that the needle assembly 66 is advanced from the launch tube and into or through approximated tissue. Once the needle assembly 66 has been advanced through the tissue, the anchor assembly 68 may be

deployed or ejected. Anchor assembly 68 is normally positioned within the distal portion of tubular sheath 64, which extends from needle assembly control or housing 62. Once the anchor assembly 68 has been fully deployed from sheath 64, the spent needle deployment assembly 60 may be removed from assembly 10 and another needle deployment assembly may be introduced without having to remove assembly 10 from the patient. The length of sheath 64 is such that it may be passed entirely through the length of tubular body 12 to enable the deployment of needle assembly 66 into and/or through the tissue.

[0054] FIG. 5A shows a detailed assembly view of the needle deployment assembly 60 from FIG. 4. In this variation, elongate and flexible sheath or catheter 64 may extend removably from needle assembly control or housing 62. Sheath or catheter 64 and housing 62 may be interconnected via interlock 70 which may be adapted to allow for the securement as well as the rapid release of sheath 64 from housing 62 through any number of fastening methods, e.g., threaded connection, press-fit, releasable pin, etc. Needle body 72, which may be configured into any one of the variations described above, may extend from the distal end of sheath 64 while maintaining communication between the lumen of sheath 64 and needle opening 74.

[0055] Elongate pusher 76 may comprise a flexible wire or hypotube which is translationally disposed within sheath 64 and movably connected within housing 62. A proximally-located actuation member 78 may be rotatably or otherwise connected to housing 62 to selectively actuate the translational movement of elongate pusher 76 relative to sheath 64 for deploying the anchors from needle opening 74. Anchor assembly 68 may be seen positioned distally of elongate pusher 76 within sheath 64 for deployment from sheath 64. Needle assembly guides 80 may also be seen protruding from housing 62 for guidance through the locking mechanism described above. FIG. 5B shows an exploded assembly view of the needle deployment assembly 60 from FIG. 5A. As seen, sheath 64 may be disconnected from housing 62 via interlock 70 to reveal the elongate pusher 76 connected to housing 62 and the distal and proximal anchors 82, 84, respectively, of anchor assembly 68.

[0056] With respect to the anchor assemblies, the types of anchors shown and described are intended to be illustrative and are not limited to the variations shown. For instance, the tissue anchor variations may also include "T"-type anchors while other variations may include reconfigurable "basket"-type anchors, which may generally comprise a number of configurable struts or legs extending between at least two collars or support members or reconfigurable mesh structures extending between the two collars. Other variations of these or other types of anchors are also contemplated for use in an anchor assembly. Moreover, a single type of anchor may be used exclusively in an anchor assembly; alternatively, a combination of different anchor types may be used in an anchor assembly. Furthermore, the different types of cinching or locking mechanisms are not intended to be limited to any of the particular variations shown and described but may be utilized in any of the combinations or varying types of anchors as practicable.

[0057] Other variations for the needle assemblies and for the anchors are described in further detail in U.S. patent application Ser. No. 10/955,245, which has been incorporated by reference above.

[0058] In operation when manipulating and securing tissue within a patient's body, a separate elongate shaft having a tool on or near the distal end of the shaft may be utilized in conjunction with the tissue manipulation assembly 14. Such tools are generally utilized in endoluminal procedures where the tools are delivered through an endoscope. Generally, several different tools may be utilized for performing a procedure endoluminally.

[0059] As illustrated in FIG. 6, one such example is shown in which a shape-lockable endoscopic assembly 90 may be advanced into a patient's stomach S per-orally and through the esophagus E. Such an endoscopic assembly 90 may generally comprise an endoscopic device which may have a distal portion which may be articulated and steered to position its distal end anywhere within the stomach S. Once desirably configured, assembly 90 may then be locked or rigidized to maintain its shape or configuration to allow for procedures to be performed on the tissue utilizing any number of tools delivered through the assembly 90. Shape-lockable assembly 90 and its variations are described in further detail in U.S. patent application Ser. No. 10/734,562 filed Dec. 12, 2003, which is incorporated herein by reference in its entirety.

[0060] Shape-lockable assembly 90 may be generally comprised of shape-lockable endoscopic body 92 having an articulatable distal portion 96. The endoscopic body 92 may define at least first and second lumens 98, 100, respectively, through the endoscopic body 92 through which one or more tools may be deployed into the stomach S. Additional lumens may be provided through shape-lockable endoscopic body 92, such as a visualization lumen 101, through which an endoscope may be positioned to provide visualization of the region of tissue. Alternatively, an imager such as a CCD imager or optical fibers may be provided in lumen 101 to provide visualization. An optional thin wall sheath 94 may be disposed through the patient's mouth, esophagus E, and possibly past the gastroesophageal junction GEJ into the stomach S. Shape-lockable body 92 may be advanced through esophagus E (and through sheath 94, if utilized) and into stomach S while disposed in a flexible state.

[0061] Distal steerable portion 96 of endoscopic body 92 may be then articulated to an orientation, e.g., whereby distal portion 96 facilitates engagement of tissue near and/or inferior to the patient's gastroesophageal junction GEJ. Accordingly, distal steerable portion 96 may comprise a number of steering features, as described in further detail in U.S. patent application Ser. No. 10/734,562, incorporated above. With distal steerable portion 96 disposed in a desired configuration or orientation, endoscopic body 92 may be reversibly shape-locked to a rigid state such that the endoscopic body 92 maintains its position within the stomach S. Various methods and apparatus for rigidizing endoscopic body 92 along its length are also described in further detail in U.S. patent application Ser. No. 10/734,562, incorporated above.

[0062] FIG. 6 shows tissue manipulation assembly 14 having been advanced through first lumen 98 and a tissue engagement member 102 positioned upon flexible shaft 104 advanced through second lumen 100. As the tissue wall of a body lumen, such as the stomach, typically comprises an inner mucosal layer, connective tissue, the muscularis layer and the serosa layer. To obtain a durable purchase, e.g., in

performing a stomach reduction procedure, tissue engagement member 102 may be advanced into contact with the tissue and preferably engages the tissue F such that when the tissue engagement member 102 is pulled proximally to draw the engaged tissue F between the jaw members 20, 22 of tissue manipulation assembly 14, at least the muscularis tissue layer and the serosa layer is drawn into tissue manipulation assembly 14.

[0063] As tissue manipulation assembly 14 may be utilized to grasp and secure the engaged tissue, any number of tools may be utilized with tissue manipulation assembly 14, e.g., through shape-lockable endoscopic body 92, to engage and manipulate the tissue of interest relative to tissue manipulation assembly 14. FIG. 7 illustrates tissue manipulation assembly 14 upon flexible body 12 with handle 16 and examples of various tools which may be used in combination with tissue manipulation assembly 14.

[0064] Turning to FIG. 7, one example of a tool utilizable in combination with tissue manipulation assembly 14 is shown in tissue engagement member 102 as a tissue piercing helix or corkscrew structure upon flexible shaft 104 (as shown in FIG. 6). Tissue engagement member 102 may be rotated about its longitudinal axis to engage the tissue of interest by rotating handle 106 located on the proximal end of flexible shaft 104. Alternatively, a tool having aggressive tissue graspers 108 positioned upon flexible shaft 110 and articulatable via handle 112 may be utilized in combination with tissue manipulation assembly 14. Another alternative tool may be tissue graspers 114 positioned upon flexible shaft 116 and articulatable via handle 118. Tissue graspers 114 may have atraumatic grasping surfaces. In yet another alternative, an endoscope 122 having optical fibers or imager 120 may be utilized for providing visualization. Endoscope 122 may be articulated via handle 124 at its proximal end.

[0065] The examples of the various tools as shown and described are intended merely to be illustrative of the range of tools which may be usable with assembly 14 and are not intended to be limiting in any manner. Any number of other tools may be accordingly utilized and are intended to be within the scope of this disclosure.

[0066] An example of performing an endoluminal tissue manipulation and securement procedure utilizing tissue manipulation assembly 14 in combination with a separate tissue grasping tool within, e.g., a patient's stomach, is illustrated in FIGS. 8A to 8D. As shown in FIG. 8A, once shape-lockable endoscopic body 92 has been introduced into the patient, e.g., trans-orally, trans-anally, percutaneously, etc., and desirably positioned relative to a tissue region of interest 130, endoscopic body 92 may be rigidized to maintain its configuration within the patient body. Alternatively, it may be left in a flexible state during the procedure.

[0067] The tissue region of interest 130 as well as the procedure may be visualized through visualization lumen 101 or a separate imager, as described above. In either case, tissue manipulation assembly 14 and tissue engagement member 102 may be advanced distally out from endoscopic body 92 through their respective lumens 98, 100. Tissue engagement member 102 may be advanced into contact against the tissue surface, as shown in FIG. 8A, and then rotated via its proximal handle until the tissue is engaged. The engaged tissue F may be pulled proximally relative to

endoscopic body 92 and tissue manipulation assembly 14 may be actuated via its proximally located handle into an open expanded jaw configuration for receiving the engaged tissue F, as shown in FIG. 8B.

[0068] Alternatively, once the tissue F has been engaged, tissue manipulation assembly 14 may be advanced distally in its open configuration onto the engaged tissue. In yet another variation, tissue engagement member 102 may be omitted entirely and tissue manipulation assembly 14 may be utilized alone to grasp onto the tissue region of interest 130. In yet another alternative, a second tissue manipulation assembly may be used in combination with tissue manipulation assembly 14.

[0069] Turning back to FIG. 8B, tissue manipulation assembly 14 may be articulated to receive the engaged tissue F. As shown in FIG. 8C, once engaged tissue F is positioned between jaw members 20, 22, the launch tube may be urged proximally to actuate upper jaw member 22 to grasp or clamp upon the tissue F. Tissue engagement member 102 may be retracted from the tissue F or it may be left within the tissue while tissue manipulation assembly engages and secures the tissue F.

[0070] FIG. 8D shows a partial cross-sectional view of the tissue F while engaged to tissue manipulation assembly 14. Tissue engagement member 102 has been omitted from this view only for the sake of clarity. As mentioned above, member 102 may be left remaining in the tissue F, disengaged from tissue F, or disengaged and removed entirely from endoscopic body 92, if so desired, and another tool may be advanced through lumen 100 to facilitate the procedure. Once jaw members 20, 22 have been actuated to clamp or grasp upon tissue F by the launch tube, the launch tube may be automatically positioned into its anchor deployment configuration. The needle assembly may then be urged via manipulation from its proximal end at handle 16 through the launch tube to pierce preferably through a dual serosa layer through engaged tissue F and past lower jaw member 20. As described above, the engaged tissue F positioned between the jaw members 20, 22 is desirably engaged such that the needle body 72, when urged through the tissue F, is disposed through the muscularis and/or serosa layers of the engaged tissue F. Once needle body 72 has passed through tissue F, one or more expandable tissue anchors may be ejected from needle body 72 through needle opening 74.

[0071] Because needle body 72 may penetrate the tissue wall twice, it exits within the body lumen if utilized within, e.g., the stomach, thus reducing the potential for injury to surrounding organs. As described above, needle body 72 may define needle lumen or opening 74 through which an expandable anchor, e.g., distal anchor 82 and/or proximal anchor 84, may be situated during deployment and positioning of the assembly. A single suture or flexible element 132 (or multiple suture elements) may connect distal anchor 82 and proximal anchor 84 to one another and end in terminal loop 134. For instance, element 132 may comprise various materials such as monofilament, multifilament, or any other conventional suture material, elastic or elastomeric materials, e.g., rubber, etc.

[0072] Once distal anchor 82 has been ejected, needle body 72 may be urged proximally back through tissue F, where proximal anchor 84 may then be ejected from needle body 72 with suture 132 still connecting the two anchors 82,

84 through tissue F. Alternatively, tissue manipulation assembly 14, with suture 132 still depending therefrom, may be disengaged from tissue F and the procedure may be repeated at a second region of tissue where proximal anchor 84 may then be ejected.

[0073] FIG. 9A shows one variation where a single fold F may be secured between proximal anchor 82 and distal anchor 84. With both anchors 82, 84 disposed externally of the launch tube and suture 132 connecting the two, proximal anchor 84 may be urged into contact against tissue F. As the anchors are urged against tissue fold F, distal anchor 82 or a portion of suture 132 may be configured to provide any number of directionally translatable locking mechanisms 136 which provide for movement of an anchor along suture 132 in a first direction and preferably locks, inhibits, or prevents the reverse movement of the anchor back along suture 132.

[0074] FIG. 9B shows another variation where a at least two folds F_1 and F_2 may be secured between proximal anchor 82 and distal anchor 84. After the anchors have been ejected from needle body 72, the anchors may be approximated towards one another over suture 132 thus bringing folds F_1 and F_2 towards one another. Although a single tissue fold and a dual fold are shown in these examples, any number of folds or tissue ridges may be created using the tools disclosed herein. Moreover, these examples are merely intended to be illustrative and not limiting in any way. In either case, it may be generally desirable to form the tissue folds such that serosa-to-serosa contact 138 occurs between the layers of secured tissue, although this may not be necessary.

[0075] Various examples of cinching devices and methods which may be utilized with the tools and devices herein are described in further detail in U.S. patent application Ser. No. 10/840,950 filed May 7, 2004, which has been incorporated herein above.

[0076] In using the launch tube as a jaw actuation mechanism, other variations of the launch tube may be utilized to ensure sufficient strength and force transmission in tissue manipulation assembly 14 for jaw member actuation. One such example is shown in the perspective view of FIG. 10A, which shows launch tube 44 having a number of reinforcement members or bars 140 aligned along one or both sides of the launch tube to provide for additional column strength. Each of the reinforcement members 140 may be pivotally attached to launch tube 44 via pivot members 144 rotatably secured within pivot channels 142, as seen in the launch tube cross-section in FIG. 10B. Moreover, each of the pivot members 144 may define cooperating adjacent members relative to one another while maintaining contact to allow for the transmission of force between the members 144. Pivot members 144 may be positioned along the length of the exposed launch tube or a portion of the launch tube; moreover, a single side of the launch tube may have pivot members 144 attached thereto. Alternatively, rather than utilizing pivot members, portions of the launch tube itself may be simply thickened to increase its column strength and force transmission capabilities.

[0077] In another variation, as shown in FIG. 11A and the launch tube cross-section in FIG. 11B, a pull wire 152 may be routed through tubular body 12 and launch tube 44 through a pull wire lumen 150 to provide a launch tube and

jaw actuation mechanism separate from the launch tube actuation itself. Pull wire 152 may be manipulated via its proximal end at handle 16 by pulling or pushing pull wire 152 to actuate launch tube 44 and/or jaw members 20, 22. Alternatively, as seen in FIG. 12, pull wire 152 may be routed through tubular body 12 and connected directly to launch tube 44 at pull wire attachment point 154 rather than routing it through the launch tube. Again, manipulation of pull wire 152 may be utilized to articulate the launch tube configuration as well as jaw member articulation.

[0078] Referring now to FIGS. 13 and 14, a variation of the anchor assembly and the needle deployment assembly is described. As with previously described needle deployment assembly 60, assembly 60' comprises needle assembly control or housing 62, tubular sheath 64 and needle assembly 66 having needle body 72 with opening 74. Elongate pusher 76 is configured for translation within sheath 64 via actuation member 78. Pusher 76 illustratively comprises a hypotube having lumen 77 defined therethrough.

[0079] In the variation of FIGS. 13 and 14, locking mechanism 136 of anchor assembly 68' is disposed proximal of proximal anchor 84, and the anchor assembly is positioned within the distal portion of tubular sheath 64, such that the distal region of pusher 76 abuts locking mechanism 136. Suture or flexible element 132' comprising distal knot or protrusion 133 extends proximally from the knot in a manner that connects distal anchor 82, proximal anchor 84 and locking mechanism 136. Element 132' then further extends through lumen 77 of pusher 76 to a proximal region of assembly 60' such that element 132' may be manipulated by a medical practitioner from outside a patient. The medical practitioner may, for example, engage previously described suture loop 134, or may engage some other control element 134', such as a ring or handle, disposed at the proximal end of suture element 132'. As will be apparent, in another variation, element 132' may extend to the proximal region of assembly 60' alongside pusher 76 rather than within a lumen of the pusher.

[0080] With reference to FIGS. 15, a method of using anchor assembly 68' and needle deployment assembly 60' is described. For the purposes of illustration, the assemblies are shown securing tissue without use of a tissue manipulation assembly. However, it should be understood that the assemblies alternatively may be used in combination with a tissue manipulation assembly, such as previously described tissue manipulation assembly 14 of assembly 10.

[0081] In FIG. 15A, needle deployment assembly 60' has been positioned in proximity to approximated tissue T. The assembly is advanced such that needle assembly 66 pierces the tissue and is advanced through and across the tissue, as in FIG. 15B. Pusher 76 is advanced within the lumen of sheath 64 via actuation member 78, such that distal anchor 82 of anchor assembly 68' is ejected through opening 74 of needle body 72 of needle assembly 66 on the distal side of approximated tissue T. Needle deployment assembly 60' and pusher 76 then are retracted such that the pusher and needle assembly 66 again are disposed on the proximal side of the approximated tissue, as in FIG. 15C. Next, pusher 76 is distally advanced relative to sheath 64 to eject proximal anchor 84 from the sheath.

[0082] In FIG. 15D, with the proximal and distal anchors of anchor assembly 68' disposed 25 on either side of the

approximated tissue, the anchor assembly is cinched by retracting control element 134' relative to needle deployment assembly 60'. Pusher 76 abuts locking mechanism 136 and urges it distally during proximal retraction of element 134', which shortens the length of suture element 132' disposed between distal anchor 82 and proximal anchor 84, thereby cinching anchor assembly 68'. Locking mechanism 136 ensures that the 30 anchors remain cinched by resisting distal passage of element 132' through the mechanism, thereby resisting subsequent separation of the proximal and distal anchors.

[0083] With anchor assembly 68' cinched, pusher 76 is retracted relative to sheath 64 such that needle assembly 66 engages suture element 132', as in FIG. 15E. The needle assembly cuts the suture proximal of locking mechanism 136, as in FIG. 15F. The medical practitioner may facilitate cutting of the suture element by manipulating control element 134' of anchor assembly 68' and/or by manipulating needle assembly control 62 of needle deployment assembly 60'.

[0084] Referring now to FIG. 16, a variation of the suture element of anchor assembly 68' is described. In FIG. 16, suture element 132" comprises segment 135 of reduced integrity. The segment may for example, comprise fewer suture strands or may be reduced in integrity via chemical, electrical, thermal or physical processing, etc. Segment 135 may locally reduce the tensile strength of element 132" to a desired threshold. When used to cinch anchor assembly 68' in combination with anchor deployment assembly 60', the segment may obviate a need to cut the suture with needle assembly 66 after cinching of the anchor assembly. Specifically, the anchor assembly may be cinched to a desired tension after which segment 135 plastically deforms and snaps, leaving the anchor assembly cinched and in place.

[0085] With reference to FIG. 17, a variation of the needle assembly of needle deployment assembly 60' is described. Needle body 72' of needle assembly 66' may comprise one or more recessed cut-outs 73 having sharpened edges E for cutting the suture element. After cinching of anchor assembly 68', the suture element may be snagged within a cut-out 73 and cut by the sharpened edge of the cut-out.

[0086] Referring now to FIG. 18, alternative control mechanisms for needle deployment assembly 60' are described. Actuation member 78' for controlling pusher 76 may be integrated with needle assembly control 62', such that the actuation member is advanceable in controlled increments relative to the needle assembly control via detents 63 of the needle assembly control that coast with actuation member 78'.

[0087] With reference to FIGS. 19, another variation of the anchor assembly and needle deployment assembly is shown. Control element 134' of anchor assembly 68' is coupled to or abuts needle assembly control 62' of needle deployment assembly 60'. When distal anchor 82 of anchor assembly 68' is disposed on the distal side of approximated tissue T, as in FIG. 19A, the proximal and distal ends of suture element 132' are constrained. Thus, as seen in FIGS. 19A and 19B, advancement of pusher 76 via actuation member 78' advances both proximal anchor 84 and locking mechanism 136 of anchor assembly 68'. This causes the anchor assembly to be progressively cinched as the proximal anchor is advanced. Once the anchor assembly has been

ejected from sheath 64, as in FIG. 19B, and adequately cinched, as in FIG. 19C, suture element 132' may be cut proximal of the locking mechanism, e.g., with needle assembly 66 as described previously.

[0088] Referring to FIGS. 20, a variation of the needle deployment assembly is described. Pusher 76' comprises suture ports 79 through which suture element 132 of anchor assembly 68' is routed. As seen in FIG. 20A, with pusher 76' disposed within tubular sheath 64 of needle deployment assembly 60', suture element 132' passes out of the pusher between the suture ports and is disposed between the pusher and the interior wall of the tubular sheath. As seen in FIG. 20B, when pusher 76' is advanced through and distal of needle assembly 66, e.g., to eject proximal anchor 84 of anchor assembly 68' from the needle deployment assembly and/or to cinch the anchor assembly, the section of suture element 132' between the suture ports is exposed. Subsequent retraction of the pusher relative to the needle assembly causes the section of exposed suture to contact the sharpened edge of needle assembly 66, thereby severing suture element 132' as in FIG. 20C.

[0089] Turning now to FIGS. 21, another variation of the needle deployment assembly is shown. In this variation, suture element 132''' may form a terminal loop 158 through which a release suture or wire 156 may be passed. Release suture or wire 156 may be routed through the length of the needle deployment assembly and through pusher 76, as described above, and both release suture or wire 156 and terminal loop 158 may both be situated within pusher 76, as shown in FIG. 21A. After deployment of the anchors into tissue and cinching of the assembly, as described above, one end of release suture or wire 76 may be pulled or tensioned proximally in the direction shown by arrow 162, as in FIG. 21B. This pulling may draw a terminal end of release suture or wire 156 through pusher 76 until terminal loop 158 of suture element 132''' has been released therefrom, as shown in FIG. 21C.

[0090] In yet another variation shown in FIG. 22A, terminal loop 158 of suture element 132''' may be seen restrained within pusher 76 via reconfigurable hook 164 of release wire 156'. Here, release wire 156' may be fabricated from a shape memory or superelastic alloy material, such as Nitinol, which has been preformed to reconfigure its terminal end from a hook 164 configuration to a straightened or opened configuration once released from the constraints of pusher 76. Thus, after deployment and cinching of the anchor assembly, release wire 156' may be advanced distally through pusher 76, as shown in FIG. 22B, until reconfigurable hook 164, which is retained in a hooked or obstructive configuration within the lumen of pusher 76, has been advanced out of pusher 76. Once free from the constraints of the lumen, hook 164 may reconfigure itself into an opened or straightened configuration to thereby release terminal loop 158 of suture element 132''', as shown in FIG. 22C. Hook 164 having released terminal loop 158, may then be withdrawn proximally back into pusher 76 in its straightened configuration.

[0091] In another variation shown in FIG. 23A, a terminal end of suture element 132''' may have an obstructive or enlarged element 160, e.g., a knot, formed thereon. The terminal end of suture element 132''' with obstructive element 160 may be looped around release suture or wire 156

and retained within the lumen of pusher 76. After anchor deployment and cinching, release suture or wire 156 may be drawn distally with looped obstructive element 160 retained securely thereto, as shown in FIG. 23B, until obstructive element 160 and release suture or wire 156 have been advanced out of pusher 76. Once free from the constraints of the pusher lumen, obstructive element 160 may be released from release suture or wire 156, as shown in FIG. 23C, to thus release suture element 132'''.

[0092] Although a number of illustrative variations are described above, it will be apparent to those skilled in the art that various changes and modifications may be made thereto without departing from the scope of the invention. Moreover, although specific configurations and applications may be shown, it is intended that the various features may be utilized in various combinations and in various types of procedures as practicable. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What is claimed is:

1. An anchor deployment assembly comprising:

at least one tissue anchor having a length of suture depending therefrom; and

an elongate member configured for advancement within a body lumen,

wherein the elongate member is configured to deploy the at least one tissue anchor, and

wherein the elongate member is further configured to disengage the suture at a location proximal to the at least one tissue anchor upon deployment of the at least one tissue anchor.

2. The anchor deployment assembly of claim 1, wherein the elongate member is configured to sever the suture at the proximal location upon deployment of the at least one tissue anchor.

3. The anchor deployment assembly of claim 2, wherein the elongate member comprises a needle assembly having a piercing tip, the piercing tip configured to sever the suture.

4. The anchor deployment assembly of claim 3, wherein the needle assembly defines at least one cut-out having sharpened edges for severing the suture.

5. The anchor deployment assembly of claim 1 further comprising a tissue grasping tool adapted to be advanced endoluminally into a body lumen, wherein the anchor deployment assembly is configured for advancement through the tissue grasping tool.

6. The anchor deployment assembly of claim 5, wherein the tissue grasping tool further comprises a first jaw member, a second jaw member pivotably coupled along the first jaw member, and a launch tube member adapted to urge the first and second jaw members between a low-profile delivery configuration and an expanded grasping configuration.

7. The anchor deployment assembly of claim 6, wherein the anchor deployment assembly is configured for advancement through the launch tube member.

8. The anchor deployment assembly of claim 6 wherein a distal end of the launch tube member is pivotably coupled to the second jaw member.

9. The anchor deployment assembly of claim 5 further comprising a tissue engagement device having a distal end effector adapted to reversibly engage tissue and further

adapted to be positioned endoluminally within the body lumen adjacent to the tissue grasping tool.

10. The anchor deployment assembly of claim 9 wherein the distal end effector comprises a helical member having a tissue piercing tip.

11. The anchor deployment assembly of claim 9 wherein the distal end effector comprises a grasper for reversibly engaging the tissue.

12. The anchor deployment assembly of claim 1 further comprising an endoscopic device having a flexible body, the flexible body adapted to be rigidized to maintain an arbitrary shape, wherein the anchor deployment assembly is configured for advancement through the endoscopic device.

13. The anchor deployment assembly of claim 12, wherein the endoscopic device comprises a steerable distal section.

14. A method of securing tissue within a hollow body organ, comprising:

advancing a needle of an anchor deployment assembly through engaged tissue;

deploying a distal tissue anchor through the needle on a distal side of the engaged tissue;

retracting the needle to a proximal side of the engaged tissue;

deploying a proximal tissue anchor through the needle on the proximal side of the engaged tissue; and

severing a suture element connecting the proximal and distal tissue anchors with the needle proximal of the proximal anchor, thereby releasing the proximal and distal anchors from the anchor deployment assembly.

15. The method of claim 14 further comprising cinching the proximal and distal anchors to secure the engaged tissue prior to severing the suture element.

16. The method of claim 14, wherein severing the suture element with the needle further comprises severing the suture element via sharpened cut-outs defined in the needle.

17. The method of claim 14 wherein deploying the proximal and distal anchors through the needle further comprises advancing a pusher through the needle.

18. The method of claim 14 further comprising, prior to advancing the needle through the engaged tissue, endoluminally advancing a tissue grasping tool pivotably coupled to a distal end of an elongate member into the hollow body organ;

reversibly engaging the tissue within the hollow body organ with a distal end effector positioned adjacently to the tissue grasping tool; and

clamping the engaged tissue with the tissue grasping tool.

19. The method of claim 18 wherein endoluminally advancing comprises advancing the tissue grasping tool transesophageally into a stomach.

20. The method of claim 18 further comprising, prior to advancing the needle through the engaged tissue, positioning the anchor deployment assembly at least partially within the tissue grasping tool.

21. A method of securing tissue within a hollow body organ, comprising:

deploying a tissue anchor assembly through a needle of an anchor deployment assembly, thereby securing engaged tissue; and

severing a suture element attached to the tissue anchor assembly with the needle proximal of the proximal anchor, thereby releasing the tissue anchor assembly from the anchor deployment assembly.

* * * * *

专利名称(译)	用于固定和展开组织锚的方法和设备		
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申请(专利权)人(译)	USGI MEDICAL INC.		
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外部链接	Espacenet USPTO		

摘要(译)

本文描述了用于固定和展开组织锚的方法和装置。组织操纵组件可枢转地联接到管状构件的远端。可重新配置的发射管也可枢转地耦合到组织操纵组件，其可以通过可形状锁定的内窥镜装置，传统的内窥镜或者直接自身进入患者体内。第二工具可以与组织操纵组件结合使用，以与组织操纵组件一起接合组织并操纵组织。提供了一种展开组件，用于通过一个或多个组织锚固件来固定接合的组织，该展开组件还被配置成在腔内或腹腔镜下脱离锚固件。

