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(54) **ANASTOMOSIS WIRE RING DEVICE**

(57) **ABSTRACT**

(76) Inventors: **Don A. Tanaka**, Saratoga, CA (US);
Mark S. Ortiz, Milford, OH (US);
Darrel Powell, Cincinnati, OH (US)

Correspondence Address:
FROST BROWN TODD, LLC
2200 PNC CENTER
201 E. FIFTH STREET
CINCINNATI, OH 45202 (US)

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An anastomotic ring device for forming a hollow rivet (ring) attachment between tissue lumens facilitates laparoscopic or endoscopic implantation by including features that facilitate actuation from a stressed, generally cylindrical shape. Economical manufacturer is achieved by weaving open ended strands into a generally cylindrical stent shape that is imparted with a Shape Memory Effect (SME) to actuate to a hollow rivet (ring) shape. Alternatively or in addition to SME inherent in the woven strands, an actuating force may be received from a helical spring element incorporated into the ring. Self-actuating ring devices are enhanced by forming woven strands into petals that diverge from opposing petals such that the strands encounter less friction when actuating. Each of these features alone or in combination enhance clinical use of anastomotic ring devices, such as a bariatric gastric bypass procedure.

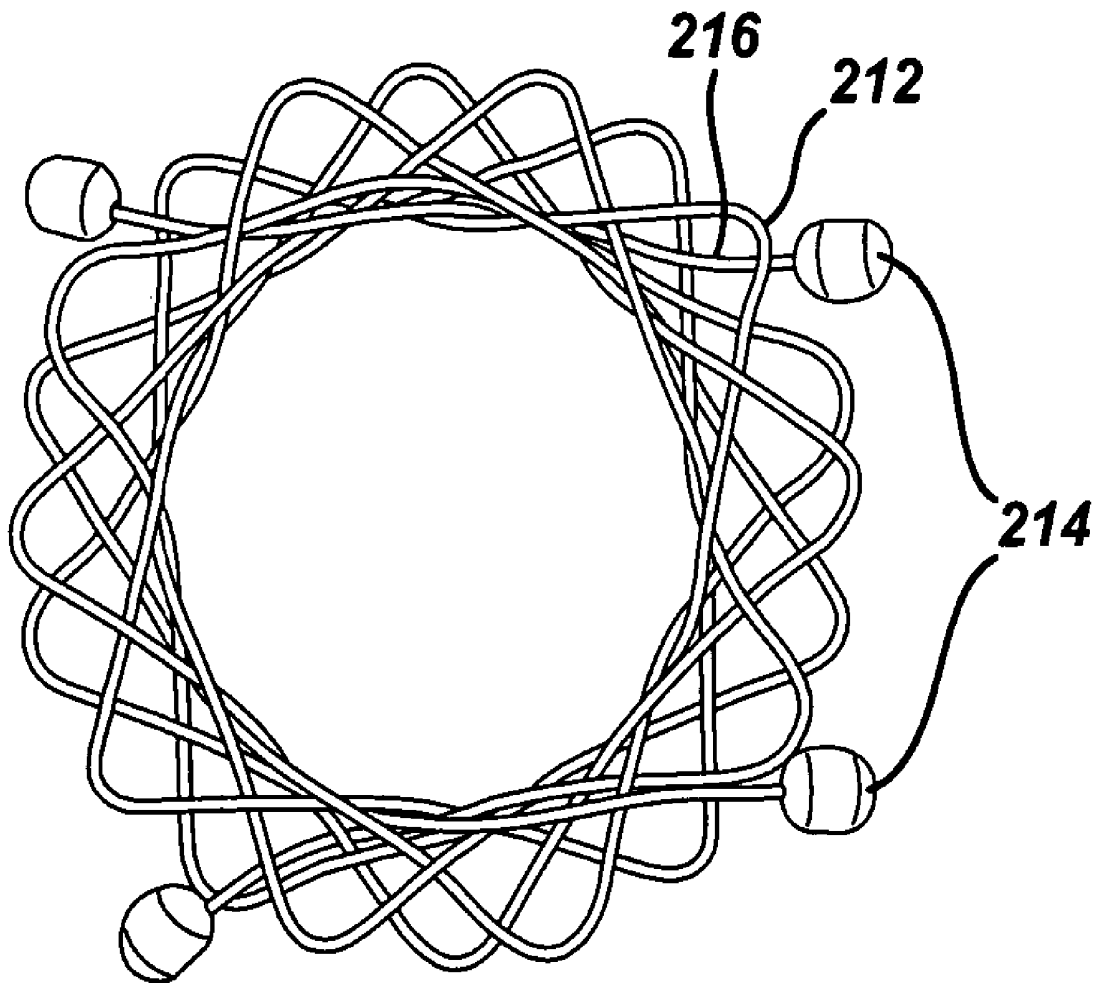
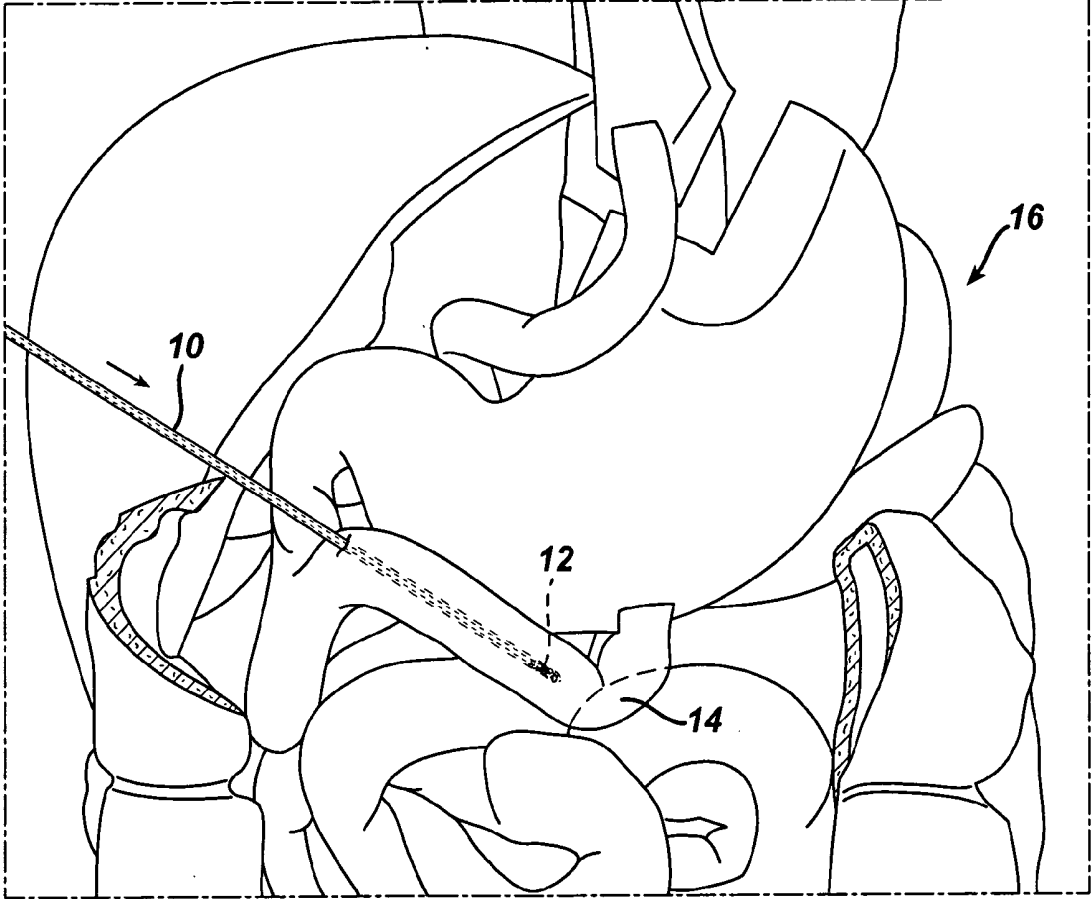
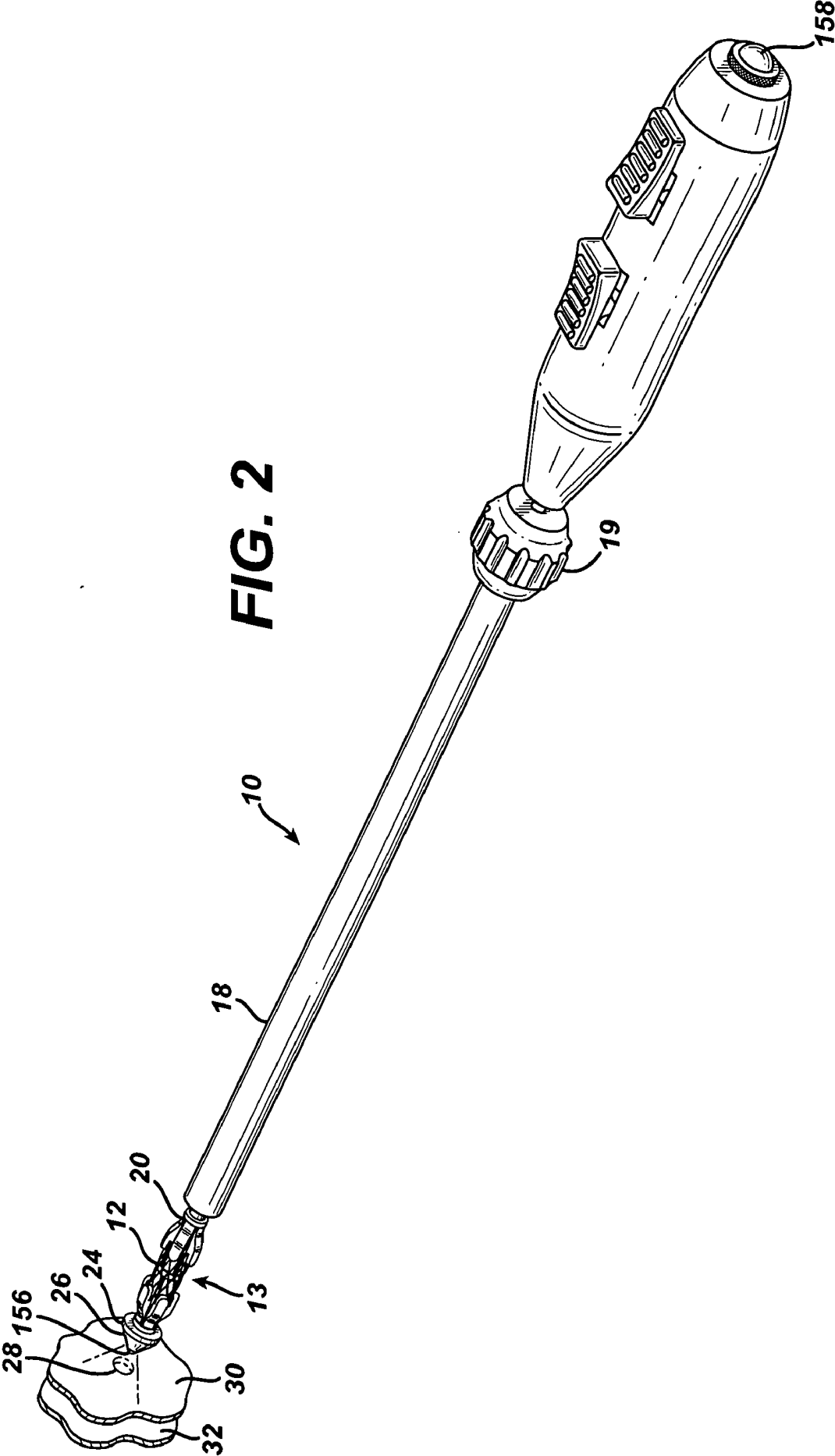
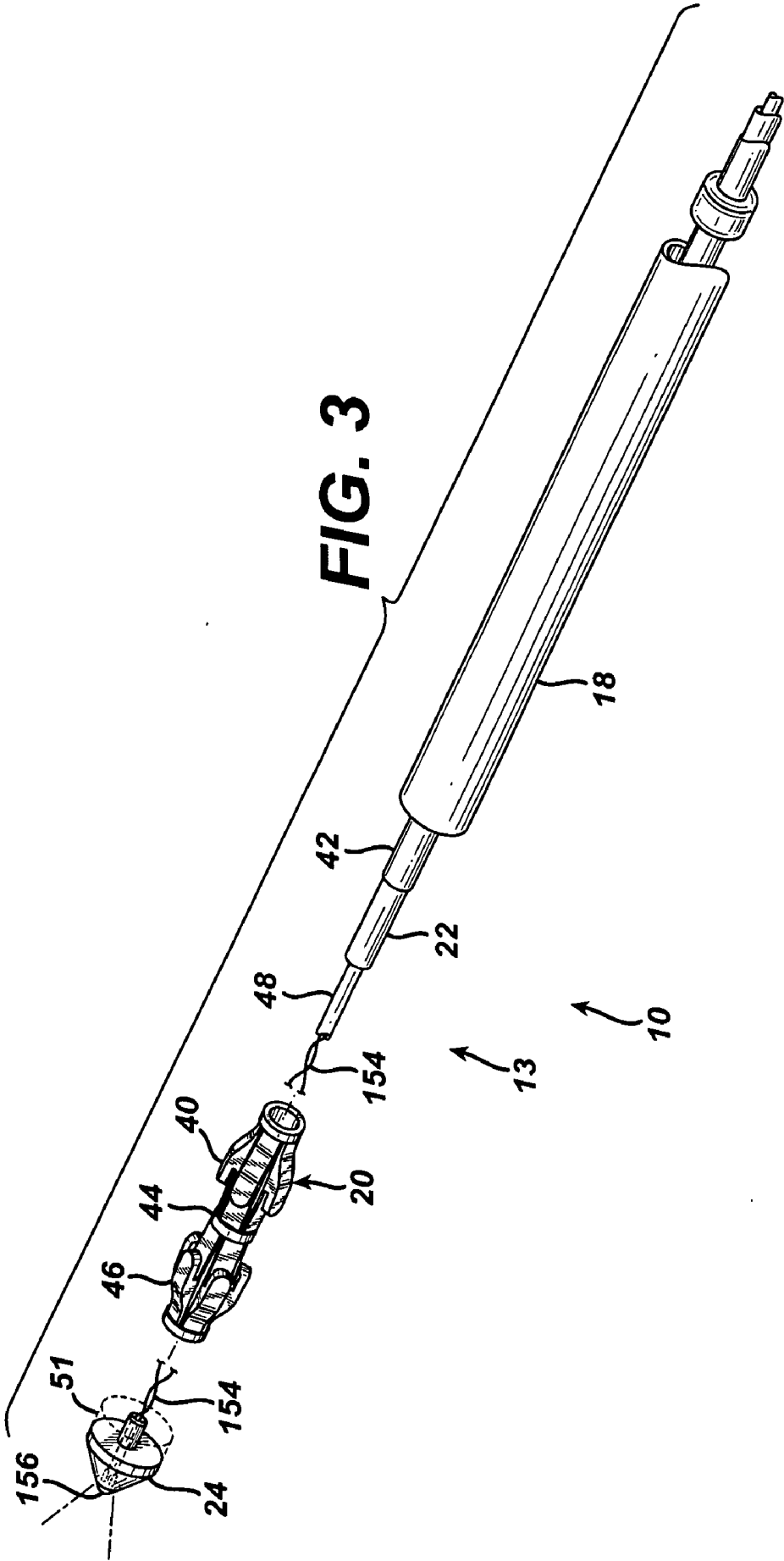


FIG. 1







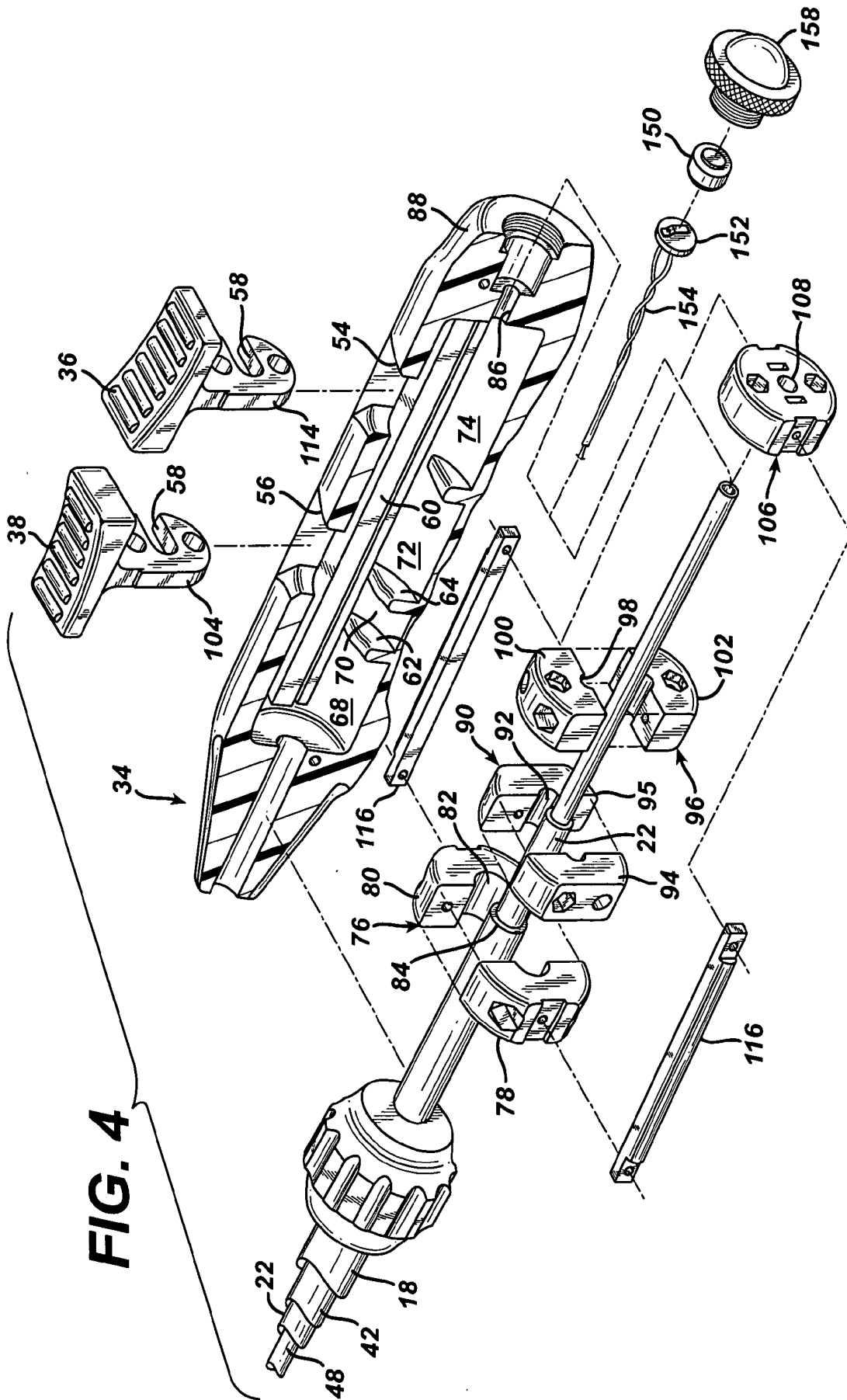
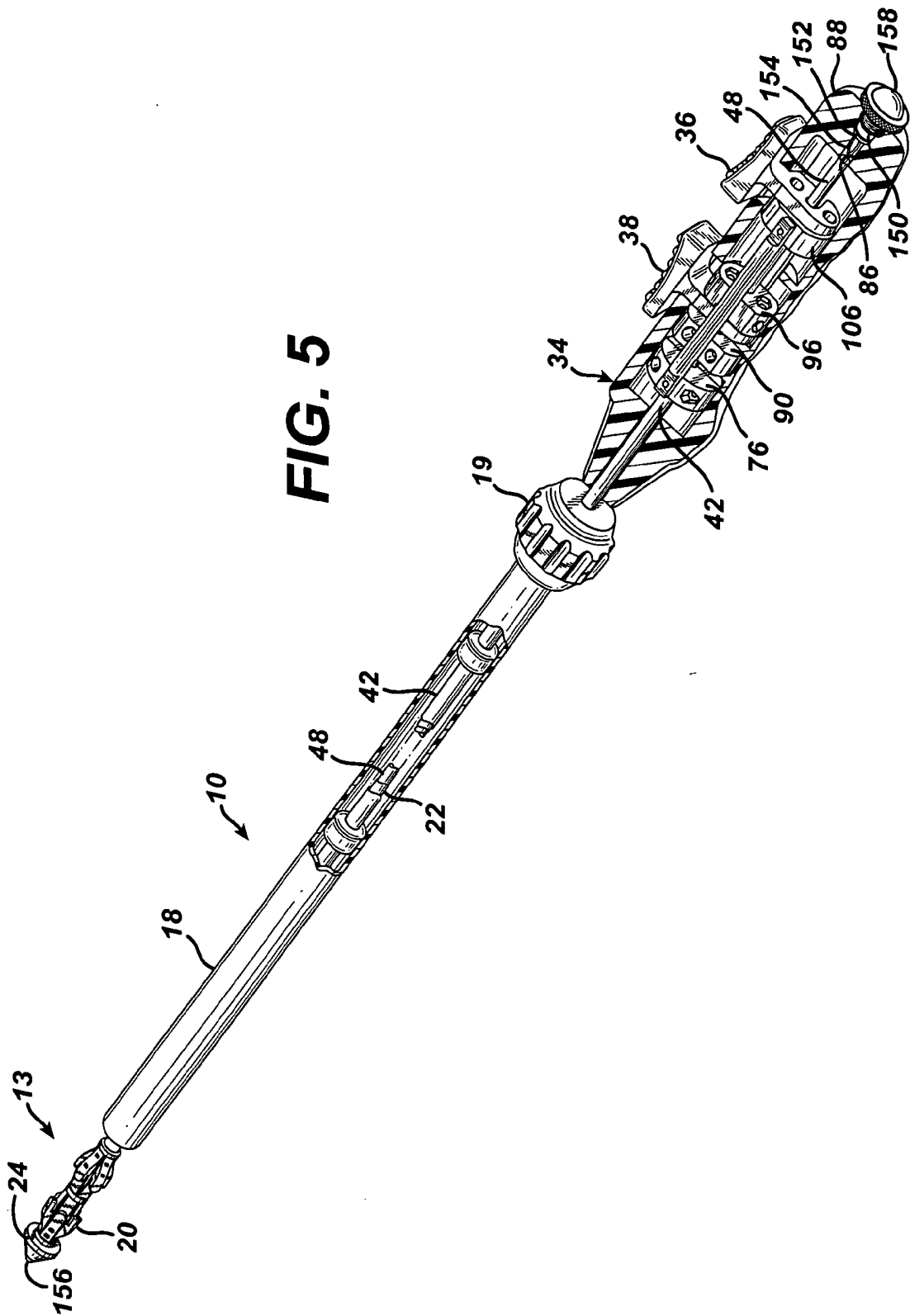
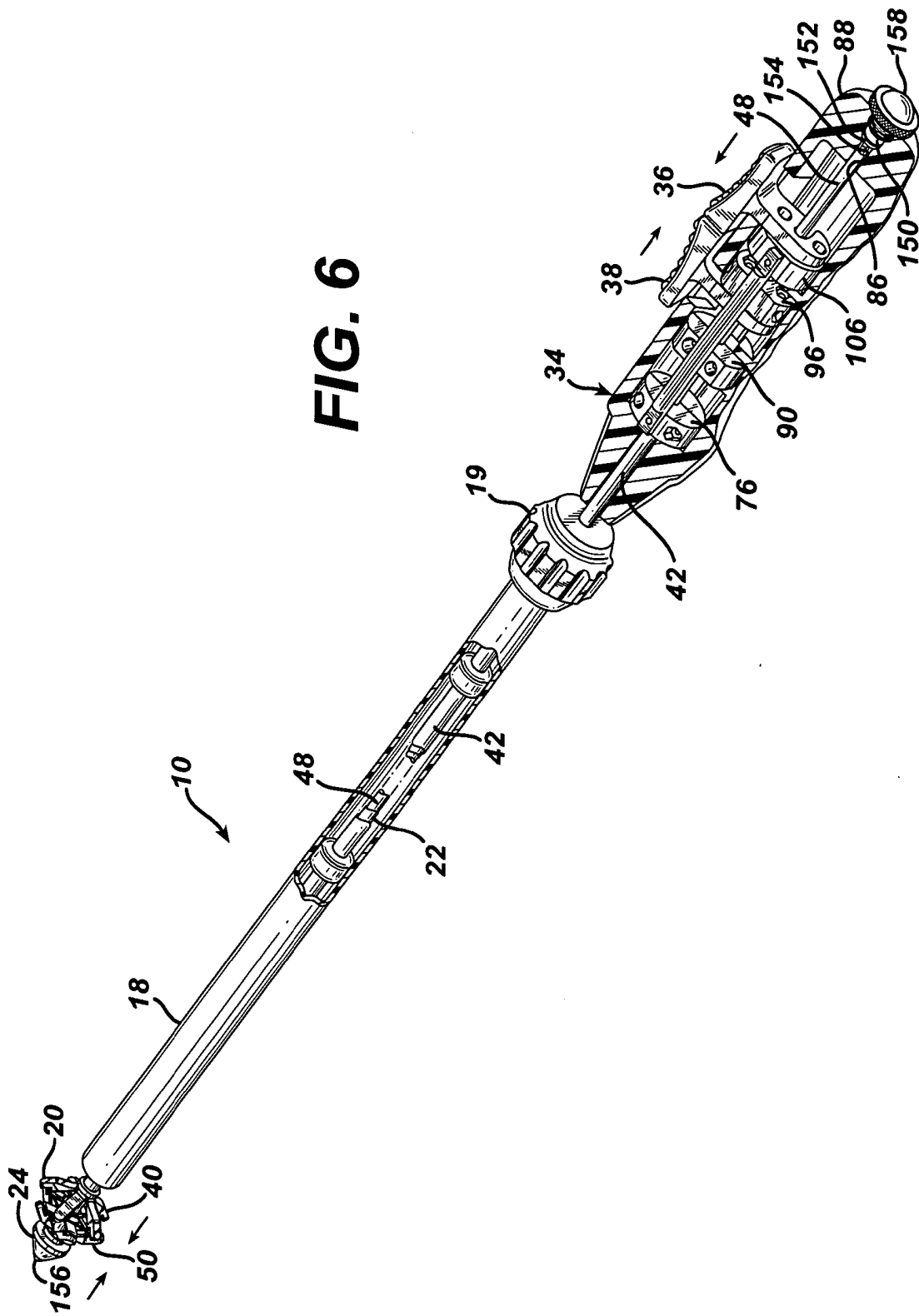
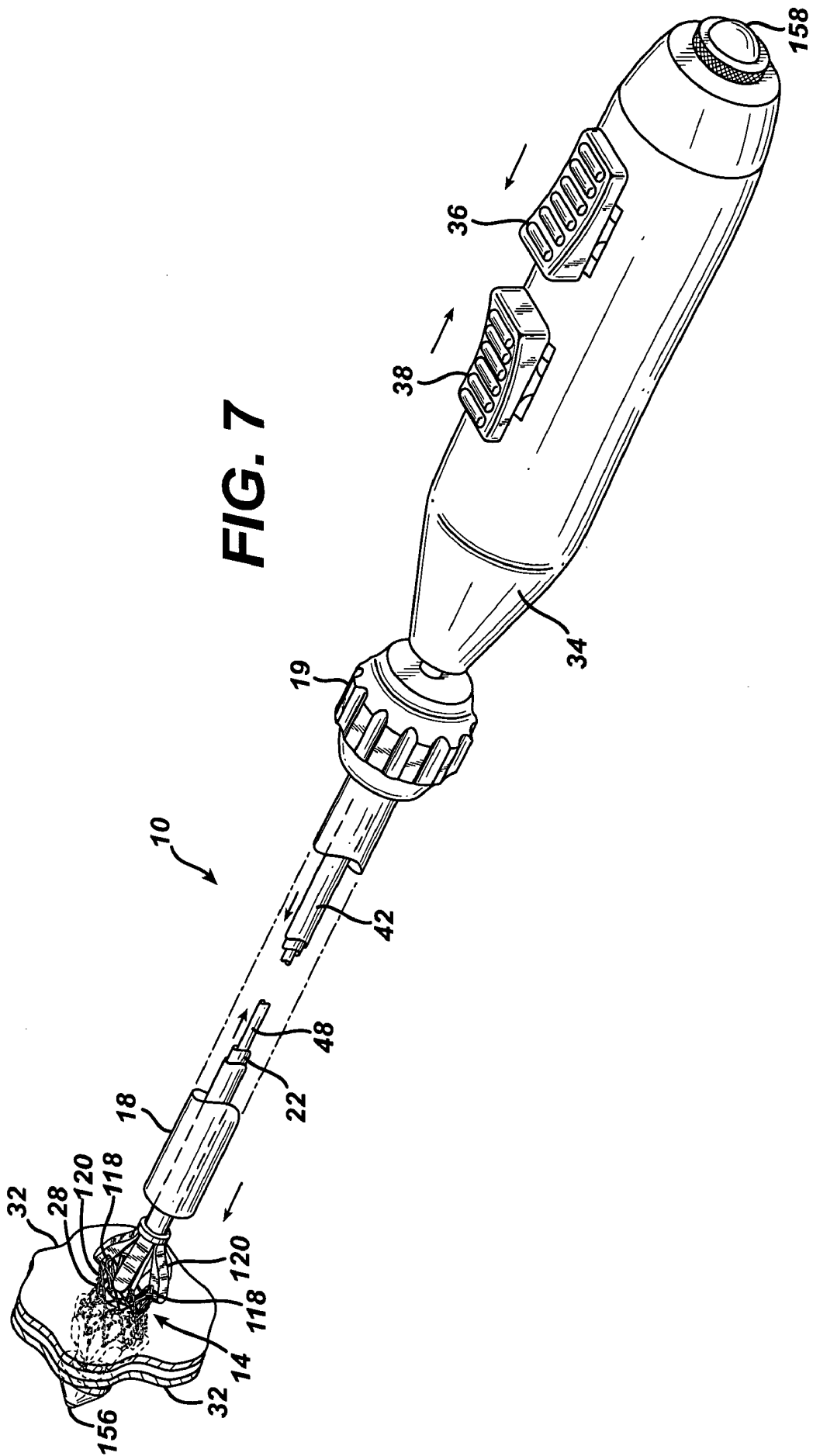


FIG. 4







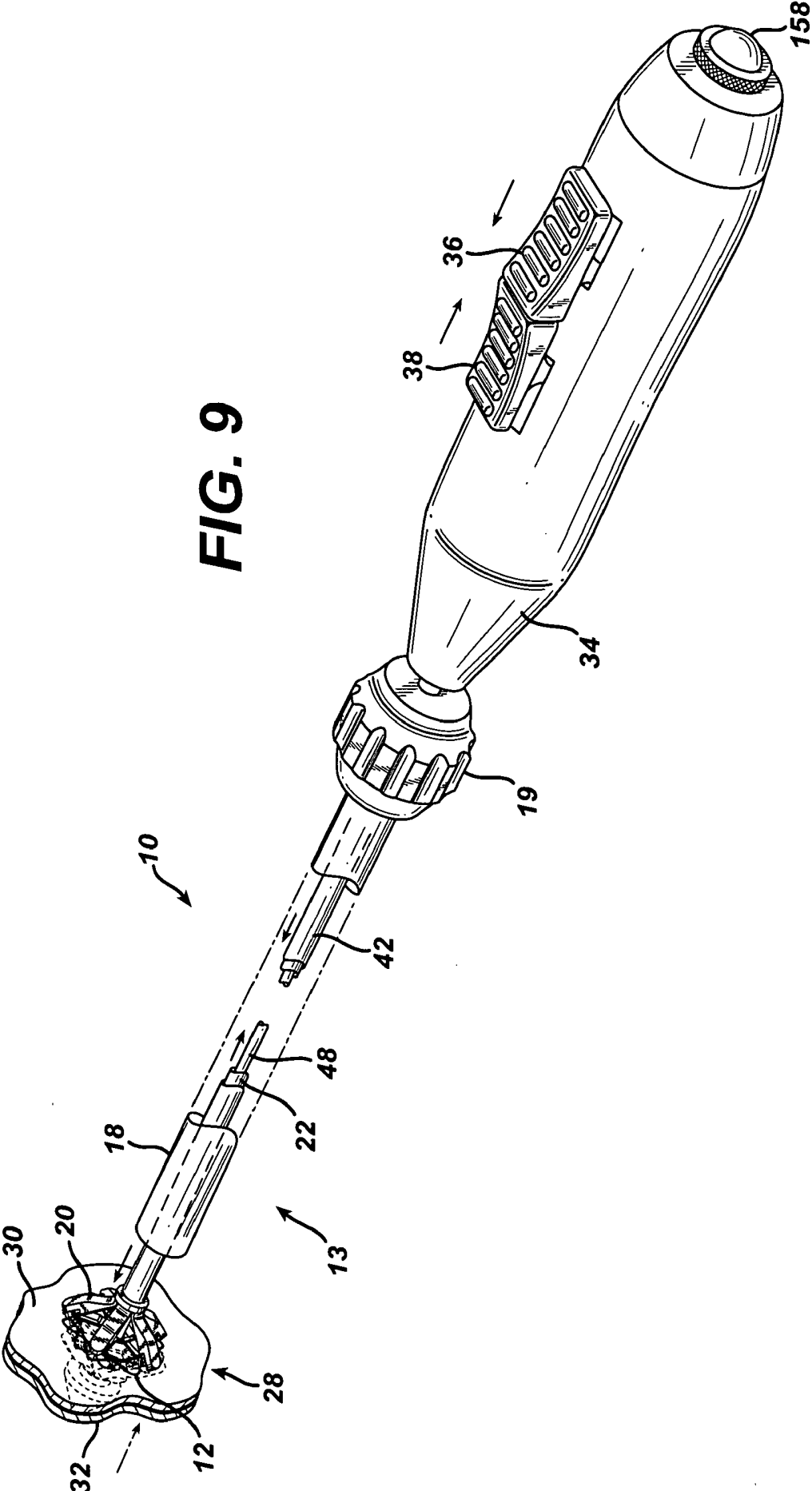


FIG. 10

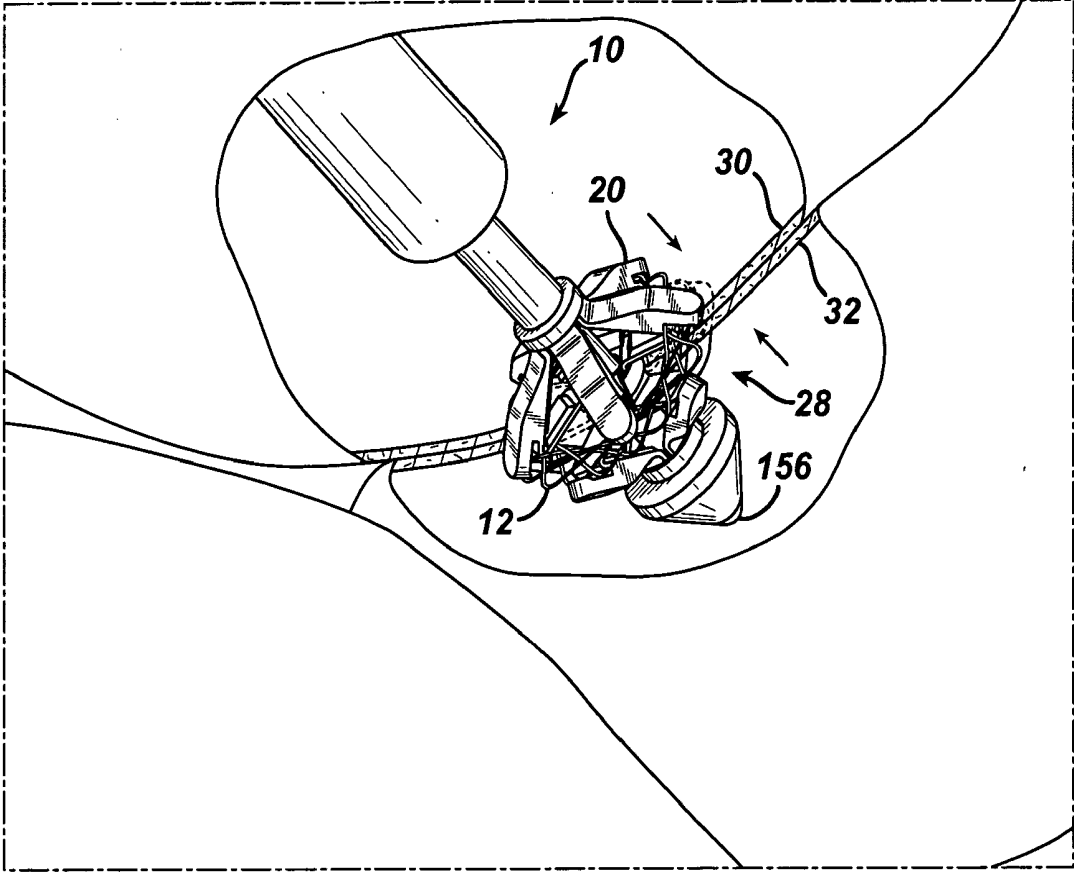
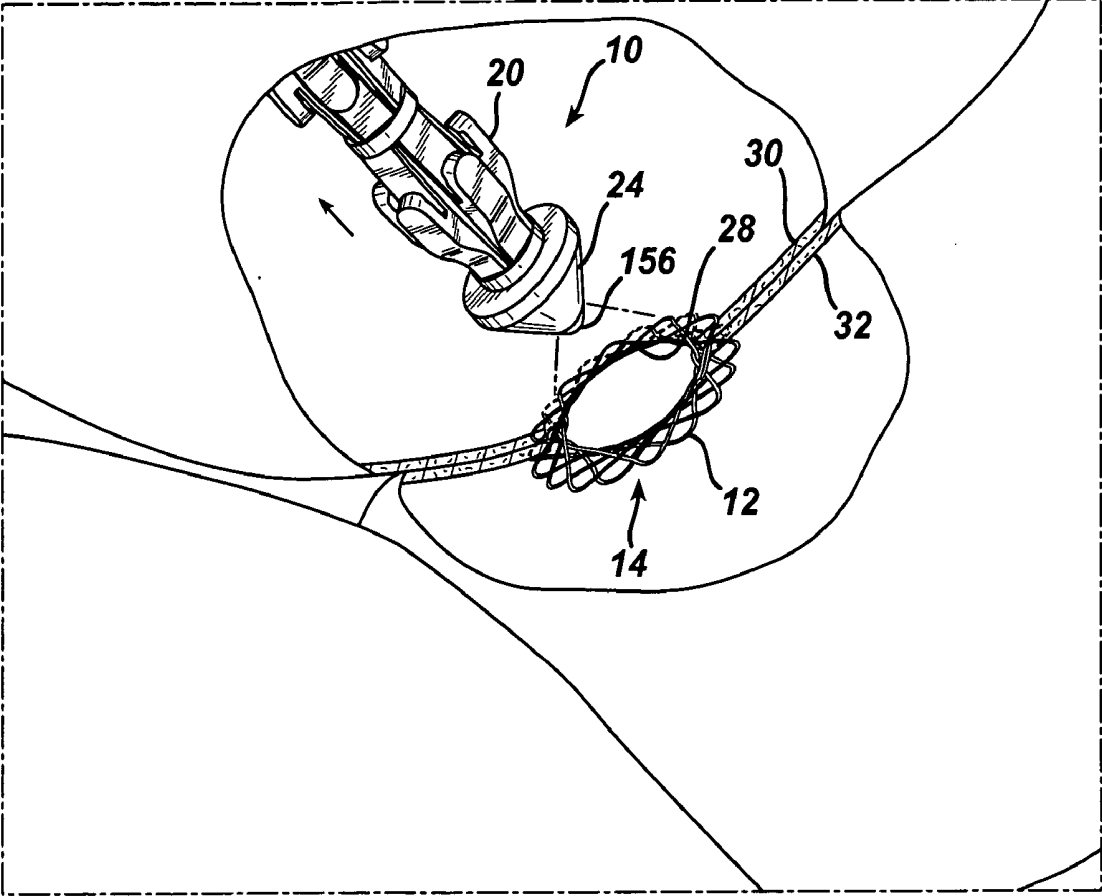


FIG. 11



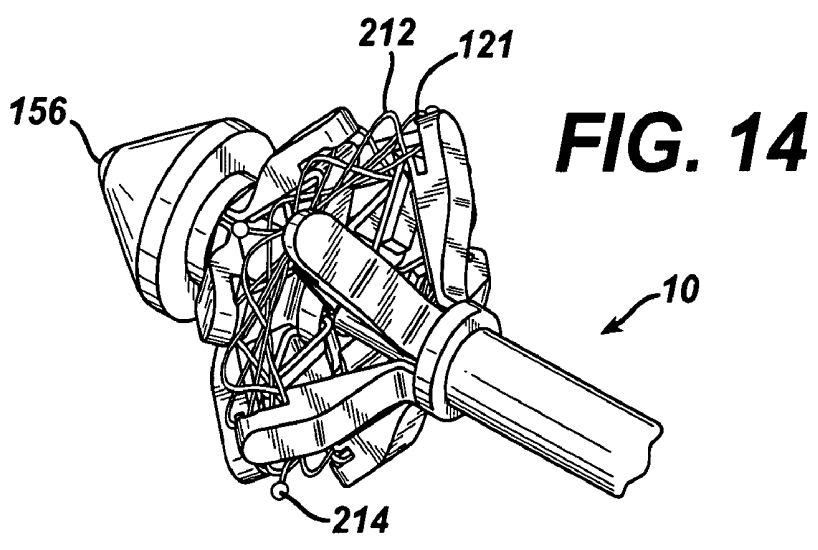
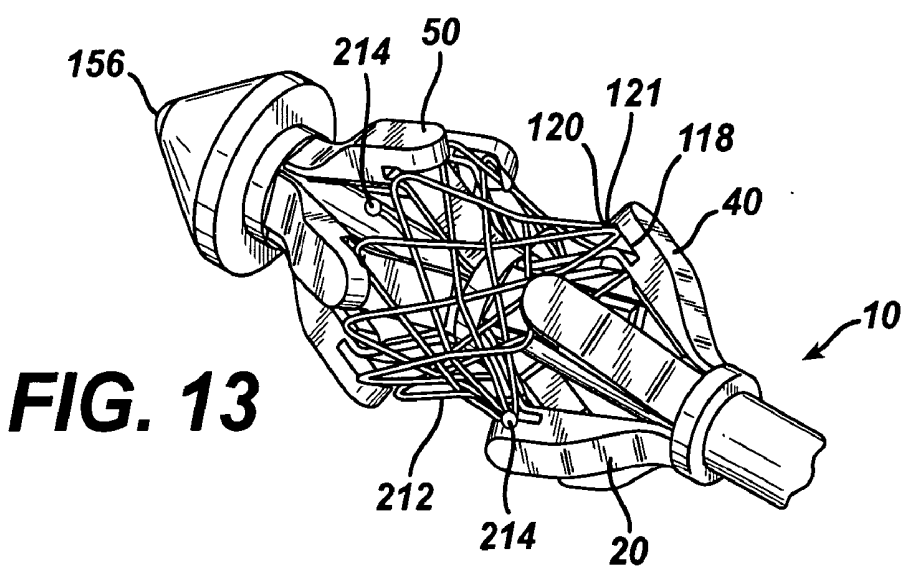
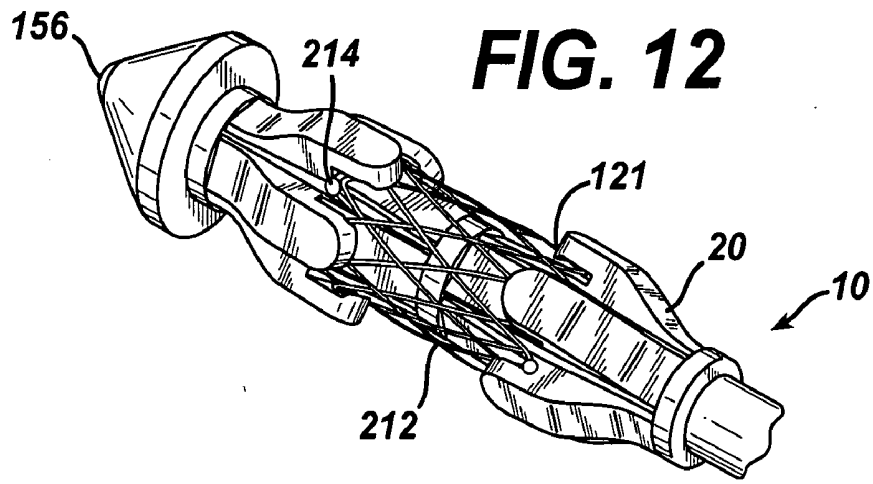


FIG. 15

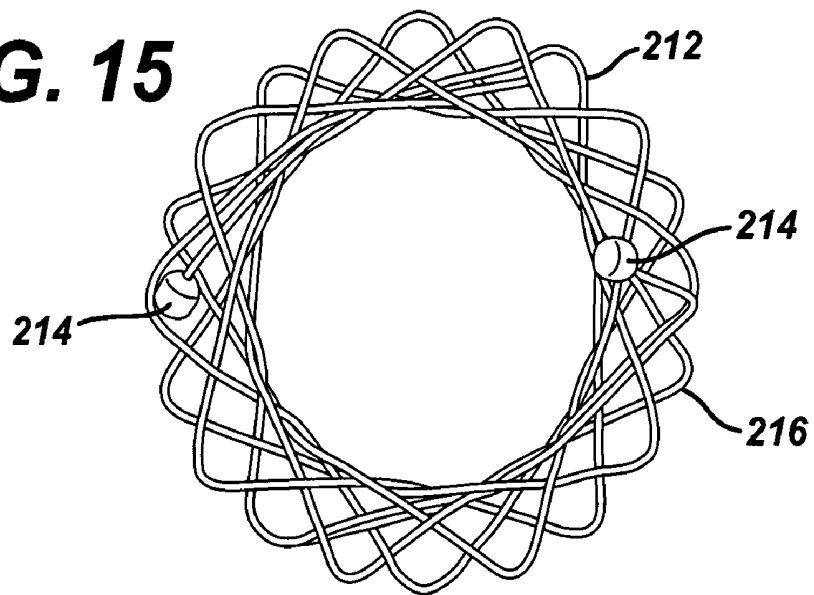


FIG. 16

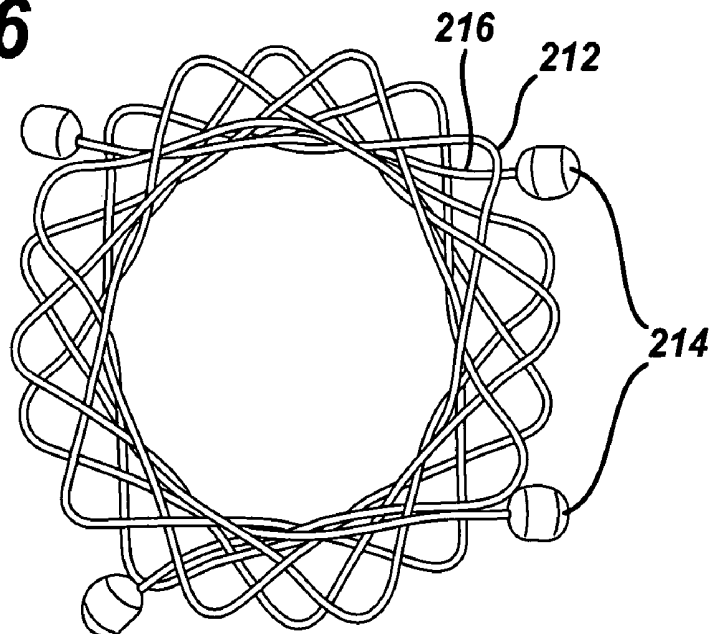
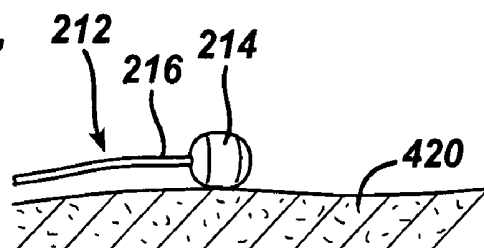


FIG. 17



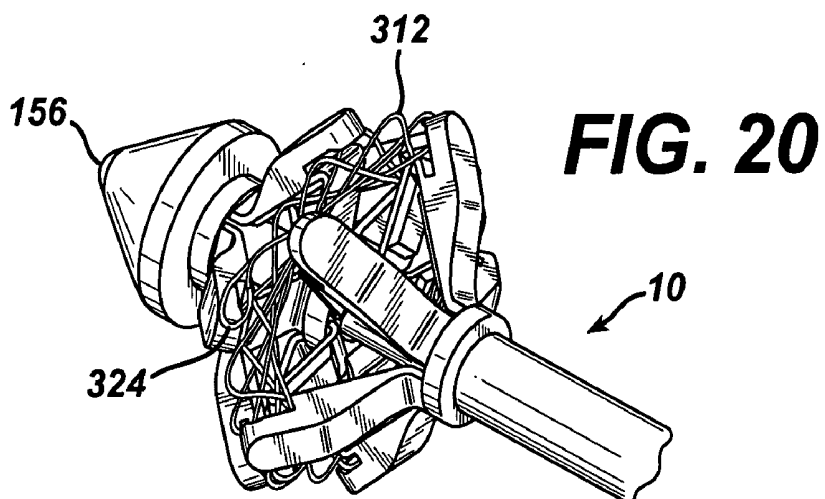
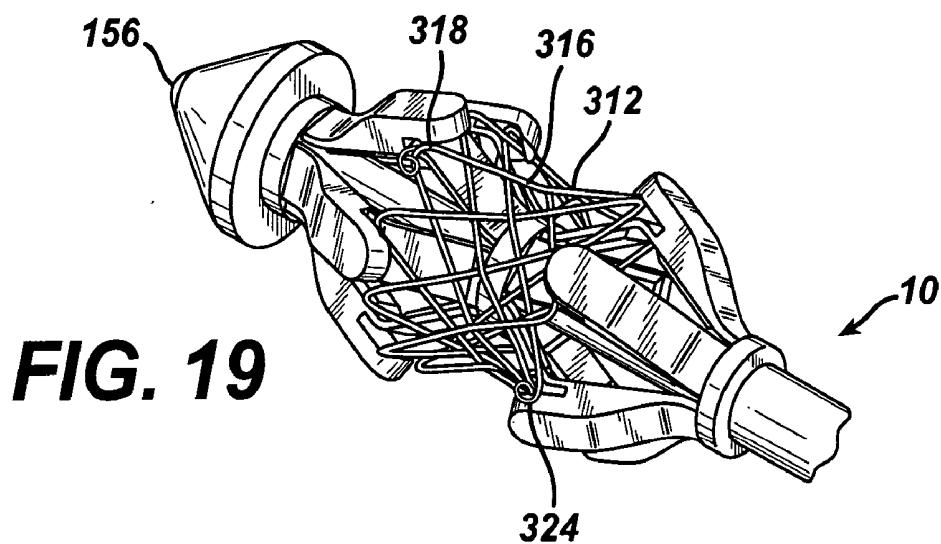
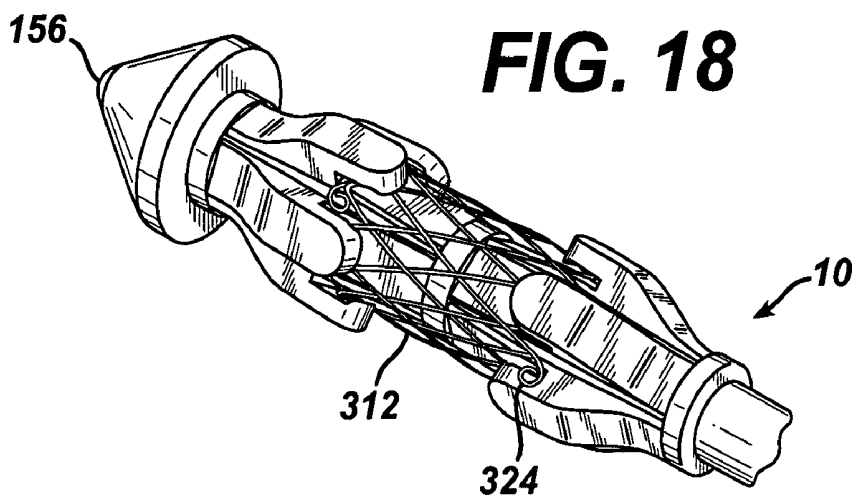


FIG. 21

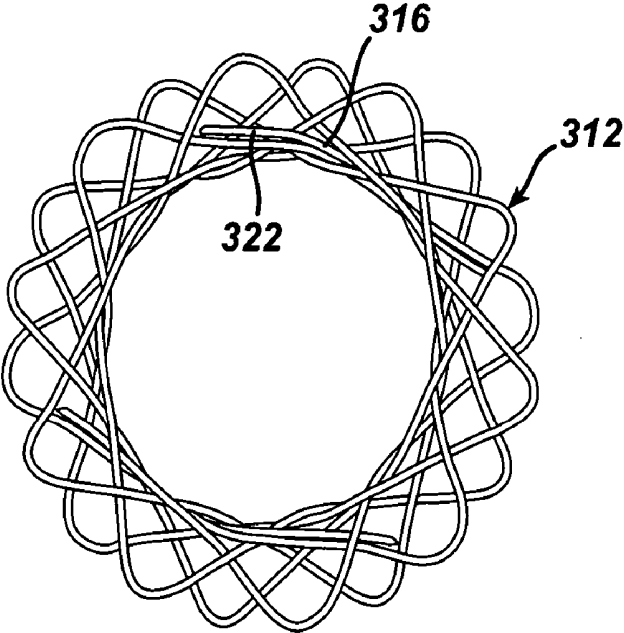


FIG. 22

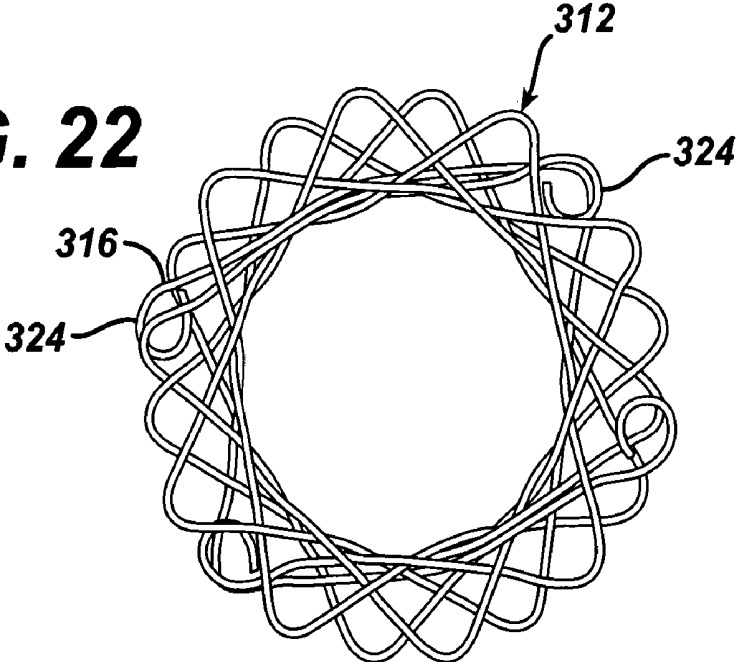
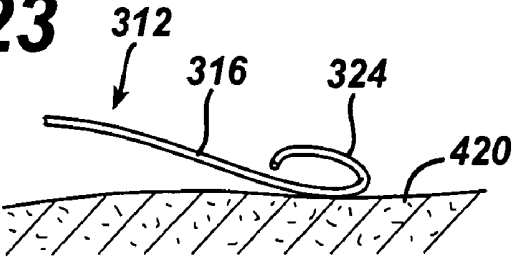


FIG. 23



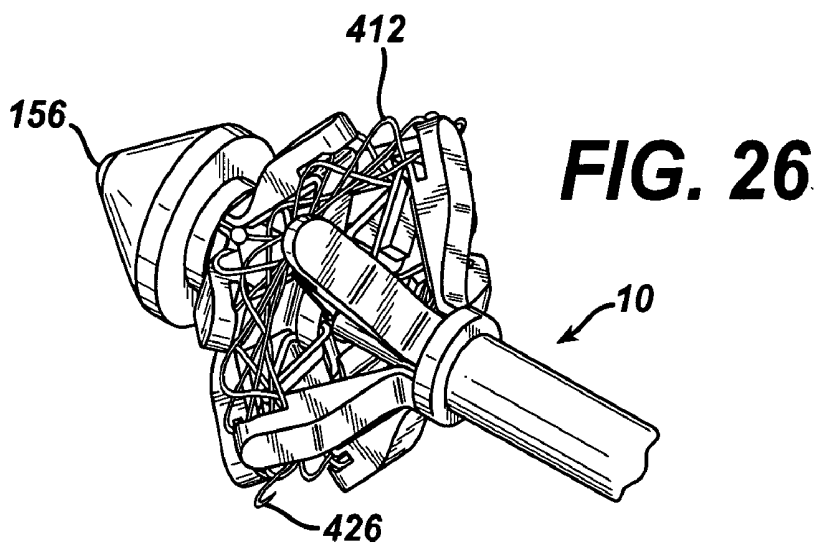
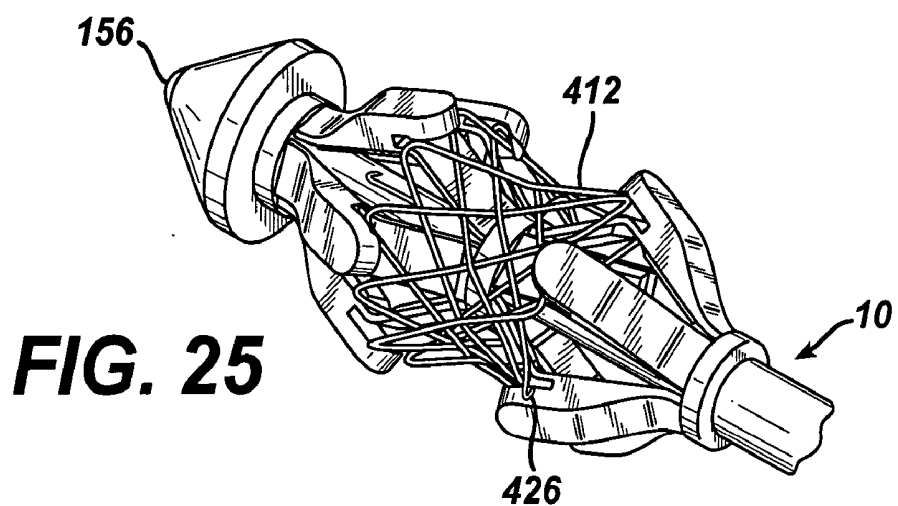
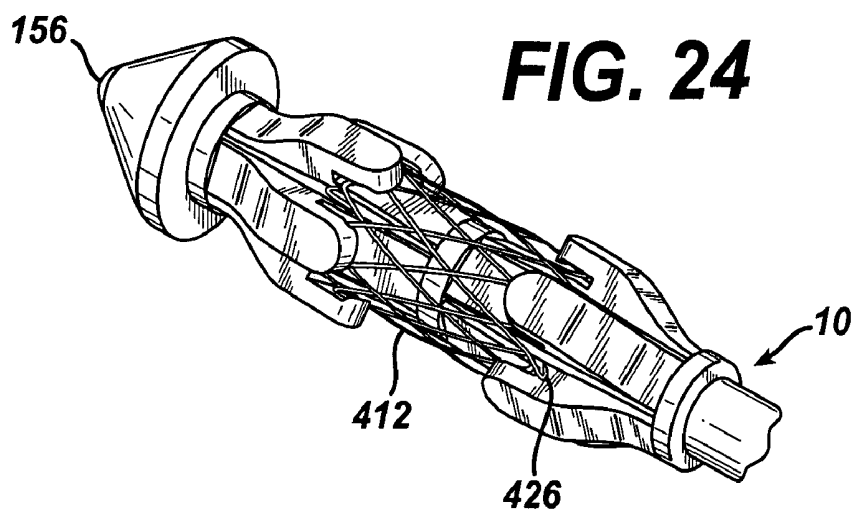


FIG. 27

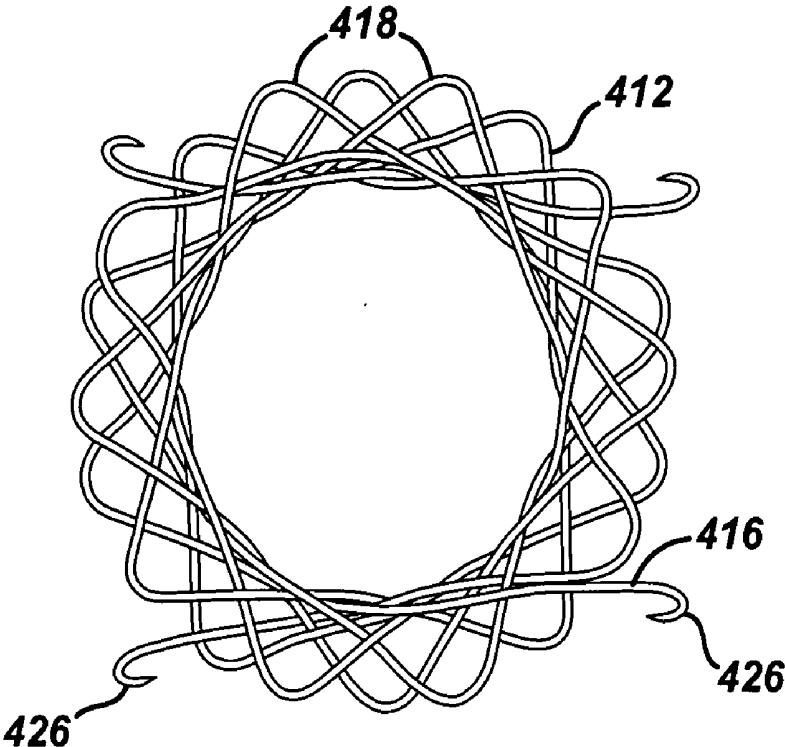


FIG. 28

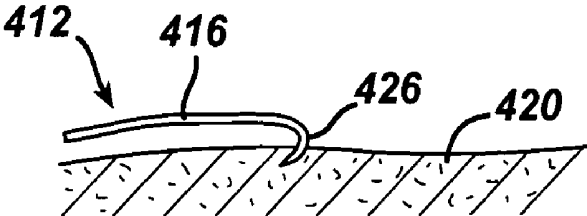


FIG. 29

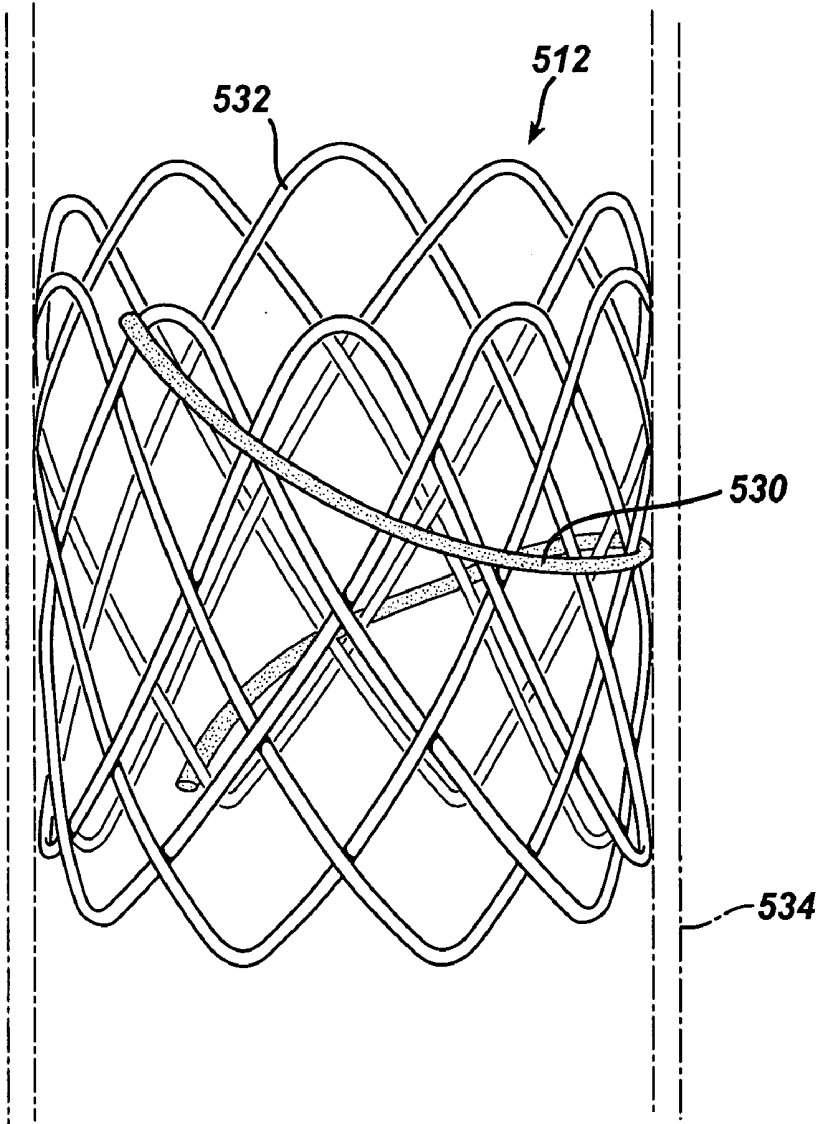


FIG. 30

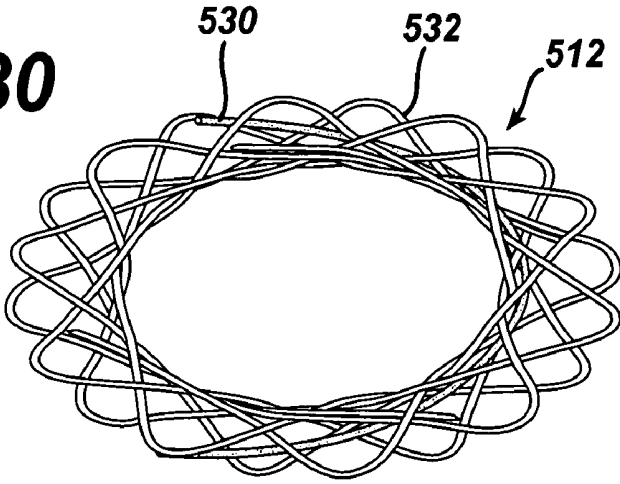


FIG. 31 PRIOR ART

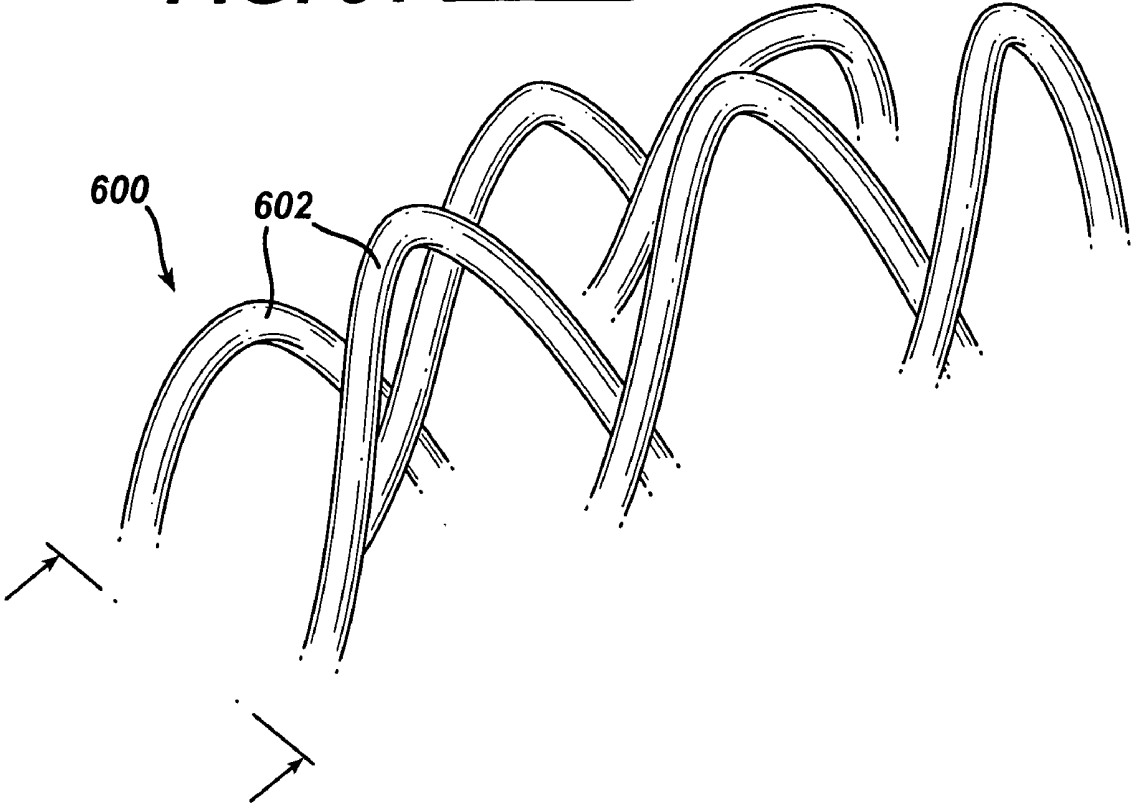


FIG. 32 PRIOR ART

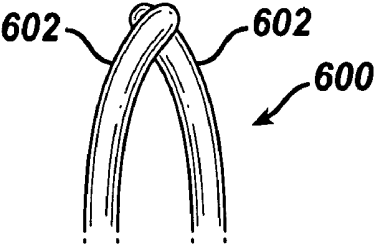


FIG. 33

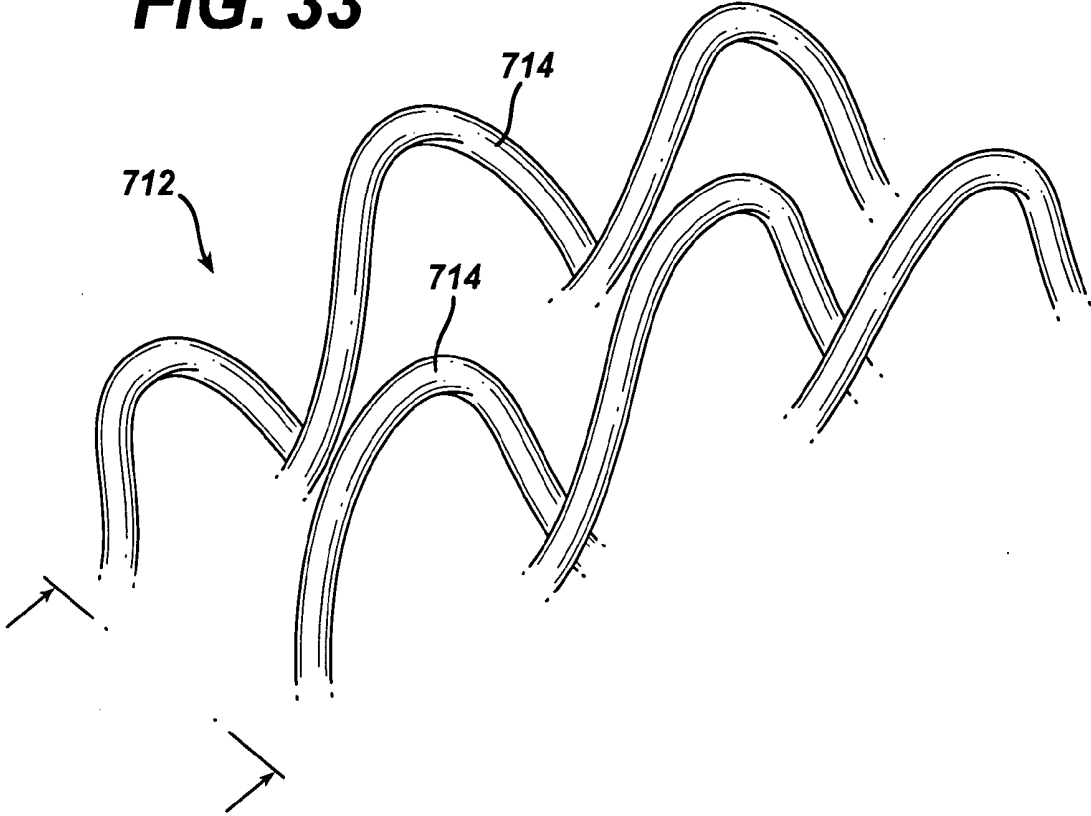


FIG. 34

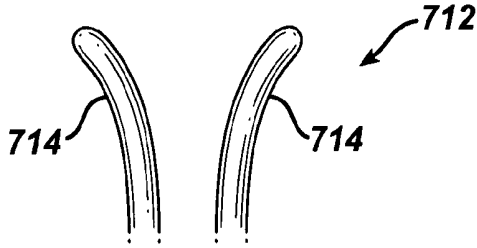
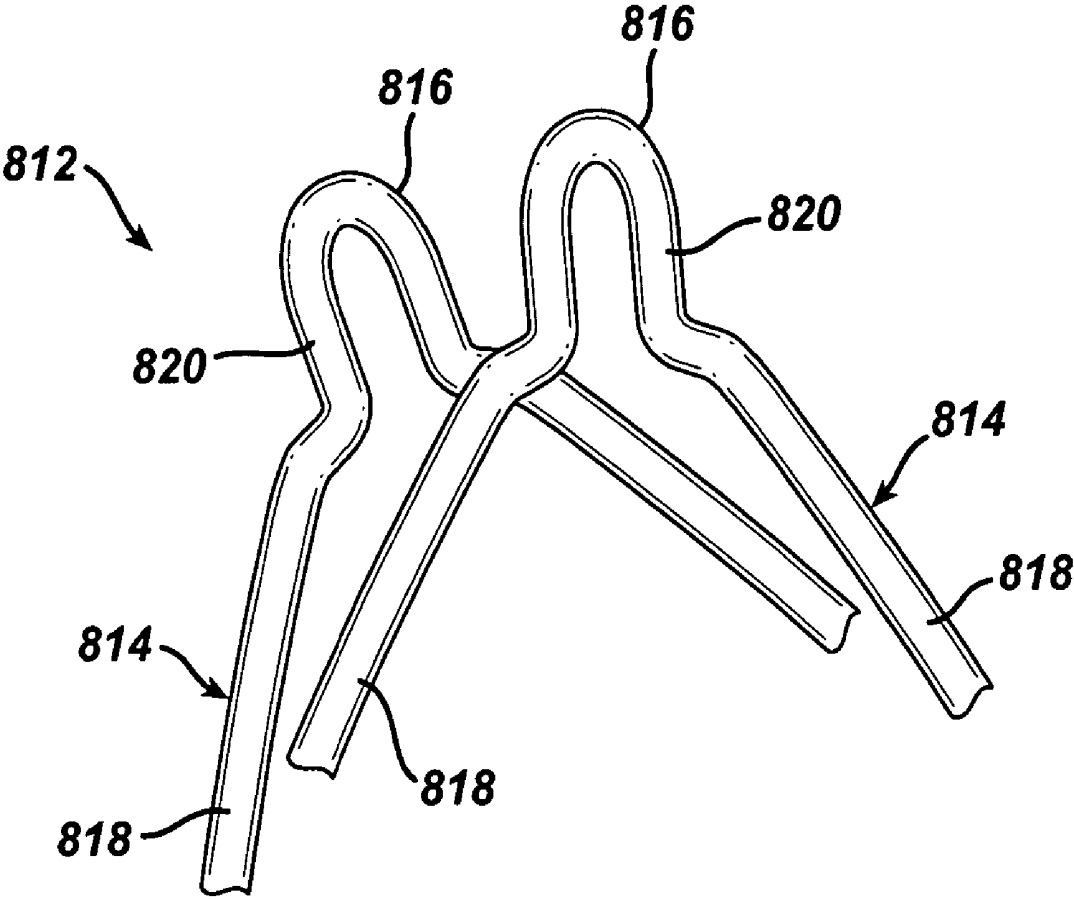


FIG. 35



ANASTOMOSIS WIRE RING DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application is related to four co-pending and commonly-owned application filed on even date herewith, the disclosure of each is hereby incorporated by reference in its entirety:

[0002] "Applier For Fastener For Single Lumen Access Anastomosis", Ser. No. _____ to Mark Ortiz;

[0003] "Unfolding Anastomosis Ring Device", Ser. No. _____ to Jean Beaupre;

[0004] "Single Lumen Access Deployable Ring for Intraluminal Anastomosis", Ser. No. _____ to Mark Ortiz; and

[0005] "Single Lumen Anastomosis Applier for Fastener", Ser. No. _____ to Mark Ortiz, Robert McKenna, Bill Kraimer, Mike Stokes, and Foster Stulen.

FIELD OF THE INVENTION

[0006] The present invention relates, in general, to surgery and, more particularly, to a method of performing a surgical procedure on the digestive system.

BACKGROUND OF THE INVENTION

[0007] The percentage of the world population suffering from morbid obesity is steadily increasing. Severely obese persons are susceptible to increased risk of heart disease, stroke, diabetes, pulmonary disease, and accidents. Because of the effect of morbid obesity to the life of the patient, methods of treating morbid obesity are being researched.

[0008] Numerous non-operative therapies for morbid obesity have been tried with virtually no permanent success. Dietary counseling, behavior modification, wiring a patient's jaws shut, and pharmacologic methods have all been tried, and though temporarily effective, failed to correct the condition. Further, introducing an object in the stomach, such as an esophago-gastric balloon, to fill the stomach have also been used to treat the condition; however, such approaches tend to cause irritation to the stomach and are not effective long-term.

[0009] Surgical treatments of morbid obesity have been increasingly used with greater success. These approaches may be generalized as those that reduce the effective size of the stomach, limiting the amount of food intake, and those that create malabsorption of the food that it is eaten. For instance, some patients benefit from adjustable gastric bands (AGB) that are advantageously laparoscopically placed about the stomach to form a stoma of a desired size that allows food to fill an upper portion of the stomach, causing a feeling of satiety. To allow adjustment of the size of the stoma after implantation, a fluid conduit communicates between an inwardly presented fluid bladder of the AGB to a fluid injection port subcutaneously placed in front of the patient's sternum. A syringe needle may then inject or withdraw fluid as desired to adjust the AGB.

[0010] Although an effective approach to obesity for some, other patients may find the lifestyle changes undesirable, necessitated by the restricted amount of food intake. In

addition, the medical condition of the patient may suggest the need for a more permanent solution. To that end, surgical approaches have been used to alter the portions of the stomach and/or small intestine available for digesting food. Current methods of performing a laparoscopic anastomoses for a gastric bypass include stapling, suturing, and placing biofragmentable rings, each having significant challenges. For instance, suturing is time consuming, as well as being technique and dexterity dependent. Stapling requires placement of an anvil, which is a large device that cannot be introduced through a trocar port. Having to introduce the port through a laparotomy presents an increased incidence of wound site infection associated with intraluminal content being dragged to the laparotomy entry site.

[0011] As an example of the latter approach, in U.S. Pat. No. 6,543,456 a method for gastric bypass surgery includes the insertion of proximal and distal anastomosis members (e.g., anvils) transorally with grasping forceps. The stomach and the small intestine are transected endoscopically by a surgical severing and stapling instrument to create a gastric pouch, a drainage loop, and a Roux limb. An endoscopically inserted circular stapler attaches to the distal anastomosis member to join the drainage loop to a distal portion of the intestine, and the circular stapler attaches to the proximal anastomosis member to join the Roux limb to the gastric pouch. Thereafter, the anastomosis members are removed to create an orifice between joined portions of the stomach and intestine. This method reduces the number of laparoscopic ports, avoids a laparoscopic insertion of an anastomosis instrument (e.g., circular stapler) into an enlarged surgical port, and eliminates the need for an enterotomy and an enterotomy closure.

[0012] While methods such as that described are a marked improvement over generally known gastric bypass and similar surgical treatments for morbid obesity, it would be desirable to achieve a gastric bypass with yet fewer procedural steps and with fewer laparoscopic insertions. Such an approach is described in U.S. Pat. Appl. Publ. No. US 2003/0032967 to Park et al., wherein gastrointestinal or enteric (including biliary) anastomosis is achieved by insertion of a sheath that perforates the walls of two tissue passages, such as the stomach and small intestine. A three-dimensional woven tube of wire of having a thermal shape memory effect (SME) ("generally-known nitinol ring device") is presented by a cannula of the sheath on both sides of the openings. Deployment of the woven tube causes the outer loops or ends of the tube to fold or loop back to hold the luminal interface of the anastomosis site in apposition. Thereby, the need for a mechanical compression component in a delivery system is reduced or avoided, reducing the size and complexity of the delivery device.

[0013] While the generally-known nitinol ring device is a significant advancement in the treatment of morbid obesity, it is believed that further improvements would be desirable. For instance, the continuous interlocking petals are difficult to manufacturer, especially since the depicted woven tube is of a continuous wire loop bent into a pattern of interlocking triangles.

[0014] In addition, the generally-known nitinol ring device is a woven tube, or stent, that is purported to be a self-actuating anastomotic ring. However, the disclosed stent sometimes will not actuate or transform completely

from its stressed cylindrical state to its relaxed clamping state, perhaps due to irregularities in undulations of its weaved designs create friction. One particular difficulty of known SME anastomotic rings are that they are designed to move from a generally cylindrical shape to a hollow rivet shape ("ring shape") by having wires that form the device move across one another. In particular, wires must move within a nodal point (i.e., an indentation or valley) created by the wire bend and must climb back out of the indentation. In some instances, the device fails to fully actuate on its own due to these sources of friction.

[0015] Consequently, there is a general need for an approach to anastomosis that will use existing trocar ports (e.g., 12 mm size) with a minimum of suturing. Moreover, aspects of the method should have application to endoscopic surgery. To that end, a significant need exists for an anastomosis device that reliably and effectively deploys and actuates to eliminate the need for surgical stapling and suturing to form an anastomosis.

BRIEF SUMMARY OF THE INVENTION

[0016] The invention overcomes the above-noted and other deficiencies of the prior art by providing an anastomosis device woven from one or more strands with end disconnected from other ends, providing a more economical manufacture.

[0017] In one aspect of the invention, a woven tube anastomotic device has each longitudinal end of its constituent strands terminate in circumferential petals. The unactuated position of the tube is of a generally cylindrical shape and the actuated position of a hollow rivet shape for insertion through and for forming an anastomotic attachment between two proximate tissue walls, respectively. An actuation force is provided by weaving a helical coil spring into the woven tube. Thereby, enhanced actuation force may be achieved without relying solely or at all upon the rest of the woven tube.

[0018] These and other objects and advantages of the present invention shall be made apparent from the accompanying drawings and the description thereof.

BRIEF DESCRIPTION OF THE FIGURES

[0019] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention, and, together with the general description of the invention given above, and the detailed description of the embodiments given below, serve to explain the principles of the present invention.

[0020] FIG. 1 is perspective view of an applier having an anastomotic ring device installed thereon being inserted laparoscopically to an anastomosis target site on each of two portions of a patient's small intestine.

[0021] FIG. 2 is a perspective detail view of the applier with sheath retracted and anastomosis target site of FIG. 1, depicting the anastomotic ring device in its undeployed, unactuated state.

[0022] FIG. 3 is a perspective, exploded and partially cutaway view of a distal portion of the applier of FIG. 1.

[0023] FIG. 4 is a perspective, exploded view of a proximal portion of the applier of FIG. 1 with a left housing half omitted.

[0024] FIG. 5 is perspective view of the applier of FIG. 1 with the left housing half omitted and an outer tube of the cannula partially cutaway to expose an intermediate tube and inner rod that actuate a molded actuating member that actuates the omitted anastomotic ring device, also to expose a deployment illuminator that allows confirming actuation of an anastomotic ring device by viewing through the translucent tissue walls.

[0025] FIG. 6 is a perspective view of the applier of FIG. 5 with the triggers and molded actuating member in an actuated position.

[0026] FIG. 7 is a perspective view of the applier of FIG. 1 in a partially actuated state.

[0027] FIG. 8 is a detail perspective view of a distal portion of the applier of FIG. 7 with tissue walls partially cutaway.

[0028] FIG. 9 is a perspective view of the applier of FIG. 1 in a fully actuated state.

[0029] FIG. 10 is a detail perspective view of the distal portion of the applier of FIG. 9 with tissue walls partially cutaway.

[0030] FIG. 11 is a detail perspective view of the distal portion of the applier returned to unactuated state and withdrawn proximally to deploy the actuated anastomotic ring device.

[0031] FIG. 12 is a detail perspective view of the distal portion of the applier of FIG. 1 in an unactuated position holding an anastomotic ring device advantageously fabricated with a ball end discontinuous weave.

[0032] FIG. 13 is a detail perspective view of the distal portion of the applier of FIG. 12 in a partially actuated position.

[0033] FIG. 14 is a detail perspective view of the distal portion of the applier of FIG. 12 in a fully actuated position.

[0034] FIG. 15 is an end view of the anastomotic ring device of FIG. 12 after actuation, depicted as a single strand discontinuous weave with a pair of ball ends.

[0035] FIG. 16 is an end view of the anastomotic ring device of FIG. 12 after actuation, depicted as a dual strand discontinuous weave, each strand with a pair of ball ends.

[0036] FIG. 17 is a detail view of a ball end of the anastomotic ring device of FIG. 12 in atraumatic contact with a tissue wall.

[0037] FIG. 18 is a detail perspective view of the distal portion of the applier of FIG. 1 in an unactuated position holding an anastomotic ring device advantageously fabricated with a loop end discontinuous weave.

[0038] FIG. 19 is a detail perspective view of the distal portion of the applier of FIG. 18 in a partially actuated position.

[0039] FIG. 20 is a detail perspective view of the distal portion of the applier of FIG. 18 in a fully actuated position.

[0040] FIG. 21 is an end view of an anastomotic ring device after actuation, depicted as a dual strand discontinuous weave each strand with straight ends.

[0041] FIG. 22 is an end view of the anastomotic ring device of FIG. 18 after actuation, depicted as a dual strand discontinuous weave, each strand with a pair of loop ends.

[0042] FIG. 23 is a detail view of a loop end of the anastomotic ring device of FIG. 18 in atraumatic contact with a tissue wall.

[0043] FIG. 24 is a detail perspective view of the distal portion of the applicator of FIG. 1 in an unactuated position holding an anastomotic ring device advantageously fabricated with a hook end discontinuous weave.

[0044] FIG. 25 is a detail perspective view of the distal portion of the applicator of FIG. 24 in a partially actuated position.

[0045] FIG. 26 is a detail perspective view of the distal portion of the applicator of FIG. 24 in a fully actuated position.

[0046] FIG. 27 is an end view of an anastomotic ring device after actuation, depicted as a dual strand discontinuous weave each strand with a pair of hook ends.

[0047] FIG. 28 is a detail view of a loop end of the anastomotic ring device of FIG. 24 in traumatic contact with a tissue wall.

[0048] FIG. 29 is a side view of an anastomotic ring device including a helical actuation coil and constrained within a sheath.

[0049] FIG. 30 is a perspective view of the anastomotic ring device of FIG. 30 in an actuated condition.

[0050] FIG. 31 is a side view of a generally known anastomotic ring having converging distal petals.

[0051] FIG. 32 is a detail view of the generally-known anastomotic ring of FIG. 31.

[0052] FIG. 33 is a perspective view of an anastomotic ring device incorporating diverging petals.

[0053] FIG. 34 is a side detail view of the diverging petals of the anastomotic ring device of FIG. 33.

[0054] FIG. 35 is side view of two arcuate members with a reduced radius point for an anastomotic ring device.

DETAILED DESCRIPTION OF THE INVENTION

[0055] Turning to the Drawings, wherein like numerals denote like components throughout the several views, FIG. 1 depicts an applicator 10 that advantageously laparoscopically or endoscopically deploys and actuates an anastomotic ring device 12 from a generally cylindrical shape to one having properties of a hollow rivet, or ring, capable of forming an anastomotic attachment at an anastomosis target site, such as in a bariatric gastric bypass of a morbidly obese patient 16. In the illustrative version, the anastomotic ring device 12 comprises a shape memory effect (SME) material such as nitinol that further assists in actuation to an engaging hollow rivet shape. As will be described in greater detail below, various improvements to the configuration of the anastomotic ring device 12 simplify manufacturer as well as adding therapeutic features. Moreover, configuration improvements further assist in actuating the anastomotic ring device 12 without wholly relying upon SME properties of the anastomotic ring device 12.

[0056] It will be appreciated that the terms “proximal” and “distal” are used herein with reference to a clinician gripping a handle of the applicator 10. It will be further appreciated that for convenience and clarity, spatial terms such as “right”, “left”, “vertical” and “horizontal” are used herein with respect to the drawings. However, surgical instruments are used in many orientations and positions, and these terms are not intended to be limiting and absolute. In addition, aspects of the invention have application to surgical procedures performed endoscopically and laparoscopically, as well as an open procedure. Use herein of one of these or similar terms should not be construed to limit the present invention for use in only one category of surgical procedure.

[0057] Anastomotic Ring Device Applicator.

[0058] In FIG. 2, the applicator 10 has the anastomotic ring device 12 advantageously retained in a generally cylindrical shape distal to an outer tube 18 upon a molded actuation member 20 forming a cannula 22 that distally terminates in a tapered tip 24. This tapered tip 24 presents a distal piercing surface 26 to form an anastomotic opening 28 through apposite tissue walls 30, 32 of two gastrointestinal passages. As discussed below, the tapered tip 24 may advantageously include illumination features that allow confirmation of placement and actuation of the anastomotic ring device 12 when viewed from a proximal direction through translucent tissue walls 30, 32.

[0059] With reference to FIGS. 2-5, a handle 34, proximal to the cannula 22, includes a pair of longitudinally aligned triggers 36, 38. The proximal trigger 36, shown at its most proximal, unfired position, is coupled to proximal leaves 40 of the molded actuation member 20 via an intermediate tube 42 of the cannula 22. Distal movement of the proximal trigger 36 thus causes longitudinal distal movement of the intermediate tube 42 and proximal leaves 40, which outwardly actuate like an umbrella by a hinged relationship to a central portion 44 of the molded actuation member 20. Similarly, the distal trigger 38, shown at its most distal, unfired position, is coupled to distal leaves 46 of the molded actuation member 20 via an internal rod 48 that is coupled for movement within the intermediate tube 42. Proximal movement of the distal trigger 38 causes longitudinal proximal movement of the rod 48 and distal leaves 50 of the molded actuation member 20, which outwardly actuate by a hinged relationship to the central portion 44.

[0060] As best viewed in FIGS. 4-5, within the handle 34, a cavity 52 includes proximal and distal apertures 54, 56 to allow the longitudinal movement of the proximal and distal triggers 36, 38 respectively. Each trigger 36, 38 includes a right opening aperture 58 that engage for longitudinal movement a leftward projecting track 60 formed within the cavity 52 of a right half shell of the handle 34.

[0061] Moving from most distal to most proximal, a first, second and third lateral ridge 62, 64, 66 across the bottom of the cavity 52 define a first, second, third, and fourth cavity segment 68, 70, 72, 74 respectively. A first block 76, formed from left and right halves 78, 80 is positioned for movement within the first cavity segment 68. A longitudinal central hole 82 defined between the two halves 78, 80 engages and moves with a terminating proximal end 84 of the intermediate tube 42. The internal rod 48 passes on through the first block 76 into the second, third and fourth cavity segments 70-74 into sliding contact with a hole 86 passing through a

proximal end **88** of the handle **34**. A second spacer block **90** locked within the second cavity segment **70** has a longitudinal central hole **92** defined between its left and right halves **94, 95** that slidably contacts and support the internal rod **48**. A third sliding block **96** has a longitudinal central hole **98** defined between its upper and lower halves **100, 102** that engage and move with the internal rod **48**. A lower portion **104** of the distal trigger **38** is attached to a distal face of the third sliding block **96**. A fourth sliding block **106** within the fourth cavity segment **74** has a longitudinal central hole **108** that slidably contacts the internal rod **48**. A lower portion **114** of the proximal trigger **36** is attached to a proximal face of the fourth sliding block **106**. A link **116** is attached to the left sides of the first and fourth sliding blocks **76, 106**.

[0062] In FIG. 6, the triggers **36, 38** have been slid toward one another to actuate the molded actuating member **20**. Specifically, the distal trigger **38** has been moved proximally, moving the third sliding block **96** and internal rod **48**, the distal terminating end of the latter being attached to tapered tip **24**. The tapered tip thus moves toward the distal end of the intermediate tube **42**. The proximal trigger **36** has been moved distally, moving fourth sliding block **106**, link **116**, first sliding block **76**, and intermediate tube **42** also distally. The molded actuating member **20** is compressed between the inwardly moving tapered tip **24** and intermediate tube **42**. The distal leaves **50** actuate lateral to the longitudinal axis, and move toward and interdigitate with the proximal leaves **40**. This movement expedites actuating of an anastomotic ring device (not shown in FIG. 6).

[0063] In use, the tapered tip **24** of the applier **10** is inserted through a trocar port into a tissue passage that has been placed proximate to another tissue passage that are to be anastomotically joined (See FIGS. 1-2). The tapered tip **24** and a distal half of the molded actuating member **20** and anastomotic ring device **12** are inserted through an anastomotic opening **28** formed therebetween and then the applier is actuated, with a partially actuated applier **10** being depicted in FIGS. 7-8. With particular reference to FIG. 8, the proximal and distal leaves **40, 50** are shown as having gripping slots **118** that grip respective petals **120** of the anastomotic ring device **12**, especially in its unactuated, generally cylindrical shape. An inwardly directed retention tip **121** or other gripping features in the gripping slots **118** may be incorporated to enhance retention. These gripping slots **118** assist in preventing the anastomotic ring device **12** from slipping off of the applier **10** or being inappropriately placed thereon for actuation. In FIGS. 9-10, the applier **10** has been fully actuated, forming the anastomotic ring device **12** into a hollow rivet shape to form the anastomotic attachment between tissue walls **30, 32**. The fully actuated proximal and distal leaves **40, 50** cause the petals **120** to disengage from the gripping slots **118**. Thereafter, the applier **10** is returned to an unactuated condition and the actuated anastomotic ring device **12** deployed by withdrawing the tapered tip **24** from the anastomotic opening **28** and ring device **12**, as depicted in FIG. 11.

[0064] Deployment Illumination.

[0065] In FIGS. 7, 9, a distal portion of the anastomotic ring device **12** are depicted in phantom to illustrate their actuated position. This phantom depiction is also suggestive of a clinical advantage of being able to view the deployment condition from a proximal point of view. Typically, an

endoscope will view the anastomotic opening **28** from a proximal position. Returning to FIGS. 2-7, adding a deployment illumination feature to the applier **10** provides this ability to view deployment through translucent tissue walls. Specifically, an illumination power source (e.g., battery) **150** and control (e.g., switch) **152** are incorporated into the handle **34** with a conductor, depicted as a twisted wire pair **154** passing through the internal rod **48** to the tapered tip **24**, which includes a proximally directed electroluminescence device **156**. Alternatively conductive ink traces may be applied longitudinally down portions of the applier **10** to provide an electrical circuit to the tapered tip **24**. An externally accessible push button **158** drives the power source **150** against the control **152**, creating an illumination circuit with the electroluminescence device **156**.

[0066] Alternatively or in addition, the molded actuating member **20** may be formed of a fluorescent or electroluminescent material that is either stimulated prior to insertion or receives light from a light source of the applier **10**.

[0067] Discontinuous Weave Anastomotic Ring Device.

[0068] Forming an anastomotic ring device with a continuous wire loop poses a difficult manufacturing process that includes joining the ends of the woven wire strand or forming a weave from a continuous wire loop. In FIGS. 12-17 an advantageous approach to fabricating an anastomotic ring device **212** includes adding ball ends **214** to each wire strand **216**. In an illustrative embodiment, a hole is laser formed in each ball end **214** and then the ball end **214** is crimped onto the wire strand **216**. The ball ends **214** assist in preventing unraveling of petals **218** formed by the woven strands **216**. In addition, the ball ends **214** form an atraumatic contact with a tissue wall **220**, as depicted in FIG. 17.

[0069] As an alternative discontinuous weave, an anastomotic ring device **312** in FIGS. 18-23 is formed by one or more wire strands **316** whose ends are not attached to one another but instead positioned within the confines of petals **318** of the anastomotic ring device **312**. Specifically, in FIG. 21, each strand **316** terminates in a generally straight end **322**. In FIGS. 18-20, 22-23, each strand terminates in a loop end **324**. In each instance, positioning each end **322, 324** within petals **318** of the anastomotic ring device **312** avoids interference with an applier while also simplifying manufacturer.

[0070] As yet a further alternative discontinuous weave, an anastomotic ring device **412** in FIGS. 24-28 is formed by one or more wire strands **416** whose ends are not attached to one another but instead are positioned outside of petals **418** of the woven strands **416**. In a depicted version, each strand **416** traumatically engages a tissue wall **420** with hook ends **426** interdigitated between the petals **416**.

[0071] Spring Closed Ring Anastomotic Device.

[0072] In FIGS. 29-30, an anastomotic ring device **512** includes a helical wire assist spring **530** fabricated from an SME material (e.g., nitinol) or from spring steel. Thus, the woven material of a stent portion **532** of the anastomotic ring device **512** need not be of an SME material, or at least need not rely entirely upon its SME properties to effect actuation. The helical wire assist spring **530** enables selection of a stent portion **532** of a desired wire thickness and of a desired material. For instance, the stent portion **532** may even be of

plastic or longitudinally cut discrete sections of a continuously woven wire braid that provide no inherent actuating capability.

[0073] In FIG. 29, the wire assisted anastomotic ring device 512 is depicted in a generally cylindrical shape constrained by a lumen 534, which may be an applicator. It will be appreciated that the wire assisted anastomotic ring device 512 may advantageously be implanted by use of the applicator 10 described above, which would advantageously affirmatively grip the wire assisted anastomotic ring device to hold it in the stressed, unactuated position prior to implantation.

[0074] Deflected Petal Anastomotic Ring Device.

[0075] The generally-known nitinol ring device 600 includes converging looped petals 602 whose distal end flare lateral to the longitudinal axis when viewed in their stressed, generally cylindrical state, and interdigitate when viewed in their relaxed, actuated state, as depicted in FIGS. 31-32. It is believed that such deflected petals 602 engage the tissue walls in a beneficial fashion. However, the resulting increase in outward slope of each petal 602 imposes an increasing amount of friction to self-actuation of the generally-known nitinol ring device 600, negating any advantage of engagement, requiring more force to self-deploy generally-known nitinol ring device 600.

[0076] As generally-known nitinol ring device 600 deploys, portions of wire forming generally-known nitinol ring device 600 move relative to each other while in contact. The curvature of the wire winding of generally-known nitinol ring device 600 forms local maxima and minima for a contacting wire to traverse. The converging looped petals cause a local minimum for a contacting wire portion that the contacting wire portion must overcome. An increasing force gradient opposing deployment occurs, and must be overcome by the internal stored energy of the generally-known nitinol ring device 600 to complete deployment.

[0077] In FIGS. 33-34, an anastomotic ring device 712 advantageously includes distal looped petals 714 that are divergent (flared away) from each other when the ring device 712 is in its relaxed, hollow rivet (ring) shape as depicted. It is further believed that deflecting the distal portions of each petal 714 away from the tissue walls may decrease excessive pressure at the anastomotic attachment site without significant degradation to its required amount of attachment forces. Moreover, for anastomotic ring devices 712 that are not formed of an absorbable material, this configuration may advantageously later more readily detach after the anastomotic attachment is permanently formed between tissue walls.

[0078] Anastomotic ring device 712, with divergent (flared away) petals, will cause a maximum in force tending to urge the anastomotic ring device 712 towards the actuated ring state.

[0079] With reference to FIG. 35, an anastomotic ring device 812 includes petals 814 whose distal portion 816 is formed with a small radius relative to its more proximal portions 818 that overlap each other and slide across each other during actuation. As depicted, straight portions 820 between the distal and proximal portions 816, 818 may be shaped such that in the stressed, cylindrical shape of the ring device 812 that the petals 814 are urged toward the actuated ring state.

[0080] It should be appreciated that the divergent position of the petals may further be enhanced by SME treatment of these distal portions wherein the stressed, generally cylindrical state of the ring device 814 may include a straight petal or even a converging petal for purposes such as enhancing user of an applicator 10 and/or achieving a good anastomotic attachment immediately upon actuation with an eventual steady-state actuation position being as depicted.

[0081] While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications may readily appear to those skilled in the art.

[0082] For example, although bariatric procedures for bypassing portions of a gastrointestinal tract are depicted, it should be appreciated that other surgical procedures may benefit by an anastomotic ring device having aspects described herein.

[0083] For another example, although an applicator 10 has been advantageously depicted that assists in actuating the anastomotic ring device 10, it should be appreciated that the anastomotic ring device 10 includes enhanced reliability and performance in self-actuating and thus may be inserted by other means, to include insertion through the opening and released without the application of an external actuating force.

[0084] For yet a further example, various improvements disclosed herein may be used in various combinations.

What is claimed is:

1. An anastomotic device, comprising a woven tube of at least one wire strand, the woven tube having each longitudinal end terminate in circumferential petals, the woven tube having an unactuated position of a generally cylindrical shape and an actuated position of a hollow rivet shape respectively for insertion through and for forming an anastomotic attachment between two proximate tissue walls at an anastomotic surgical site, wherein each of the at least one wire strand includes unattached ends.

2. The anastomotic device of claim 1, wherein at least one unattached end of at least one wire strand terminates in a ball.

3. The anastomotic device of claim 1, wherein at least one unattached end of at least one wire strand terminates in loop.

4. The anastomotic device of claim 1, wherein at least one unattached end of at least one wire strand terminates in a hook registered to engage a tissue wall of the anastomotic surgical site when the woven tube is in an actuated position.

5. An anastomotic device, comprising:

a woven tube of at least one wire strand, the woven tube having each longitudinal end terminate in circumferential petals, the woven tube having an unactuated position of a generally cylindrical shape and an actuated position of a hollow rivet shape respectively for insertion through and for forming an anastomotic attachment between two proximate tissue walls at an anastomotic surgical site, and

a helical spring coupled to the woven tube for imparting an actuating force thereto to urge the woven tube from the unactuated to the actuated position.

6. The anastomotic device of claim 5, wherein the helical spring comprises a spring steel strand formed into a helical shape.

7. The anastomotic device of claim 5, wherein the helical spring compresses a Shape Memory Effect material.

8. The anastomotic device of claim 5, wherein the woven tube comprises a longitudinally cut segment of a continuous woven cylindrical tube.

9. The anastomotic device of claim 5 wherein the woven tube comprises a Shape Memory Effect material.

10. An anastomotic device, comprising a woven tube of at least one wire strand, the woven tube having each longitudinal end terminate in circumferential petals, the woven tube having an unactuated position of a generally cylindrical shape and an actuated position of a hollow rivet shape respectively for insertion through and for forming an anastomotic attachment between two proximate tissue walls at an anastomotic surgical site, an underlying portion of each petal presenting a monotonic slope to an overlying portion of an adjacent petal for mitigating resistance to actuation.

11. The anastomotic device of claim 10, wherein a distal portion of each petal comprises a radially narrowed elongate distal portion and a radially diverging proximal portion.

12. The anastomotic device of claim 10, further comprising a helical spring coupled to the woven tube for imparting

an actuating force thereto to urge the woven tube from the unactuated to the actuated position.

13. The anastomotic device of claim 12, wherein the helical spring comprises a spring steel strand formed into a helical shape.

14. The anastomotic device of claim 12, wherein the helical spring compresses a Shape Memory Effect material wherein each of the at least one wire strand includes unattached ends.

15. The anastomotic device of claim 10, wherein the woven tube comprises at least one strand having unattached ends.

16. The anastomotic device of claim 15 wherein the unattached ends each terminate in a ball.

17. The anastomotic device of claim 15, wherein the unattached ends each terminate in a loop.

18. The anastomotic device of claim 10, wherein at least one unattached end of at least one wire strand terminates in a hook registered to engage a tissue wall of the anastomotic surgical site when the woven tube is in an actuated position.

* * * * *

专利名称(译)	吻合线环装置		
公开(公告)号	US20050070934A1	公开(公告)日	2005-03-31
申请号	US10/674371	申请日	2003-09-30
[标]申请(专利权)人(译)	田中穿上 ORTIZ的标记S 鲍威尔达雷尔		
申请(专利权)人(译)	田中DON A. ORTIZ MARK S. 鲍威尔达雷尔		
当前申请(专利权)人(译)	ETHICON - 内切手术, INC.		
[标]发明人	TANAKA DON A ORTIZ MARK S POWELL DARREL		
发明人	TANAKA, DON A. ORTIZ, MARK S. POWELL, DARREL		
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摘要(译)

用于在组织管腔之间形成空心铆钉(环)附件的吻合环装置通过包括便于从受应力的大致圆柱形状致动的特征而有利于腹腔镜或内窥镜植入。经济的制造商是通过将开口的股线编织成大致圆柱形的支架形状来实现的,该支架形状被赋予形状记忆效应(SME)以致动到空心铆钉(环)形状。作为编织股线中固有的SME的替代或补充,可以从结合到环中的螺旋弹簧元件接收致动力。通过将编织股线形成为从相对的花瓣分叉的花瓣中来增强自动环装置,使得股线在致动时遇到较小的摩擦。这些特征中的每一个单独或组合增强了吻合环装置的临床使用,例如减肥胃旁路手术。

