(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 March 2014 (13.03.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/039651 A1

(51) International Patent Classification:
A61B 17/04 (2006.01)

(21) International Application Number:
PCT/US2013/058224

(22) International Filing Date:
5 September 2013 (05.09.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/698,279	7 September 2012 (07.09.2012)	US
61/710,516	5 October 2012 (05.10.2012)	US
13/839,199	15 March 2013 (15.03.2013)	US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

[Continued on next page]

(54) Title: WOUND CLOSURE DEVICES AND METHODS OF USE

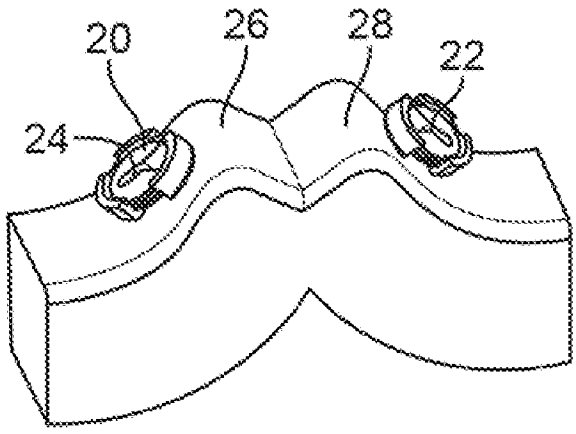

FIG. 2A

(57) Abstract: Wound closure devices and methods of their use are described herein. A deployment instrument may be used to deploy and position tissue anchors which may be locked or secured along lengths of suture in suturing and plicating soft tissues, particularly along tissue regions located in areas of the body where space is limited. Generally, the fastening device may comprise a housing having one or more adjustable tissue anchors aligned longitudinally, wherein each of the one or more adjustable tissue anchors defines a receiving channel along a periphery of the tissue anchors, a tether having a length which is positionable within the receiving channel of each of the tissue anchors, and a plunger translatable relative to the housing, where movement of the plunger urges the one or more tissue anchors to attach securely to the tether.

WO 2014/039651 A1

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

WOUND CLOSURE DEVICES AND METHODS OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. App. 13/839,199 filed March 15, 2013 and U.S. Prov. Apps. 61/698,279 filed September 7, 2012 and 61/710,516 filed October 5, 2012, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to medical devices used for securing and approximating wounds and tissue regions. More particularly, the present invention relates to apparatus and methods for approximating wounds and tissue regions towards one another for wound repair and/or securing portions of tissue for various treatments.

BACKGROUND OF THE INVENTION

[0003] Suturing deep tissues and performing suturing techniques in confined spaces remains a difficult challenge. The ability to tie knots requires a two-handed technique and is fraught with challenges especially when using endoscopic and/or laparoscopic instruments for treating, e.g., oropharyngeal tissues, or regions of the body where space constraints or exposed knots are an issue.

[0004] In addition to the difficulty in performing such techniques, the treatment outcomes are often less than ideal. For instance, when closing the oropharyngeal tissue with suture such as for an uvulopalatopharyngoplasty (UPPP) procedure, the suture typically tends to pull through the friable mucosa and may result in pain inflicted upon the patient due to the exposed or extruded suture knots. Additionally, the time required can often exceed 20 minutes for the closure. The same problems are often seen in other procedures performed upon mucosal tissues such as for bowel anastomosis, closure of biopsy wounds, plications of the stomach, etc. This phenomenon is not only limited to mucosal tissue but also other areas where soft tissues are approximated or secured, such as for shoulder plications, etc.

[0005] Thus, there is a need for instruments and procedures which allow for the deployment of tissue securement devices which enable the securement of soft tissue regions, particularly in areas of the body where space is limited.

BRIEF SUMMARY OF THE INVENTION

[0006] A deployment instrument which deploys and positions tissue anchors which may be locked or secured along lengths of suture may be used in suturing and plicating soft tissues, particularly along tissue regions located in areas of the body where space is limited (e.g., gastrointestinal tissues, oropharyngeal, laryngeal, vascular tissues, etc.). The variations of the tissue anchors described herein may also function to lock against suture lengths without the need for tying knots or exposing terminal suture lengths which typically produce negative clinical outcomes. The instruments and tissue anchors may also produce tissue closures with reduced procedure times, create more durable closures, and create improved patient outcomes with reduced pain and improved healing.

[0007] Generally, the fastening device may comprise a housing having one or more adjustable tissue anchors aligned longitudinally, wherein each of the one or more adjustable tissue anchors defines a receiving channel along a periphery of the tissue anchors, a tether having a length which is positionable within the receiving channel of each of the tissue anchors, and a plunger translatable relative to the housing, where movement of the plunger urges the one or more tissue anchors to attach securely to the tether.

[0008] The one or more tissue anchors may be aligned within an anchor cartridge which may be attached to the housing. With this deployment instrument, one example of a method for fastening tissue may generally comprise passing a tether through a first portion of tissue until a first anchor attached to the tether is placed against the first portion of tissue, passing the tether through a second portion of tissue, aligning a second anchor with the tether, and tensioning the first anchor and the second anchor relative to one another such that the first and second portions of tissue are approximated towards one another. With the approximated tissue, they may then be maintained by securing the second anchor to the tether such that the first and second portions of tissue remain secured to one another.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Figs. 1A-1C shows an example of a UPPP procedure where the oropharyngeal tissue at the back of the throat is typically localized and sutured.

[0010] Fig. 2A shows a perspective view of one variation of a single pair of locking anchors (or caps) which are tethered to one another through plicated tissue via a length of suture extending between the anchors and through the approximated tissue.

[0011] Fig. 2B shows a perspective view of another variation of multiple adjacent locking anchors secured to a corresponding anchor through a length of plicated tissue.

[0012] Figs. 3A to 3C show top and perspective views of another variation of locking anchors which are rotatable relative to one another to secure a length of suture or a tether within the anchor.

[0013] Figs. 4A to 4D show an example of how a length of suture may be introduced along a side window of a rotatable anchor and secured.

[0014] Fig. 5 shows an example of a Fibonacci curve or spiral which may be reproduced along a profile of a locking window of rotatable anchor.

[0015] Figs. 6A to 6D show perspective and top views of a locking anchor variation having a Fibonacci spiral profile which allows the anchor to secure itself to variable diameter suture lengths.

[0016] Figs. 7A to 7E show top views of the locking anchor of Fig. 6A illustrating how a suture length may be loaded along a side window and secured to the anchor by the relative rotation of the anchor portions.

[0017] Figs. 8A and 8B show perspective and exploded assembly views of another variation of a locking anchor utilizing a cam mechanism to secure a suture to the anchor.

[0018] Figs. 9A to 9D illustrate an example of how the anchor of Fig. 8A may introduce a suture length along a side channel of the anchor and subsequently locked via a cam mechanism.

[0019] Figs. 10A to 10C show top views of the anchor of Fig. 8A illustrating the introduction of the suture along the side channel of the anchor and locking of the suture via the bearing cam.

[0020] Fig. 11 shows a perspective and detail perspective view of one variation of a deployment instrument utilizing an anchor cartridge.

[0021] Figs. 12A to 12C show partial cross-sectional side views of a variation of the deployment instrument illustrating the anchor cartridge and optional tissue grasper integrated with the instrument.

[0022] Figs. 13A and 13B show cross-sectional side views of the tissue grasper which may be configured to receive an anchor.

[0023] Fig. 14A shows a perspective view of another variation of the deployment instrument having a hooked grasping arm.

[0024] Figs. 14B and 14C show side views of the instrument of Fig. 14A illustrating how the hooked grasping arm may be actuated relative to the instrument housing.

[0025] Figs. 15A and 15B show side views of another variation of the deployment instrument having a receiving window or channel along the instrument housing.

[0026] Figs. 16A and 16B show side views of yet another variation of the deployment instrument having a V-shaped groove receiving channel actuatable relative to the instrument housing.

[0027] Figs. 17A and 17B show detail cross-sectional side views of how a pair of locking anchors may be staged for deployment from the anchor cartridge.

[0028] Figs. 18A to 18I illustrate an example of how the pair of locking anchors may be staged from the anchor cartridge and subsequently ejected from the deployment instrument for securement to the tissue region of interest.

[0029] Fig. 19 shows an assembly view of another variation of a deployment instrument with a pair of locking anchors and a suture length attached to a suturing needle prior to deployment in the tissue region.

[0030] Fig. 20 shows a perspective view of the deployment instrument of Fig. 19.

[0031] Figs. 21A to 21C show detail side and perspective views of the deployment instrument of Fig. 19 illustrating how a plunging portion may be moved relative to an anvil portion to secure an anchor to the tissue region.

[0032] Fig. 22 shows a perspective view illustrating how a suture length attached to a deployed locking anchor secured to a first portion of tissue may be attached to the deployment instrument.

[0033] Figs. 23A to 23H show another variation of how a first locking anchor may be secured to the first portion of tissue and tightened to a second corresponding locking anchor secured to a second portion of tissue via the deployment instrument and subsequently tightened to approximate the first and second portions of tissue.

DETAILED DESCRIPTION OF THE INVENTION

[0034] In suturing and plicating soft tissues, particularly along tissue regions located in areas of the body where space is limited (e.g., gastrointestinal tissues, oropharyngeal, laryngeal, vascular tissues, etc.) a deployment instrument which deploys and positions tissue anchors which may be locked or secured along lengths of suture may be used. The variations of the tissue anchors described herein may also function to lock against suture lengths without the need for tying knots or exposing terminal suture lengths which typically produce negative clinical outcomes. The instruments and tissue anchors may also produce tissue closures with reduced

procedure times, create more durable closures, and create improved patient outcomes with reduced pain and improved healing.

[0035] Figs. 1A-1C shows an example of a UPPP procedure where the oropharyngeal tissue **OP** at the back of the throat is typically localized and sutured. An example of how such tissue **OP** may be resected is illustrated by the line of resection **10** along which the resected tissue **12** may be removed to enlarge the passageway. However, once the resected tissue **12** is approximated or removed, one or more sutures **14** are typically used to approximate the resected edges of the tissue towards one another to facilitate healing of the wound. Such a procedure provides an example of one application for the instruments and anchors described herein. The apparatus and methods described herein may thus be used in a variety of regions and for various procedures. For example, aside from closing the tonsillar pillars in a UPPP procedure, the anchors and instruments may be used in other procedures such as dental procedures such as tooth extractions, surgeries involving the gastrointestinal and genitourinary systems, etc.

[0036] Fig. 2A shows a perspective view illustrating how a single pair of tissue anchors may have each corresponding anchor locked to a length of suture, wire, or a tether and passed through two approximated tissue regions and terminating at each anchor. In this example, a first anchor **20** may be secured to a first end of the suture or tether **24** and secured near or at a first tissue region **26** to be approximated. The suture or tether **24** may be passed through the tissue such that the first anchor **20** acts as a stop against the tissue surface to allow the first tissue region **26** to be pulled towards the second tissue region **28**. The suture or tether **24** may also be passed through the second tissue region **28** and secured along the second anchor **22**. The first and second anchors **20**, **22** may be approximated towards one another while the first or second anchor **20**, **22** slides along the suture or tether **24** until the edges of the first and second tissue regions **26**, **28** are drawn towards one another into contact to facilitate healing between the tissue regions **26**, **28**. With the anchors **20**, **22** and respective tissue regions **26**, **28** desirably positioned, the suture or tether **24** may be tensioned and secured to the anchors **20**, **22** to maintain the position of the tissue. Because the tissue anchors **20**, **22** may provide a relatively widened contact surface against the tissue surfaces, the forces imparted upon the respective tissue regions **26**, **28** may be distributed over the surfaces of the anchors **20**, **22** and prevent or inhibit the anchors **20**, **22** from pulling through or extruding through the tissue.

[0037] Fig. 2B shows a perspective view of another example of how multiple pairs of corresponding tissue anchor assemblies may be positioned adjacent to one another to secure a length of tissue. With the respective first and second tissue regions **26**, **28** shown in apposition to one another, distinct or separate anchor pairs are illustrated securing the tissue together. For

instance, a first anchor pair **30**, a second anchor pair **32**, and a third anchor pair **34** are illustrated extending between the tissue regions **26**, **28** adjacent to one another in an interrupted suture pattern. However, other variations may utilize a continuous suture or tether along the length of the tissue regions **26**, **28**.

[0038] LOCKING ANCHOR DEVICES

[0039] The tissue anchors described herein may be deployed and secured to one or more tissue regions utilizing the deployment instruments also described herein. As such, variations of the tissue anchors or caps are now described.

[0040] One variation is shown in the top and perspective views of Figs. 3A to 3C which illustrate a rotational locking mechanism. In this suture side loading variation, this design includes two components; an inner crimping disc **40** and an outer housing **42**. In this variation, the crimping disc **40** and outer housing **42** are each formed into a circular configuration to facilitate respective rotation of the components. The inner crimping disc **40** may optionally define a peripheral slot **56** around a circumference of the disc **40** into which a retaining lip **44** defined by the outer housing **42** may reside, as shown in the perspective view of Fig. 3B. Prior to deployment and loading a suture or tether into the anchor, the crimping disc **40** may be rotatably positioned to have peripheral slot **56** of disc **40** aligned with retaining lip **44** such that the inner crimping disc **40** may be partially snapped into the outer housing **42** to form a single assembly, as shown in the perspective view of Fig. 3C.

[0041] The outer housing **42** component may be constructed from materials or dimensions that cause it to be less flexible and/or malleable than the inner crimping disc **40**. A slot in the side of both components communicates from the circumference to at least the center line **54**. For instance, inner crimping disc **40** may define a disc opening **46** which tapers radially towards centerline **54** to form a disc slot **48** for receiving a suture or tether. Likewise, outer housing **42** may also define a housing opening **50** which tapers radially towards centerline **54** to form a housing slot **52**. These respective openings **46**, **50** may include a mouth with an opening substantially larger than the suture or tether diameter and tapers to their respective slots **48**, **52** width similar in size to the tether diameter, e.g., 0.004 in. to 0.020 in. The slots **48**, **52** in the assembly provide the advantage of allowing the suture or tether to engage into the anchor without passing through a hole in the assembly. That is, because the openings **46**, **50** are defined along a periphery of the anchor assembly, the anchor may engage the suture or tether at any point along its length. Additionally, it is not a requirement for the potentially relatively rigid and large diameter tissue piercing component of the closure system to travel through the assembly to mate the suture or tether and anchor.

[0042] Figs. 4A to 4D illustrate an example of how the locking anchor may engage the suture or tether and are locked in place. With the crimping disc **40** positioned about the retaining lip **44** of outer housing **42**, suture or tether **24** may be introduced through the respective openings **46**, **50** which are initially aligned with one another, as shown in Fig. 4A, until the suture or tether **24** is positioned along the slots **48**, **52**, as shown in Fig. 4B. The two components may be compressed and snapped together in the compressed state mainly in the axial direction such that crimping disc **40** is pressed within outer housing **42** and secured via retaining lip **44**, as shown in Fig. 4C. The interference fit between the inner crimping disc **40** outer diameter and the outer housing **52** inner diameter may cause the inner crimping disc slot **48** to collapse at least partially as the parts mate. The collapsing inner slot **48** may crimp onto the suture or tether fixing the anchor assembly to the suture or tether. Each of the components to be designed to rotate relative to one another as shown. For example as shown in Fig. 4D, the crimping disc **40** may be rotated at least partially relative to outer housing **42** such that the openings **46**, **50** are moved out of alignment with one another to ensure that the suture or tether is confined in the centerline **54** of the anchor assembly.

[0043] An alternative rotational locking mechanism is illustrated in the perspective and top views of Fig. 6A to 6D. The variation shown may utilize a spiral or curved cinching mechanism which may utilize a cap having spiraled or curved profile, e.g., a Fibonacci spiral or curve **60**, as shown in Fig. 5. Such a variation may accommodate a wide range of suture or tether diameters through a graded relative rotation between components of the locking anchor. Also, such a locking anchor may be readily unlocked and removed from the suture, if desired. As with the previous variation, an inner crimping disc **70** may be rotatably positioned within an outer housing **72** while secured via retaining lip **74**. The inner crimping disc **70** may define a disc opening **76** which narrows to a disc slot **78** which may be defined by the Fibonacci spiral or curve **60**. The outer housing **72** may likewise define a housing opening **80** which tapers to a housing slot **82**.

[0044] As shown, the suture or tether **24** may slide into the anchor through the disc opening **76** and housing opening **80** side slots when aligned with one another. The openings **76**, **80** may range over opening angle Θ which may be varied to accommodate any number of different size sutures or tethers **24**. In this variation, the housing slot **82** may be slightly smaller in width than the suture or tether **24** outer diameter and include a bottom face geometry that ensures the suture or tether **24** stays engaged in the assembly preferentially opposite the opening **80**. This configuration may provide for the suture or tether **24** to freely move within the anchor prior to the locking step. This may also accommodate any external lateral forces being applied to

the suture or tether **24** without preferentially forcing the suture or tether **24** to disengage from the assembly. The outer housing **72** may be tapered and sized to accept sutures or tethers having diameters of up to 2-0 (e.g., 0.3-0.35 mm), as shown by suture **24** in Fig. 6C, and down to 5-0 (e.g., 0.1-0.15 mm), as shown by suture **24'** in Fig. 6D.

[0045] As described, the disc slot **78** may define a spiral or partial spiral profile along the face that engages the suture tether. A partial spiral may be modeled, e.g., using the Fibonacci spiral or curve **60** to ensure that a force vector normal to the main axis of the outer housing **72** housing slot **82** may be achieved. This force vector direction may ensure secure engagement of the suture or tether **24** in the depth of the cinching slot prior to pinching or approximating between the components.

[0046] An example is shown in the top views of Figs. 7A to 7E. Initially, the slots **76**, **80** may be aligned to allow the suture or tether **24** to be placed into the anchor assembly through a periphery of the assembly, as shown in Fig. 7A. Once the suture or anchor **24** has been received within the respective slots **76**, **80**, the inner disc **70** may be rotated relative to the outer housing **72**, e.g., by engaging disc engagement opening **84** via an instrument, until the suture or tether **24** is retained within housing slot **82** by disc slot **78**, as shown in Figs. 7B and 7C. As the disc **70** is rotated further, the spiraled or curved profile of disc slot **78** (e.g., Fibonacci spiral or curve **60**) may urge the suture or tether **24** further against housing slot **82** as the disc **70** depending upon the degree of rotation of disc **70** relative to outer housing **72**, as shown in Figs. 7D and 7E.

[0047] Yet another variation of a locking anchor is shown in the perspective and assembly views of Figs. 8A and 8B which shows a cam locking mechanism **90** which may accommodate a wide range of suture or tether diameters. In this variation, a compression bearing or ball **90** may wedge the suture or tether **24** against the housing **94**, as shown in the perspective views of Figs. 9A to 9D. A force applied from a direction of the tissue face and opposing cap may preferentially lock the anchor to the suture or tether **24**, as shown in the top views of Figs. 10A to 10C. The locking anchor may be readily unlocked and removed by forcing the anchor assembly to slide relative to the suture or tether **24** towards the tissue.

[0048] The cam locking anchor may utilize an assembly having a relatively rigid sleeve **92**, outer housing **94**, and cam ball **90**. The outer housing **94** may be made of a rapidly bioresorbable and highly elastic material to ensure the main body primarily interacting with the surrounding tissue and anatomy may flex as required. This may allow for a larger force distributing footprint without acting as a cast or rigid splinting body. The inner sleeve **92** may be manufactured such that the mechanical characteristics include the rigidity, strength and toughness required to lock the suture or tether **24** against the cam ball **90**. In this embodiment, the suture or

tether **24** may be introduced into the anchor assembly through a housing opening **96** and sleeve opening **98** which may be aligned relative to one another. The suture or tether **24** may initially slide freely through the anchor assembly through suture thru-hole **100** to allow for adjustment of the anchor positioning relative to the tissue prior to securing the anchor to the suture **24**. One or more retaining projections **102** may be optionally defined within the thru-hole **100** to help inhibit the suture or tether **24** from falling out of the housing and sleeve openings **96**, **98**.

[0049] Once the anchor has been desirably positioned along the suture or tether **24** relative to the tissue to be secured, tension may be applied to the suture or tether **24** relative to a grounded sleeve **92** and housing **94** assembly by preferentially applying a moment about the rotational axis of the cam ball **90**. As the ball **90** may continue to rotate with the sliding tether until it bottoms out against the inner wall/base of the sleeve **92**.

[0050] Aside from the variations shown, other alternative embodiments of the locking anchor may include, e.g., a hinge-locking mechanism, where a force applied from the direction of the tissue face and opposing cap may preferentially lock the cap to the tether. Moreover, each of the locking anchors may utilize a side-loading channel for receiving the suture or tether length. This may allow for various sizes or geometries of tissue piercing needles to be used with the suture lengths as the locking anchors may be engaged along the suture lengths proximal to the needle.

[0051] Additionally, alternative configurations of the tissue anchors may be used. For example, various geometric shapes that conform to the tissue may be used. In one embodiment that shape will be circular, in others it will be linear, curved, oval, etc. The shape of each implant may create the ideal suturing characteristic for tissue closure, for instance, the circular attachment may create eversion of the tissue while flat exposed areas may spread tension on the circular plate. A flat surface may reduce pain felt by the patient during the degredation of the suture and implant and reduce dehiscence secondary to the direction and diffusion of tension. In other embodiments, the attachment can be linear, creating a sealing of the tissue closure when placed linearly.

[0052] The locking anchors may be made of a resorbable or non-resorbable material (e.g., a polymeric material). In certain embodiments, the anchors may be made of a resorbable polymeric material such as a polyester. In other variations, the anchors may made of a resorbable material such as poly(lactic-co-glycolic acid).

[0053] While the locking anchors may be made of a biocompatible material, such as a biocompatible polymer, they may be made of a biocompatible and bioresorbable material, e.g., polyester, polyanhydride, polyphosphazene, polyacrylate, polymethacrylate, etc. In other

variations, the locking anchors may be made of, e.g., poly(lactic-co-glycolic acid) (PLGA), poly(L-lactic-co-glycolic acid) (90% glycolide:10% L-lactide), etc. Such biocompatible and bioresorbable materials may be absorbed in approximately 1 to 4 weeks during use or approximately 4-6 weeks during use. Other variations may be absorbed approximately 6-8 weeks during use or even longer, such as approximately 2-3 months during use.

[0054] In alternative variations, the locking anchors may be comprised of a bioresorbable, synthetic polymeric material, e.g., co-polymer, block polymer, linear polymer, branched polymer, dendritic polymer, cross-linked polymer, etc. In other variations, the polymer may comprise, e.g., polyester, polyurethane, polyvinyl chloride, polyethylene, polyolefin, polyanhydride, polyamide, polycarbonates, polycarbamate, polyacrylate, polymethacrylate, polystyrene, polyurea, polyether, polyalkylether, or polyamine. Exemplary polymers that may be used to make the device include poly(lactic acid), poly(glycolic acid), poly(lactic-co-glycolic acid) (PLGA), poly(anhydride), polyphosphazenes, and poly(caprolactone). In certain embodiments, the polymer is a poly(glycolide-co-lactide) (PLGA). In certain embodiments, the device is made of 50% D,L-lactide and 50% glycolide co-polymer. In certain embodiments, the device is made of 50% L-lactide and 50% glycolide co-polymer. In certain embodiments, the device is made of 85% D,L-lactide and 15% glycolide co- polymer. In certain embodiments, the device is made of 85% L-lactide and 15% glycolide co-polymer. In certain embodiments, the device is made of 90% D,L- lactide and 10% glycolide co-polymer. In certain embodiments, the device is made of 90% L-lactide and 10% glycolide co-polymer. In certain embodiments, the polymer is polyglycolic acid. In certain embodiments, the polymer is poly-β-hydroxybutyrate. In certain embodiments, the polymer is polyacrylic acid ester. In certain embodiments, the device is made of Pebax, Polyimide, Braided Polyimide, Nylon, PVC, Hytrel, HDPE, or PEEK. In certain embodiments, the device is made of a fluorinated polymer such as PTFE, PFA, FEP, and EPTFE. In certain embodiments, the device is made of latex. In certain embodiments, the device is made of a natural polymer. In certain embodiments, the natural polymer is a polysaccharide such as cellulose or derivatives thereof. In certain embodiments, the natural polymer is a protein. The locking anchors may be made of a material that is bioabsorbed after the device is no longer needed (e.g., after the tissues have healed). For example, the device may degrade in vivo after 1 week, 2 weeks, 3 weeks, 1 month, 2 months, 3 months, 4 months, 5 months, 6 months, etc. In certain embodiments, the device is designed to degrade after approximately 4-6 weeks in vivo.

[0055] In certain embodiments, the fastening device may also be constructed of a shape memory plastic or metallic material. Such shape memory plastic or metallic materials can return to some previously defined shape or size when subjected to the appropriate thermal procedure or

similar form of energy. That is, shape memory alloys or plastics can be plastically deformed at some relatively low temperature and, upon exposure to some higher temperature, will return to their original shape. Metal materials that exhibit the shape memory effect include a number of copper allow systems and the alloys of gold-cadmium, nickel-aluminum, and iron-platinum. In addition, plastic materials that exhibit the shape memory effect have been developed and include, for example, materials disclosed in U.S. Patent Nos. 6,720,402, 6,388,043, 6,160,084 (each of which is incorporated herein by reference in its entirety).

[0056] In certain embodiments, the fastening device may be provided in a shape that is easily inserted into the mucosa. Thermal energy may then be applied to cause the fastening device to change shape (e.g., make the fastening device close together), thus providing a rapid closure of the fastener through the mucosal flaps with merely an application of heat or energy. In certain embodiments, the fastening device may comprise an elastomeric material, including for example, a polyhydroxyalkanoate (PHA) material. In certain embodiments, the fastening device may comprise a crystalline or amorphous polymer combined with an elastomeric polymer. For example, a highly crystalline polylactide may be blended with a polyhydroxybutarate; specifically 80- 97% Poly-L-Lactides (PLLA) and 20-3% PHA in certain embodiments. Similarly, caprolactone or trimethyl carbonate may be added to a crystalline polymer to make it more elastic. Elasticity of the construct can be achieved through the addition of the caprolactone or trimethyl carbonate to a lactide or glycolide monomer since the caprolactone and trimethyl carbonate have relatively low melting temperatures (e.g., 60°C for carpolactone).

[0057] Such material can provide an elasticity that is similar to that of the surrounding tissue. By providing a similar elasticity to the surrounding material, the fastening device can flex with the surrounding tissue. This can increase the ability of the fastening device to maintain approximation of the tissue during healing, and can reduce the likelihood that the fastening device will tear or otherwise damage the surrounding tissue.

[0058] Moreover, the locking anchors and/or sutures may be optionally coated with one or more various agents. For instance, examples of coatings may include a timed release formulation of a pharmaceutical agent such as a hemostatic agent, anti- inflammatory agent, a steroid, antibiotic, anesthetics, pain reliever, hemostatic agent, etc. The agent may be released over hours, to days, to weeks, to months. In certain embodiments, the coating is a polymeric coating impregnated with a therapeutic agent. Classes of therapeutic agents that may be delivered by the device include DNA, RNA, nucleic acids, proteins, peptides, or small molecules. Exemplary therapeutic agents include antibiotics, anti-inflammatory agents, corticosteroids, vasoconstrictors, vasodilators, coagulants, pain relievers, etc. The coating may also include a

radioopaque agent for imaging of the device.

[0059] In other variations, the devices may be made of a non-biodegradable material or otherwise coated with, e.g., Teflon (PTFE), hyaluronidate, polymers, polysaccharide such as hyaluronate, etc. The locking anchors may also be coated to make the device more biocompatible. Many coatings for medical devices are known in the art and may be applied to the inventive fastening devices.

[0060] Although custom tether materials and sizes may be housed within the deployment instrument for automatic deployment, the anchors and instruments herein may be compatible with multiple conventional sutures available in the operating room due to the locking mechanisms employed within the entry and exit cap assemblies and the side loading nature of the anchors.

[0061] Additionally, the locking nature of the anchors may allow for the adjustment of tension on the suture and similarly may allow for adjustment of the length of the tether or suture between the locking cap assemblies as well as the position of the needle exit and entry sites relative to the tissue flap edges. This may provide for the physician to adjust the tissue fastening site mechanics relative to the spacing between tissue flaps associated with the amount of tissue excised. This also allows the physician to adjust the cap and tether deployment relative to the types of tissue and healing characteristics at the target site. Alternatively, many staple or auto-knot tying devices include a fixed throw of a piercing needle or fixed length of suture or tether between tissue engaging components. The fixed aspect of these devices equates to significant variance in the amount of tension applied to the target tissues when closing wounds with different gap dimensions.

[0062] Because of the adjustability of the locking caps and delivery instruments, the physician may use both tactile and visual feedback to close wounds. This may enable the physician to alter their approach based on surgical experience.

[0063] DEPLOYMENT SYSTEMS

[0064] Deployment instruments for holding and applying the various locking anchors to close or approximate two or more tissues are also provided. Such instruments may include a space for holding a plurality of fastening devices that may be needed in a given surgery or procedure. The instrument may include a handle for comfortable gripping of the instrument and may work by applying the fastening anchors to the mucosa or other tissues to be joined and fastening the device. The deployment instrument may be disposable or suitable for sterilization and re-use. The delivery system may include a combination of disposable and reusable components. For example, in one variation, the cartridge of caps and reel of suture may be

sterilized and packaged from a reusable or disposable delivery instrument including, e.g., a handle, actuator, etc.

[0065] The deployment instrument may optionally include an energy source within the handle, e.g., battery supply, or may be in communication with an external energy source such as a radio-frequency generator to deliver energy that may be used to actuate, deform, or assemble components of the cap and tether configuration.

[0066] Generally, the deployment instrument may (1) lock an initial entry cap onto a tether and needle assembly (2) assist in the initial pass of the needle portion of the assembly through the first tissue flap (3) assist in passing the needle through the second tissue flap (4) engage the exit side suture with the distal assembly, including at least one locking cap (5) cinch the exit locking cap against the tissue with sufficient force to mate the two edges/flaps of the wound (6) lock the exit cap to the exit side tether (7) lock the next entry cap to the needle and tether assembly extending from proximal face of the first exit cap (e.g., simultaneous to (6) locking the exit cap to the exit side tether) (8) cut the exit tail of the tether between the locked exit cap and next locked entry cap to complete the first wound closure and prepare the second needle/tether/entry cap assembly for the second wound closure site. Moreover, the deployment instrument may mate with a disposable cartridge having, e.g., at least 10 but nominally 30 locking anchor assemblies to provide at least 5 but nominally 15 total wound closure sites per procedure. Although other variations may incorporate few or additional locking anchor assemblies.

[0067] A piercing needle may be omitted from the deployment instrument and furthermore, the deployment instrument does not require any piercing element to pass through the instrument as having a curved or large diameter needle would potentially require a relatively larger deployment instrument. Moreover, the deployment instrument may utilize a side-loading channel much like the locking anchors thus enabling the instrument to engage exposed suture at any point along its length. This may further allow the deployment instrument to engage close to the target tissue closure site potentially inside a body cavity and/or after exposed from a distal end of laparoscopic tooling. This may also allow for the deployment instrument to engage suture at a distance from the target tissue closure site where visualization of a suture tail may be easier such as from the mouth, nose, or surgical created body cavity. Because a single instrument provides multiple functions (e.g., needle/tissue pick up, closure cap attachment, suture-trimming, etc.), the deployment instrument may mate with other laparoscopic tool lumens.

[0068] An example of one variation of the deployment instrument is shown in the perspective view of Fig. 11. The deployment instrument **110** may apply an axial compression force to the locking anchor assembly described herein. Alternative locking anchor designs may

utilize alternative mechanisms at the distal end of the delivery tool to actuate/lock the entry and exit caps to the tether. However, the primary sequence of events and methods disclosed here would apply to any locking anchor and tether closure assembly disclosed herein.

[0069] The deployment instrument **110** may generally comprise a proximal handle **112**, main shaft **114** attached to the handle **112**, and distal assembly **116** positioned at a distal end of the main shaft **114**. The proximal handle **112** may include ergonomic features to comfortably fit in one hand of the user and mechanical actuators to translate proximal motion to distal motion as used by the locking anchors and needle gripper. The distal assembly **116** may also incorporate a main distal housing **118** which defines a distal housing opening **119** as shown in the detail view of distal assembly **116**. A locking cap cartridge **120** may also be attached to the main shaft **114** and/or distal housing **118** and may contain the locking anchors for deployment into or against the tissue. A locking cap staging housing **122** may also be defined within the distal housing **118** where the anchors may be chambered into the distal housing **118** for loading of the suture or tether for deployment into the tissue.

[0070] Optionally, a gripper tool **124**, such as forceps or graspers, may be actuatable and slidably disposed through the distal housing **118** and adjacent to the locking cap cartridge **120**. The gripper tool **124** may define one or more cutting edges or blades **126** for selectively severing the suture or tether, and it may also define a surface for grasping or manipulating a needle and/or the suture or tether as well. Moreover, the distal housing **118** (through which the gripper tool **124** may translate) may further define a suture slot having a length **128** and width **130** which extends longitudinally along the distal housing **118** for receiving the suture or tether into the locking anchors prior to or during deployment, as further described herein.

[0071] The optional needle gripper **124** and the locking cap cartridge **120** are shown in the cross-sectional side views of Fig. 12A to 12C. As illustrated in this variation of the deployment instrument **110**, the gripper **124** may be slidably contained within the distal housing **118** of the distal assembly **116** and may be utilized as a needle pick up similar to conventional surgical tooling as well as an inner plunging tool for controlling the position and state of the locking anchors. As a plunging tool, the needle gripper **124** may apply the compression locking force to the locking entry and exit anchors. The gripping tool **124** may also incorporate the suture or tether cutting element **126** at the distal most point of its claws used to cut the trailing/exit end of the suture or tether upon completion of each wound closing step.

[0072] The distal housing **118** may define the suture slot **128** through its outer wall that aligns with the mouth and slot of the locking anchor assemblies during the tether engagement step of the closure process. This slot **128** may be wide enough to easily accept the suture or tether

element and long enough to ensure the suture or tether fully engages at least two locking anchor assemblies (exit and entry). The assembly may also include an anchor staging housing **122** mounted off axis from the main body assembly and may further include a proximal mating feature to accept a locking anchor cartridge **120**. This cartridge **120** may contain multiple locking anchor pairs **132**, e.g., an entry **136** and exit **138** anchor pair, and may be packaged separately from the tool, as shown in Figs. 12A and 12B. The cartridge **120** may include as few as 5 and as many as 20 locking anchor pairs **132**. In one embodiment the separately packaged cartridge **120** and anchors may be disposable and configured to mate with the reusable delivery device main body.

[0073] During use, the anchor pairs **132** may be ejected from the cartridge **120** via a cartridge housing spring tab **140** located along the cartridge **120** in proximity to the anchor staging housing **122** which may push or slide the anchor pairs from the cartridge **120**, through a cartridge opening **142** defined between the cartridge **120** and distal housing **118**, and into the distal housing **118** for loading and deployment into or against the tissue, as described in further detail below. The next anchor pair **132** may be pushed or urged distally through the cartridge **120** via a biasing element **134**, such as a spring, into position adjacent to the distal housing **118**.

[0074] Manipulation of the optional gripper tool **124** includes advancement and retraction of the claws relative to the distal housing opening **119**. These claws may be urged open by, e.g., a biasing element **146** such as a spring, positioned near the pivot point at their base. The claws may spring hinge about pivot **144** to open when they are advanced beyond the distal housing opening **119** and are no longer constrained within the housing inner diameter. When retracted, the distal face inner edge of the housing may interface with the ramping proximal face **148** of the claws to force them closed. The position of this interface relative to the claw pivot **144** may be modified to increase or decrease the claw closing force relative to the tensile force applied at the handle by the user. The severity of the angle of this proximal ramping face **148** of the claws **124** may be modified to change the amount of longitudinal motion required to apply the range of gripping forces and the coarse or fine adjustment capabilities for this gripping feature of the instrument.

[0075] Figs. 13A and 13B show detail cross-sectional side views of an alternative gripper configuration which takes advantage of a telescoping motion between the inner components and an outer sheath. Both configurations may be easily incorporated into the deployment instrument herein.

[0076] Fig. 14A shows a perspective view of another alternative gripper configuration. This variation illustrates a hook grabber configuration which may utilize a bent arm **154**

extending from the retraction arm **152** to hook needle **156**. The arm **154** may retract to trap the needle **156** between the inner bend radius of the bent arm **154** and face of the main body **150**. Figs. 14B and 14C illustrates a side view of how the bent arm **154** may be projected or retracted to capture the needle **156** or suture **24**.

[0077] Figs. 15A and 15B show side views of yet another variation of a gripper which utilizes an inner mandrel **162** which may include a through-hole **164** sufficiently large enough to easily accept the needle **156**. The main body **160** may include a mating hole that allows for full communication through the instrument when aligned. In use, the needle **156** and/or suture **24** may be passed into or through the through-hole **164** and the inner mandrel **162** may be retracted relative to main body **160** to trap the needle **156** (or suture) between the mandrel proximal face **166** and main body distal surface **168**. The retraction of the mandrel **162** may be varied to accommodate various size needles and/or sutures lengths.

[0078] Figs. 16A and 16B show side views of yet another variation where either variation may include a "V"-shaped groove at the mandrel proximal face **176** to promote increased grip on the needle **156**. With the through-hole **174** aligned, the needle **156** may be passed through the instrument. The inner mandrel **172** may be retracted relative to the main body **170** to lock the needle **156** between the mandrel proximal face **176** and main body distal surface **178**.

[0079] With this or any of the needle/suture manipulation instruments variations, any of the embodiments may be optionally incorporated with the deployment instrument **110** in various combinations.

[0080] The deployment instrument may also incorporate an optionally removable multiple anchor cartridge **120** which allows for rapid deployment of interrupted closures along a wound. As described, the deployment instrument may house two or more locking anchor assemblies that may serve as an entry and exit cap at surfaces of the opposing wound tissue flaps. These anchors may be deployed to the target site at a distance ranging from about, e.g., 6 to 12 inches, for UPPP like procedures or using a flexible main shaft and deployed through an endoscope or laparoscopic ports requiring longer and smaller diameter tooling.

[0081] Figs. 17A and 17B illustrate cross-sectional side views of one variation of an anchor cartridge **120** which is configured to allow for a pair **132** of locking anchors which are stacked or aligned with one another within the cartridge **120** to move from the staging housing to the main body. If the optional needle gripper **124** is used, the needle gripper **124** may be positioned in its distal working position such that its proximal body fills the annular space in the main housing **118** preventing the locking anchors from sliding sideways. When the gripper **124** is

fully retracted using the controls on the proximal handle, the spring tab is free to push an exit/entry anchor assembly laterally through cartridge opening **142** and into the main housing **118** distal to the claws of the gripper **124**, as shown. Simultaneously, the anchor cartridge compression spring **134** may slide the remaining anchors **132** distally staging the next exit/entry anchor pair.

[0082] Once the exit/entry anchor pair **132** is positioned distal to the gripper **124** in the main housing **118**, it may be pushed forward until flush with the distal opening **119** of the main housing **118**. With the exit/entry anchor pair **132** in the distal position, the deployment instrument **110** may be configured to engage the needle and suture or tether near the needle exit point from the tissue.

[0083] As shown in the partial cross-sectional side views of Figs. 18A to 18I, the distal detail of the deployment instrument **110** and position of the locking anchors **132** and gripper **124** as anchor components are shuttled from the staging position **122** to the distal main housing **118** ready to accept the tissue exiting suture or tether and needle. The anchor cartridge **120** and instrument housing are shown along with the gripper **124** in its home position at a distal position within the main housing **118**, as shown in Fig. 18A. Fig. 18B shows the gripper **124** retracted proximally in its second home position proximal within the main housing **118** and adjacent to the staging area **122**. Fig. 18C shows the gripper **124** fully retracted opening a space in the main housing **118** for receiving the locking anchor pair **132**.

[0084] Fig. 18D shows a locking anchor pair **132** pushed laterally via cartridge housing spring tab **140** into the main housing **118**. Fig. 18E shows the gripper **124** pushing the locking anchor pair **132** to a distal position through the main housing **118**. Fig. 18F shows the gripper **124** compressing the locking anchor pair **132** to lock both exit **136** and entry **138** anchor to an axially positioned suture or tether which may be introduced through the longitudinal suture slot **128** defined along the distal portion of main housing **118**. Fig. 18G shows the gripper **124** claws in an open position, e.g., for grasping or manipulating a needle or suture length and Fig. 18H shows the gripper claws in its closed position. Finally, Fig. 18I shows the gripper **124** claws in tether cutting position to release the anchor pair **132** deployed within the tissue.

[0085] Fig. 19 shows an assembly view of another variation of a deployment instrument (which may optionally omit the anchor cartridge) having a shaft **180** with a locking anchor staging housing **186** attached at a distal end at also attached to a stationary handle **194** at its proximal end. Fig. 20 also shows a perspective view of the deployment instrument. A suture slot **188** may be defined longitudinally along a length of the staging housing **186** for receiving a suture length into an anchor for deployment. An adjacent actuation shaft **184** attached at its distal

end to a housing **182** may also be attached **192** to an actuation handle **190** at its proximal end where the actuation handle **190** may be translated relative to the stationary handle **194**. Also illustrated is a pair of locking anchors **132** and a suture length **24** attached to a suturing needle **156** as part of the assembly prior to deployment in the tissue region.

[0086] Figs. 21A to 21C show detail side and perspective views of the deployment instrument of Fig. 19 illustrating how a plunging portion (e.g., housing **182**) may be moved relative to an anvil portion (e.g., anchor staging housing **186**) to secure an anchor to the tissue region. In an example of use, one or more of the anchors such as anchor **138** may be placed within anchor staging housing **186** with the open slot of the anchor aligned with the suture slot **188**. A length of suture or tether **24** may be introduced through suture slot **188** as well as within the open slot of the anchor positioned within anchor staging housing **186** and the actuation shaft **184** may be actuated to close housing **182** relative to anchor staging housing **186**, as shown in Fig. 21C. Actuating the assembly may secure or crimp the anchor upon the suture or tether **24** for placement upon or against the tissue for approximating the tissue regions.

[0087] CLOSURE METHODS

[0088] In another aspect methods of using the fastening devices and/or the instruments are provided. The devices and instruments may be used in a variety of surgeries or procedures. For example, the surgeries or procedures may involve the approximation of mucosal surfaces of the head and neck. Other procedures may involve surgeries or procedures involving the oral cavity, oropharynx, hypopharynx, throat, or laryngeal surfaces such as UPPP procedures, tonsillectomies, etc.

[0089] For example, the apparatus and methods herein may be used to close the tonsillar pillars. Sealants such as a fibrin-based products, chitosan-based products, thrombin-based products, alpha-cellulose based products, collagen-based products, albumin-based products, etc. can be used in conjunction with the fastening devices in order to reduce pain, reduce bleeding, and/or otherwise improve the outcome. In alternative procedures, coatings, such as protein or growth factor based products, can be used in conjunction with the fastening devices in order to enhance healing and/or otherwise improve the outcome. For instance, tonsillectomy procedures may be performed with the devices and apparatus herein along with a sealant placed on the tonsillar bed.

[0090] Other procedures or applications for these devices and methods may include, e.g., removal of a tumor of the head or neck, dental or oral surgery, closing of laryngeal or pharyngeal defects, procedures on the gastrointestinal tract and genitourinary system, neurosurgery procedures such as dural closure, etc.

[0091] The devices described herein may be optionally embodied in a kit. For instance, such a kit may include one or more sizes of the locking anchors, pharmaceutical agents (e.g., anesthetics, antibiotics, etc.), a deployment instrument for applying/fastening the locking anchors, a separate instrument for removing the anchors, instructions for use, etc. Moreover, the items may be sterilely packaged for the use by a treating physician.

[0092] Generally in use for closing a wound or approximating two regions of tissue towards one another, a force distributing anchor may be attached to a suture length having an attached needle. The suture and a first anchor assembly may be passed through a first tissue flap of the target closure site until the first anchor is flush with the needle entry point through the tissue. A second and third locking anchor may be simultaneously locked to the suture such that the second anchor is flush with the tissue at the needle exit site along a second tissue flap while the first and second tissue flaps are approximated towards one another along the suture and placed into contact. Simultaneously and/or subsequently, the suture between the second anchor and the third anchor may be severed (automatically by the deployment instrument or manually by the physician) to prepare the third anchor for a subsequent tissue closure.

[0093] The second anchor or the deployment instrument may be used by the physician to control the amount of tension applied to the tether when approximating and/or securing the tissue to one another. Optionally, the deployment instrument may be calibrated to automatically lock the second anchor to the suture when a predetermined amount of force is applied. The deployment instrument may also attach the second anchor to the suture and simultaneously sever the suture when it exits the second anchor. Additionally, the deployment instrument may also be optionally calibrated to attach the second anchor to the suture when a predetermined tension has been achieved and/or simultaneously sever the suture where it exits the second anchor when placed against the secured tissue.

[0094] In approximating and secure two apposed tissue regions, the anchor pairs may be deployed and secured with the deployment instrument, e.g., repeated at least 3 times, 5 times, or 10 times, or more. In certain procedures, the steps are performed in the context of a uvulopalatopharyngoplasty (UPPP) with or without tonsillectomy procedure. In other procedures, the steps are performed in the context of a uvulopalatal flap (UPF) procedure. In other procedures, the steps are performed in the context of removal of a tumor. In still other procedures, the steps are performed in the context of closing a laryngeal or pharyngeal defect. In still other procedures, the steps are performed in the context of closing an Eustachian tube orifice. In certain procedures, the steps are performed in the context of a dental procedure. In certain procedures, the steps are performed for laparoscopic bowel surgery, cholesystectomy, endoscopic

gastric surgery or orthopedic soft tissue surgery, or interventional gastroenterology procedures involving manipulating an instrument through the working channel of an endoscope. In specific procedures, the method further comprises applying a tissue sealant to the approximated tissues. In certain procedures, the tissue sealant is a fibrin-based sealant, while in other procedures, the tissue sealant is a chitosan based product, thrombin based product, alpha-cellulose based product, collagen based product, or albumin based product.

[0095] Although suitable for use in closing or approximating mucosal tissues, the fastening devices may be used in other non-mucosal tissues, e.g., approximating a mucosal surface to a non-mucosal surface; approximating a non- mucosal surface to a non-mucosal surface, etc.

[0096] Turning now to Fig. 22, a perspective view of a variation of the deployment instrument **110** is shown illustrating how a suture or tether length **24** attached to a deployed locking anchor **136** secured to a first portion of tissue **26** may be attached to the deployment instrument **110** by having the deployment instrument **110** grab the needle **156** via grabbing jaws **124** as it exits the first portion of tissue **26**.

[0097] Figs. 23A to 23H illustrate how a first locking anchor **136** may be secured to the first portion of tissue **26** and tightened to a second corresponding locking anchor **138** secured to a second portion of tissue **28** via the deployment instrument **110** and subsequently tightened to approximate the first **26** and second portions **28** of tissue.

[0098] Fig. 23A shows how the first locking anchor **136** may be pulled to sit flush against the first tissue portion **26**. The deployment instrument **110** may be positioned to grab and control the needle **156** as it exits the first tissue flap **26** if a grasper **124** is used with the deployment instrument **110**. Otherwise, the physician (or assistant) may manually grasp the needle **156** and apply the suitable tension. As shown in Figs. 23B and 23C, the needle **156** grasped and engaged by the grasper **124** (or manually via another instrument) may be passed through a second tissue flap **28** to be approximated with the first tissue flap **26**.

[0099] Once the suture or tether **24** has been passed through both tissue portions **26**, **28** to be approximated or affixed, the suture or tether **24** may then be placed against along suture slot **128** of main housing **118** and loaded along a side opening slot of at least a second anchor **138** cycled within the main housing **118**, as shown in Figs. 23D and 23E. Optionally, a third anchor may also be cycled within the deployment instrument to load the subsequent anchor into the distal tether engagement position for the next anchor deployment.

[0100] Fig. 23F illustrates how with the needle 156 and exit suture or tether 24 in one hand, the physician (or assistant) may engage the exit suture or tether 24 close to its exit from the

second tissue flap 28. The suture or tether 24 may slide into the slot 128 in the tool main housing 118 and continue the engagement with the tool 110 until concentric with the next locking anchor pair. The deployment instrument 110 may be pushed toward the target tissue while tension is maintained on the exit suture or tether 24 and needle 156, as shown in Fig. 23G. This causes the deployment instrument 110 to slide down the exit suture or tether 24, contact the exit tissue flap 28, and cinch the tissue flaps 26, 28 to one another. Using the proximal handle controls, the physician (or assistant) advances the deployment instrument needle grabber 124 assembly and compresses the exit and entry anchors against the tissue surface. This compressive force snaps both anchors 136, 138 closed fixing the exit suture or tether 24 to both anchors 136, 138. The tissue flaps 26, 28 are fixed together at this closure site.

[0101] Fig. 23H shows how the deployment instrument 110 may then be disengaged from the locked exit and entry anchors 136, 138, suture or tether 24 and needle 156. The physician may apply tension to the needle/tether and advance the needle grabber assembly 124 from the distal end of the deployment instrument 110. The distal pinchers of the grabber jaws 124 may be used to cut the suture or tether 24 between the exit and entry anchors 136, 138 creating the next entry anchor 200, needle 156, and suture or tether 24 assembly.

[0102] The applications of the disclosed invention discussed above are not limited to certain treatments or regions of the body, but may include any number of other treatments and areas of the body. Modification of the above-described methods and devices for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the arts are intended to be within the scope of this disclosure. Moreover, various combinations of aspects between examples are also contemplated and are considered to be within the scope of this disclosure as well.

CLAIMS

What is claimed is:

1. A fastening device, comprising:

a housing having one or more adjustable tissue anchors aligned longitudinally, wherein each of the one or more adjustable tissue anchors defines a receiving channel along a periphery of the tissue anchors for receiving a tether; and

a plunger translatable relative to the housing, where movement of the plunger urges the one or more tissue anchors to attach securely to the tether.

2. The fastening device of claim 1, wherein the tether has a length which is positionable within the receiving channel of each of the tissue anchors.

3. The fastening device of claim 2, wherein the tether comprises a suture.

4. The fastening device of claim 1, wherein the housing comprises a cartridge having a plurality of tissue anchors aligned therein.

5. The fastening device of claim 1, wherein the housing defines an opening therealong for receiving the tether.

6. The fastening device of claim 1, wherein the plunger comprises a grasper.

7. The fastening device of claim 1, further comprising a handle extending from a proximal end of the housing.

8. The fastening device of claim 1, wherein the tissue anchor comprises a first portion which defines a first receiving channel and a second portion which defines a second receiving channel, the first portion being rotatable relative to the second portion from an open position where the first and second receiving channels are aligned to a locking position where the first receiving channel and second receiving channel are misaligned.

9. The fastening device of claim 8, wherein the first receiving channel defines a spiraled or curved profile.

10. The fastening device of claim 1, wherein the tissue anchor comprises a cam mechanism.

11. The fastening device of claim 10, wherein the cam mechanism comprises a collar body and an insert positionable within the collar body and a bearing slidably positionable within the insert.

12. The fastening device of claim 1, wherein the tissue anchors are made of a biocompatible and/or bioresorbable material.

13. The fastening device of claim 1, wherein the tissue anchors are coated with an agent.

14. A method of fastening tissue in a procedure, comprising:

passing a tether through a first portion of tissue until a first anchor attached to the tether is placed against the first portion of tissue;

passing the tether through a second portion of tissue;

aligning a second anchor with the tether;

tensioning the first anchor and the second anchor relative to one another such that the first and second portions of tissue are approximated towards one another; and,

securing the second anchor to the tether such that the first and second portions of tissue remain secured to one another.

15. The method of claim 14, wherein passing a tether comprises passing a needle having a length of suture attached through the first portion of tissue.

16. The method of claim 14, further comprising attaching the tether to the first anchor along a receiving channel defined along a side periphery of the first anchor prior to passing a tether through a first portion.

17. The method of claim 14, wherein passing the tether through a second portion comprises passing a needle having a length of suture attached through the second portion of tissue.

18. The method of claim 14, wherein aligning a second anchor comprises introducing the tether through a receiving channel defined along a periphery of the second anchor.

19. The method of claim 18, wherein the second anchor is positioned within a deployment instrument.

20. The method of claim 14, wherein tensioning the first anchor and the second anchor comprises tensioning the tether through the second anchor positioned within a deployment instrument.

21. The method of claim 14, wherein securing the second anchor to the tether further comprises securing a third anchor to the tether.

22. The method of claim 14, further comprising cutting the tether from the second anchor.

23. The method of claim 14, wherein the procedure comprises an uvulopalatopharyngoplasty (UPPP) procedure.

24. The method of claim 23, wherein the procedure further comprises a tonsillectomy procedure.

25. The method of claim 14, wherein the procedure comprises a tonsillectomy procedure.

26. The method of claim 14, wherein the procedure comprises an uvulopalatal flap (UPF) procedure.

27. The method of claim 14, wherein the procedure comprises a gastric tissue approximation procedure.

28. The method of claim 14, wherein the procedure comprises an intestinal tissue approximation procedure.

29. The method of claim 14, wherein the procedure comprises a tendon approximation

procedure.

30. The method of claim 14, wherein the procedure comprises a ligament approximation procedure.

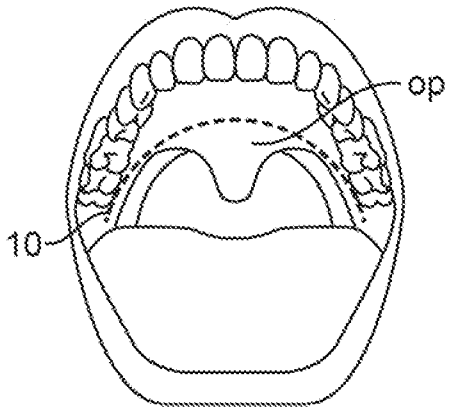

FIG. 1A

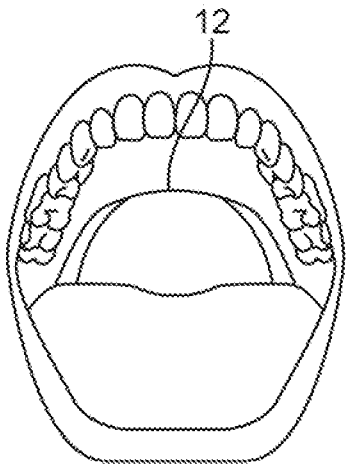

FIG. 1B

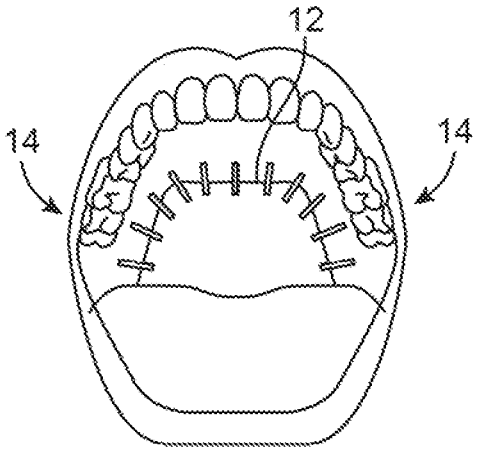

FIG. 1C

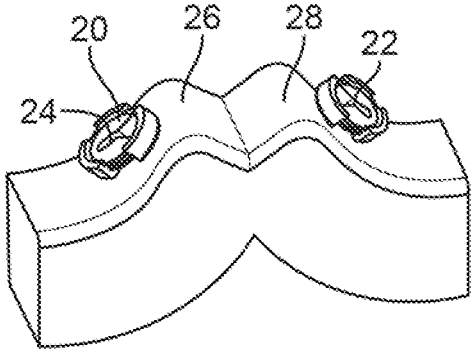

FIG. 2A

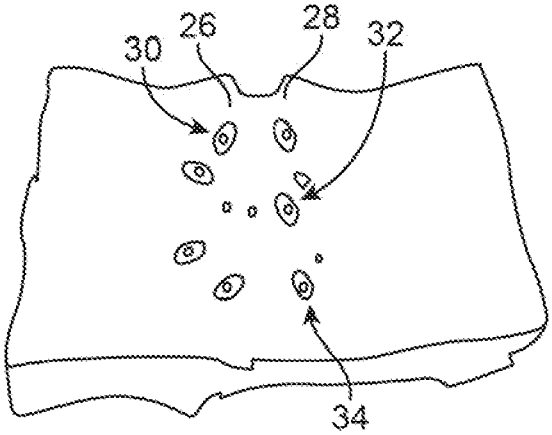

FIG. 2B

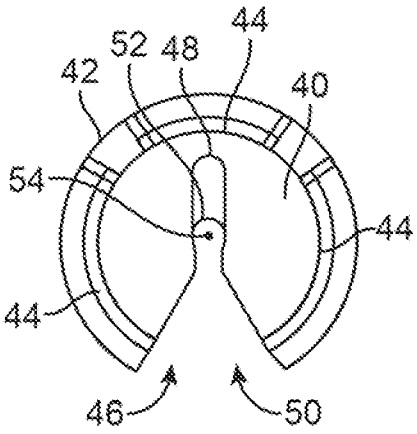

FIG. 3A

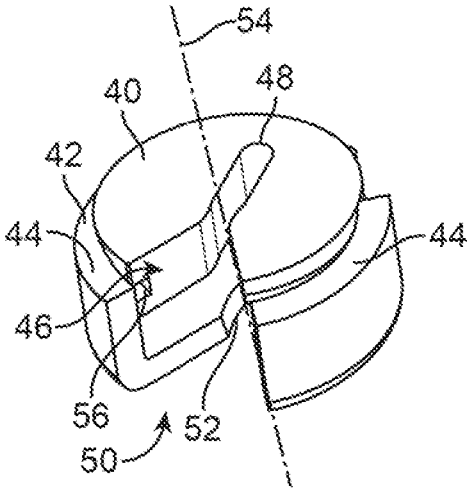

FIG. 3B

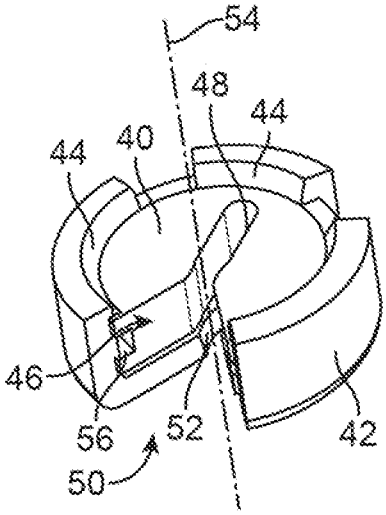

FIG. 3C

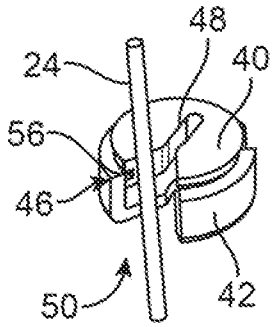

FIG. 4A

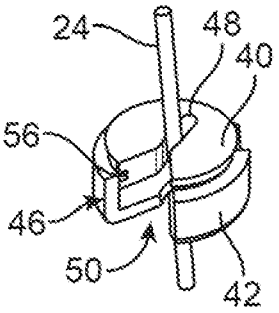

FIG. 4B

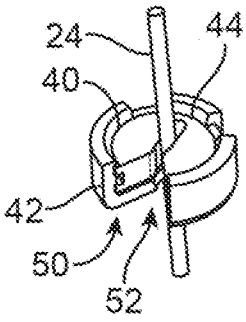

FIG. 4C

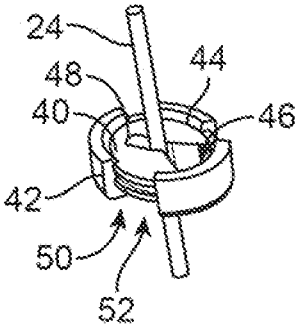

FIG. 4D

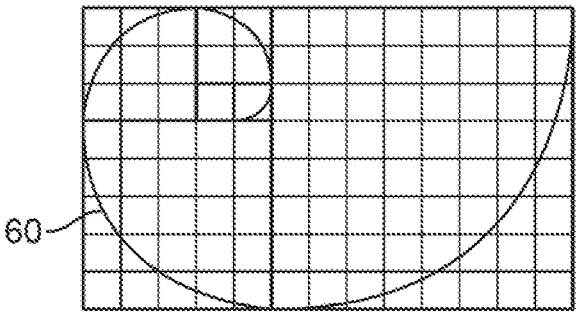

FIG. 5

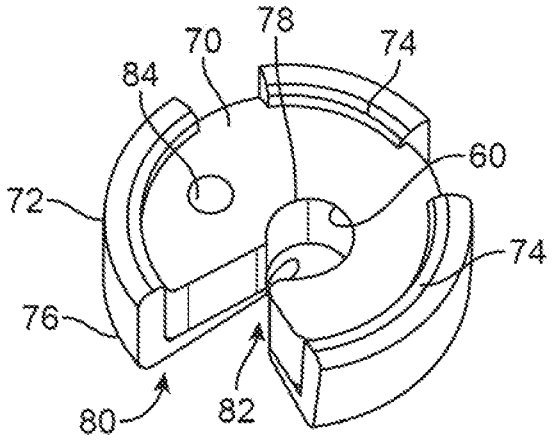

FIG. 6A

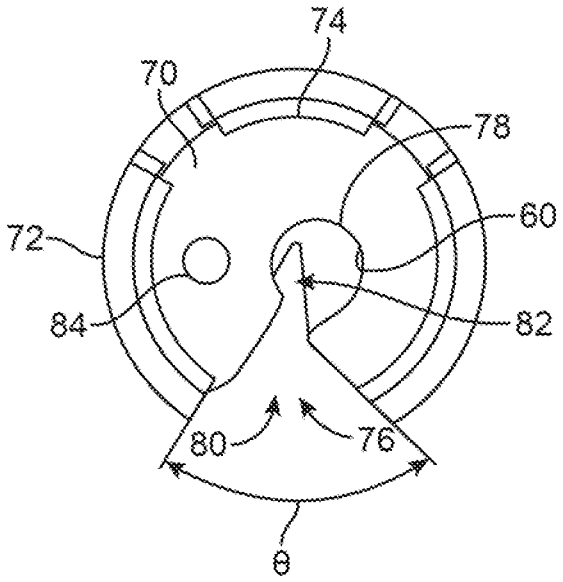

FIG. 6B

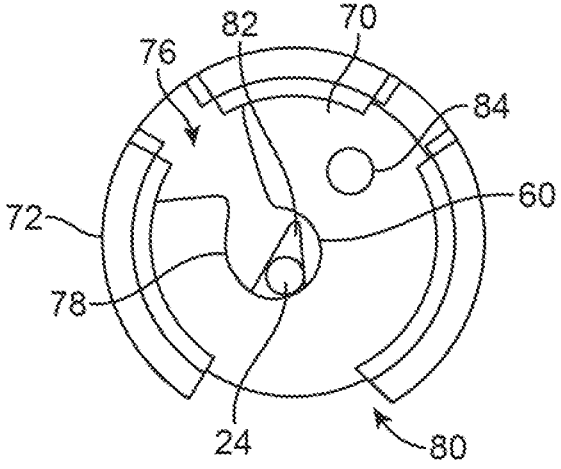

FIG. 6C

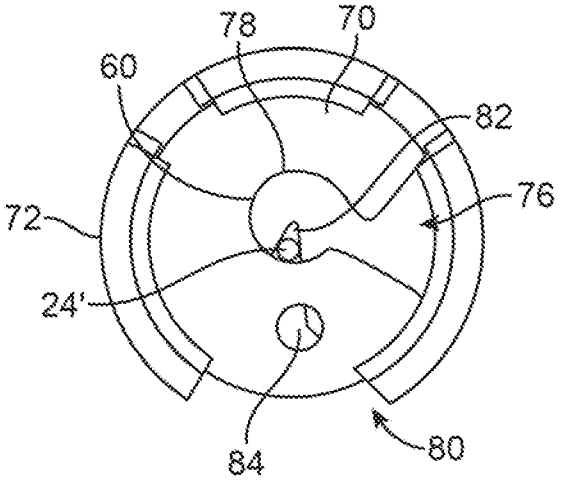

FIG. 6D

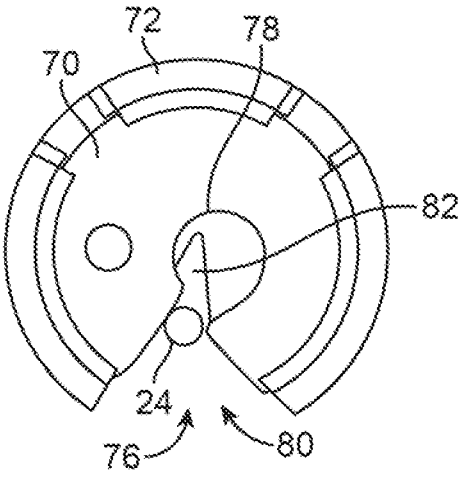

FIG. 7A

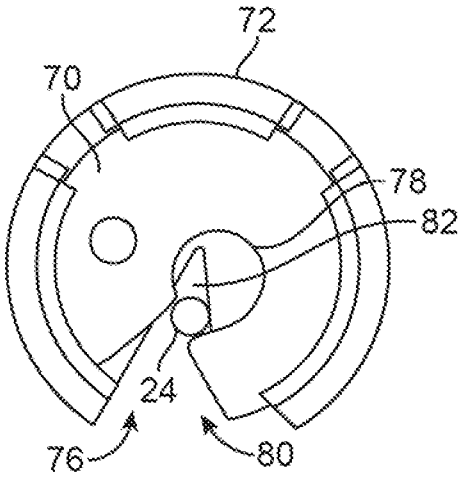

FIG. 7B

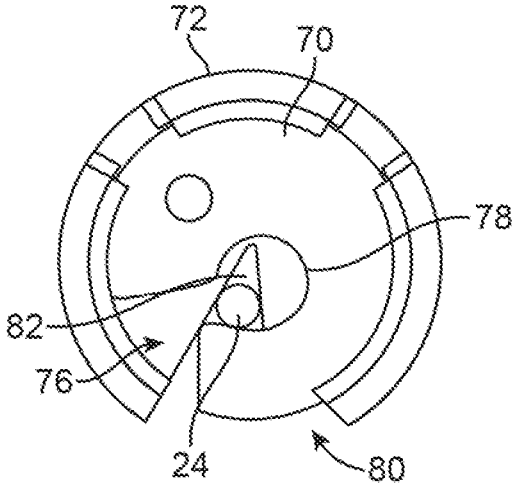

FIG. 7C

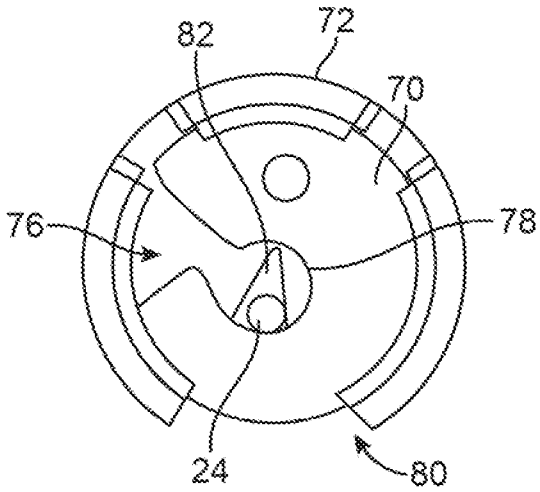

FIG. 7D

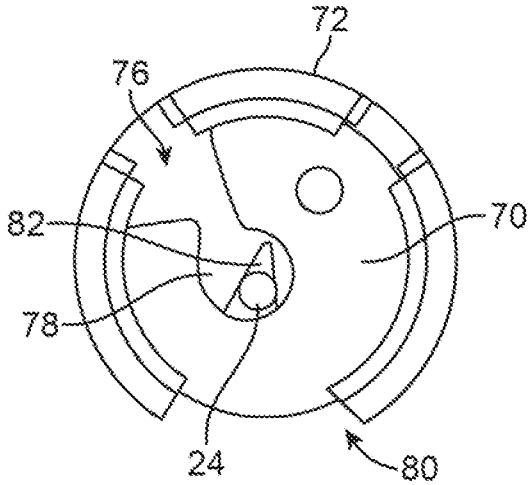

FIG. 7E

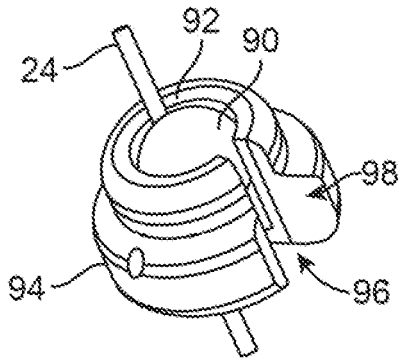

FIG. 8A

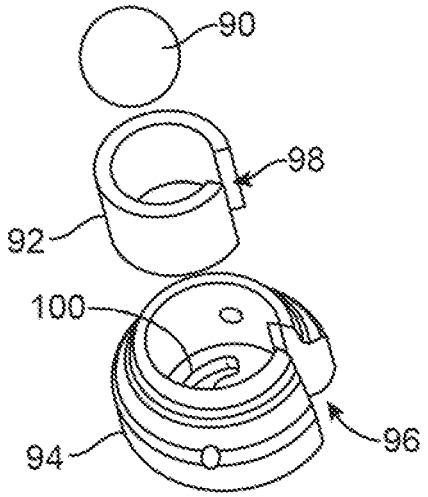

FIG. 8B

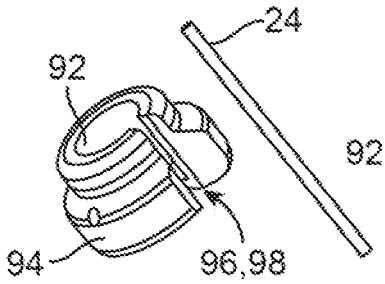

FIG. 9A

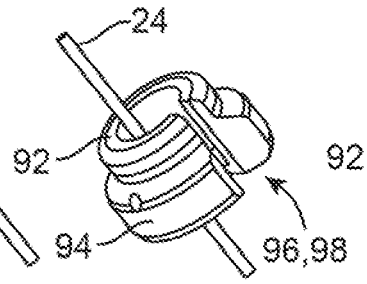

FIG. 9B

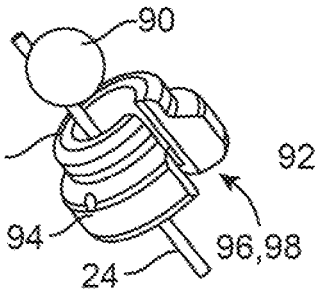

FIG. 9C

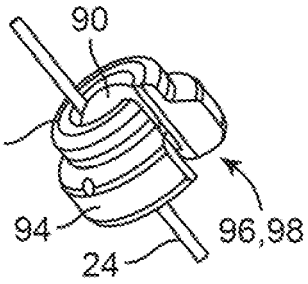

FIG. 9D

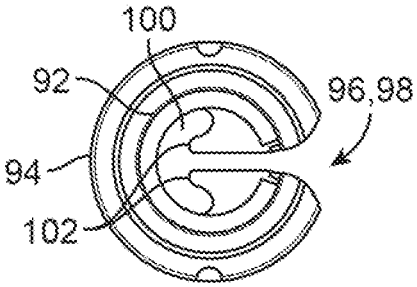

FIG. 10A

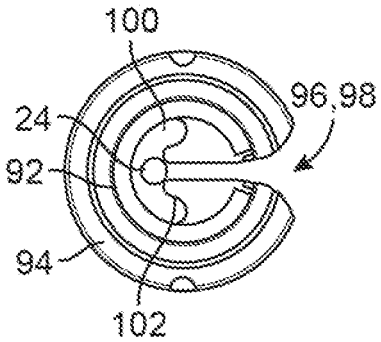

FIG. 10B

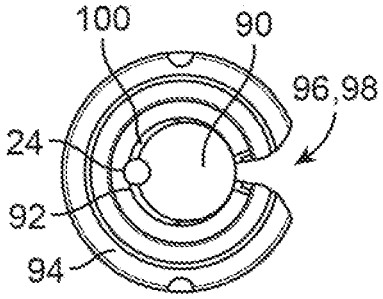

FIG. 10C

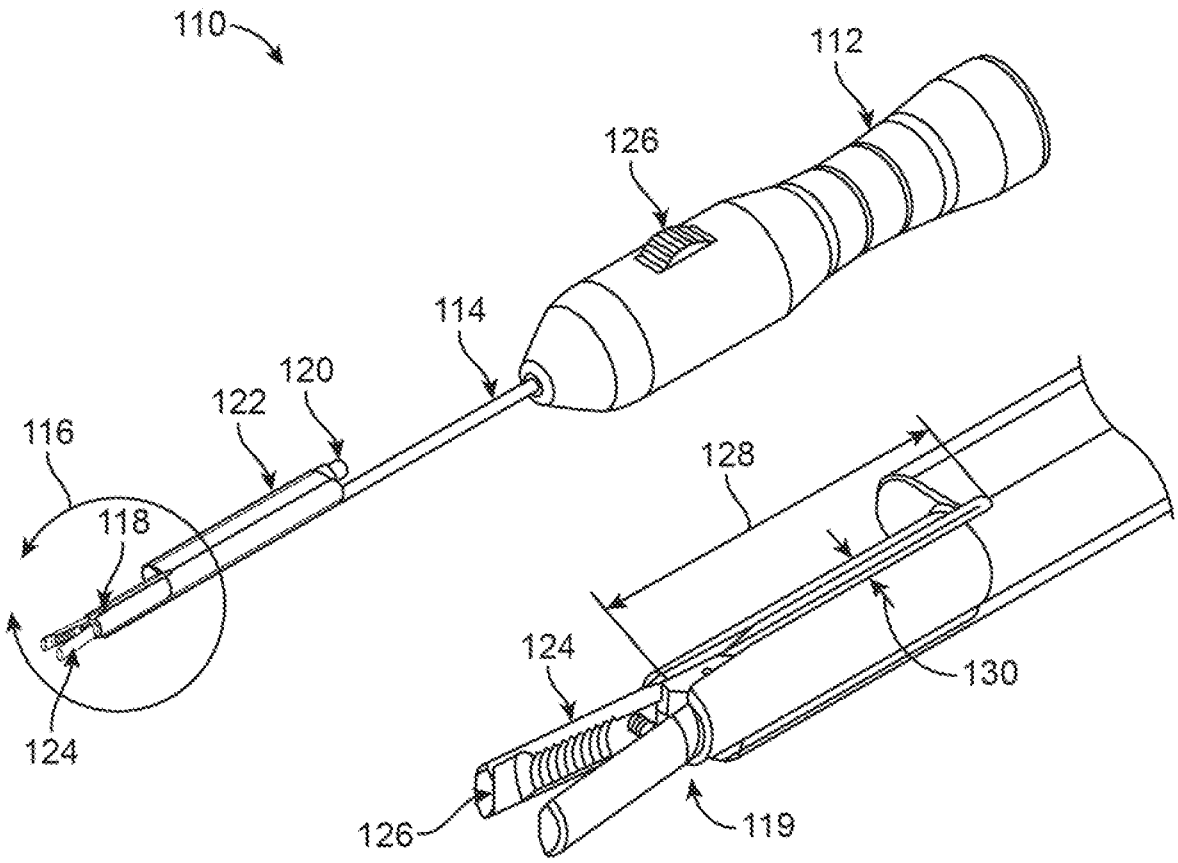

FIG. 11

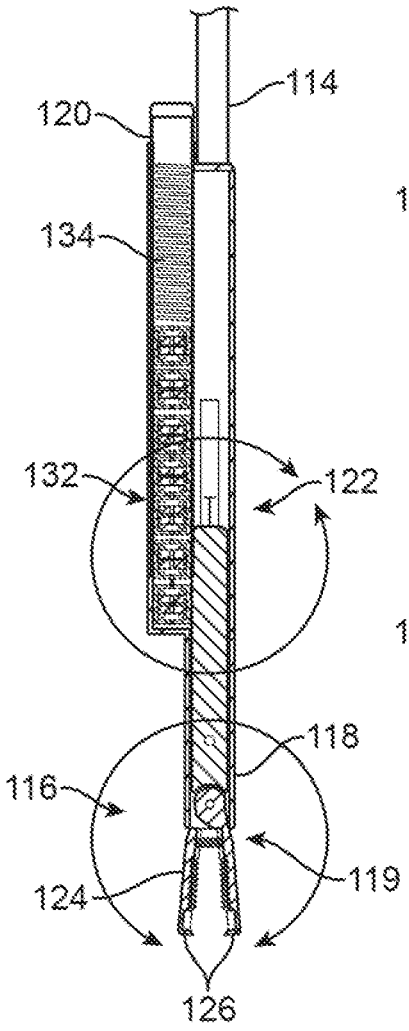

FIG. 12A

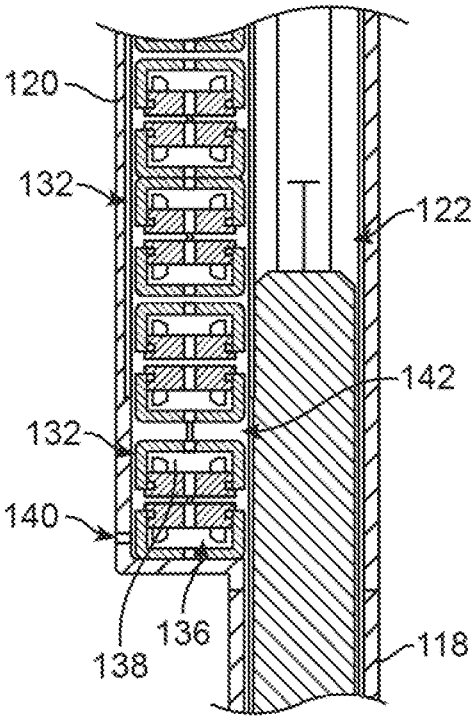

FIG. 12B

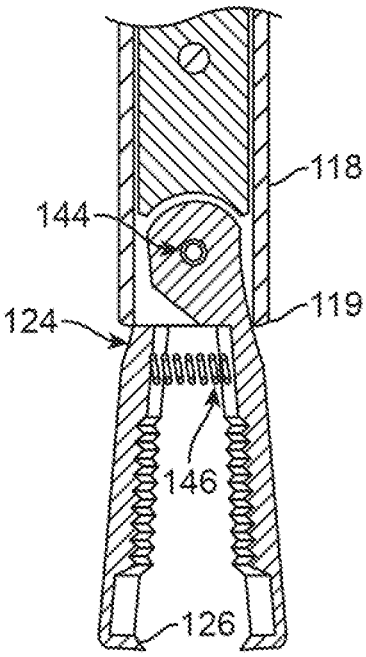

FIG. 12C

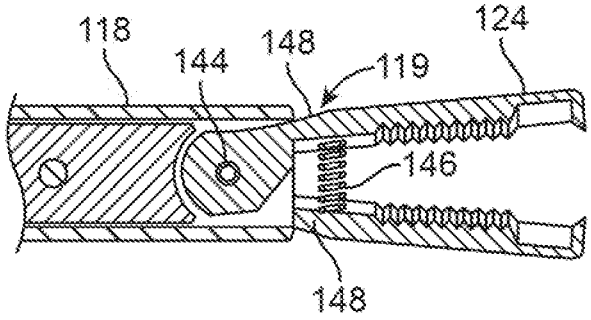

FIG. 13A

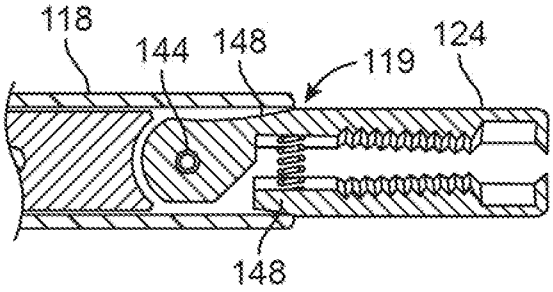

FIG. 13B

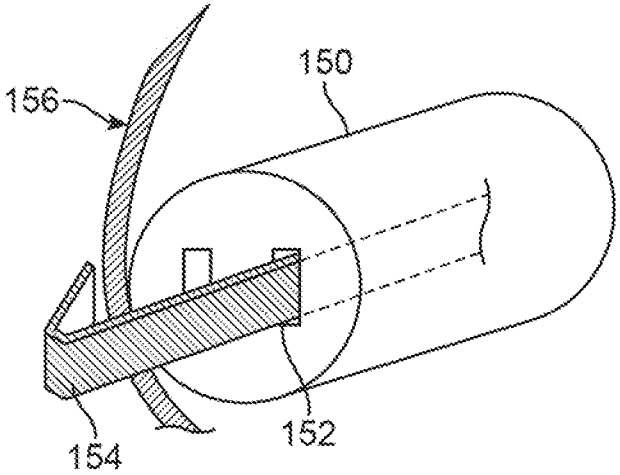

FIG. 14A

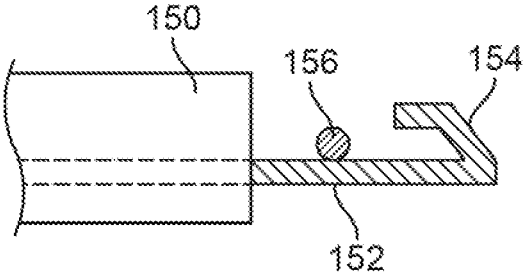

FIG. 14B

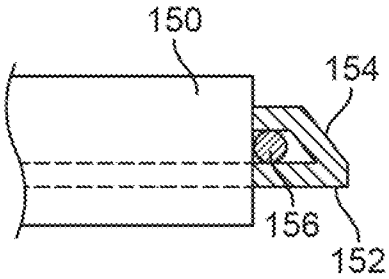

FIG. 14C

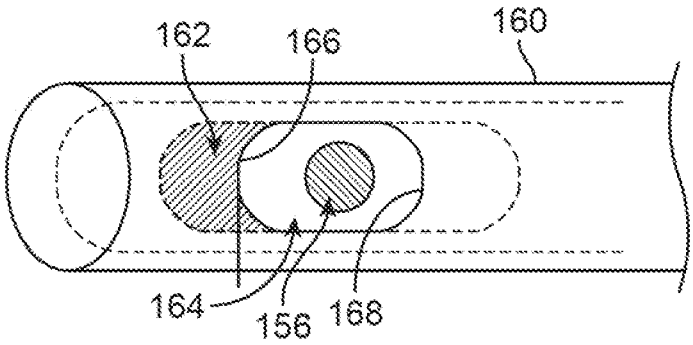

FIG. 15A

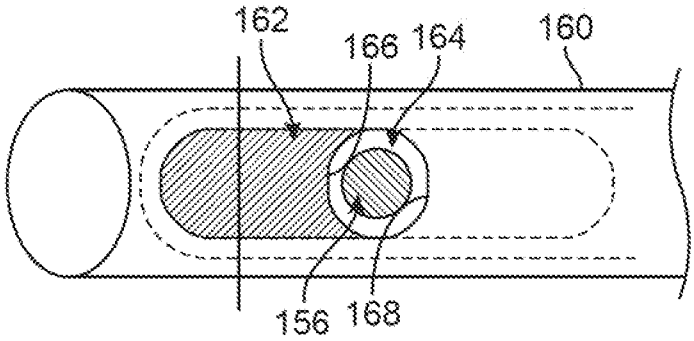

FIG. 15B

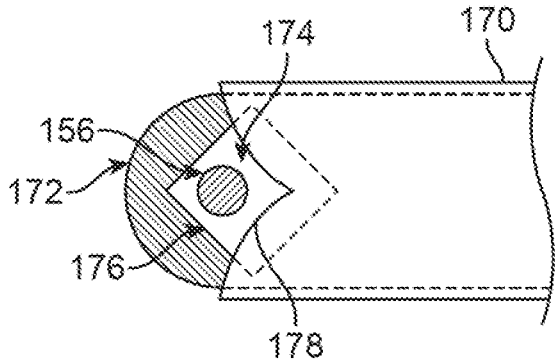

FIG. 16A

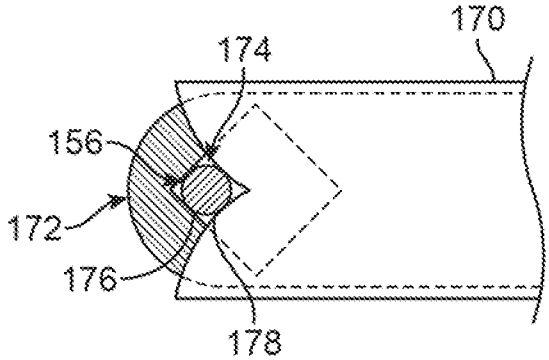

FIG. 16B

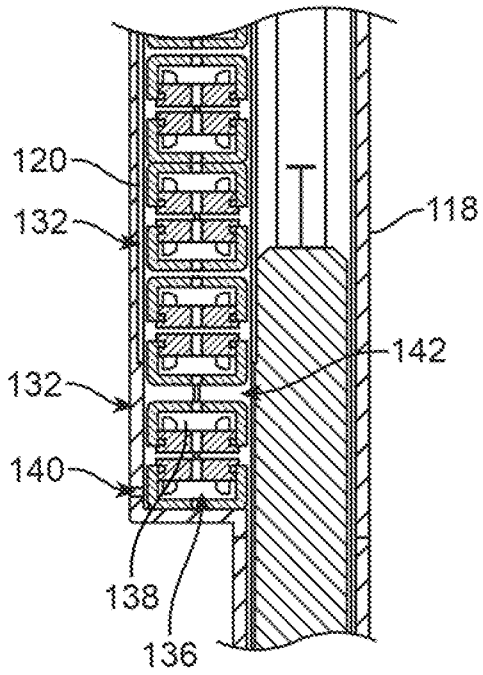

FIG. 17A

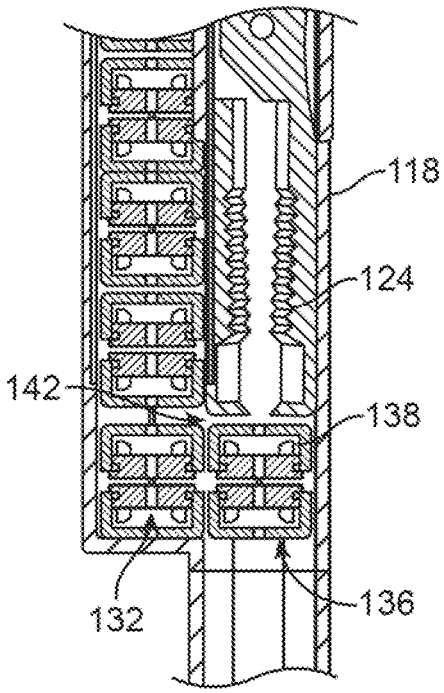

FIG. 17B

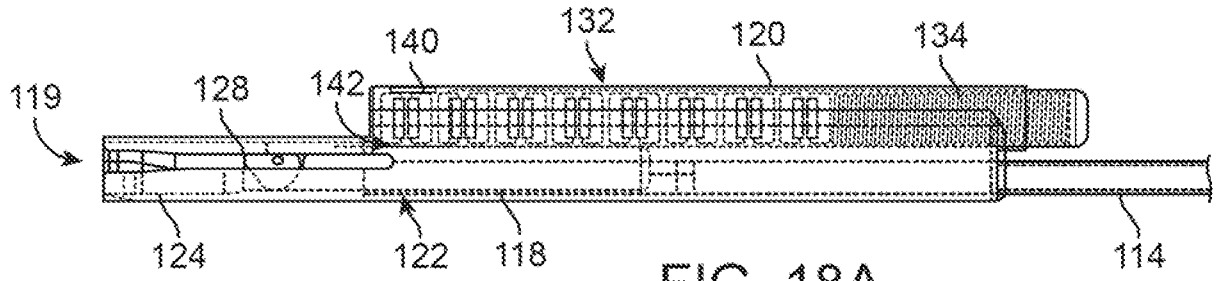

FIG. 18A

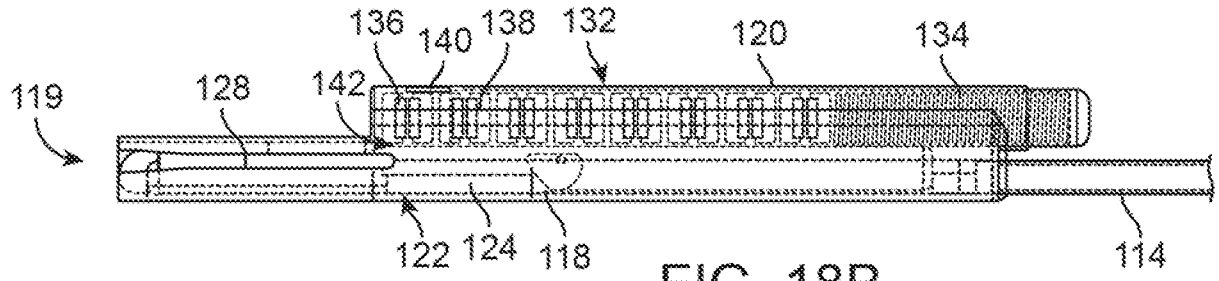

FIG. 18B

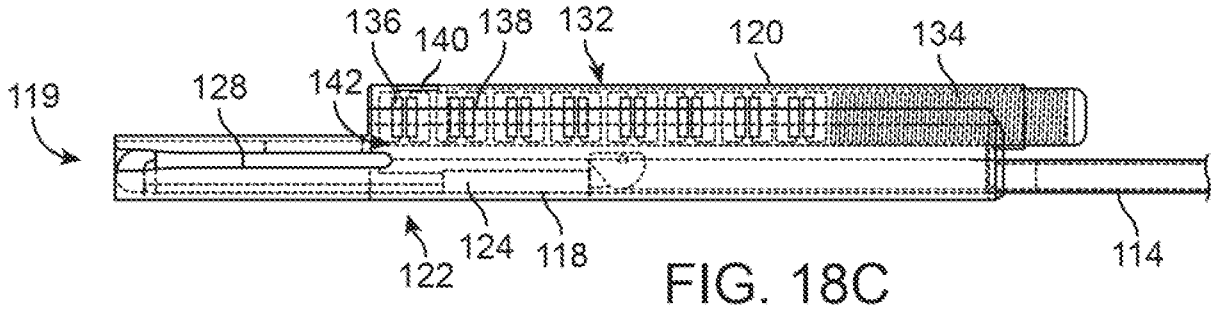

FIG. 18C

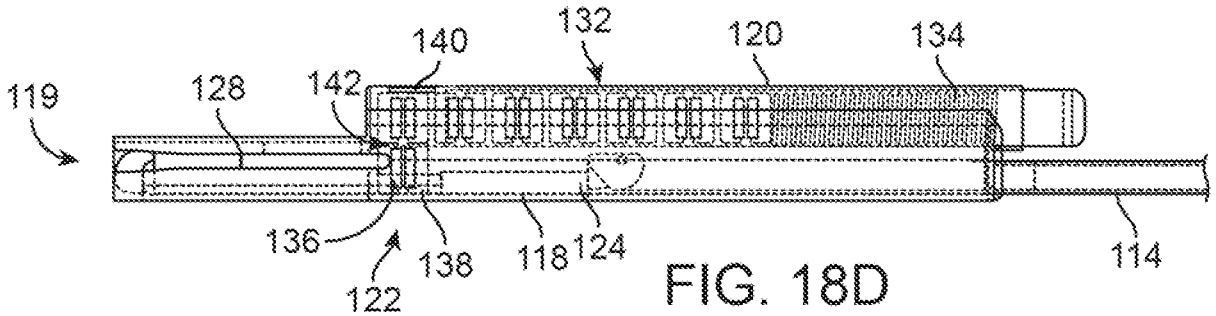

FIG. 18D

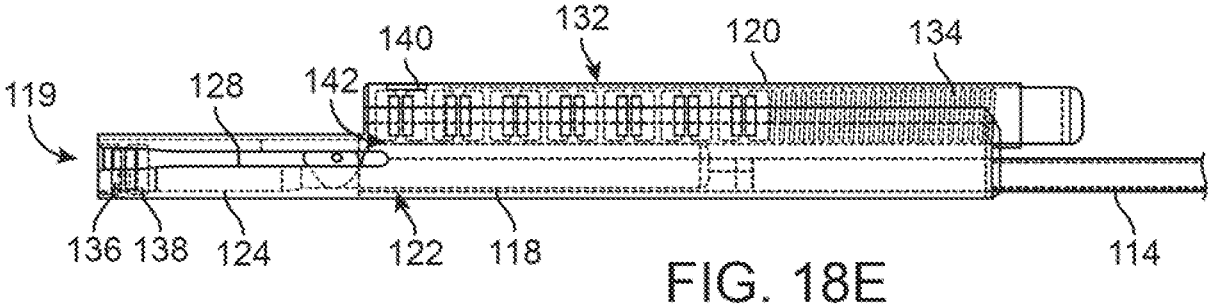

FIG. 18E

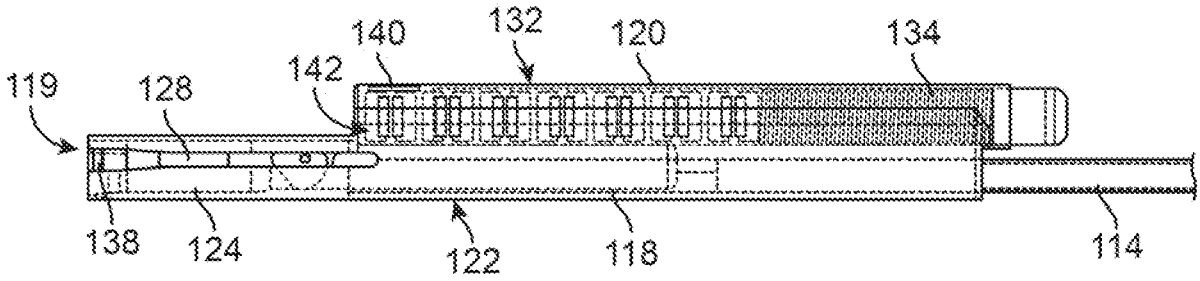

FIG. 18F

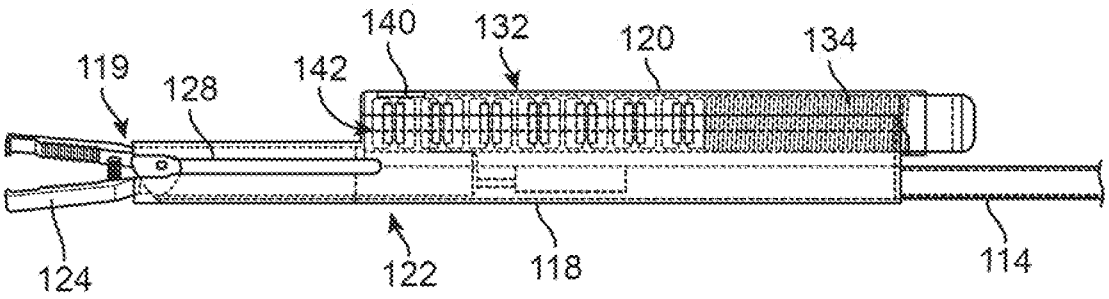

FIG. 18G

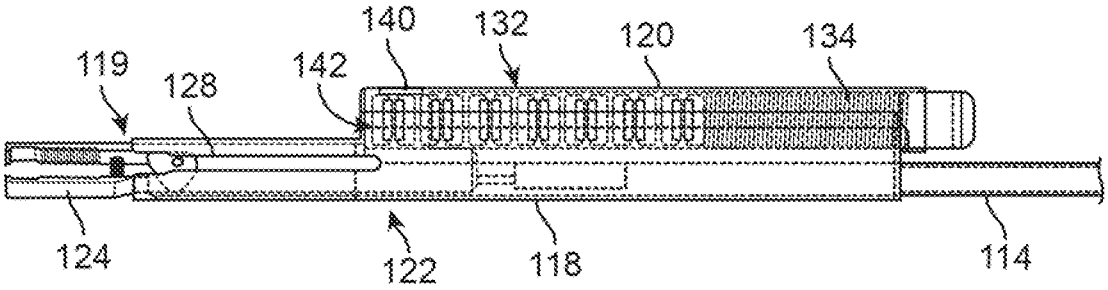

FIG. 18H

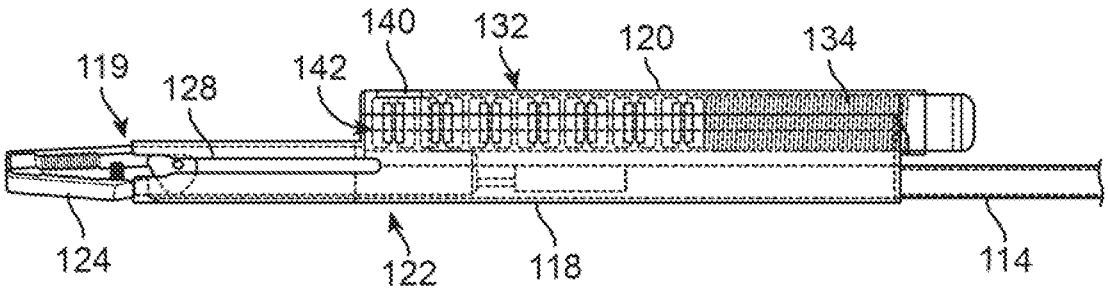

FIG. 18I

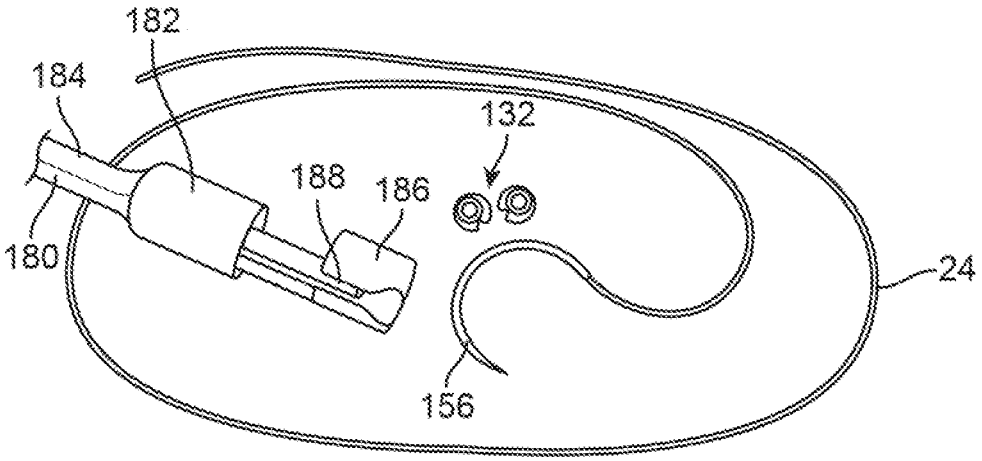

FIG. 19

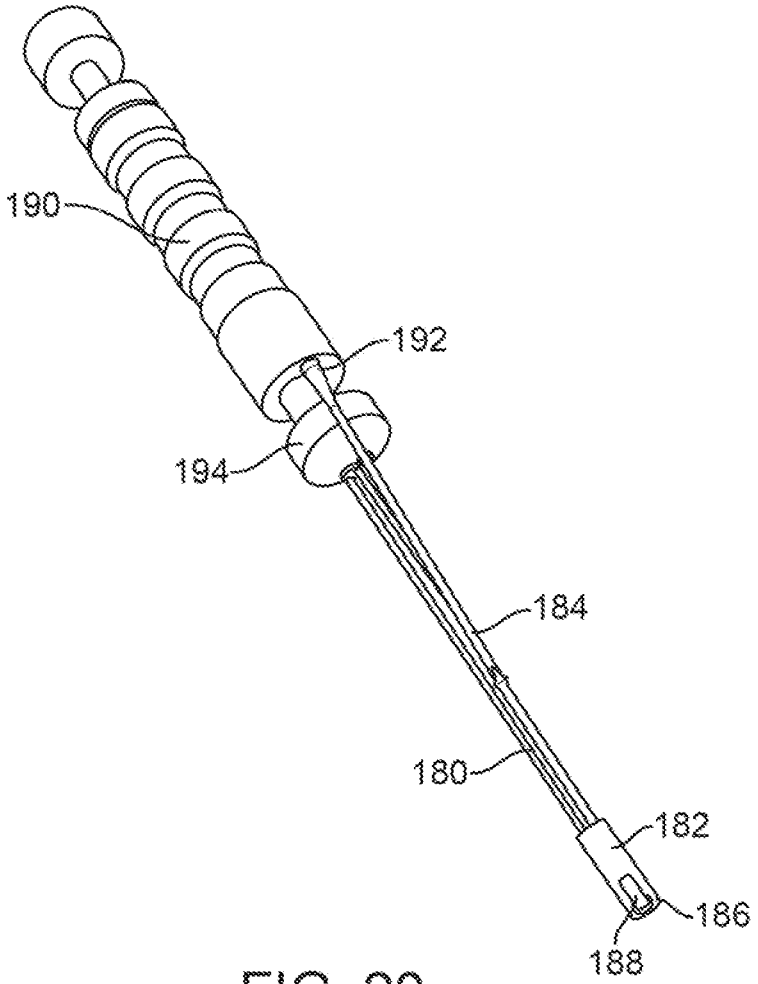

FIG. 20

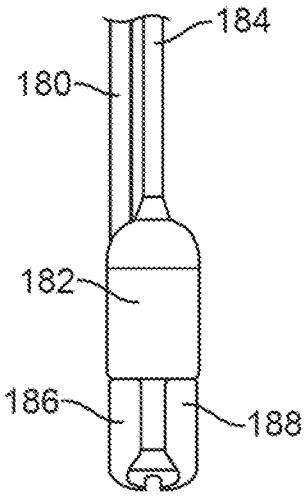

FIG. 21A

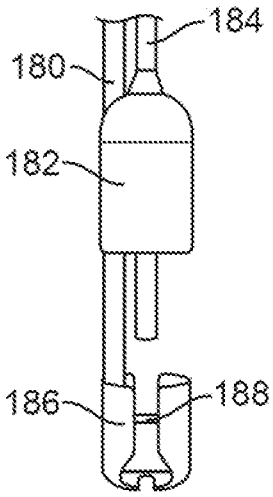

FIG. 21B

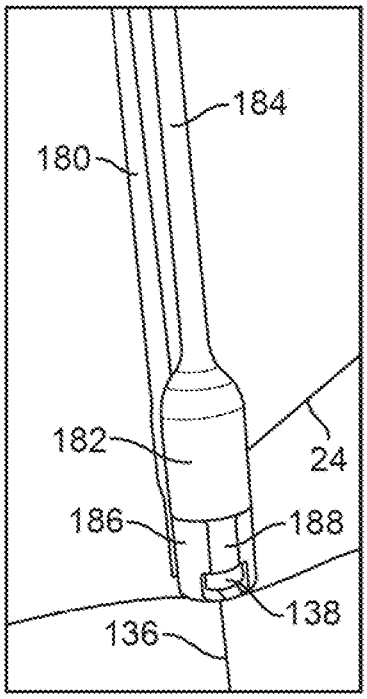

FIG. 21C

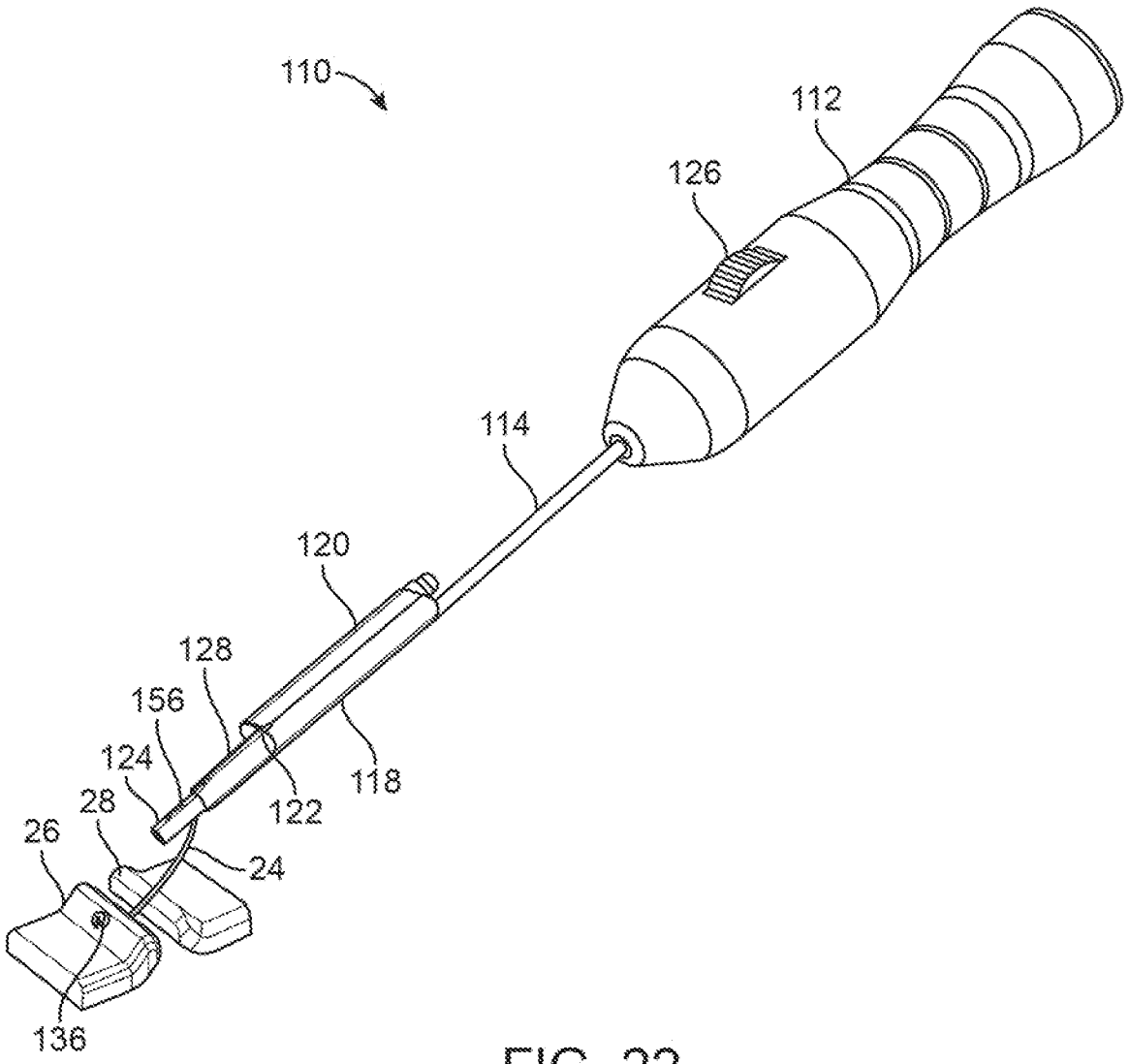

FIG. 22

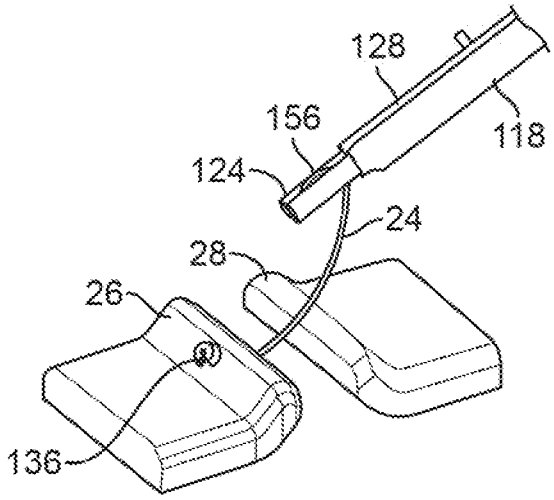

FIG. 23A

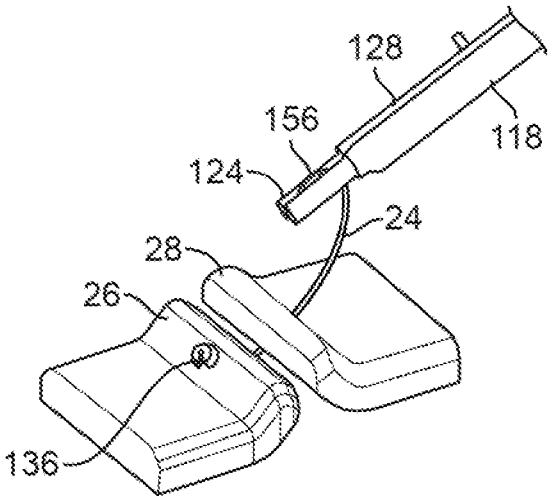

FIG. 23B

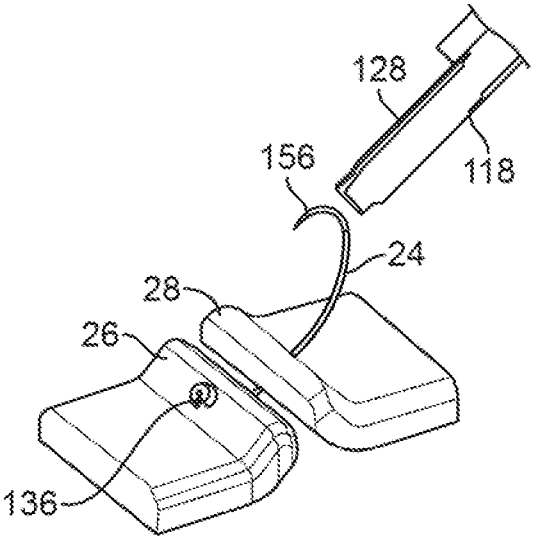

FIG. 23C

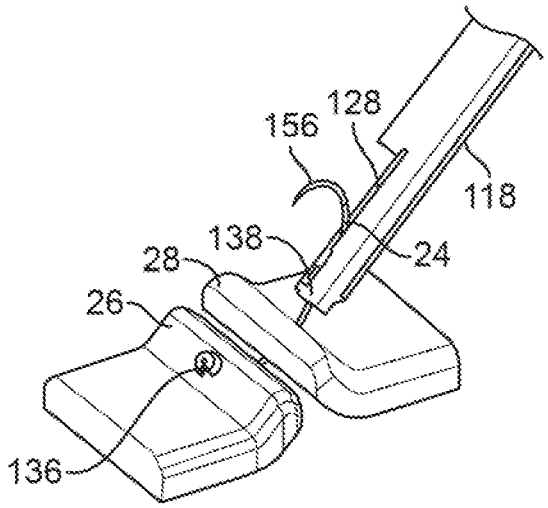

FIG. 23D

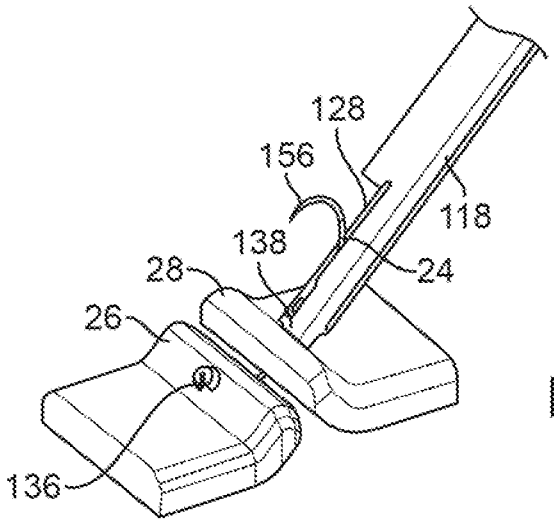

FIG. 23E

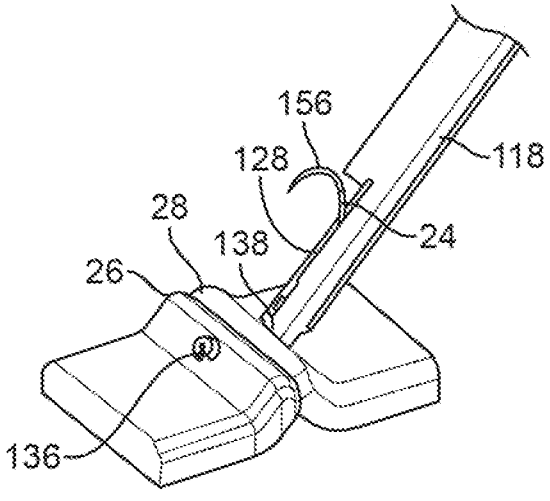

FIG. 23F

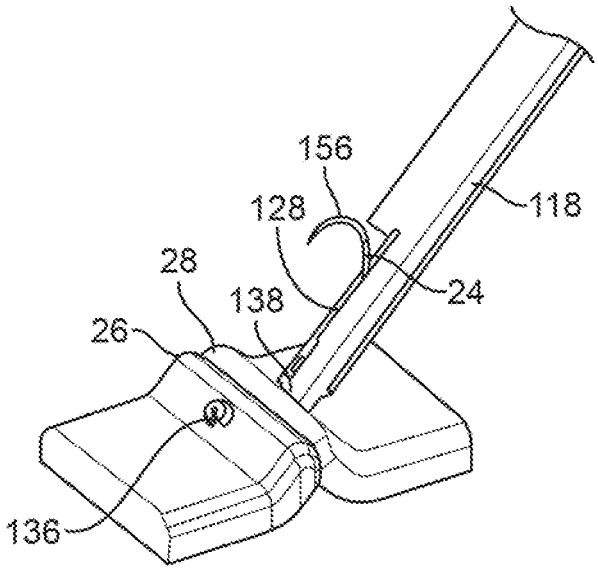

FIG. 23G

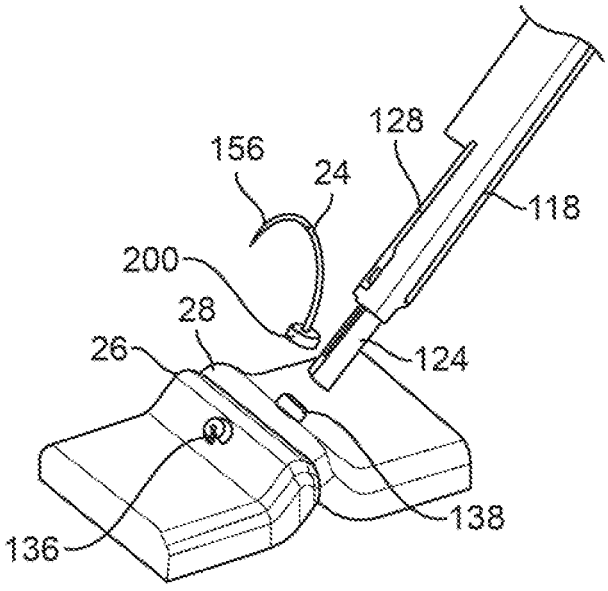

FIG. 23H

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/058224

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/04 (2013.01)
USPC - 606/139
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/00, 17/04 (2013.01)
USPC - 606/139, 144, 145, 146, 147, 151, 228, 232

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 17/00, 17/04, 17/0401 (2013.01)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2010/0023024 A1 (ZEINER et al) 28 January 2010 (28.01.2010) entire document	1-5, 7 --- 6, 10, 12, 13, 22
X --- Y	US 2005/0251157 A1 (SAADAT et al) 10 November 2005 (10.11.2005) entire document	14-21, 27, 28 --- 22-26, 29, 30
Y	US 4,493,323 A (ALBRIGHT et al) 15 January 1985 (15.01.1985) entire document	6
Y	US 5,702,397 A (GOBLE et al) 30 December 1997 (30.12.1997) entire document	10
Y	WO 01/078799 A1 (SKIBA) 25 October 2001 (25.10.2001) entire document	12, 13
Y	US 2008/0215090 A1 (GONZALES et al) 04 September 2008 (04.09.2008) entire document	23-26
Y	US 5,061,283 A (SILVESTRINI) 29 October 1991 (29.10.1991) entire document	29, 30
A	US 8,187,301 B2 (LYONS et al) 29 May 2012 (29.05.2012) entire document	1-30
A	US 5,269,809 A (HAYHURST et al) 14 December 1993 (14.12.1993) entire document	1-30
A	US 2010/0204731 A1 (HART et al) 12 August 2010 (12.08.2010) entire document	1-30

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
25 November 2013	05 DEC 2013
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)