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(72) Inventor; and
(71) Applicant : **FÜGLISTER, Fabian, Hermann, Urban** [CH/CH]; Feldstrasse 35, CH-5436 Würenlos (CH).

(74) Agent: **MOETTELI & ASSOCIES SARL**; St. Leonhard-strasse 4, CH-9000 St. Gallen (CH).

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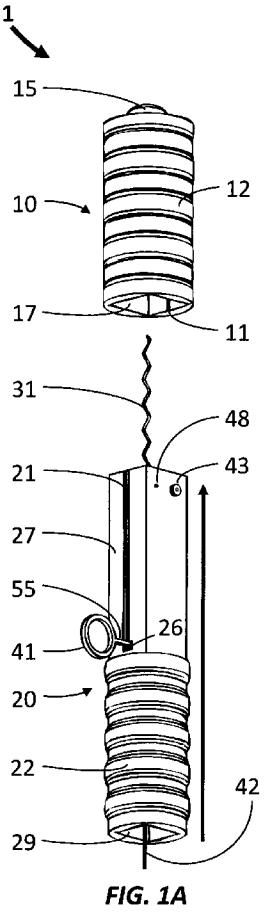

FIG. 1A

(57) Abstract: A method and apparatus for inserting inserts helically into soft tissue is provided. The inserter is made up of a housing assembly, a hollow helical needle; and a matched first and second hypoid gear. In its basic form, the apparatus includes a housing assembly, a hollow helical insert guide, a helical insert drive and a guide removal device. The hollow helical insert guide is held in functional relationship by the housing assembly and is adapted to be loaded with the insert for helical transport therewith into the soft tissue. The helical insert drive drives the helical insert guide in rotation and translation into the soft tissue. When an insert is present within the insert guide, the guide removal device removes the insert guide while leaving the insert in its intended implant location in the soft tissue. The method and apparatus insert an implantable member helically into soft tissue, thereby better fixing the implantable member in the soft tissue when such tissue is deformed.

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HELICAL INSERTER

Cross Reference to Related Applications

This application claims the benefit of U.S. Provisional Application No. 61/417,937, filed 30th of November 2010, the content of which is incorporated herein by reference thereto.

Copyright & Legal Notice

Background of the Invention

This invention relates to a device for inserting a flexible member into a living body, more particularly, for inserting a flexible member through a helically formed hollow needle.

A flexible, electrically conductive member is often used as an electrode for Functional Electrical Stimulation. Such member may be a regular electrode, a shape memory alloy or an electroactive polymer. Needle insertion into soft tissue is probably the most common surgical procedure for either therapeutic drug deliver or tissue sample removal from deep within the body. Hollow needles can also be used to implant electrodes or other members which fit through the lumen. Such needles are predominantly straight. For some procedures, needles can be bent in a preferred way, however, there are far fewer implanting procedures which involve helices. Devices and methods for medical inserting procedures, which make use of the helix, are known in the prior art. For example, tips of cardiac electrodes are often formed as a helix for the purpose of anchoring one end to a muscle of the heart, for example, the myocardium. The helix/coil at the end of the electrode is used to screw and hold it in place. There are several procedures which rely on the same basic tissue anchoring mechanism to affix an inserted member to a specific tissue location. There

are even endoscopical procedures, such as described in US Patent Application 12/363,137, to Fox, entitled SURGICAL DEVICE, the content of which is incorporated herein by reference thereto, which, during surgery, only temporarily fixes an overtube to an organ wall using a helical anchoring mechanism.

Still further, there are procedures involving helical needles for the delivery for fluids. As an example, in US Patent No. 7,309,325 to Mulier *et al*, entitled HELICAL NEEDLE APPARATUS FOR CREATING A VIRTUAL ELECTRODE USED FOR THE ABLATION OF TISSUE, the content of which is incorporated herein by reference thereto, a helical needle is used to deliver a conductive fluid to a target site.

US Patent Application 11/834,186, to Rioux, entitled CORKSCREW HELICAL INSERTER PORT, the content of which is incorporated by reference hereto, describes a method and a device for inserting a helical member into a septum for injection or extraction of fluid therein. The device may include a handle having an actuator lever rotatably coupled thereto. The device may also include a helical member which has a tissue piercing distal tip. The helical member is coupled to the handle via a linkage operating so that, as the actuator lever is rotated in a first direction relative to the handle, the helical member is rotated and moved distally to screw into tissue along a substantially helical path.

In US Patent No. 7,637,918, to Dant, entitled HELICAL SUTURING DEVICE, the content of which is incorporated by reference hereto, a helical hollow needle is used to helically insert a suture, which is retrieved at one end with a straight retriever along the axis of the helix.

Nevertheless, what is needed is an inserter, which can insert an electrode or a shape memory alloy into soft tissue through a helical hollow needle along a helical punctured pathway and do so quickly, safely and precisely, so as to minimize or eliminate drift or wander. Furthermore, if the member inserted must maintain a desired orientation with respect to the tissue of the punctured pathway, a mechanism is needed which ensures precise delivery without twisting of the member, as the needle withdraws from the pierced tissue.

Still further, what is needed is a method of inserting a flexible member in soft tissue precisely along a predefined helical path, with a mechanism, which can push said member out of a helical hollow needle when withdrawing it, with said member maintaining its orientation with respect to the tissue.

Summary of the Invention

A method and apparatus for inserting inserts helically into soft tissue is provided. The inserter is made up of a housing assembly, a hollow helical needle guide; and a needle insertion drive. In its basic form, the apparatus includes a housing assembly, a hollow helical insert guide, a helical insert drive and a guide removal device. The hollow helical insert guide is held in functional relationship by the housing assembly and is adapted to be loaded with the insert for helical transport therewith into the soft tissue. The helical insert drive drives the helical insert guide in rotation and translation into the soft tissue. When an insert is present within the insert guide, the guide removal device removes the insert guide while leaving the insert in its intended implant location in the soft tissue.

In one embodiment, the helical insert drive includes a matched first and second hypoid gear. The first hypoid gear wheel is affixed to the proximal side of the helical needle and held in axial position through the housing assembly for rotational insertion into the soft tissue. The second hypoid gear wheel is matched to the first hypoid gear wheel and held in axial position through the housing assembly. The second gear wheel drives an implantable member insertion mechanism. The insertion mechanism is adapted to insert an implantable member by its being transported into its final position in soft tissue by the hollow helical needle into the soft tissue as the hollow helical needle is driven in rotation and translation into the soft tissue.

An object of the invention is to provide a method and apparatus to insert a flexible member helically into soft tissue in a fast in a precise and safe way.

Another object of the invention is to provide a method and apparatus for inserting an implantable member helically into soft tissue, thereby better fixing the implantable member through the geometrical structure of the helical pathway in the soft tissue, when such tissue is deformed. For deformable body sections, especially muscles, tissue incompressibility is commonly assumed, as the tissue is highly aqueous. As a muscle contracts, it gets compressed, which means shorter along the axis of the muscles fiber orientation and wider viewed from a perpendicular plane according to Poisson's ratio. A helically implanted flexible member can behave in a same manner, by substituting diameter of the helix for length/height along its axis, when the muscle contracts and expands. This is why a flexible, but non-elastic member like a stranded cable electrode may be implanted into these body sections, which undergo a relatively large change in length between septum access and distal end of the member.

Another object of the invention is to provide an improved method of helical insertion of a flexible member, which allows planning of a precise pathway regarding its orientation and position inside the tissue and ensuring a piercing and insertion exactly along this desired pathway in a safe and reliable manner. It is

therefore also possible to plan and pierce a pathway through the tissue having a desired orientation of the punctured pathway at a certain distance. As an example, the helical puncture pathway of the member may be through two muscles in contact with each other where it is required that the pathway crosses these muscle layers is in a desired orientation, because of specific deformations and displacements occurring at the muscle layer boundary.

Another object of the invention is to provide a method of helical inserting with superficial tissue layers not helically pierced providing means to only helically pierce posterior layers.

Brief Description of the Drawings

FIG. 1A is a perspective view of an exemplary injection assembly according to the present invention with distal and proximal housing separated.

FIG. 1B is a perspective view of an exemplary injection assembly according to the present invention with proximal housing inside distal housing (fully injected).

FIG. 1C is a perspective view of an exemplary injection assembly according to the present invention with proximal housing inside distal housing (fully injected).

FIG. 2A is a front view of an exemplary injection assembly.

FIG. 2B is a longitudinal cross sectional view A-A as indicated in FIG. 2A through distal and proximal housing, mechanism inside excluded from cross section, member push out mechanism open (deactivated), like during inserting procedure of needle into tissue.

FIG. 3A is a front view of the proximal housing fully injected

FIG. 3B is a longitudinal cross sectional view B-B as indicated in FIG. 3A through distal and proximal housing, mechanism inside excluded from cross section, mechanism closed and activated like when fully injected before withdrawal of proximal inserter.

FIG. 3C is a longitudinal cross sectional view C-C as indicated in FIG. 3B, mechanism closed

FIG. 4A is a bottom view of an exemplary injection assembly, mechanism closed.

FIG. 4B is a transverse cross sectional view D-D as indicated in FIG. 3B through the mechanism in closed position.

FIG. 5A is a front view of the needle part.

FIG. 5B is a perspective view of needle part.

FIG. 5C is a perspective view of needle part

FIG. 6A is longitudinal cross sectional view E-E as indicated in FIG. 5A through needle drive crown wheel.

FIG. 6B is a longitudinal cross sectional view E-E of an alternative solution for needle drive wheel, longitudinal cross section through needle drive crown wheel with helical needle bent toward center inside wheel.

FIG. 7 is a perspective view of proximal housing with longitudinal cross section through the proximal housing in section 27 inner profile, in which only rack 13 of distal housing 10 is shown and the mechanism is in closed position.

FIG. 8 is a perspective view of the drive mechanism in closed position with rack 13, not showing the housing 10.

FIG. 9 is a perspective view of an exemplary alternative wedge triggering mechanism with front shaft 67 and rod 55 semi-transparent, without driven wheel.

FIG. 10 is a perspective view of a wedge triggering mechanism with only one shaft part (68) shown.

FIG. 11A and **11B** are perspective semi-transparent views showing all parts.

FIG. 12A is a front view of the mechanism in a deactivated state.

FIG. 12B is a front view of the mechanism in an activated state.

FIG. 13a is a front, oblique, partially disassembled view of an alternate, screw thread version of the invention.

FIG. 13b is a front, oblique, assembled view of an alternate, screw thread version of the invention.

FIG. 14 is a perspective view of the alternate embodiment of the invention.

FIG. 15a is a perspective view of the distal housing of the alternate embodiment of the invention.

FIG. 15b is a perspective view of the distal housing of the alternate embodiment of the invention, with the housing tilted backward to expose a portion of the inner thread.

FIG. 16a is a cross sectional, perspective view F-F, as indicated in FIG. 15A, of the distal housing of the alternate embodiment o the invention.

FIG. 16b is a cross sectional, perspective view G-G, as indicated in FIG. 15 B, of an alternate distal housing of the alternate embodiment of the invention.

FIG. 17a is a cross sectional view F-F, as indicated in FIG. 15A, of the distal housing of the alternate embodiment o the invention.

FIG. 17b is a cross sectional view G-G, as indicated in FIG. 15 B, of an alternate distal housing of the alternate embodiment of the invention.

FIG. 18 shows two cross sectional, perspective views of opposing sections of the proximal housing of the alternate embodiment of the invention.

FIG. 19 shows two cross sectional views of the opposing sections of the proximal housing of the alternate embodiment of the invention.

FIG. 20a is a side view of the needle and gear assembly used in the alternate embodiment of the invention.

FIG. 20b is an oblique, side view of the needle and gear assembly used in the alternate embodiment of the invention.

FIG. 20c is an oblique side view of the needle and gear assembly used in the alternate embodiment of the invention, tilted forward.

FIG. 21a is a cross sectional H-H, as indicated in FIG. 20A, partial side view of the needle and gear assembly which may be used in the alternate embodiment of the invention.

FIG. 21b is a cross sectional H-H, partial side view of the needle and gear assembly of a preferred embodiment used in the alternate embodiment of the invention.

FIG. 22 is a perspective view of a part into which the helical needle mounts in the alternate embodiment of the invention.

FIG. 23 is a perspective partially assembled view of the needle and gear assembly used in the alternate embodiment of the invention.

FIG. 24a is a cross sectional, side view of the needle and gear assembly used in the alternate embodiment of the invention, showing an open position of the inserter mechanism of the invention.

FIG. 24b is a cross sectional, side view of the needle and gear assembly used in the alternate embodiment of the invention, showing a closed position of the inserter mechanism of the invention.

FIG. 25a is a close up, oblique, cross sectional view of the needle and gear assembly used in the alternate embodiment of the invention showing a open position of the triggering mechanism of the invention.

FIG. 25b is a close up, oblique, cross sectional view of the needle and gear assembly used in the alternate embodiment of the invention showing a closed position of the triggering mechanism of the invention.

FIG. 26a is a close up, oblique, partially assembled view of the needle and gear assembly used in the alternate embodiment of the invention showing an open position of the triggering mechanism of the invention.

FIG. 26b is a close up, oblique, partially assembled view of the needle and gear assembly used in the alternate embodiment of the invention showing a closed position of the triggering mechanism of the invention.

FIG. 27a is a close up, partially assembled view of the needle and gear assembly used in the alternate embodiment of the invention showing an open position of the triggering mechanism of the invention.

FIG. 27b is a close up, partially assembled view of the needle and gear assembly used in the alternate embodiment of the invention showing a closed position of the triggering mechanism of the invention.

FIG. 28a is a close up, bottom, partially assembled view of the needle and gear assembly used in the alternate embodiment of the invention showing a closed position of the triggering mechanism of the invention.

FIG. 28b is a close up, bottom, partially assembled view of the needle and gear assembly used in the alternate embodiment of the invention showing an open position of the triggering mechanism of the invention.

FIG. 29a is a close up, oblique, cross sectional view of the needle and gear assembly used in the alternate embodiment of the invention showing the open position of the triggering mechanism of the invention.

FIG. 29b is a close up, oblique, cross sectional view of the needle and gear assembly used in the alternate embodiment of the invention showing the closed position of the triggering mechanism of the invention.

FIG. 30 is a close up, top, partially assembled view of the gear assembly used in the alternate embodiment of the invention showing a closed position of the triggering mechanism of the invention.

FIG. 31 is an alternate, partially assembled transverse cross sectional view D-D as indicated in FIG. 3B through the mechanism showing an other embodiement.

FIG. 32A is a perspective view of an exemplary injection assembly according to the present invention with distal and proximal housing separated.

FIG. 32B is a perspective view of an exemplary injection assembly according to the present invention with proximal housing inside distal housing (fully injected).

FIG. 32C is a perspective view of an exemplary injection assembly according to the present invention with proximal housing inside distal housing (fully injected).

FIG. 33A is a front view of an exemplary injection assembly.

FIG. 33B is a side view of an exemplary injection assembly.

FIG. 33C is a longitudinal cross sectional view I-I as indicated in FIG. 33B through distal and proximal housing, mechanism inside excluded from cross section, member push out mechanism open (deactivated), like during inserting procedure of needle into tissue.

FIG. 34A-34D are a cross sectional views as indicated in FIG. 33B with the inserter at different positions with the corresponding transverse cross sectional view J-J as indicated in FIG. 33A through the mechanism in different positions.

FIG. 35A and **B** are close up transverse sectional views of FIG. 34 A and C

FIG. 36 is a perspective view of a guide tube fixation.

FIG. 37A is a front view of an exemplary guide tube.

FIG. 37B is a perspective semi-transparent view of an exemplary guide tube

FIG. 38 is a front view semi-transparent of an exemplary guide tube and needle part

FIG. 39A is a perspective view of the alternate guide tube fixation in separated state.

FIG. 39B is a perspective view and a top view of the alternate guide tube fixation in open state.

FIG. 39C is a perspective view and a top view of the alternate guide tube fixation in closed state

FIG. 40 is a front view semitransparent of the needle part 730 showing the implantable member inside from tip of needle to the proximal needle orifice, and a cross section as indicated.

FIG. 41A is a schematic cross section of the activation mechanism with an integrated locking mechanism in a locked position.

FIG. 41B is a schematic cross section of the activation mechanism with an integrated locking mechanism in the unlocked position.

FIG. 42 is a schematic diagram illustrating screw thread helix of distal inserter and corresponding pitch angle compared to helix of hollow need and corresponding pitch angle.

FIG. 43 is a specification table for typical needles of the prior art.

FIG. 44 is an exemplary drawings showing use of the inserter in a submental approach for the treatment of obstructive sleep apnea.

FIG. 45 is a schematic view of the fixator for fixing the patient and inserter of the invention.

Those skilled in the art will appreciate that elements in the Figures are illustrated for simplicity and

clarity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the Figures may be exaggerated relative to other elements to help improve understanding of various embodiments of the present invention. Furthermore, the terms `first`, `second`, and the like herein, if any, are used inter alia for distinguishing between similar elements and not necessarily for describing a sequential or chronological order. Moreover, the terms `front`, `back`, `top`, `bottom`, `over`, `under`, `proximal`, `distal` and the like in the Description and/or in the claims, if any, are generally employed for descriptive purposes and not necessarily for comprehensively describing exclusive relative position. Skilled artisans will therefore understand that any of the preceding terms so used may be interchanged under appropriate circumstances such that various embodiments of the invention described herein, for example, are capable of operation in other configurations and/or orientations than those explicitly illustrated or otherwise described.

Detailed Description of the Preferred Embodiment

The following descriptions are of exemplary embodiments of the invention and the inventors' conception of the best mode and are not intended to limit the scope, applicability or configuration of the invention in any way. Rather, the following description is intended to provide convenient illustrations for implementing various embodiments of the invention. As will become apparent, changes may be made in the function and/or arrangement of any of the elements described in the disclosed exemplary embodiments without departing from the spirit and scope of the invention.

A method and apparatus for inserting inserts helically into soft tissue, as well as an insert guide which optionally contains an insert, is provided. In its basic form, the apparatus includes a housing assembly, a hollow helical insert guide, a helical insert drive and a guide removal device. The hollow helical insert guide is held in functional relationship by the housing assembly and is adapted to be loaded with the insert for helical transport therewith into the soft tissue. The helical insert drive drives the helical insert guide in rotation and translation into the soft tissue. When an insert is present within the insert guide, the guide removal device removes the insert guide while leaving the insert in its intended implant location in the soft tissue.

The hollow helical insert guide 31, 210 is held in functional relationship by the housing assembly wherein the guide is loaded with the insert 500 for helical transport therewith into the soft tissue. The helical insert guide drive is made up of components 13, 33, 43, 44, 49, 50; 100, 110, 220, 230; 250, 420, 470, ;709, 734, 738, 739, 740, 781, depending on the embodiment. The guide drive drives the helical insert guide in rotation into the soft tissue. The guide removal device is made up of several components 13,

28, 33, 41, 43, 44, 45, 49, 50, 51, 52, 53, 54, 55; 250, 420, 430, 470; 709, 781, 782, depending on the embodiment, which, when the insert 500 is present within the insert guide 31, 210, removes the insert guide while leaving the insert in its intended implant location in the soft tissue.

In an exemplary embodiment, the inserter 1 is made up of a housing assembly, a hollow helical needle; and a matched first and second hypoid gear. The first hypoid gear wheel is affixed to the proximal side of the helical needle and held in axial position through the housing assembly for rotational insertion into the soft tissue. The second hypoid gear wheel is matched to the first hypoid gear wheel and held in axial position through the housing assembly. The second gear wheel drives an implantable member insertion mechanism. The insertion mechanism is adapted to insert an implantable member through the hollow helical needle into the soft tissue after the hollow helical needle has been rotationally driven into the soft tissue.

As can be appreciated even by those of extraordinary skill in the art, inserting a member helically through a helical hollow needle is more difficult than doing the same with a straight needle in at least three ways, thus presenting the need to develop solutions beyond the skill of those of ordinary skill in the art. These three aspects are described below.

First, in order to gain an advantage of the invention, each puncture pathway made by a helical needle is oblique in relation to an outer surface of the septum. These diagonal puncture pathways wrap around the injection/withdrawal axis enhancing the ability of the implanted member to deform and elongate equally with the tissue. The path the needle cuts through tissue can be influenced, because both a rotational and a simultaneous linear motion of the needle are required. Through altering the ratio of these two motions, the deformable tissue is either expanded or contracted when "screwing" the needle in the soft tissue. This has direct influence for resulting path and endpoint inside the tissue. Therefore, it is not just the form of the helical hollow needle which influences the resulting path; the forces applied during insertion of the needle do as well. That's a crucial point, in order to ensure that the inserted member fits in its insertion position in length and orientation. Controlled insertion enables the planning of a desired path through tissue and guarantees predictable results.

Second, the needle must be forced to rotate about the axis to screw into tissue along a substantially helical path. During the inserting procedure, the member will be hanging out of the proximal aperture of the needle and then be rotated along the middle axis of the helix as the needle turns. Therefore the member cannot be affixed to a part which doesn't turn outside the proximal aperture of the helical needle as it would twist the member.

Third, once the desired location inside the tissue is reached and the orientation of the member inside the needle in relation to the tissue is correct, the member must now be pushed out as the needle is withdrawn. This is easier to do with a straight needle, because of lower friction forces (as compared to turning along a curvature) and no member deformation forces at the section of the needle, where the member moves from the center of the axis to the helical section. The needle will turn as it is withdrawn, but the member should only experience a linear push out force. In contrast with a straight needle, the length of the needle (=length helix) and the distance access/end point (height of helix) are different. A gearbox adjusts for that difference as it transforms the pull back movement into linear push out force, as the inserter is withdrawn.

Therefore, the insertion device provides three functions:

1. Rotation: for translating a linear motion into a circular motion, so that the hollow helical needle screws in and out along its helical path.
2. No Twisting: for free rotation of the implantable member outside the proximal aperture of the needle, during insertion of the needle.
3. Linear push out: for transforming the pull-back motion when withdrawing the needle into a linear push out force for the member inside the hollow needle. The difference in length of the helix and linear pull back distance (=height of helix) is matched through a gearbox with precise gear ratio.

Before inserting: Planning of Surgery and needle (helix) determination:

Referring to **FIGs. 42** to **44**, as opposed to a straight needle, where only length and diameter of the needle (needle gauge) have to be chosen, inserting a helical needle needs further determination: the helix needs to be specified, and this influences the surgery as well as the result. Collection of fundamental patient data and planning of surgery is therefore required. The following steps should therefore be performed:

1. Gather Data: CT or MRI of body section, if necessary with tissue in a deformed state
2. Estimate/Calculate (iterative):
   - Point of access, end point, effects *overall height of helix needle*
   - Desired path
   - Check for obstacles (veins, arteries, nerves) effects *desired path for surgery*
   - Elongation and deformation extremes estimate effects arc length, pitch, No. turns effects *desired path regarding deformation of member*
3. Determine needle to be used: arc length, pitch, no. of turns

Needle specifications: Range of values for the treatment of obstructive sleep apnea with submental inserting:

Height of helix:	50mm-100mm	**typical: 75mm**
Arc length:	1.5mm-15mm	**typical: 3-4mm**
Turns:	3-7	**typical: 4-5**
Pitch (resulting: height/turns)	7mm-33mm	**typical: 15mm**
Needle gauge:	14-21	**typical: 16-17 (with increased wall thickness for load)**

Hypodermic needles are available in a wide variety of outer diameters described by gauge numbers. Smaller gauge numbers indicate larger outer diameters. Inner diameter depends on both gauge and wall

thickness. There is another gauge system: The French scale or French gauge system (most correctly abbreviated as Fr, but also often abbreviated as FR or F) is commonly used to measure the size (diameter) of a catheter. 1 Fr = 0.33 mm, and therefore the diameter of the catheter in millimeters can be determined by dividing the French size by 3: D (mm) = Fr/3 or Fr = D (mm) × 3. An increasing French size corresponds to a larger-diameter catheter. This is contrary to needle-gauge size, where the diameter is 1/gauge, and where the larger the gauge the narrower the bore of the needle.

Referring to **FIG. 45**, exemplary drawings show use of the inserter in a submental approach for the treatment of obstructive sleep apnea.

For use of the invention in the treatment of Sleep Apnea, the following steps are performed:

1. Place head in fixed position using a fixator 800 (See **FIG. 45**) controlled and stable position)
2. Collect data of tongue in rest position and other deformation extremes (CT better than MRI [time]), create 3D model
3. Determine needle size
4. Put inserter in position or mount on rack (precise access through tissue in 3 dimensions)
5. Confirm desired position of tongue and head with scan before inserting (CT or Ultrasound)
6. Apply mechanism; may be verified/controlled with ultrasound during surgical procedure, but no CT (due to possible radiation of surgeon)
7. Confirm position with scan (CT or Ultrasound)

Utilization of drive inserter

As shown in **FIG. 1A-1C**, an embodiment for a flexible member helical drive inserter includes a distal housing **10** with a rack inside, a left-handed helical hollow needle **31** and the proximal actuator housing **20** with a mechanism inside, driven by the main drive pinion **43**. The implantable member **42** is already inside the hollow needle part, just below the tip of the needle **37**.

The distal inserter housing **10** is either held with one hand or optionally mounted on a rack, for securely attaching the assembly in a desired location on or near the body to provide a stable base on which to rest. Once the distal housing **10** is orientated with regard to the tissue access point and all three axes, the proximal actuator housing **20** is pushed inside the distal **10**, as indicated by the arrow in **FIG. 1A**. This rotates the needle **31** and pierces and threads it inside the tissue along a substantially helical path. When the proximal housing **20** has been pushed fully inside the distal housing **10,** the inserting mechanism activator rod **55** is automatically pressed down by the edge of the distal housing **10**, as indicated by the small arrow in **FIG.1B**; due to the adapted position of rod **55** and aperture **26**. This activates the flexible member push out mechanism inside the proximal actuator **20**. Now, while the proximal actuator housing **20** is pulled out of the distal housing **10**, the inserting mechanism activator rod **55** must remain in a pulled position (mechanism active) and the implantable part **42** is automatically pushed out of the helical hollow needle **31**; as it retracts from the pierced tissue. The forefinger keeps the trigger **41** in that position and it is of help withdrawing the proximal actuator **20**. Once the actuator **20** reaches the end of the distal housing **10**, the tip **37** of helical needle **31** is already outside the tissue. The inserting mechanism activator trigger **41** is now pushed towards the distal housing **10** (initial position) to disengage the push out mechanism. Now, the distal housing **10** may be slightly pulled back to open up a gap between skin/tissue and the boss **15** of the inserter. Then the implantable member **42** may be grabbed by fingers or a clamp between the needle orifice port **14** and skin/tissue, to cautiously pull the remainder of the member **42** through the disengaged inserter/needle **20, 31** and out. This finishes the helical inserting procedure for a flexible member **42** into soft tissue.

Distal housing 10

The functions of the distal housing **10** are as follows:

1. Hold the inserter in position regarding tissue access point and path of the needle **31**.
2. Provide stability during the inserting procedure.

3. Drive the whole mechanism inside the proximal housing **20** (turning of needle and push out of member) by acting as counterforce.

Referring again to **FIG. 1A, 1B, 1C**, the distal housing **10** is a hollow cylinder, closed on top (distal); open at the bottom (proximal). The top of the inserter, which is in contact with skin, may include a boss or bulge **15** for better skin contact and tension at the septum access point of the needle. On top of the boss **15** is the needle orifice port **14,** with a minimal diameter equal to the diameter of the whole helical needle **31**. It maybe of slightly conical shape to guarantee that the needle tip **37** always enters the port **14** and no damage to the tip takes place when assembling the distal housing **10** with the proximal housing **20**. Note that in order to improve retention and control of the needle **31** at the distal end, an insert guide having a helical port formed therein (not shown but similar to the guide **740** except that it is free to rotate in the orifice port **14**), may be rotatably inserted into the port **14**. The outer hull of the distal inserter **10** may have a textured, structured or grooved surface to provide good grip for the handhold **12**. Anchor arms or some sort of rack could optionally be used, if the inserter should be securely attached at or near the body.

Referring to **FIGs. 1A, 2A, 2B, 3A,** and **3B** and cross-section **FIG.4B**, the inner profile **17** of the distal housing **10** could have many different forms; it must only ensure that the proximal actuator **20** can glide in/out, so that the rack **13** inside the distal inserter **10** is in good contact with the main drive pinion **43**. In an exemplary assembly, the inner profile **17** of the distal housing **10** is of rectangle shape, as well as the outer distal profile **27** of the proximal actuator **20**. The inner profile of the distal housing **17** has two cut-in sliding guides **11** for the proximal actuator **20,** which has corresponding sliding bars **21** on a distal side **27**. The rectangle shape of distal housing and distal side **17** and **27**, respectively, are only of the same length on the sliding guide side. The sliding guides restrict movement with respect to the other axis. On one side, there is extra space required for the pinion **43** and on the other side there may be hinge pins **47/48**, which require extra space as well (as can be seen in the transversal cross-section of **FIG. 4B**).

A solution without sliding guides would require the inner profile of the distal housing **17** and the distal profile of the proximal inserter **27** to be almost congruent, which requires that no hinge pins be cut in rack (not shown in drawings).

An exemplary cross- sectional view for profile without sliding guides and hinge pins is found on page 18 of the priority application incorporated by reference hereto.

At the bottom (proximal) end of the distal housing **10**, an optional stop block prevents the proximal actuator **20** from coming out of the distal inserter housing **10,** e.g. at the end of the rack (not shown in the drawings).

The helical hollow needle part/helical insert guide 30

The functions of the helical hollow needle part 30 are as follows:

1. Pierce tissue helically
2. Make helical needle rotatable and drivable
3. If the member is not already in the needle when the needle is driven into soft tissue, provide an aperture for pushing the member into and through needle.

Bevel tip design influences forces and deformations on the pierced tissue and this influences the resulting path. There already exists fundamental scientific knowledge regarding that matter and how to simulate the behavior. As shown in **FIG. 5A** and **5B**, the sharp tissue piercing distal tip **37** includes an aperture which opens a lumen extending through the needle to the proximal needle aperture **39**. The inner diameter is constant and determined by the diameter of the flexible implantable member **42**. The left-handed helix of the needle is determined using the process already explained. Regarding the needle tip **37**, there are numerous different tip designs available, in advanced medical applications predominantly laser cut, such as shown on page 19 of the priority application incorporated by reference hereto. The bevel tip **37** is preferably oriented to the inside of the helix as indicated in **FIG. 5A** to **5C.**

Typically, the helical part of the needle is about 75mm in height (length), arc length 3mm, turns 5. This part of the needle must be outside the needle orifice port **14** of the distal housing **10** and will be fully injected into the tissue. As a result, the needle must be longer by the distance inside the inserter beginning from the orifice **14**. A needle drive crown or hypoid gear **33** is affixed to the proximal side of the helical needle **31**, with a gearing **34** at the bottom (proximal) to make the needle part **30** rotatable and drivable. At the proximal side of drive wheel **33**, the needle needs to be a straight concentric tube **36**, with an aperture **39,** in which the member **42** will be pushed into to get it through the needle either before of after the

insertion, or as a subsequent step to insertion of the needle **31**. Fixing a wheel to the needle is a necessary step, because the needle itself is too small in diameter to directly cut in gearings into the tube section **36**.

Referring now to **FIGs. 5A** to **C**, and **FIG 6A** to **6B**, proximal to the tissue penetrating helical needle section **31**, the helix must change its path **32** to be concentric to the wheel **33** and from there on it is essentially a straight tube **36** along the axis of the helix. It should gradually deform from helix to straight with a steady path, so that the member inside glides and deforms smoothly. The question is: is the wheel affixed before or after it is bent towards the center as can be seen in cross section **FIG. 6A** and **6B**. If the wheel **33** is made of metal, a hole needs to be drilled in the center, then the wheel **33** must be pulled over the tube section **36** and (for example, laser) welded to it (**FIG. 5 & 6A**, cross section **E-E**). If the wheel **33** is made of hard plastic, helix-to-straight section **32** could be inside the wheel **33** which would help fix the needle to the wheel (**FIG. 6B**).

A helical needle **31** is relatively simple to produce: a regular straight hollow needle made of e.g. a conventional 304 SS is helically bent cold worked and then heat treated . However, today, there are high performance alloys like e.g. "JAVELIN" (available from Creganna Inc, of Cambell, California) used in medical applications, which offer excellent shape set resilience, greater material hardness, higher column strength and superior resistance to damage. The result is a smaller diameter of needle due to decreased wall thickness. The desired needle gauge is about 16, nominal outer diameter 1.651mm (about 5 French scale). Thin-wall needles have identical outer diameters but larger inner diameters for a given gauge, thus a gauge 17 (1.473mm, about 4 French scale) would suffice. Since forces applied to the helical needle differ significantly from those applied to straight needles, the wall-thickness must be increased. The wall thickness could even be gradually increased from tip **37** to the force exerting wheel **33** (not shown in drawings). This may be fabricated through a progressive extrusion process or by locally grinding the exterior of a tube blank before being formed into a helix. As the needle pierces the tissue, friction forces between needle and tissue may deform the tissue slightly, which would influence and potentially cause the needle to deviate from its intended helical pathway. That needs to be accounted for, if necessary, through the transmission ratio (to expand or contract tissue). If it is desired to minimize friction force of the needle **31** penetrating the tissue, the outer hull of the needle could be coated with a fluoropolymer, which would result in extremely low friction forces; for example spray-coating a thin layer of ETFE after the heat treatment of the helically bent needle.

The wheel **33** serves as crown wheel with right hand hypoid gearing **34** to drive/rotate the needle, which is driven by the left hand hypoid gear pinion **49**. The distal side of the wheel **33** is a smooth surface, which is used as one side of a sliding contact together with the proximal actuator top **23**, which has a hole

for the needle. (**FIG. 5C**) At the proximal side of the wheel **33**, the gearings **34** require extra distance to the needle bushing beam **24**, which serves as bushing for the proximal tube section **36** of the needle to run through. It is achieved through an elevated sliding contact **35**. Top sliding contact **23** (for **FIG. 6A** with or for **FIG. 6B** without bushing) and needle bushing beam **24** provide a confined space for the needle drive wheel **33**. Friction forces are low by virtue of an adequate combination of materials.

Proximal actuator housing 20

The functions of the proximal actuator housing 20 are to act as a:

1. Casing/housing for the helical needle and the mechanism which drives it
2. Casing for the flexible member injection mechanism
3. Actuator for the whole helical inserter: pushing the needle into the tissue and rotating it to screw in along a substantially helical path and activating/driving the member injection mechanism

The proximal actuator **20** has two different sections: the distal profile **27** and the cylindrical shaped proximal handhold **22**; which may have a structured, grooved or otherwise textured surface for good grip. The bottom (proximal) end of the inserter **29** is open, such that the implantable member **42** can hang out and rotate freely during helical tissue penetration of the needle **31** (to avoid twisting) and move through the whole inserter, when pushing it out (member **42** not on spool). Inside the distal section **27** is the inserting mechanism **40**.

The drive inserter variant:

Referring again to **FIG. 2B**, the rack **13** drives the pinion **43**, which is outside the distal profile **27** of the proximal actuator **20**. Referring to **FIG. 3A-3C**, the pinion **43** is affixed to the shaft **50** running through the whole distal profile **27**; on the pinion's opposing outer surface limited by a hinge pin or retaining device **47**. The shaft **50** drives the whole needle part **30** as well as the member injection wheels **44/45**, which push the implantable part **42** into the needle aperture **39** and subsequently out of it. The shaft **50** drives the needle drive crown wheel **33** through another pinion **49.** The direction of the drive carried by the shaft **50** has to be transferred through 90 degrees to drive the needle crown wheel **33**. But the drive wheel **44** on shaft **50** pushes the member **42** inside the aperture **39**, which is also the center of the crown wheel **33** that needs to be driven by the same shaft. This makes a bevel gear design impossible; the drive wheel **44** on shaft **50** would intersect the member **42**. The member injection drive wheel **44** needs to be dislocated, which also dislocates the whole shaft **50**, puts it off-axis and results in a hypoid gear **34** to drive the needle part **30**. A bevel gear solution is undesirable, because at least one extra gear is required, as well as an axis which does not intersect with the member **42** or aperture **39**. A schematic representation of this arrangement is found on page **22** of the priority application incorporated by reference hereto.

It is known that hypoid gears are best for the applications requiring large speed reductions with non-intersecting shafts and those applications requiring smooth and quiet operation, such as a medical procedure. The left hand hypoid gear pinion **49** drives the right hand hypoid gearing **34** of the needle drive crown wheel **33.** With that, the whole needle part **30** rotates and pierces the tissue along a helical path as the proximal actuator **20** is pushed in or pulled out of the distal inserter **10**. Depending on required forces of transmission, the crown wheel and the hypoid gear may even be wheels without gear teeth. The member injection drive wheel **44** together with the driven wheel **45** push the implantable member **42**, which is already inside the needle just below the tip **37**, into the proximal hollow needle aperture **39**, through the whole needle **31** and out at the distal needle tip side **37** when withdrawing the inserter. With only one shaft **50**, the gearbox drive transmission must precisely match for two separate gear ratios simultaneously, in the following manner:

1. The rotation of the helical hollow needle must be matched to the linear push-in/pull out distance such that the pierced tissue isn't expanded or contracted, and

2. The gear transmission for the flexible member injector wheels **44/45** must adjust for difference in the length of helical needle and linear pull back distance of the proximal actuator **20** to push the member **42** out as the needle retracts.

For driving the needle: the gear ratios of rack **13**/main drive pinion **43** and hypoid gear pinion **49** /crown wheel of the needle **34** must be adjusted. – what is needed is 1 rotation of needle per pitch of distance.

For the pushing out of the implantable member: the gear ratio of rack **13**/main drive pinion **43** and the circumference of the drive wheel **44** must be adjusted.

This is an optimization problem: the helix specifications are given and both functions/mechanisms are interdependent through the shaft **50** (this will be considered mathematically later).

The difference between these two mechanisms is that the needle drive is always on, but the member push out is only needed while withdrawing the inserted needle. Furthermore, the same mechanism must ensure that the implantable member **50** cannot be twisted during the needle injecting procedure; consequently, the implantable member **42** should freely rotate inside the proximal actuator **20**.

Push out mechanism & activation

The simplest solution is to open up the space between the wheels **44/45** which push the member out. Because the drive wheel **44** is fixed to the shaft **50**, the driven wheel **45** is moved. There are several appropriate mechanisms that accomplish this: move the driven wheel **45** away from the drive wheel **44,** such that contact area of the wheel groove **46** between the wheels opens up for the member **42** and it is no longer pulled/pushed or twisted by movements of the proximal actuator **20**. The drive wheel **44** will still turn, but with no effect to the member. Because the member **42** is flexible, the wheels need to be as close as possible to the aperture **39,** that the member cannot kink when pushing it in. These wheels will be deep inside the proximal housing **20;** which itself is inside the distal housing **10**, by the time the mechanism needs to be activated (like in **FIG. 3**). The distal housing **10** however should not have a cut-open section on one side to push the driven wheel **45** in with a button-like mechanism; this would negatively impact usability because the hands holding the two inserter parts **10/20** would have to move over each other.

It is preferred to have a trigger, which can be pulled over a short distance (<1cm) to activate the push out mechanism. An assembly of rods make the activator trigger **41** easy accessible with one finger on

the outside of the proximal actuator **20**. Such a mechanism should guarantee that the trigger doesn't intersect the distal housing **10**, as well as that the trigger can be used to better hold and pull the proximal actuator **20** out of the distal housing **10** (pull back/ member push out move).

The driven wheel **45** can freely turn on a fork like axle **53**, the driven wheel fork, which rotates about a fulcrum pin **54**. It doesn't necessarily need to be a fork because a lever on one side could achieve the same result; but for equal force distribution, a fork is, for the moment, considered superior. The fulcrum pin **54** runs through the whole distal profile **27** of the proximal actuator **20**, limited by hinge pins **48** outside the distal profile **27** (see **FIG. 4B**). In an alternative embodiment, the fulcrum pin **54** does not run through driven wheel fork **53**, but rather, it runs through just one part with pins **54** on each side (not shown in drawings). Turning the fork **53** about the fulcrum pin **54** opens or closes the contact between driven wheel **45** and drive wheel **44**. Both wheels in contact push the implantable member **42** into the proximal needle aperture **39**. If the driven wheel **45** on fork **53** should open to the upside, the wheel groove **46** of the driven wheel **45** must pass the aperture **39** as the fork **53** rotates. Opening to the upside is preferred, because as the mechanism closes and the gearings of the wheel come into contact, it immediately creates a small pushing force on the member. The driven wheel **45** turns, when it closes, with the drive wheel **44** remaining stationary. This could be of use, for example if the distal part of the member **42** has an anchoring mechanism. The member would be pushed out for the small amount, such that the anchoring arms are already inside the tissue before the withdrawal process starts. This guarantees a more exact orientation of the tip of the member **42**. During insertion of the needle, the fork is upward and wheels open, which opens a gap for the implantable member **42**, in which it can rotate (**FIG. 2B** and **2C**). Pulling the activator trigger **41** turns the fork **53** to a horizontal position (**FIG. 3B** and **3C, 4A** and **4B, 7, 8**) and the wheels are closed, in contact and the member push out activated. In an exemplary assembly, the rotation of the driven wheel fork **53** is distally limited by the needle bushing beam **24** and by a stop block **28** (see **FIG. 3C, 4A**) proximal. The stop block **28** limits the movement of the fork **53** to a stable horizontal position, as long as the rod/trigger **55/41** remains pulled. This is the reason why the rod **51** manipulating the driven wheel fork **53** is on the inner side of the fork (**FIG. 4A** and **4B, 7, 8**). The stop block **28** is only on one side inside the proximal actuator **20**, because the opposing side is needed for the hypoid pinion **49** (see **FIG. 3C**).

Referring now to **FIGs. 7** and **8**, the driven wheel fork **53** is manipulated through a piston engine like rod system, which translates the rotation of the fork **53** into a linear motion (fork **53** would be the equivalent of crankshaft). Accordingly, two more rods are needed in order that: the connecting rod fork **51**

and the activator rod **55** (equivalent of piston); which are again connected through a fulcrum pin **52** limited by hinge pins on each side **48.** The activator rod **55** slides inside the proximal housing **20** in a sliding guide **25. (FIGs. 1B, 2A, 2B, 3A-3C).** The length of the rod and the position of the activator aperture **26** are designed such that, once the proximal housing **20** is fully inside the distal housing **10,** the edge of the distal housing **10** pushes the rod **55** down automatically and activates the mechanism. The rod **55** must remain in that position for the entire withdrawal of the proximal housing **20** out of the distal housing **10,** until the needle is at least about 1cm outside the tissue. In an exemplary assembly, the forefinger keeps the trigger **41** in that position and helps in withdrawing the proximal actuator **20** as well. Alternatively, a latch mechanism could achieve the same result (not shown in the drawings).

Referring to **FIGs. 9-12,** an alternative wedge triggering mechanism **60** operates upon being pulled as well. In this embodiment, a sliding wedge **61** of the rod **55** pushes the corresponding wedge **62** of a sliding axle part **63** forward inside a spring **65** biased shaft **68** and **69** of the proximal actuator housing **20.** The angle of the wedge determines forces vs. distance as indicated in **FIG. 12A** and **12B.** The index finger can easily pull/push the trigger **41** over a distance of 10mm. Because the driven wheel **45** needs to be dislocated only by a short distance (2-5mm), the wedge angle can be smaller than 45° (in the drawings it is 20°). Pulling the rod **55** pushes the sliding bar **64** of the axel part **63** along a sliding guide **67** of the shaft on the left **68** and right **69.** The driven wheel **45** on the axle **66** is therefore not rotated about the fulcrum, the linear pulling force of the rod **55** is transformed into a linear pushing motion for the axle part **63,** which makes it possible for the groove of the wheel **46** to be even closer to the proximal needle aperture **39.** Without a latch for the rod **55,** letting go of the trigger **41** with the index finger will disengage the mechanism. As the surfaces of the wedge **61** and **62** are made so as to be of low friction, the spring **65** inside each shaft **68** and **69** will push the sliding axle part **63** towards the rod **55,** moving it to an initial position.

Insertion Wheels

For the insertion wheels **44/45,** three things have to be considered: (1). a groove changes the diameter of the wheel, in which the member **42** is in contact, resulting in change of circumference; (2). the member should not be bruised, which is determined by force distribution (groove and/or materials); (3). The outer hull of the member **42** is most probably a fluoropolymer, essentially all varieties of which have extremely low frictional properties which effects the grip between member/wheels.

Referring again to **FIGs. 7** and **8**, in an exemplary assembly, both wheels **44** and **45** are grooved and of the same diameter as lateral gearings, which is the preferred solution. Whether a groove having a changing wheel diameter influences the correct distance of the member to be pushed out, is a question of relative sizes between the diameter of the wheels and the diameter of the member they push. If the wheels are, for example, only 5mm in diameter, and the diameter of the member is 1mm, a half groove would decrease the diameter by 0.5mm, which equals a decrease of 10% and leads to a reduction of circumference of 1.6mm (15.7-14.1) per turn which needs to be considered in order that the mechanism guarantees that for each unit of distance the needle retracts, the member will be pushed out by the same distance. The problem can be avoided by increasing the diameter of the wheels 44/45.

The groove **46** allows for equal force distribution over a larger contact area between wheels and flexible member **42**, as well as maintaining the member **42** inside a confined space for free rotation when the fork **53** is open by creating a tiny gap between the grooves during the inserting procedure. The gearing is cut in a manner so as to adjust for decreased diameter of the groove as well as to transmit forces between the wheels without slipping.

However, there exist other possibilities to achieve the same result. The groove **46** may have a tiny band of rubber disposed about it to further avoid bruising of the member **42** as well as decrease the possibility for slippage. More aggressive gearings or knurlings can thus be avoided except where the wheels are made of hard material with low friction values (metal, hard plastic) that do not create enough friction to generate the required force transmission. In fact, the wheels do not needs grooves where the wheels are made of a soft material (rubber or the like), so that the wheels may be placed in contact to the member and/or against each other to generate friction. If the drive wheel is half-grooved and made of hard material, then the driven wheel could be un-grooved and without gearing, provided it is made of a soft material. The driven wheel turns just by pressing the implantable member into the groove of the drive wheel **44**. These are only general design constraints, since the actual design of the groove and materials of the wheels largely depend upon the specific characteristics of the member **42** regarding required force and force distribution for pushing.

Rotation directions of gears

*Rotation directions seen as in perspective view **FIG. 7** of an exemplary assembly; CW – clock wise; CCW – counter clock wise*

Whether the helix of the needle is right handed or left handed determines rotation directions and gear design. The helix orientation given, there are two setups that achieve this result: to rotate the needle in

the required direction and to push out the member when withdrawing the actuator. Position/side of rack **13** vs. pinion **43** determines the shaft **50** direction and with that the position for the hypoid pinion **49**.

Left-handed helix needle: to screw in, the needle part **30** must rotate CCW. The position of rack **13** (left) and pinion **43** (right) makes the shaft **50** turn CCW when pushing inside. As a result, the hypoid gear pinion **49** must be on the main drive pinion **43** side of the shaft **50** for making the needle part **30** turn CCW. When withdrawing the inserter, the shaft **50** will turn CW and serve as an axle for the drive wheel **44** to push the member into the needle aperture **39**.

Alternatively, the contact side of rack **13** and pinion **43** may be switched, with the shaft **50** turning CW when pushing in, the hypoid pinion **49** switched to other side of pinion **43**; and switching the side (right of shaft) of the driven wheel **45**, but this is considered geometrically undesireable.

Right-handed helix needle: vice versaGear matching: Calculating the adequate gear transmission:

Because the wheels push out the member, the bigger the diameter means greater contact area, and so no bruising of the member. However, the contact area depends on the fragility of the member. As the wheels are to insert a highly complex, filigree and fragile member, the diameter of the wheels **44/45** is chosen to be 10mm in this example; the other values are already determined by the needle.

Given:

D = Diameter of helix = arc length x 2

P = Pitch

N = Number of turns of helix

W = Diameter of member injection wheels

H= Height of helix

Find:

L_T = *Total length of helix*

A = Diameter main drive pinion 45

gr_{hypoid} = *Gear ratio hypoid drive*

F = Diameter of hypoid pinion 49

G = Diameter of needle drive crown wheel 33/34

Total length of helix:

The circumference of a circle of diameter D is: $C = \pi \times D$

Now if we stretch this circumference, it will form the base of a triangle whose other leg is equal to the pitch of the helix. Hence the length of the wire that makes one helix turn is the hypotenuse of the triangle which is:

$$L_C = \sqrt[2]{C^2 + P^2}$$

The total length of the helix therefore is:

$$\boldsymbol{L_T = N \times L_C}$$

Diameter A of main drive pinion 45:

The wheels need to push out the length of the helix over the pull back distance

$$No.turns\ required\ drive\ pinion\ T_{req} = \frac{Total\ lenght\ of\ helix\ L_T}{circumference\ drive\ wheel} = \frac{L_T}{W \times \pi}$$

T_{req} is the no. turns the pinion needs to make over the pull back distance

$$Circumference\ drive\ pinion\ A \times \pi = \frac{Height\ of\ helix\ H}{No.turns\ required\ drive\ pinion\ T_{req}} = \frac{H}{T_{req}}$$

Filling in and solving for diameter of the pinion A:

$$A = \left(\frac{H}{\frac{N \times \sqrt[2]{(\pi \times D)^2 + P^2}}{W \times \pi}} \right) \Big/ \pi$$

Gear transmission ratio for the hypoid drive gr_{hypoid}:

$$gr_{hypoid} = \frac{circumference\ drive\ wheel \times No.Helix\ turns}{Total\ lenght\ of\ helix\ L_T} = \frac{W \times \pi \times N}{L_C \times N} = \frac{W \times \pi}{\sqrt[2]{C^2 + P^2}}$$

$$gr_{hypoid} = \frac{W \times \pi}{\sqrt[2]{(\pi \times D)^2 + P^2}}$$

The above yields the ratio that the hypoid drive must provide. Once one diameter of one wheel is chosen, it can be solved for the other.

Materials, Sizes

By choosing the diameters of the gears well, hard plastics may be used. The needle is preferably medical grade metal. Even the bearings may be made of solid plastic so as to exhibit dry-running lubrication-free behavior.

General design constraint for screw thread inserter

Referring now to **FIG. 13a** to **17b**, an alternate embodiment uses a screw thread **110** to drive the inserter and includes a distal housing **100** with a female left hand screw thread **110** inside, a left-handed helical hollow needle **210** affixed to a screw thread drive wheel **220**, which is freely rotatable coupled to the proximal actuator housing **300**. As the actuator **300** is pushed into the distal housing **100**, male pins or cam follows **230** (best shown in **FIG. 27a** and **27b**), engage the threads, which in combination with the female thread **110**, force the wheel **220** to screw inside the distal housing **100**, which forces the helical hollow needle **210** to pierce the tissue along a helical path. Screw thread orientation and pitch of distal housing and helical hollow needle must be equal so that the pierced tissue isn't expanded or contracted. A suitable relationship between helix needle arc length, height, turns and the inner diameter of the screw thread housing **100** must be determined to ensure proper operation. Referring in particular to **FIG. 42**, a layout compares the screw thread helix of distal inserter and corresponding pitch angle with the helix of hollow needle and corresponding pitch angle. The path A represents the screw thread helix of the distal inserter and corresponding pitch angle, wherein the helix specs are the same, but the arc length is doubled to 6mm, resulting in a pitch angle of 31 degrees. The path B represents the helix of the hollow needle and corresponding pitch angle, where the arc length is 3mm, the height 76mm, the number of turns is 4, which results in a pitch angle of about 48 degrees The inserter only works if the pitch angle (helix angle) of the screw thread inside the distal inserter is large enough. The smaller the angle, the more of a wedge effect it creates. The largest possible angle (theoretically) is restricted by the diameter of helical needle which must fit through the distal inserter (indicated by dashed lines). Since the screw thread is on the inner side of the distal housing, this diameter must be larger than the one from the hollow needle. Larger diameter means smaller pitch angle. Therefore the helix of the hollow needle influences the size (diameter) of the entire inserter. As mentioned, the pitch angle of an exemplary needle is only about 48°, with a diameter of 6mm. As a result, the entire member push out mechanism must fit inside it. In order to generate more space, the diameter of the distal inserter could be increased, which increases the diameter of the helix screw thread as well. However, at a certain diameter, the pitch angle of the screw thread drops below 30° and the wedge effect starts to set in. In the example, if the inner diameter of the distal housing is 12mm, the resulting pitch angle is already about 31°. Therefore, there is give and take with this embodiment. This embodiment uses components with very low friction forces between the inner surface of the distal housing **100** with screw thread **110** and the wheel **220** of the needle with its pins **230** gliding along.

In more detail, in this embodiment, the distal housing **100** is either held with one hand or mounted on a rack using the fixation arms **160**. Once the distal housing **100** is orientated regarding tissue access

point and axis, the proximal actuator housing **300** is pushed inside as indicated by the arrow in **FIG. 13a**. This screws the needle **210** helically inside the tissue. When the actuator **300** is fully inside the distal housing **100**, the push-button **360** is pressed, which activates the drive mechanism inside **300** through a control rod **350**. Now the actuator **300** is pulled out of the distal housing **100** and the implantable part **500** is automatically pushed out of the needle **210**. Once the actuator reaches the end of the distal housing **100** and the needle **210** is outside, the push-button **360** is pulled back or released into its initial position in order to disengage the drive mechanism. Now the implantable member **500** can be held by hand or some sort of clamp at the distal needle tip side **215** to cautiously pull the remainder of the implantable part **500** through the inserter and out of the needle **210**. This completes the process of inserting the member.

The outer surface of the screw thread drive wheel **220** and inner surface of the distal housing **100** should be nearly form fitting (i.e., exhibit very little play) and the cylindrical wheel **220** should be of sufficient height, that the two parts cannot jam or seize. As indicated in **FIGs. 24, 25, 29**, the proximal actuator housing **300** is of lesser diameter than the screw thread drive wheel **220**. However, it could be of same diameter as the screw thread drive wheel **220**, except that would increase friction forces.

The male screw threads or cam followers, indicated as pins **230**, are not limited to only one or two; optionally multiple threads could be used. For the thread form of the female thread **110** and pins **230**, there are numerous different profiles in use today. Small play of the screw thread drive wheel **220** and distal housing **100**, height of cylindrical screw thread wheel **220** and the threadform **110** and **210** can be selected to guarantee that the needle part **200** screws into the distal housing **100** with low friction forces and no possibility to cant and jam. The needle **210** with the drive wheel **220** must be freely rotatably coupled to the proximal actuator housing **300**. Referring now to **FIGs. 18** and **19**, the axle bushing **340** through the center of actuator **300** provides a bearing surface for the hollow driving shaft **240**. The inside and outside of the housing **300** together with wheel **220** and **250** restrict movement in the perpendicular plane. Again, friction forces should be low by choosing adequate materials.

In the drive inserter of **FIGs. 1A-8**, the rack **13** and pinion **43** must drive the needle **30** and the push out mechanism through a shared shaft **50**. In contrast with the drive inserter solution, the screw thread drives the needle directly--only force transmission for the push out mechanism is needed. The mechanism needs to fulfill the same function: it must be disengaged while inserting the needle with the member being free to rotate, and engaged when withdrawing the needle until it is outside the tissue, to disengage it again and pull the remainder of the member through the needle.

Referring now to **FIGs. 24A-30**, a drive and a driven wheel again needs to push the flexible member or insert **500** inside the proximal aperture **245** of the needle. The rotating force of the mechanism drive wheel **250** needs to be translated to a push out force for the member. The direction of the drive carried by the hollow shaft **240** has to be transferred through 90 degrees to drive an axel **480** with a drive wheel **420** affixed on it. Again, the aperture **245** lies in the center of the axis and so a bevel gear solution is not feasible without more parts. Therefore, the axle **480** needs to be offset again, which results in a hypoid gear design, as can be seen in **FIGs. 27a** and **27b**. Because of the small forces required to push out the member, the hypoid gear can be a straight cut gear **470**. Hypoid gears can be made with straight-cut gears, if applied forces are low, as in this application. In the drive inserter solution, the forces applied on the gearing are higher because it must produce the force for the needle to rotate and pierce the tissue. Here, the hypoid gearing produces the force needed to push the member into the aperture of the needle, which is substantially lower. In contrast with the drive inserter, this approach disconnects the member push out mechanism completely, which means that the drive wheel **420** is not turned during the needle inserting procedure, If only the driven wheel **430** should be disconnected, the two mechanisms described in **FIGs. 1-12** work as well. A bridge element **400** turning about a fulcrum pin **410** inside the groove **310** of the housing **300** serves as a second class lever and dislocates the straight cut hypoid gear **470** from the drive gears **255** of the mechanism drive wheel **250**. By pressing the push-button **360**, the control rod **350** inside a sliding guide **320** forces the bridge to rotate about the fulcrum **410/310** inside the housing. The hypoid gear **470** is connected through driving shaft **480** with the drive wheel **420** inside the bridge. The driven wheel **430** is mounted on a first class lever, turning about a fulcrum pin **460** connected to the bridge **400**. One side of the control lever **440** serves as fixation arm for the axle **465** of the driven wheel **460**. The other side of the control lever **450** is spring loaded **490/495**. With the lever in parallel position to the bridge, the driven wheel **430** is in contact with the drive wheel **420**, which is referred as the closed position or mechanism engaged. In initial (disengaged) position, the spring pulls the control lever **450** towards the spring fixation **325**, which in turn pulls the bridge **400** with it. Pushing the button **360** activates the drive mechanism, as indicated in **FIG. 24**.

Referring now to **FIG. 18, 19, 29**, the control rod **350** pushes the bridge **400** towards the positive stop block for the bridge **330** and the hypoid drive is in contact with the drive gears **255**. By pressing the bridge upwardly, the control lever on the wheel side **440** moves towards its positive stop block **335** as well. This pushes down the lever **440**, such that the drive and driven wheel are in contact and the mechanism engaged. Pulling the button **360** will disengage the spring loaded mechanism. Regarding the drive and driven wheel design, the same constraints as with the drive inserter solution apply. The drawings for the screw thread inserter show a solution without gearings. Now referring to **FIG. 41A** and **B**, in another

embodiment **1'''**, a needle locking mechanism in combination with the mechanism of the rod **350** and the bridge **400** already described, allows for screwing, rather than pushing, of the proximal inserter housing into the distal housing by means of locking the mechanism drive wheel **250** with an arm of an prolonged rod **350**. When screwing the proximal housing in, the locking arm **351** blocks the needle through the groove **260** in wheel **250**. Once screwed in, activating the mechanism of the bridge through **352** also unlocks the wheel **250**. The proximal inserter housing must of course have a corresponding groove for the now longer rod **350**. Pulling the proximal housing out of the distal works now as previously explained. To activate, the button **360** is first pushed in one direction for the arm **354** to move inside the proximal housing by means of bending. Once the arm **354** clears the housing, the button can be pushed inside as already described, further integrating a groove **355** to lock the arm **354** to hold the rod and therewith the bridge in active state.

Referring now to **FIGs. 16a, 17a, 22** and **23** which deal with the stability of needle: The needle could be provided with further stabilization before exiting the inserter and then entering the soft tissue. Stability can be provided by several means. Two exemplary possibilities include a conical aperture and a special, needle stabilizing aperture.

Referring now to **FIGs. 16b** to **17b**, item **130**, if not **5a**, aperture **130** through distal housing **100** may be slightly conical, with diameter of helix of the needle (the outer diameter) so that the needle always fits inside the conical aperture **130** at the proximal side, as distal and proximal handles **100**, **300**, respectively, are assembled. The distal aperture side is of equal diameter to the needle **210**. This stabilizes the needle.

Alternatively, a needle stability aperture stabilizes the needle. A disk holder **140** is provided inside distal housing **100** for the stability aperture disc **150**, which has an aperture **155** for the needle **210** to run through. This is similar to US Patent 11/834,186, to Rioux, mentioned in the background, except that there is no guide aperture because it doesn't "guide" the needle in terms of rotation forces, pitch, no. turns. Rather, it rotates freely and therefore it can only add to the stability of the needle before being pushed into the tissue in the transversal plane as indicated with the arrow in **FIG. 23**.

Referring now to **FIGs. 32-38**, an alternate embodiment uses a helical guide tube **740** to make the needle **730** turn and move along its helical pathway and a push out mechanism for the member **500** without a rack and pinion or a drive mechanism as already explained, rather using only wheels with a rubber surface. Unlike the inserter embodiments already explained, here the mechanism for the needle and the push in mechanism are separated from each other with no direct force transmission between these two. As shown in **FIG. 40**, it should be noted, as already explained with the other inserter types, that the

implantable flexible member **500** may already be inside the needle **731** just before the tip **732** before the beginning of the inserting procedure, and so passes all the way through the hollow needle and out of the proximal needle aperture **733**. The member is flexible having an inner **501** structure and a low friction outer hull **500**, for example a fluoropolymer which are corrosion resistant and biocompatible, in contact with the inner wall of the needle **731**. The outer hull of the member **500** and the inner wall of the needle **731** is separated by a small gap **502**, which could be filled before insertion with an antiseptic fluid or lubricant.

This type of inserter is of particular benefit if only a soft tissue structure posterior to another structure of the body should be pierced helically, leaving the structures superficially intact. Referring now to **FIGs. 36, 37A** and **37B**, the guide tube **740** can be separated from the distal inserter housing **710** for ease of handling and placing at the site that should be pierced helically without having to move the rest of the inserter with it. A small incision is necessary to access the site, and the helical guide tube **740** held between thumb and fingers is cautiously slipped in until the distal guide orifice **745** reaches the desired location from which helical piercing should begin, for example, between or under muscles. The distal orifice **745** is of rounded shape having no edges which might damage the tissue. Only placing the orifice **745** of a helical tube on site where the helical piercing should start can guarantee that superficial structures are unharmed by the helical needle **730** and superficial tissue layers unstreched. The helical guide tube **744** should have the same pitch and diameter of the helix as the needle **731** which is pushed through it (or withdrawn from it) and which is helically driven by it. The diameter of the tube **744** is slightly larger than the diameter of the needle **731** such that it slidingly fits through. Preferably the helical guide tube **744** and the helical needle **731** are made of medical grade metal which could cold worked and formed using a CNC-controlled coiling and bending machine for the production of torsion springs or tension springs, for example like the FMU series from producer Wafios of Germany. The helical tube **744** is affixed to an over tube **741**, for example by means of laser spot welding, to create a simple form for docking the helical guide tube **740** to the distal housing **710**. Furthermore the tube **741** might be cone shaped on the proximal end **742** to fit easily into the needle guide port **715** of the distal housing **710**. With the guide tube **740** held by fingers in its position and the distal orifice **745** being inside the body at the desired location, the distal housing **710** is moved towards the guide tube **740** to first dock with and then lock both. For the fixation of the guide tube **740** to the housing **710**, arms **743** are mounted to the tube **741**. The arms **743** are wedge shaped to fit easily into the corresponding groove of the distal housing **710** when docking the guide aperture **740** through the needle guide port **715** to the distal housing **710**.

A suitable locking mechanism is provided for locking the helical guide tube **740** to the distal housing **710**. Referring now to **FIGs. 32, 33, 36** and **37**, the helical guide tube **740** is locked to the distal housing **710** by means of a fork like pin fastening mechanism **770** that can pressed into holes **717** of the distal inserter **710**, preferably in a manner to snap in place. The holes **717** pass through the docking port **715** and into holes **747** in the arms **743** of the guide tube. The arms **743** have corresponding holes **747** along the axis of the inserter holes **717**. With the guide tube **740** docked to the port **715**, pushing the fork pin **770** into place locks the guide tube **740** to the housing **710**.

Referring now to **FIG 39A**, in an alternate embodiment, the helical guide tube **740** is locked to the distal housing **710** by means of a bayonet fastening mechanism **760**. The distal housing provides a bayonet slot **716** for the bayonet pins **762** of the bayonet **760**. Referring now to **FIG. 39 B** and **39C**, turning the bayonet **760** changes the position of the arm clearance slot **761**. **FIG. 39B** shows open state, the arms **743** of the guide tube **740** can now be docked into the port **715**. **FIG. 39C** shows closed position: turning the bayonet **760,** as indicated with the arrow, locks the guide tube **740** to the distal housing **710** as the arm clearance slot **761** is now blocking the arms **743**.

Now referring to **FIGs. 32A** to **32C** and **33A** to **33C**, with the helical tube **740** locked to the distal housing **710**, the trajectory of the inserter must be assured as already explained. Next, the proximal actuator housing **720** can be inserted into the distal housing **710** using the corresponding sliding guide **711** and **721**.

The needle part **730** must have a sliding contact bearing with the proximal housing **720**. For that, two discs **738** and **739** (see **FIG. 38**) with a hole in center are affixed to the tube section **736** of the already formed needle. The sliding contact disc **738** serves only as a bearing surface together with the corresponding profile inside the proximal inserter **720**. The second disc **739** serves to distribute forces: once affixed to the needle, it is used as a base for the tube **734**. The tube **734** is affixed to the helix section **737** inside the tube as well as to the disc **739** to better distribute the linear force exerted by the pushing in of the proximal inserter **720**. In this manner, a simple supporting structure can be created for the structurally weak section **736**, **735** to the helix section **737**, which allows keeping the wall thickness of the needle to a minimum.

Now pushing the proximal housing **720** inside the distal **710**, as the tip of the needle **732** reaches to proximal guide orifice **746**, the needle part **730**, which is freely rotatably coupled to the proximal actuator housing **720**, must be put inside the proximal orifice **746** by putting thumb and index finger through the window **713** of the distal housing **710**, holding the needle **731** just below the tip **732** and placing it into the cone shaped proximal orifice **746**. For this reason, the proximal tube orifice must be outside of the tube **741**, and the tube itself must be long enough to fit through the whole profile of the distal inserter housing **710** at the needle guide port **715**. From now on, while pushing the proximal housing **720** into the distal

housing **710**, the helical guide tube **740** forces the needle **730** to rotate along its corresponding helical pathway, as can be seen in the transparent view of **FIG. 38**. As the needle tip **732** reaches the distal orifice **745**, the helical piercing of the soft tissue begins along the central axis of the distal housing **710**. Once the proximal housing **720** is fully inside the distal housing **710**, the needle **731** is also fully inside the tissue along its helically pierced pathway. In this embodiment, the trigger **750** acts as a positive stop block, but, of course, other solutions are possible, and may, for example, include a stop block inside the distal housing **710**. A stop block avoids contact between the tube **734** of the needle **730** and the proximal orifice **746** of the guide tube **740**, as it might otherwise bend or damage these parts.

Now referring to **FIGs. 34A** to **34D**, which is a cross section I-I as shown in **FIG. 33B** and the corresponding transverse cross section J-J as in **FIG. 33A**, showing the proximal inserter inside the distal housing **710** at four different states. **FIG. 35 A** and **B** are transverse cross sections J-J, side by side layout showing the trigger **770** in two extreme positions of **FIG. 34A** and **FIG. 34C**.

FIG. 34A shows the proximal inserter fully inside the distal housing **710**, the trigger **770** acting as a stop block. The wings **752** of the trigger are outside the distal housing **710** and the member push out wheels **782** not in contact, leaving a gap open.

FIG. 34B shows the proximal inserter fully within the distal housing **710**, the trigger **770** being pushed inside through the activation trigger aperture **718** for the wings **752**. The member push out wheels **782** are now in contact with the member **500** disposed between them. The drive wheel **781**, in contact with the back wall **709** of the distal inserter, can now drive the whole mechanism.

FIG. 34C shows the proximal inserter **720** half way outside the distal housing **710**, the needle tip **732** being already inside the guide tube orifice **745**, showing the member **500** as it would be inside the tissue. The wings **752** are confined in its groove inside the proximal inserter **720** by the inner wall of the distal inserter **710** keeping the wheels **782** closed and the mechanism active.

FIG. 34D shows the proximal inserter **720** just before leaving the distal housing **710**. The trigger **770** can now be pulled out, disengaging the mechanism and leaving a gap for the member **500**. The tip of the needle **732** is already outside the proximal needle orifice **732** and the member **500** can be grabbed by fingers through the window **713**. The length of the member **500** on the proximal sid of the inserting wheels must at least the length inside the needle; otherwise the member cannot be fully inserted. The inside diameter of the guide tube **744** is substantially larger than the inside diameter of the needle **733**, allowing the member **500** to be pulled easily through the guide tube **740**.

In an advantage of the invention, the invention provides a method and apparatus for inserting an implantable member helically into soft tissue, thereby better fixing the implantable member through the structure of the helical pathway in the soft tissue when such tissue is deformed.

In another advantage of the invention, an improved electrode is provided for insertion into deformable body sections, especially muscle tissue which undergo a change in length between septum access and distal location of the member.

The patents and articles mentioned above are hereby incorporated by reference herein, unless otherwise noted, to the extent that the same are not inconsistent with this disclosure.

Other characteristics and modes of execution of the invention are described in the appended claims.

Further, the invention should be considered as comprising all possible combinations of every feature described in the instant specification, appended claims, and/or drawing figures which may be considered new, inventive and industrially applicable.

Multiple variations and modifications are possible in the embodiments of the invention described here. Although certain illustrative embodiments of the invention have been shown and described here, a wide range of modifications, changes, and substitutions is contemplated in the foregoing disclosure. While the above description contains many specifics, these should not be construed as limitations on the scope of the invention, but rather as exemplifications of one or another preferred embodiment thereof. In some instances, some features of the present invention may be employed without a corresponding use of the other features. Accordingly, it is appropriate that the foregoing description be construed broadly and understood as being given by way of illustration and example only, the spirit and scope of the invention being limited only by the claims which ultimately issue in this application.

APPENDIX—Element list

Helical Needle Drive Inserter 1, reference lists:

10 **Distal inserter housing**
11 Sliding guide
12 Distal handhold
13 Rack
14 Needle orifice port
15 Skin tension boss
17 Inner profile of distal inserter, corresponding 27

20 **Proximal actuator housing**
21 Sliding guide bars
22 Proximal handhold
23 Proximal actuator top, top sliding contact bearing for needle drive wheel
24 Needle bushing beam, bottom bushing for needle tube section 36
25 Sliding guide for activator rod
26 Aperture for activator rod
27 Distal profile of proximal inserter
28 Stop block for 53
29 Aperture for member 42

30 **Needle part**
31 Helical hollow needle, right-handed
32 Helical hollow needle centrically bending section
33 Needle drive crown wheel
34 Hypoid gearing
35 Elevated sliding contact
36 Hollow needle tube section
37 Needle tip, distal hollow needle aperture
39 Proximal needle aperture

40 **Inserter mechanism**
41 Inserting mechanism activator trigger
42 Implantable member
43 Main drive pinion
44 Member injection drive wheel, geared laterally
45 Member injection driven wheel, geared laterally
46 Half-round wheel groove, 2 x groove width = diameter member 42
47 Shaft hinge pin
48 Hinge pin
49 Hypoid gear pinion
50 Shaft
51 Connecting rod fork
52 Fulcrum pin for 51
53 Driven wheel fork
54 Fulcrum pin for 53
55 Activator rod

Alternate Wedge Triggering Mechanism—Reference List

60 Wedge triggering mechanism
61 activator rod wedge
62 corresponding wedge sliding axle
63 sliding axle part
64 slide bar
65 spring
66 axle
67 sliding guide
68 shaft part (left)
69 shaft part (right); semi transparent
70 spring counter force

Helical Needle Screw Thread Inserter 1', reference lists:

100 **Distal inserter housing**
110 Female screw thread, right-handed
120 Inlet aperture for male screw thread pins
130 Conical aperture
140 Stability aperture disc holder
150 Freely rotatable stability aperture disc
155 Stability aperture
160 Fixation arms

200 **Needle part**
210 Helical hollow needle, right-handed
210A Helical hollow needle with proximal end bent centrically
210B Helical hollow needle with proximal end unchanged
215 Needle tip, distal hollow needle aperture
220 screw thread drive wheel
225A Straight tube through wheel
225B Helical tube through wheel
230 Male screw thread pins
240 Hollow driving shaft

245 Proximal needle aperture
250 Mechanism drive wheel
255 Drive gears
260 Mechanism drive wheel locking groove

300 Proximal actuator handle
310 Bridge fulcrum pin groove
320 Sliding guide for control rod
325 Spring fixation
330 Positive stop block for bridge 400
335 Positive stop block for control lever 440
340 Bushing for driving shaft 240
350 Control rod
351 Locking arm
352 Activator arm for bridge 400
354 Retainer
355 Locking groove
360 Push-button

400 Bridge mechnism(second class lever)
410 Bridge fulcrum pin
420 Half-Round groove member injection drive wheel
430 Half-Round groove member injection driven wheel
435 Force transmission edge between 420/230; optionally geared surface, gear ratio 1:1
440 Control lever, driven wheel side (first class lever)
450 Control lever, spring load side (first class lever)
460 Fulcrum of control lever
465 Member injection driven wheel axle
470 Straight cut hypoid gear
480 Bridge driving shaft
490 Pull-spring unloaded
495 Pull-spring loaded
500 Implantable part, member

Helical guide drive 1", reference list:
710 Distal inserter housing
709 Back wall for drive wheel
711 Sliding guide bars
712 Distal handhold
713 Access window
714 arm slot or keyway
715 needle guide port
716 bayonet slot
717 hole for pin
718 activation trigger aperture
719 disengage trigger aperture

720 Proximal actuator housing
721 Sliding guide
722 Proximal handhold
723 Assembly screw holes
729 Aperture for member 500,Needle orifice port
730 Needle part
731 Helical hollow needle, left-handed
732 Needle tip, distal hollow needle aperture
733 Proximal needle aperture
734 Needle stability tube
735 Helical hollow needle centrically bending section
736 Hollow needle tube section
737 Helical section affixed inside tube 734
738 Sliding contact disc
739 Force distribution disc

740 Helical guide tube part
741 Tube
742 Docking cone
743 Arms
744 Helical guide tube
745 Distal guide orifice
746 Proximal guide orifice
747 Arm hole for pin
750 Trigger
751 Hole for thumb
752 Wings
760 bayonet mechanism
761 arm clearance slot
762 bayonet pins
770 fork pin mechanism Mechanism
781 Drive Wheel
782 Driven Wheel,
783 Axle pin for wheels784 Activation Wheel, same diameter as 782

800 Head and mandible fixation cage

What is Claimed is:

1. A helical inserter (1, 1', 1", 1"') for inserting an insert (500) helically into soft tissue including:

    a. a housing assembly (10, 20, 100, 300, 300A, 300B, 710, 720);

    b. a hollow helical insert guide (31, 210) held in functional relationship by the housing assembly, the guide adapted to be loaded with the insert (500) for helical transport therewith into the soft tissue;

    c. a helical insert guide drive (13, 33, 43, 44, 49, 50; 100, 110, 220, 230; 250, 420, 470, ;709, 734, 738, 739, 740, 781) which drives the helical insert guide in rotation into the soft tissue; and

    d. a guide removal device (13, 28, 33, 41, 43, 44, 45, 49, 50, 51, 52, 53, 54, 55; 250, 420, 430, 470; 709, 781, 782) which, when an insert (500) is present within the insert guide (31, 210), removes the insert guide while leaving the insert in its intended implant location in the soft tissue.

2. The helical inserter of claim 1, wherein the helical insert guide drive comprises a cam surface (110) which, when a cam follower (230) mounted on a component (220, 300) which moves relative thereto follows the cam surface, the guide drive drives the insert guide in rotation and translation.

3. The helical inserter of claim 2, wherein the cam surface (110) of the helical insert guide drive is disposed in a helical groove cut in a housing component (100) and the cam follower (230) is affixed to another housing component (220, 300).

4. The helical inserter of claim 3, wherein, in the helical inserter guide drive, in order to drive the helical guide (31, 210) into the soft tissue, the another housing (220, 230) is rotated by the operator relative to the housing component (100), the cam surface (110) directing the cam follower (230) so as to guide the insert guide in rotation and translation.

5. The helical inserter of claim 1, wherein the helical insert guide drive includes a rack (13) and pinion (43) arrangement.

6. The helical inserter of the above claim 5, wherein the rack is an elongated surface (709) and the pinion (781) is a wheel which is frictionally engaged with the elongated surface.

7. The helical inserter of the above claim 6, wherein the pinion (781) comprises a rubber material.

8. The helical inserter of claim 1, wherein the helical insert guide drive converts defined relative translation between two assemblies (10, 20; 100, 300; 710, 720) into defined relative translational and rotational motion to the guide (31, 210).

9. The helical inserter of claim 1, wherein a rack and pinion arrangement (13, 43; 709, 781) is used to drive a gear train (33, 44, 45, 49, 250, 420, 430, 470) which imparts the defined relative translational and rotational motion to the guide.
10. The helical inserter of claim 1, wherein a helical guiding device (740) imparts the defined relative translational and rotational motion to the guide.

11. The helical inserter of the above claim 10, wherein the guiding device (740) is a helical guiding device including a helical channel (737), the guiding device being held stationary with respect to the housing (710).

12. The helical inserter of claim 11, wherein the guiding device includes a drive train (13, 28, 33, 41, 43, 44, 45, 49, 50, 51, 52, 53, 54, 55; 250, 420, 430, 470) which maintains the position of the insert (500) in the soft tissue as the drive train removes the insert guide.

13. The helical inserter of claim 10, wherein the helical guiding device (740) is removable so as to be interchangeable with other helical guiding devices of differing characteristics.

14. The helical inserter of claim 10, wherein the helical guiding device (740) is affixed with a clip or retainer (760, 770), such that it can be easily removed and another affixed.

15. The helical inserter of claim 1, wherein the guide removal device (13, 28, 33, 41, 43, 44, 45, 49, 50, 51, 52, 53, 54, 55; 250, 420, 430, 470) is gear driven.

16. The helical inserter of the above claim 15, wherein the guide removal device includes an idler gear (45, 430), selectively engageable by an operator in order to ensure select functioning for removal of the helical insert guide from the soft tissue.

17. The helical inserter of claim 10, wherein the guide removal device is driven by a rack and pinion arrangement (13, 43; 709, 781).

18. The helical inserter of the above claim 17, wherein the rack (709) comprises an elongated surface and the pinion (781) is a wheel which frictionally engages the elongated surface.

19. The helical inserter of claim 10, wherein the guide removal device is driven, directly or indirectly, by the guiding device (740).

20. The helical inserter of the above claim 19, wherein the guiding device (740) drives the guide (31) to which a drive gear (33, 250) is attached which drives the guide removal device.

21. The helical inserter of claim 1, wherein the guiding device (740) includes at least one wing (743) which engages into a corresponding slot (714) so as to lock the guiding device against relative rotation with the distal housing.

22. The helical inserter of claim 20, wherein a retaining device further retains the guiding device (740) in non-rotating engagement with the distal housing (710).

23. A helical inserter (1, 1', 1", 1"') for inserting inserts helically into soft tissue, the inserter comprising:

(a) a housing assembly (12, 22; 100, 300; 710, 720);

(b) a hollow helical needle (31);

(c) a first hypoid gear wheel (33) affixed to the proximal side of the helical needle (31) and held in axial position through the housing assembly (10) for rotational insertion of the helical needle into the soft tissue; and

(d) a second hypoid gear wheel (49) matched to the first hypoid gear wheel (33) and held in axial position through the housing assembly, the second gear wheel driving an implantable member insertion mechanism, the insertion mechanism adapted to insert an implantable member through the hollow helical needle into the soft tissue by means of the hollow helical needle which is rotationally and translationally driven into the soft tissue.

24. The helical inserter of the above claim, wherein the driving of the implantable member insertion mechanism is accomplished by a rack and pinion mechanism.

25. A device for inserting an implantable member helically into soft tissue as herein described in reference to the accompanying drawings.

26. A method for inserting an implantable member helically into soft tissue as herein described in reference to the accompanying drawings.

27. The method of claim 26, wherein the soft tissue is of a living organism and wherein the method is adapted to insert an electrode or shape memory alloy helically into the living organism for treatment of sleep apnea.

28. A method of installing an insert helically into soft tissue, the method including the following steps:

a. using a helical inserter of claim 1, load the hollow helical insert guide into the inserter;

b. if the insert is not already loaded in the hollow insert guide, load the insert into the hollow helical insert guide;

c. position the helical inserter against soft tissue, orienting the inserter along an axis along with insertion is desired;

d. activating the helical inserter to insert the helical insert guide helically into soft tissue; and

e. activating a guide removal device which, when an insert is present within the insert guide, removes the insert guide in helical rotation while leaving the insert in its intended implant location in the soft tissue.

29. A method of use of the helical inserter of claim 1 for the treatment of Sleep Apnea, the method including the following steps:

a. place head of patient in fixed position using a rack;

b. collect data of tongue in rest position and other deformation extremes, to create 3D model;

c. determine needle size;

d. place inserter in position or mount on rack in order to ensure precise access through tissue in 3 dimensions;

e. confirm desired position of tongue and head with scan before inserting;

f. activate helical inserter mechanism to insert insert helically in soft tissue; and

g. optionally, confirm position with a scan.

30. The method of claim 29, wherein, in step (d), the data is gathered using a CT scan.

31. The method of claim 29, wherein in step (e), confirmation of position is performed using a CT scan or ultrasound.

32. A hollow helical insert guide (31, 210) for use with the helical inserter of claim 1, wherein the guide is a hollow needle having one end which is helically formed and another end (42) which is substantially straight.

33. The hollow helical insert guide of claim 32, wherein an insert is pre-installed within the guide.

34. The hollow helical insert guide of claim 33, wherein the insert is selected from a group of inserts consisting of a regular electrode, a shape memory alloy and an electroactive polymer.

35. The hollow helical insert guide of claim 34, wherein a fluid is disposed between the insert and the guide.

36. The hollow helical insert guide of claim 35, wherein the fluid is an antiseptic fluid.

37. The hollow helical insert guide of claim 32, wherein the guide is disposable.

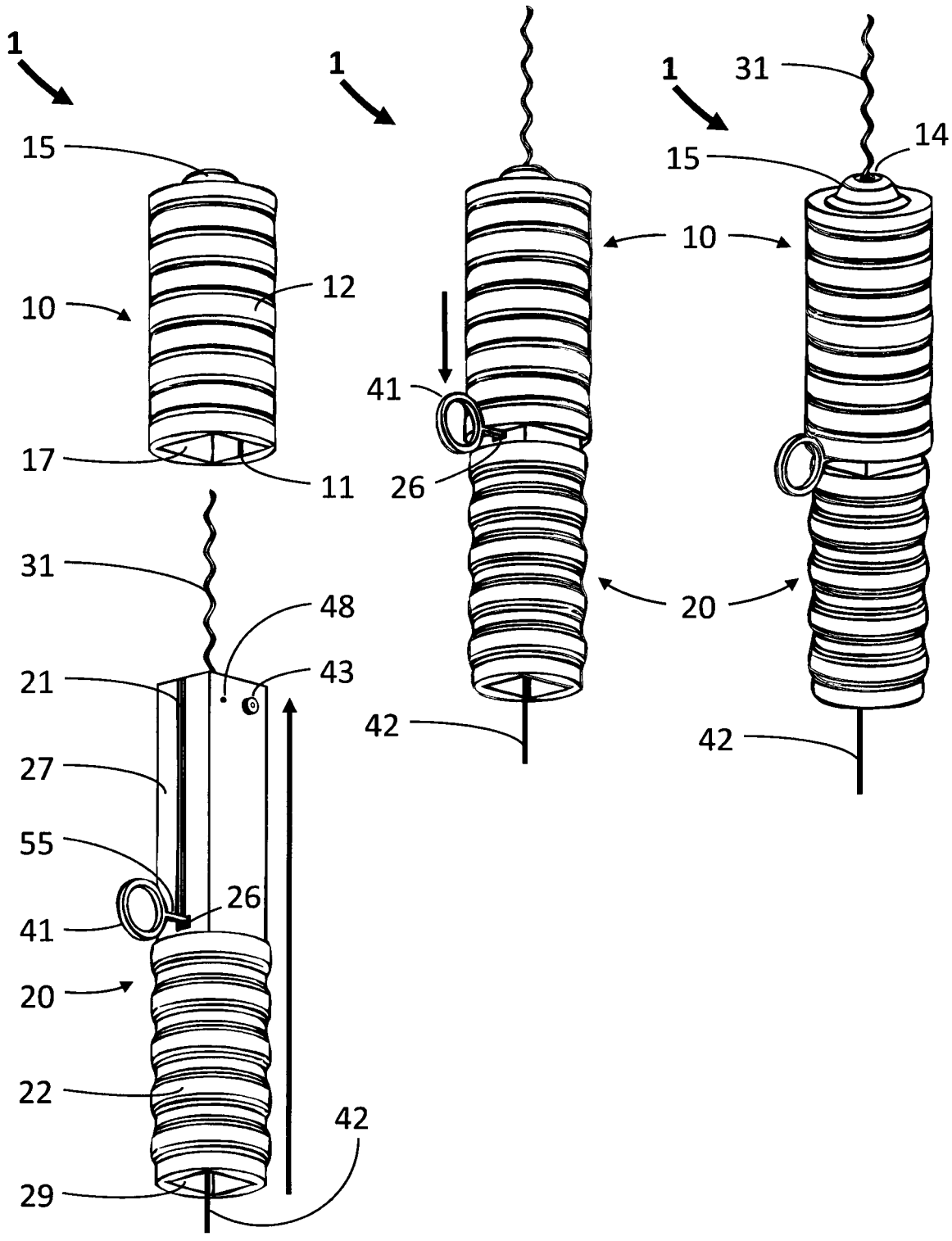
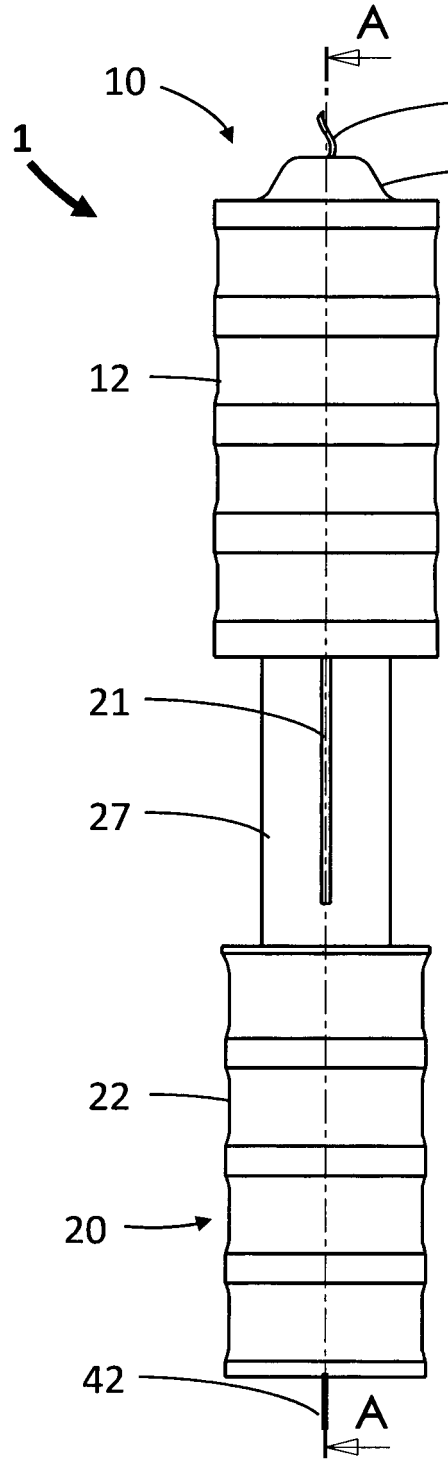


FIG. 1A FIG. 1B FIG. 1C


A
10
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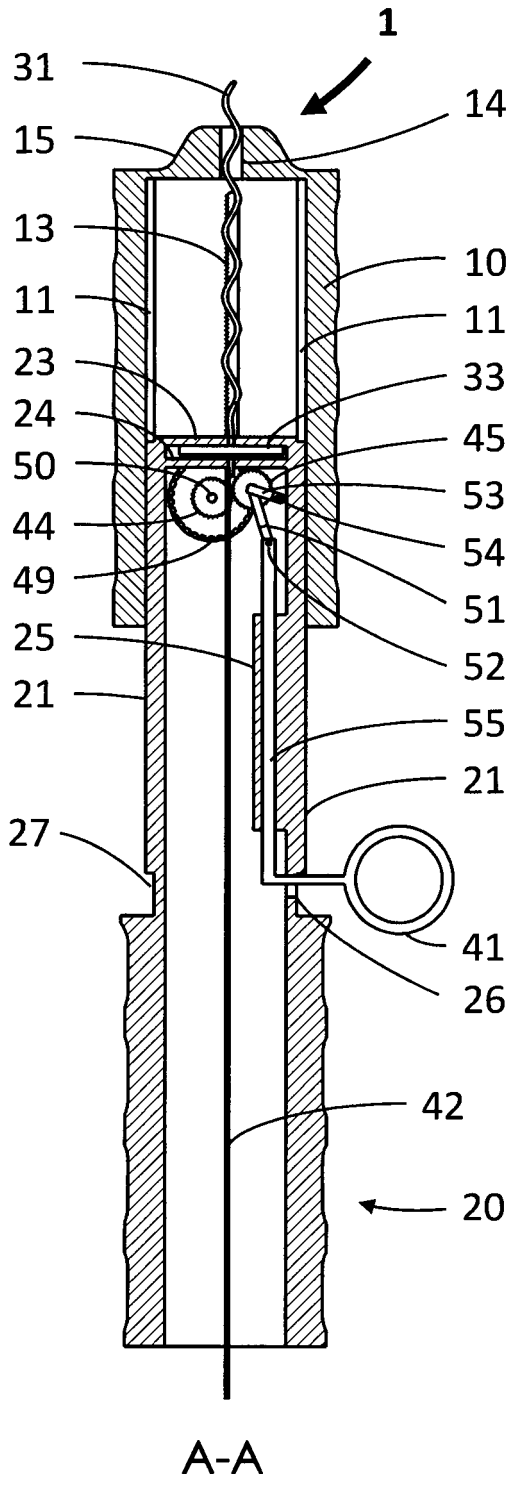
31
15
12
21
27
22
20
42
A

FIG. 2A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41
26
42
20
A-A

FIG. 2B

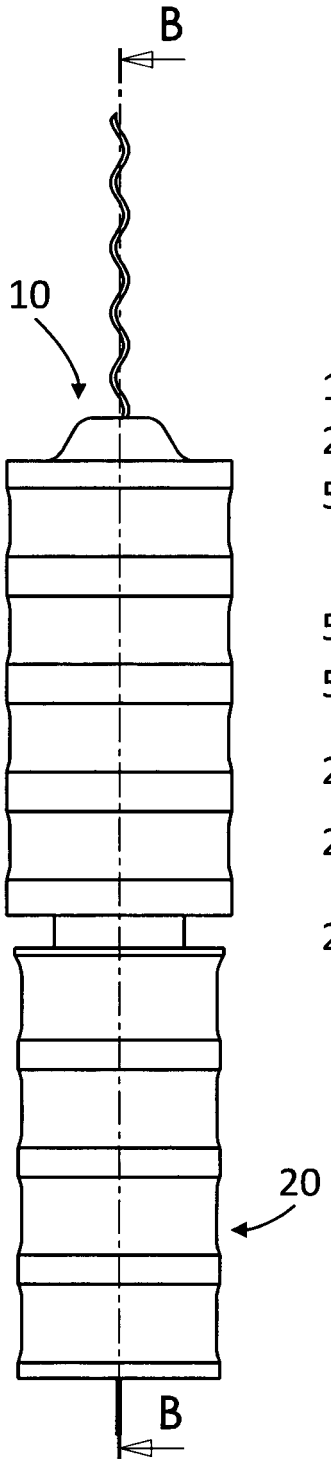


FIG. 3A

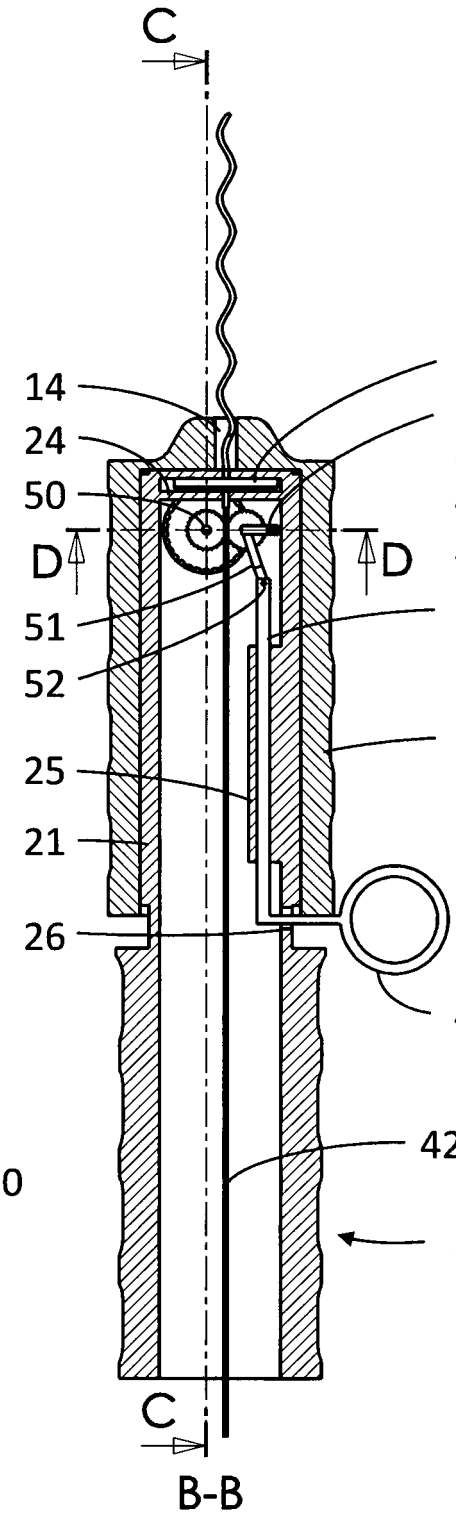


FIG. 3B

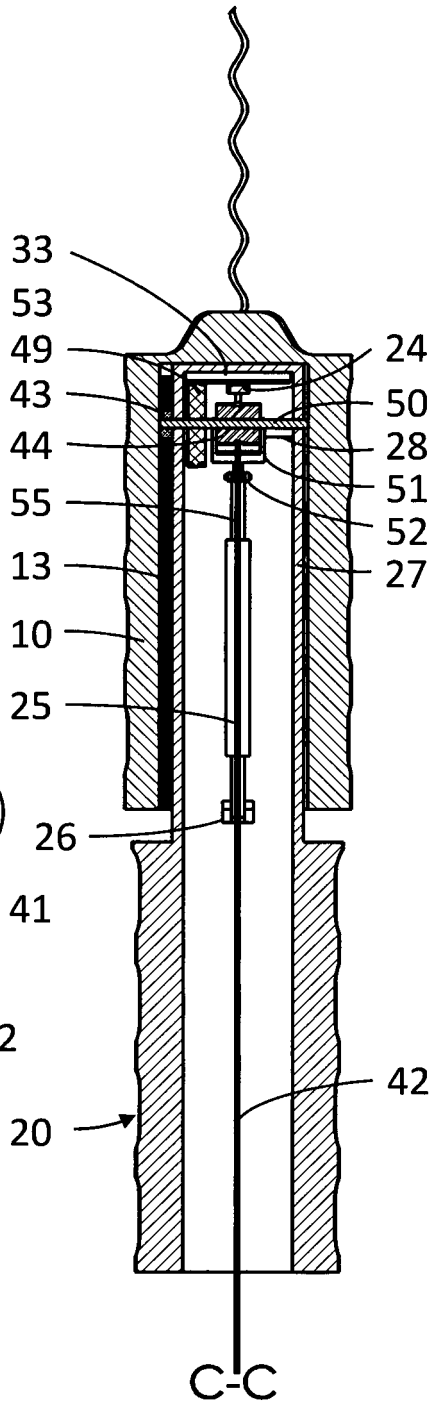
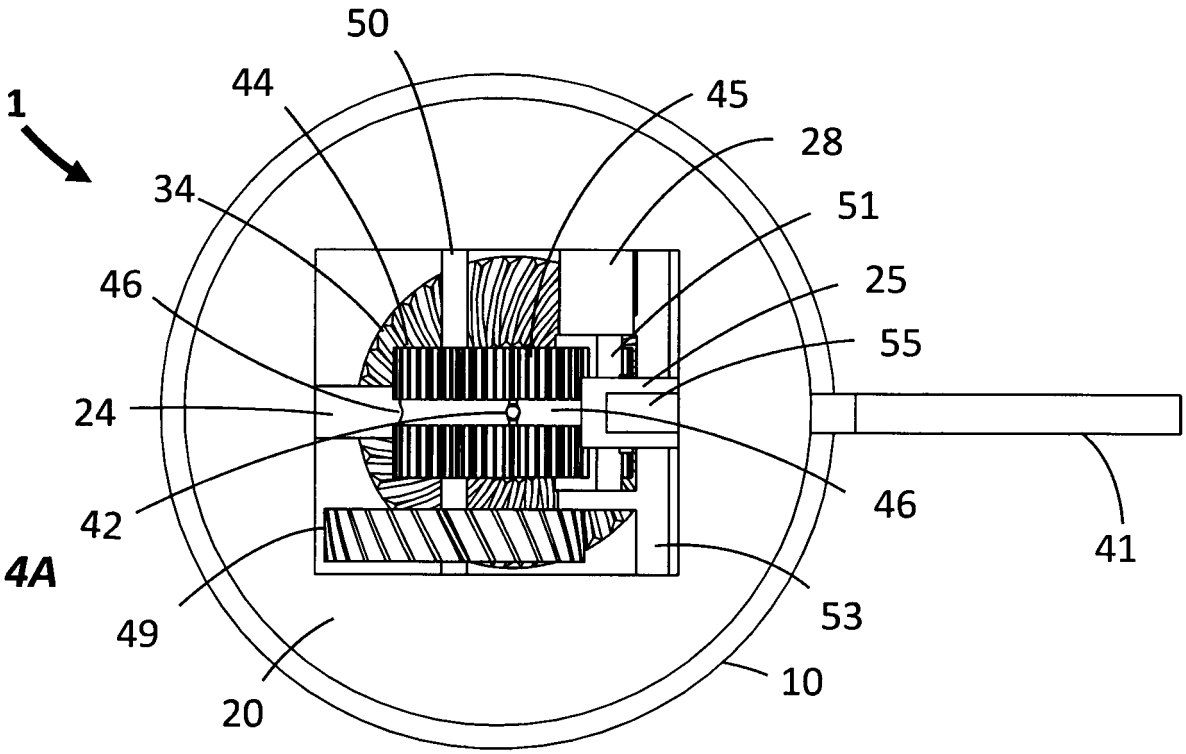


FIG. 3C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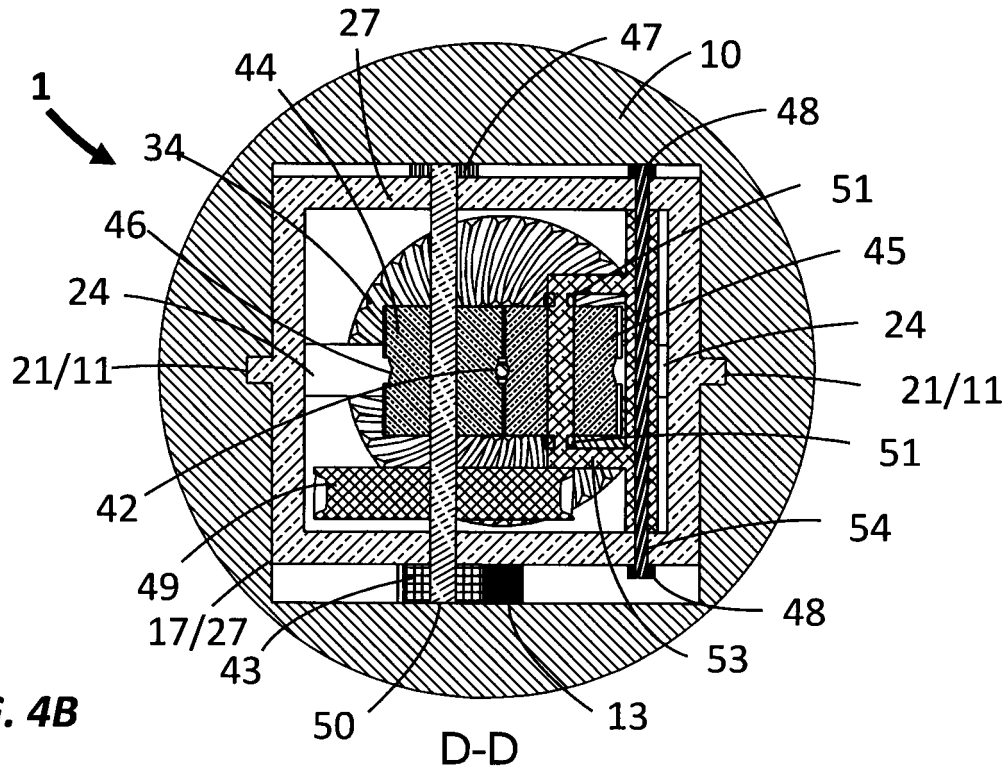
49
10
20

FIG. 4A


1
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21/11
21/11
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42
54
49
48
17/27
43
53
50
13
D-D

FIG. 4B

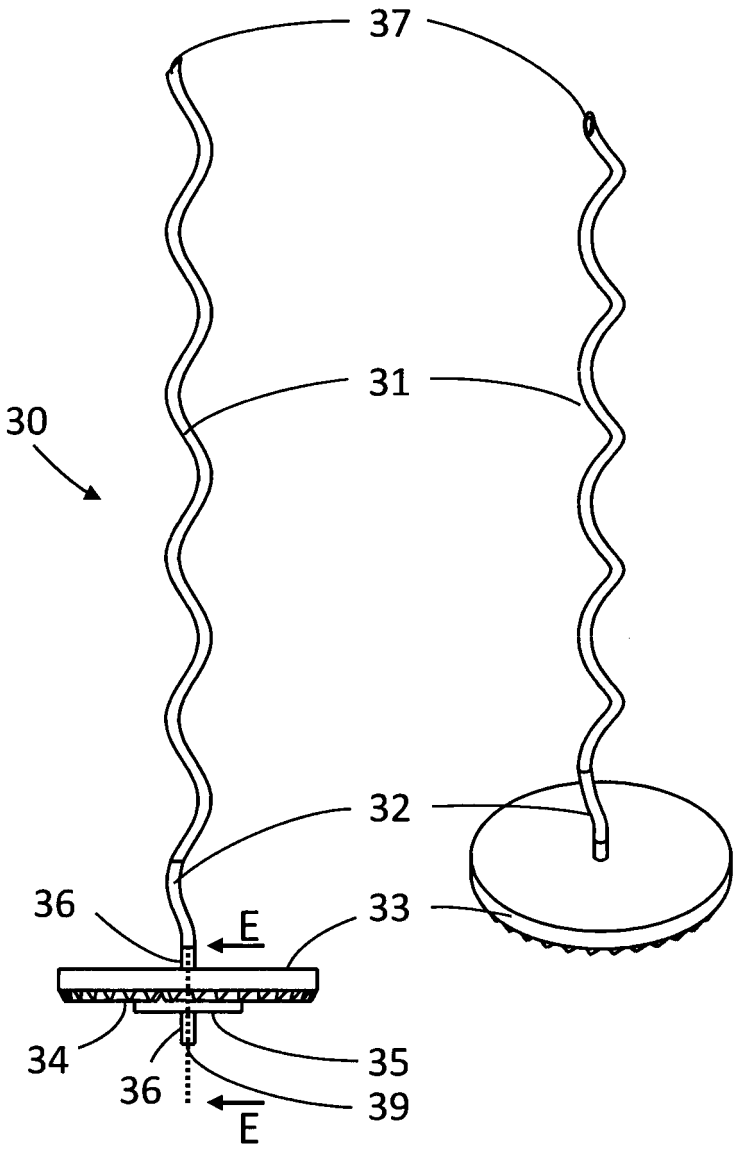


FIG. 5A

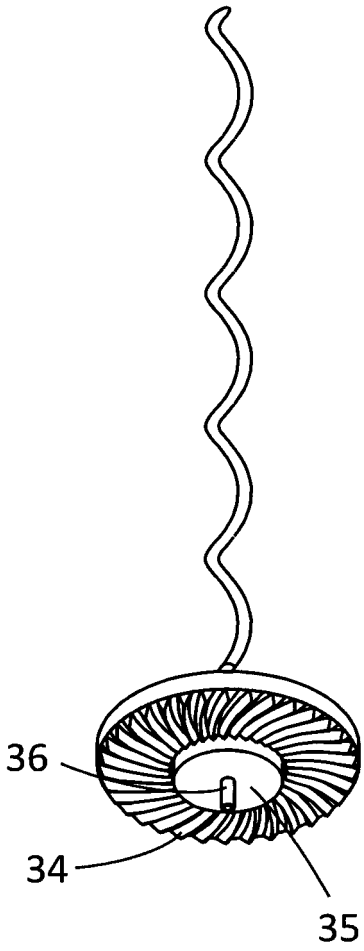


FIG. 5B

FIG. 5C

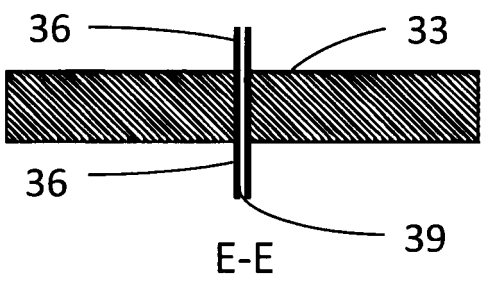


FIG. 6A

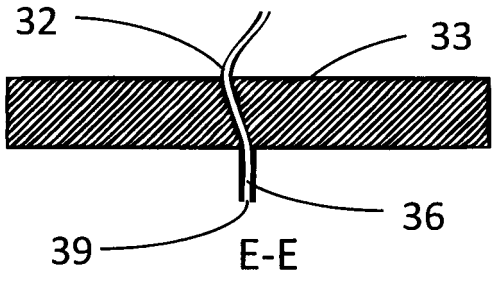


FIG. 6B

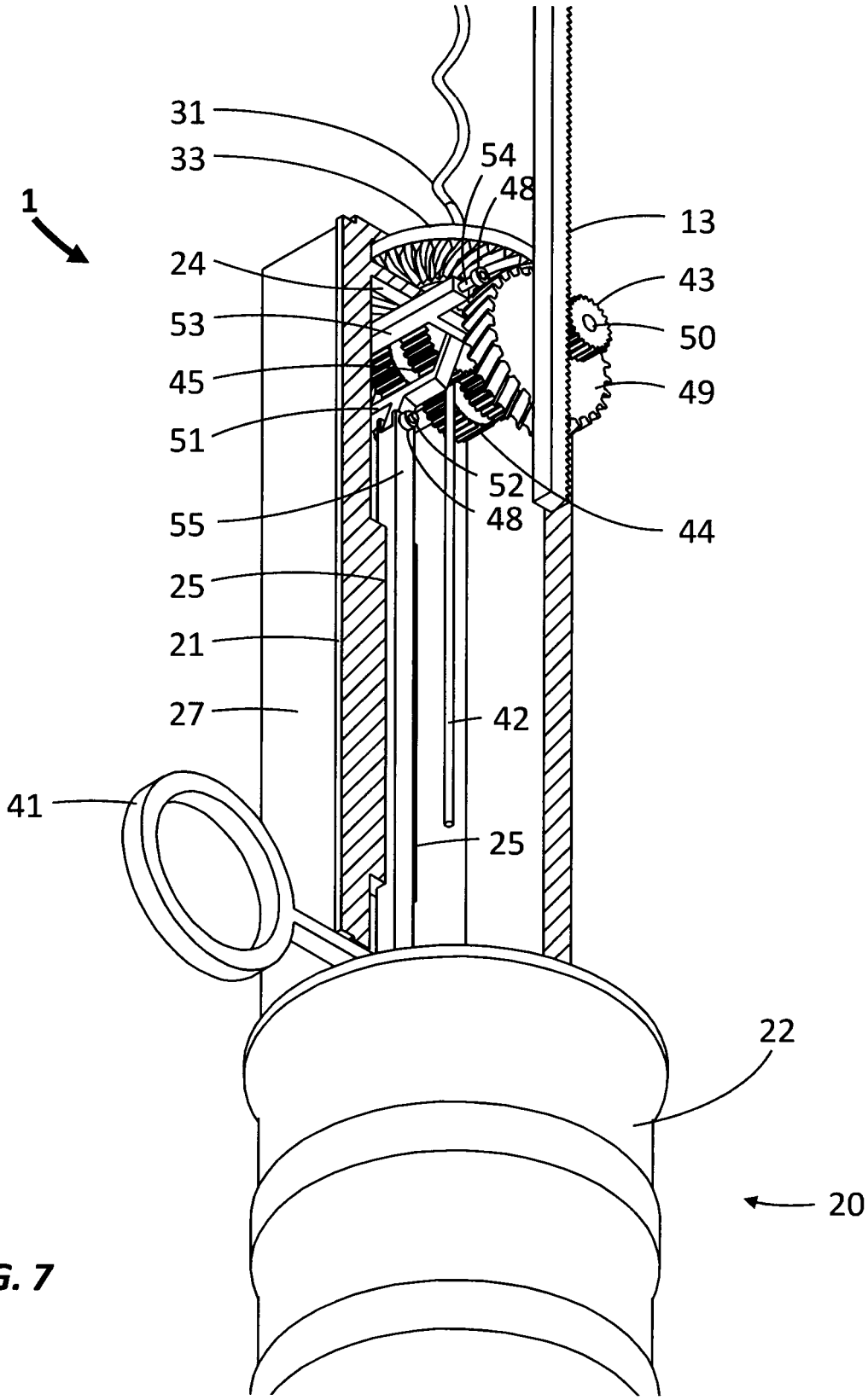


FIG. 7

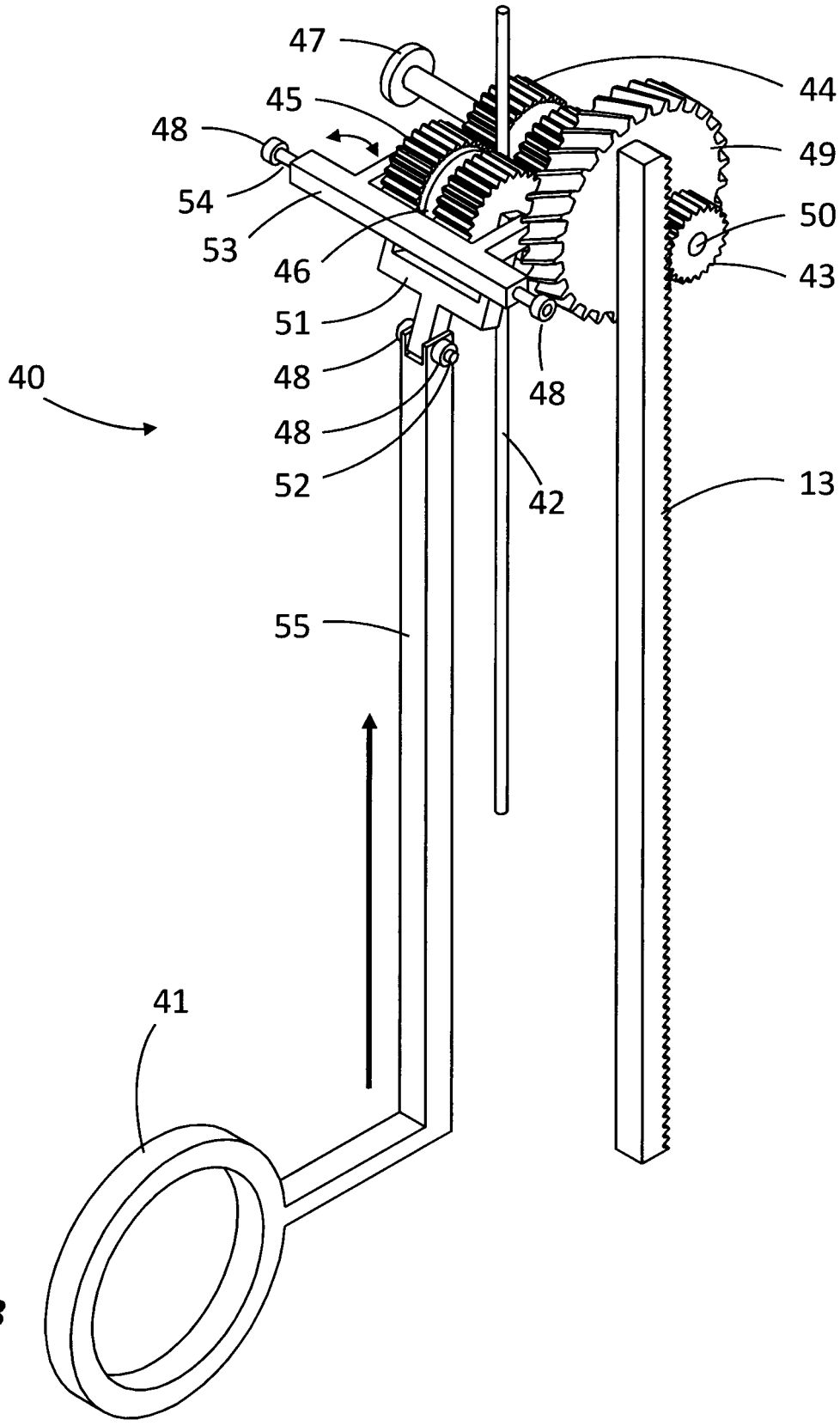


FIG. 8

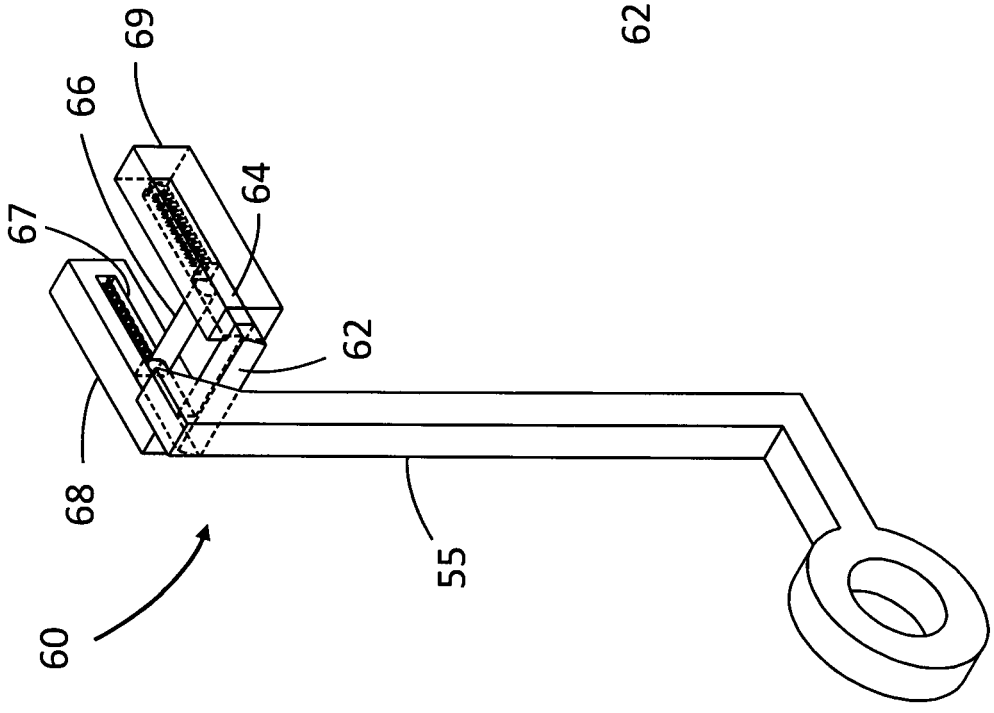


FIG. 9

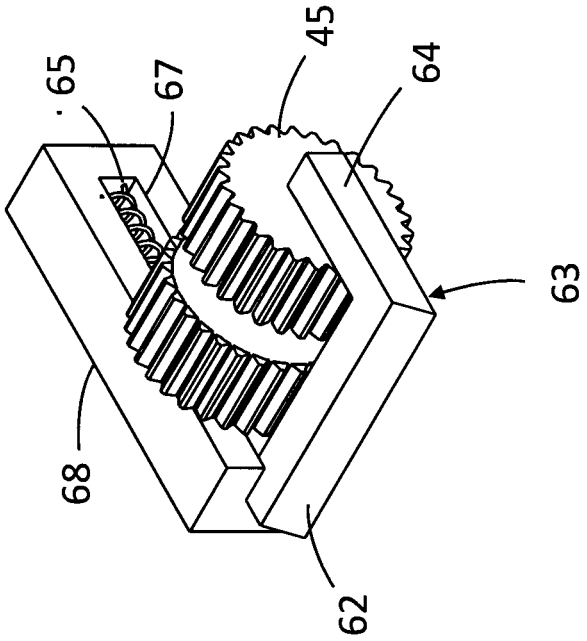


FIG. 10

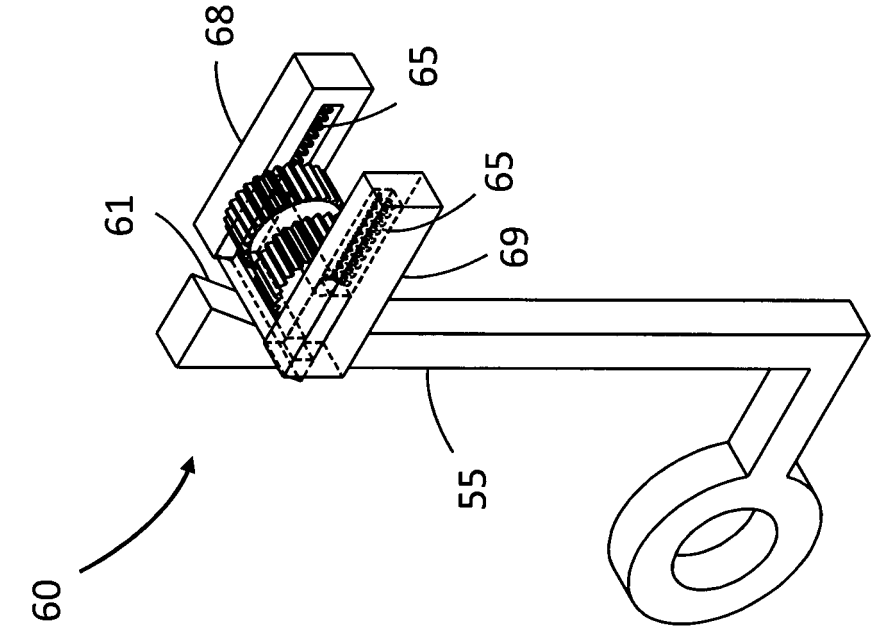


FIG. 11B

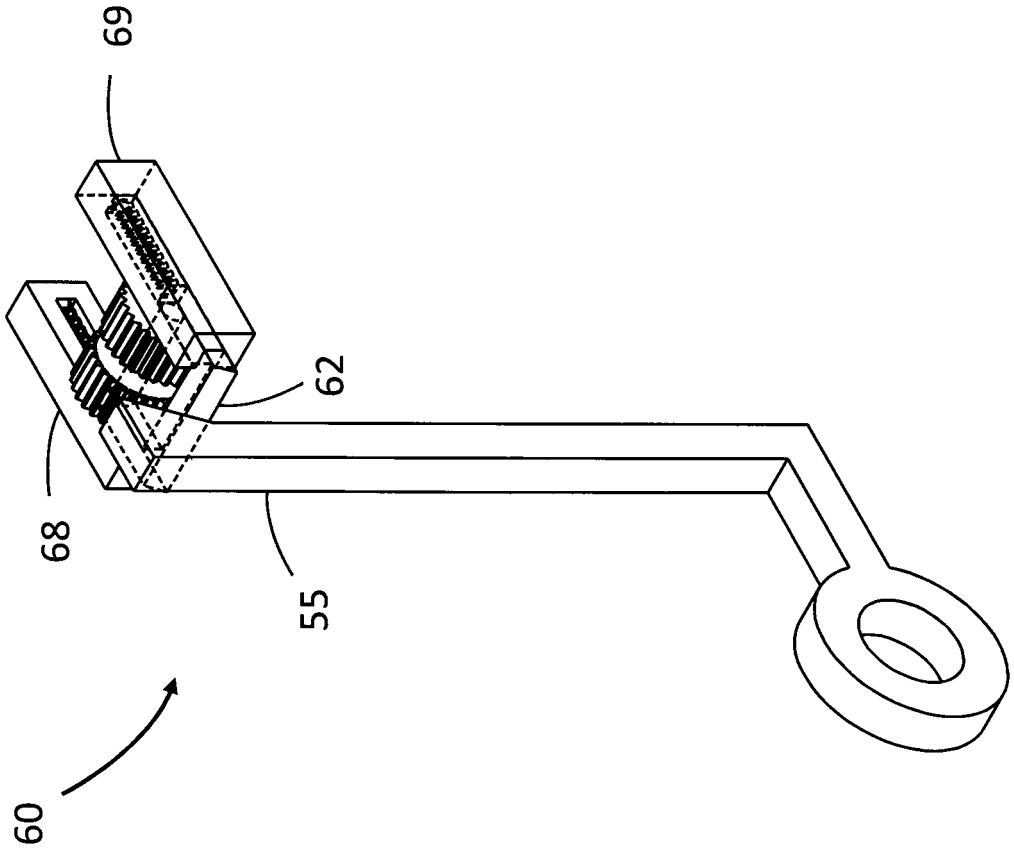


FIG. 11A

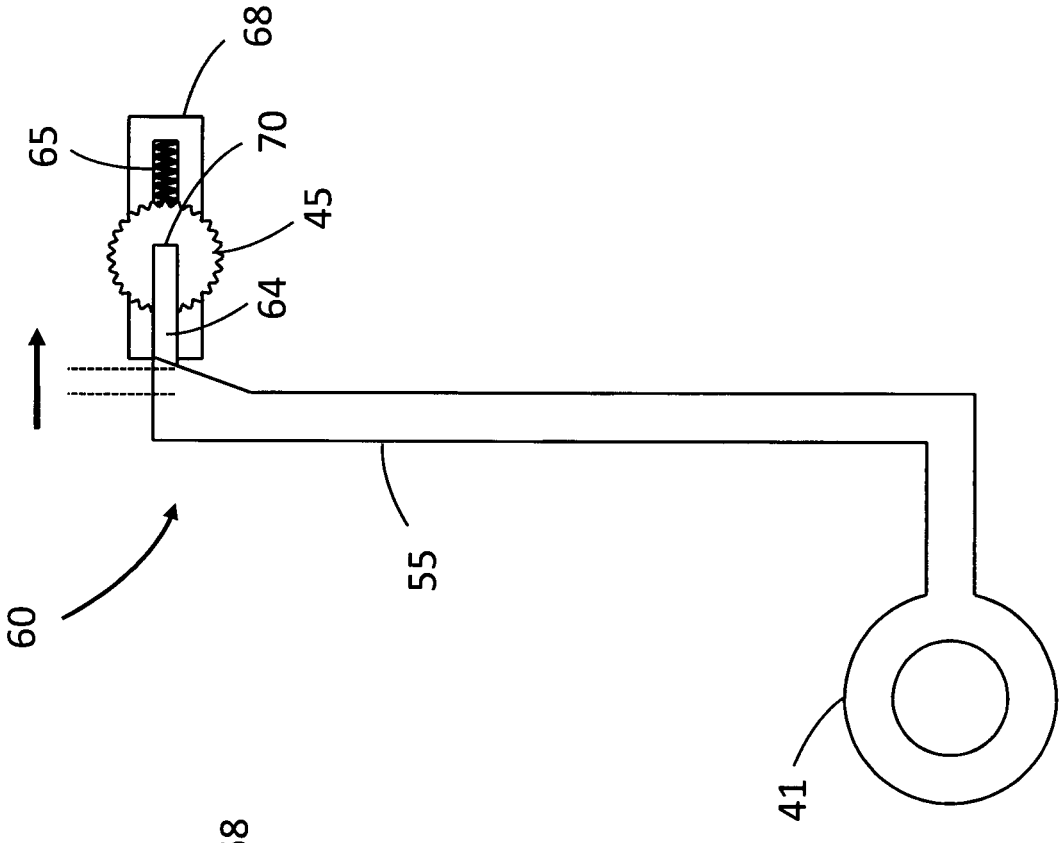


FIG. 12B

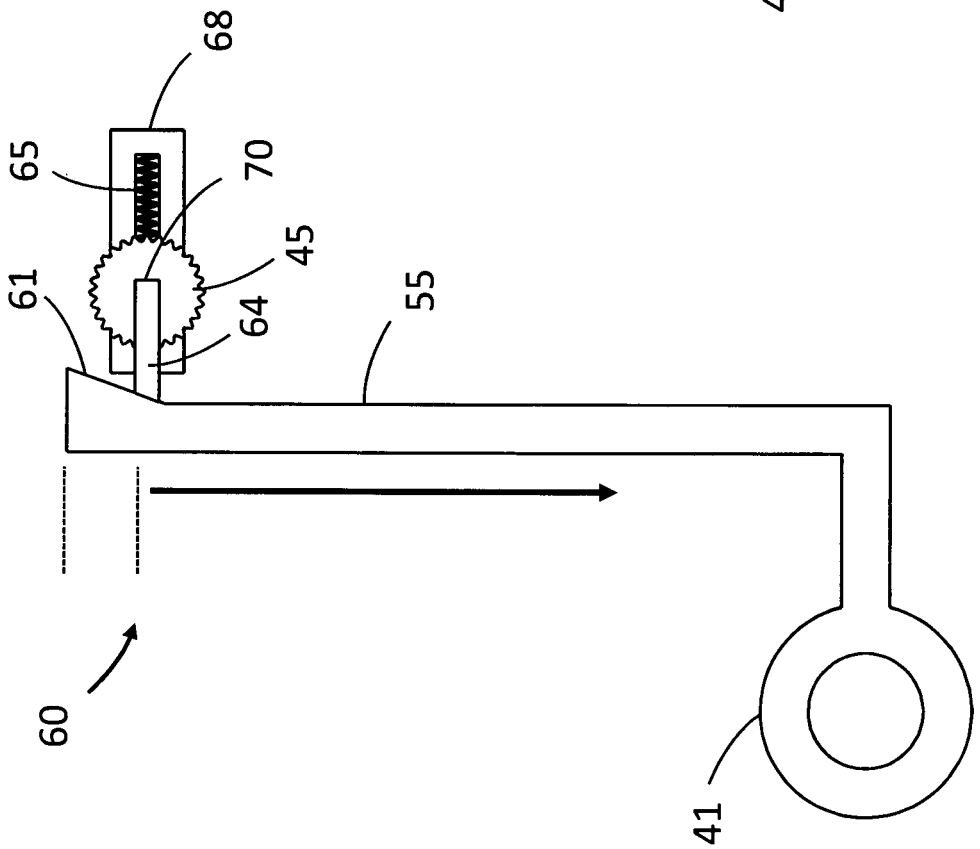


FIG. 12A

FIG. 14

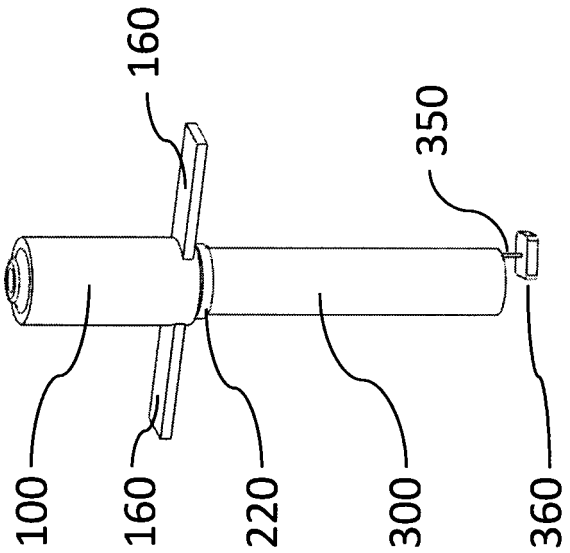


FIG. 13B

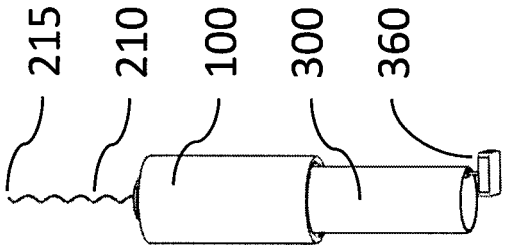
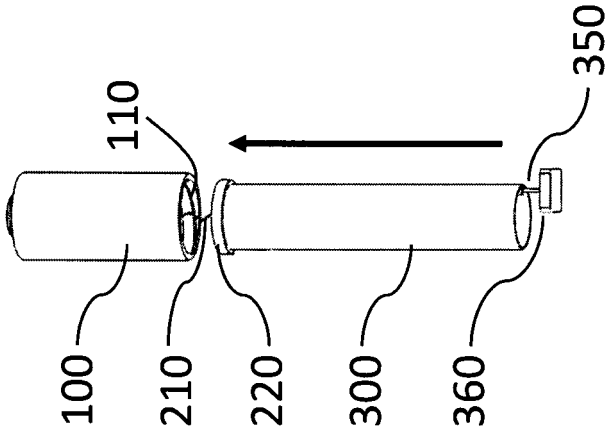


FIG. 13B



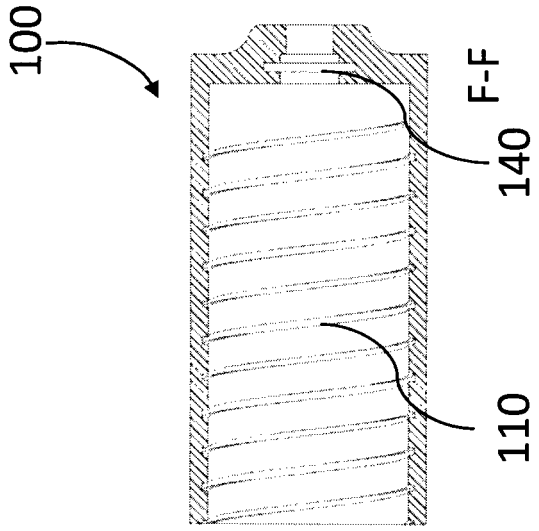


FIG. 17A

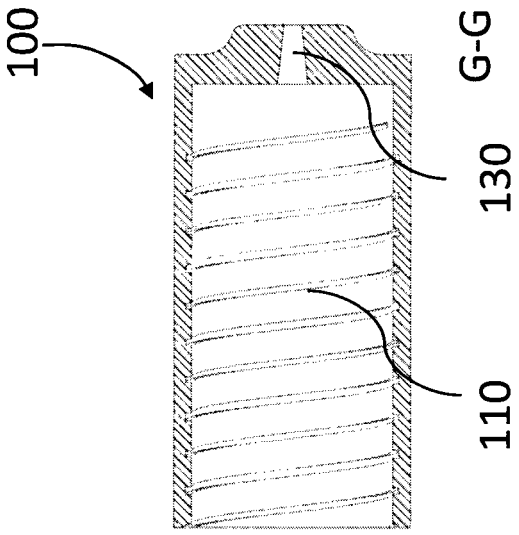


FIG. 17B

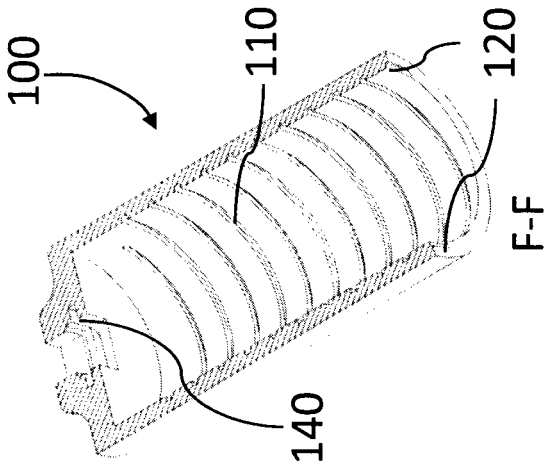


FIG. 16A

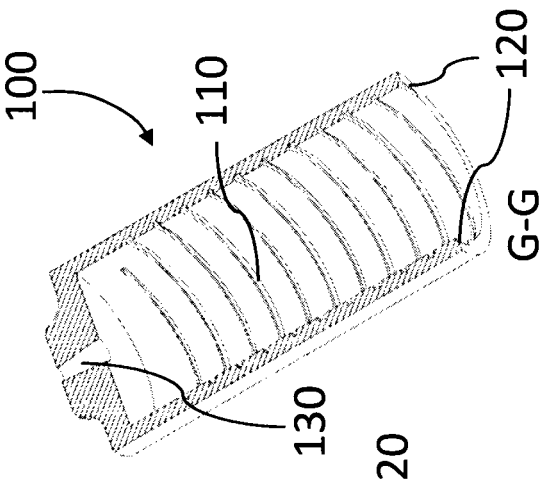


FIG. 16B

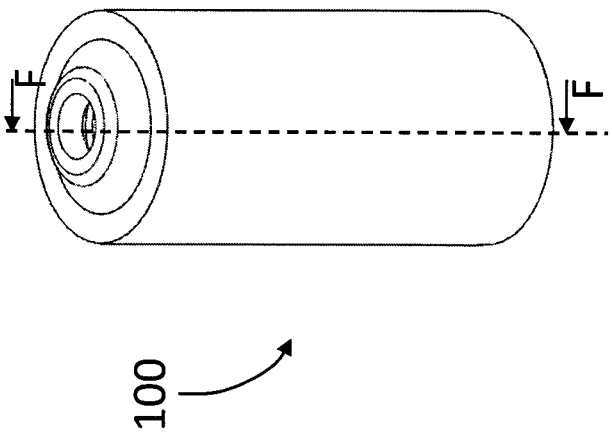


FIG. 15A

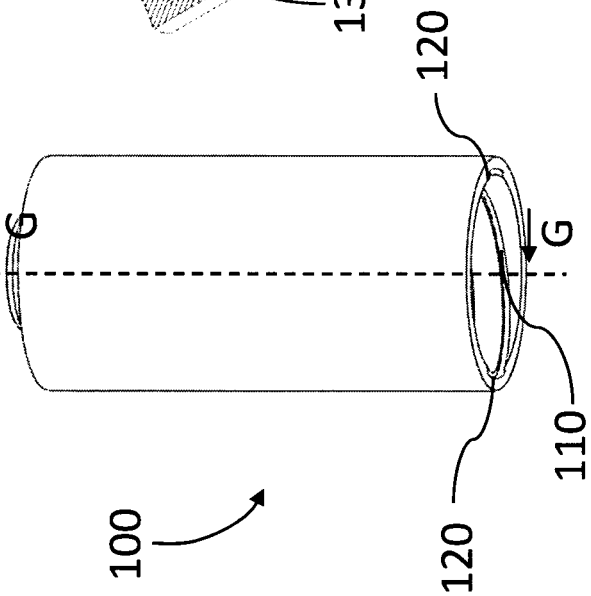


FIG. 15B

FIG. 19

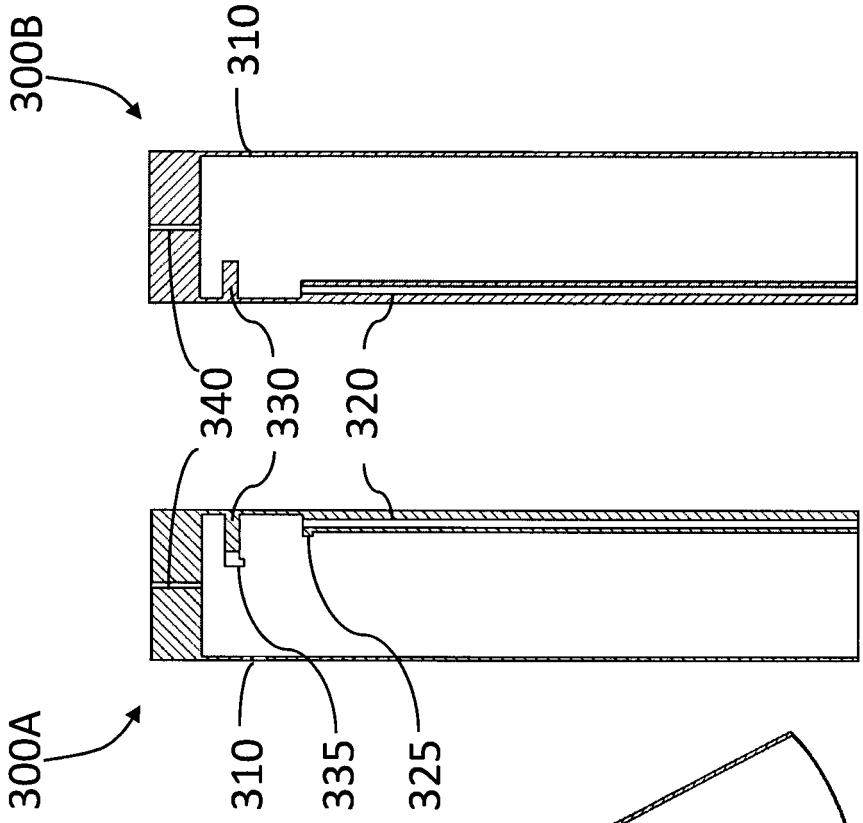
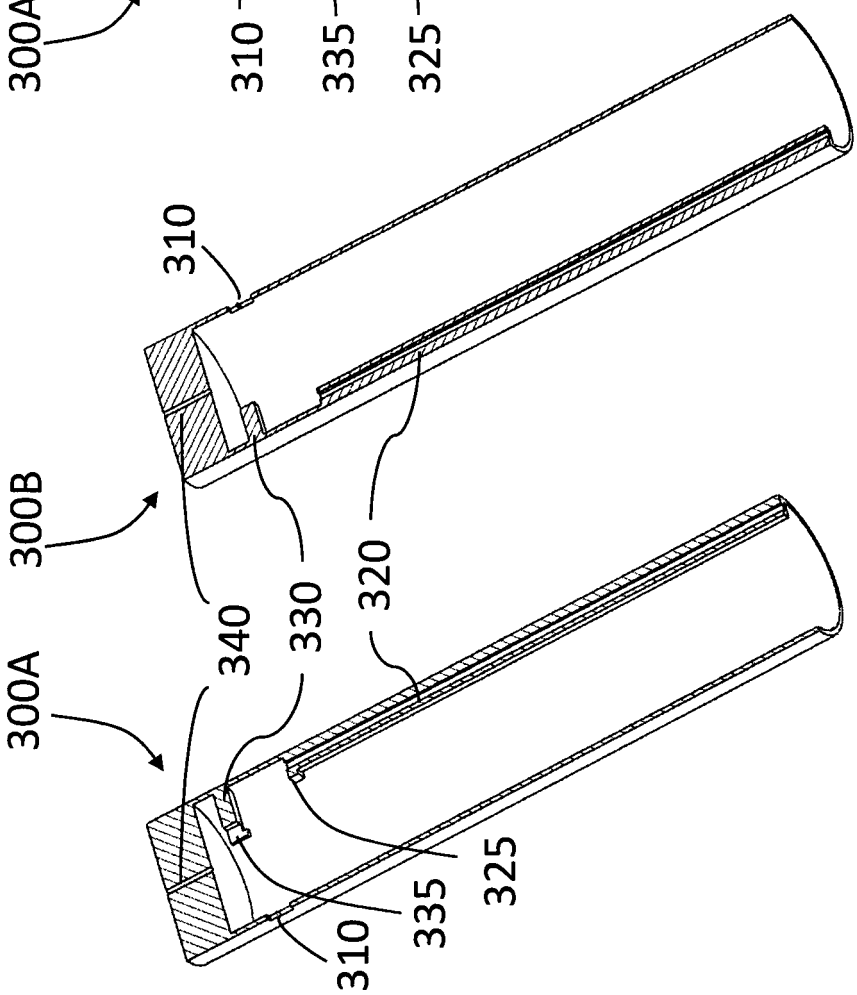

300B
310
340
330
320
300A
310
335
325

FIG. 18


310
300B
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300A
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335
325

FIG. 20A

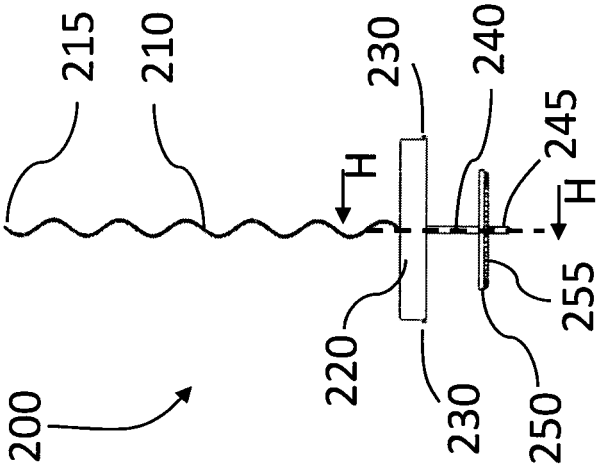


FIG. 20B

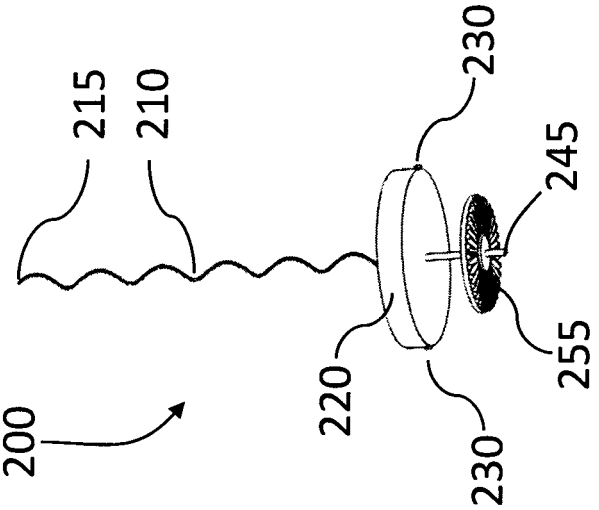


FIG. 20C

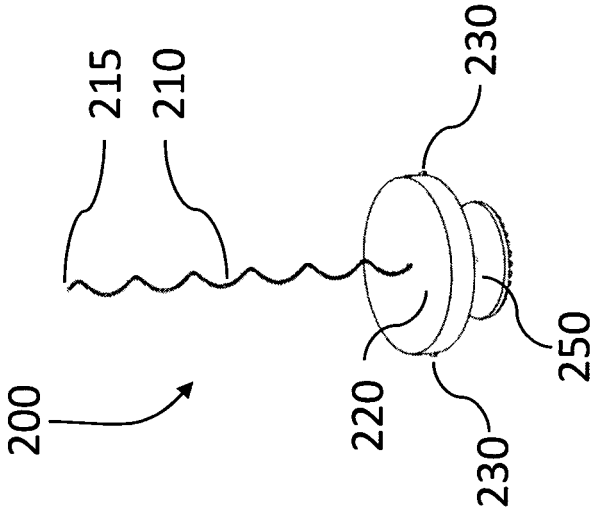


FIG. 21A

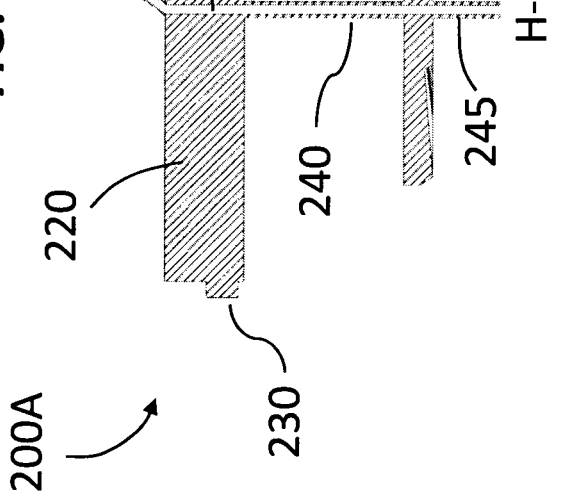


FIG. 21B

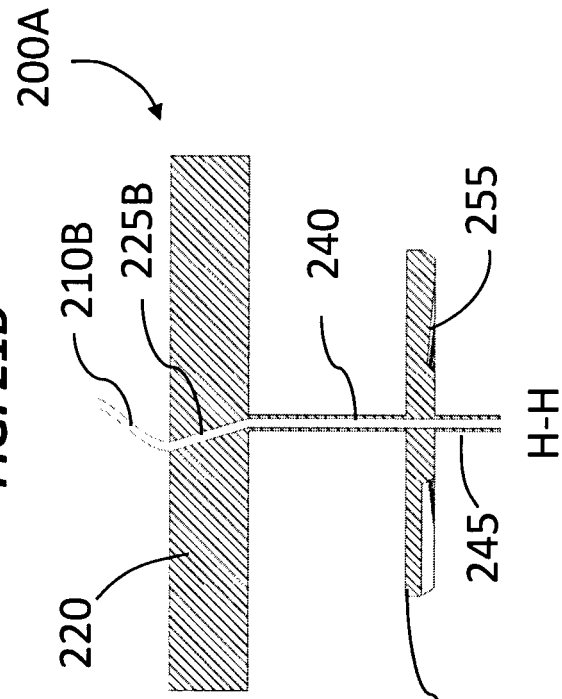


FIG. 23

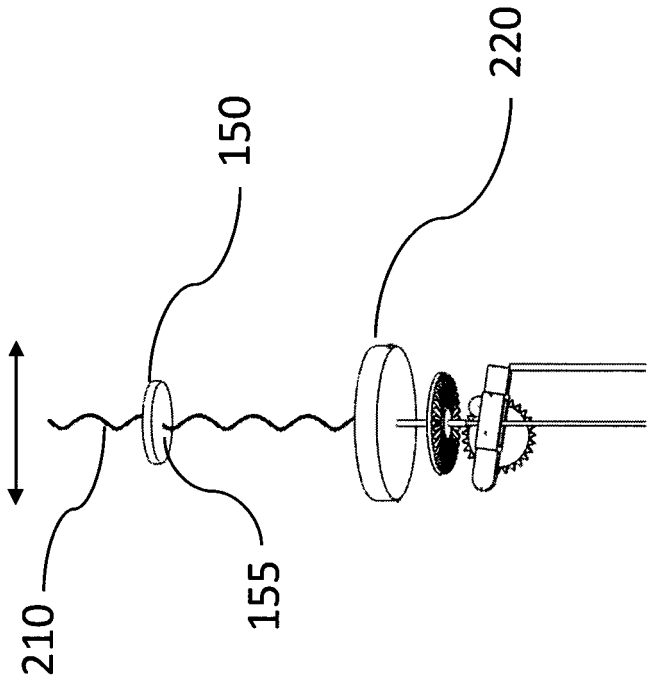
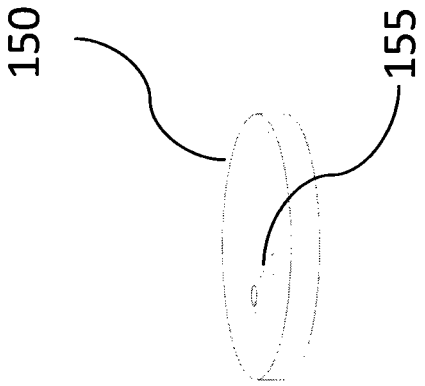


FIG. 22



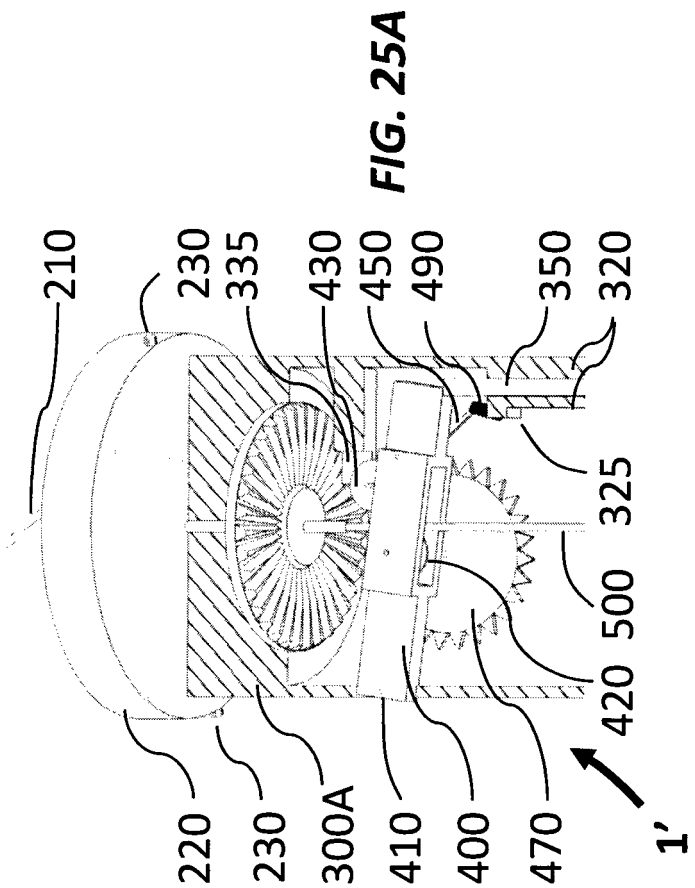


FIG. 25A

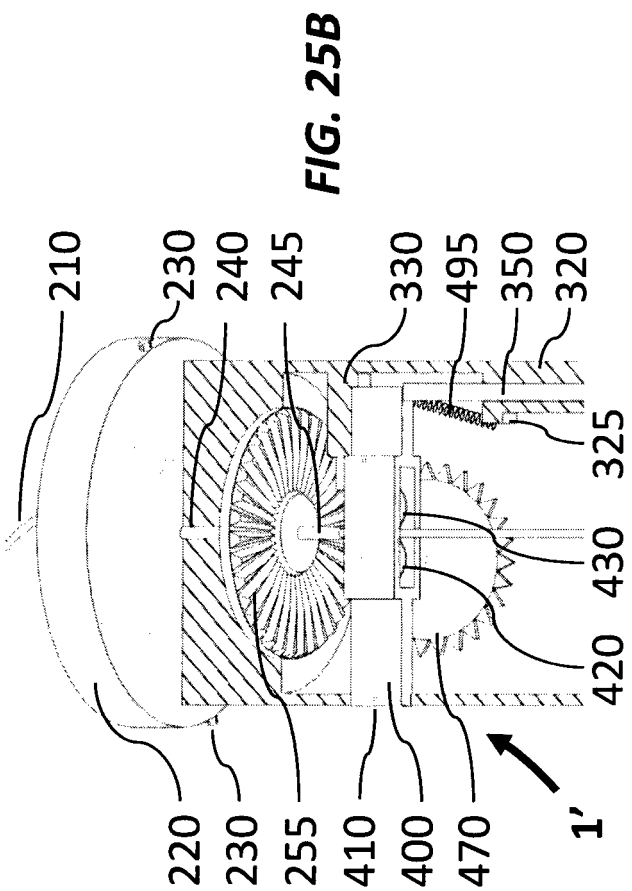


FIG. 25B

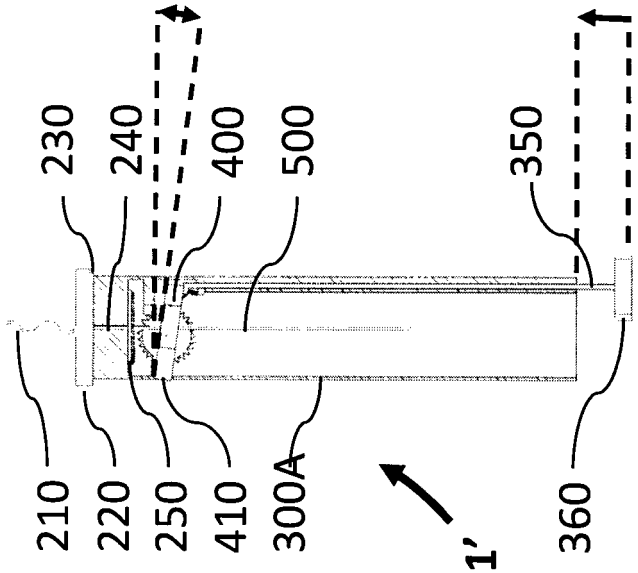


FIG. 24A

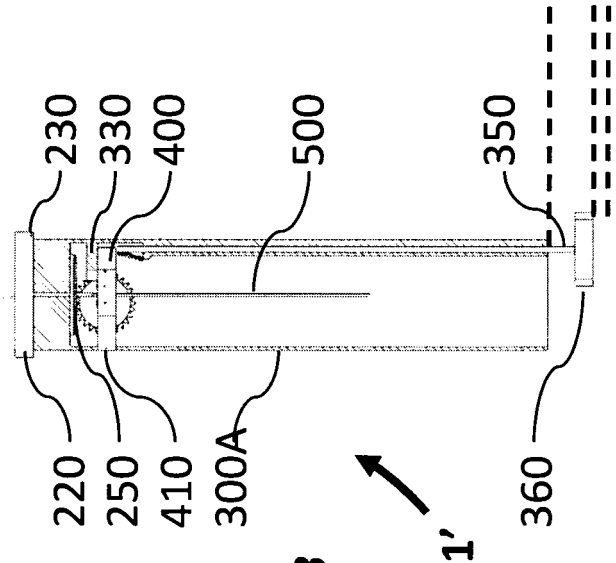


FIG. 24B

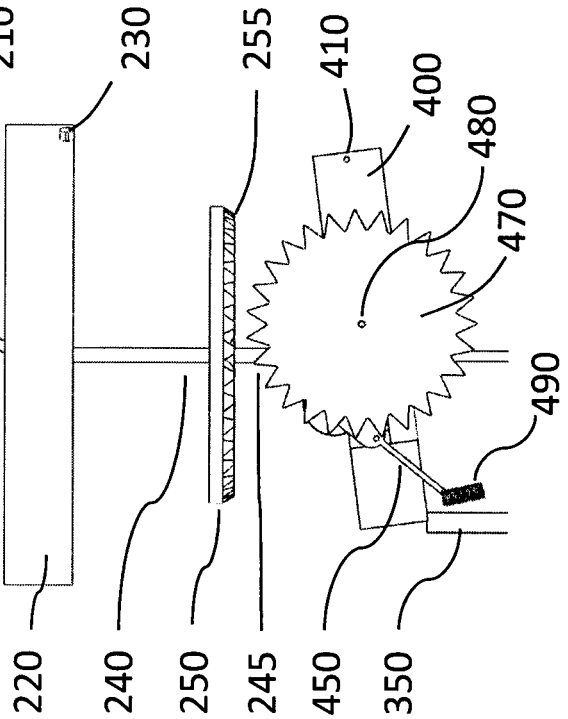


FIG. 27A

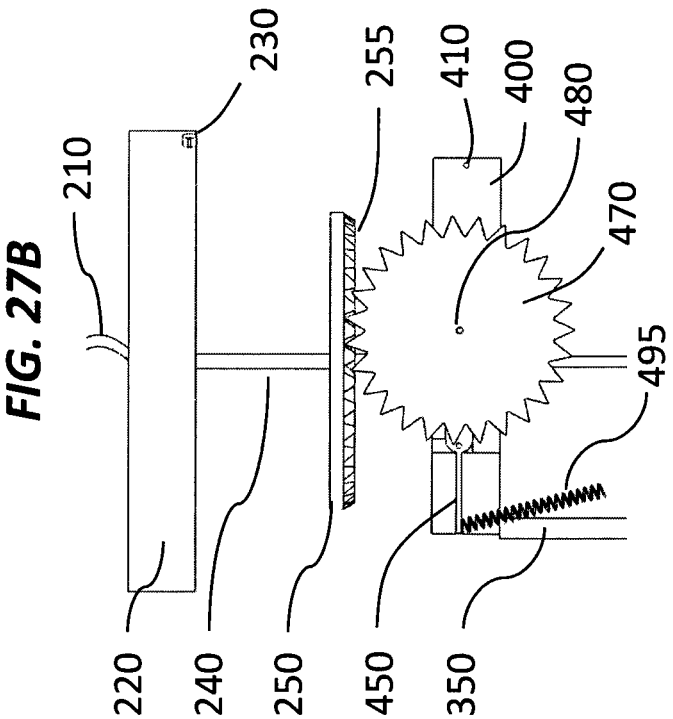


FIG. 27B

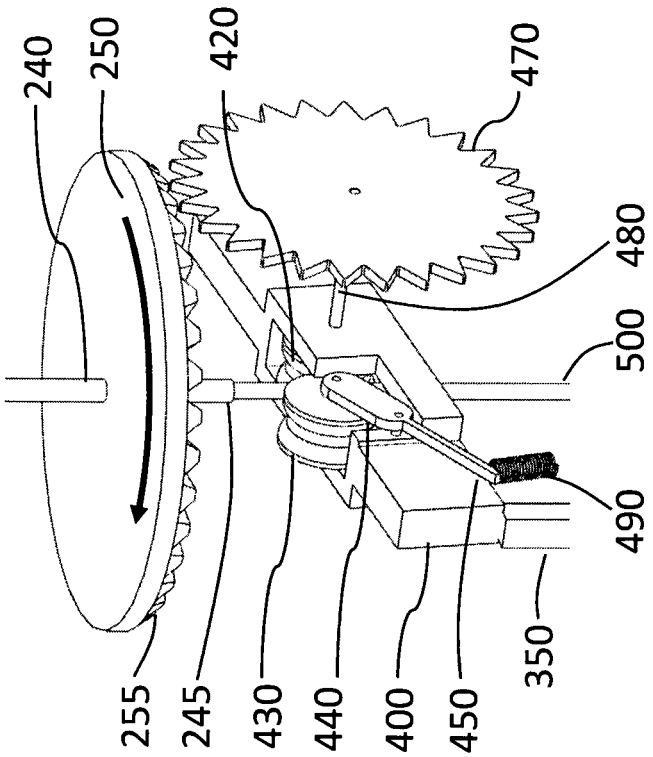


FIG. 26A

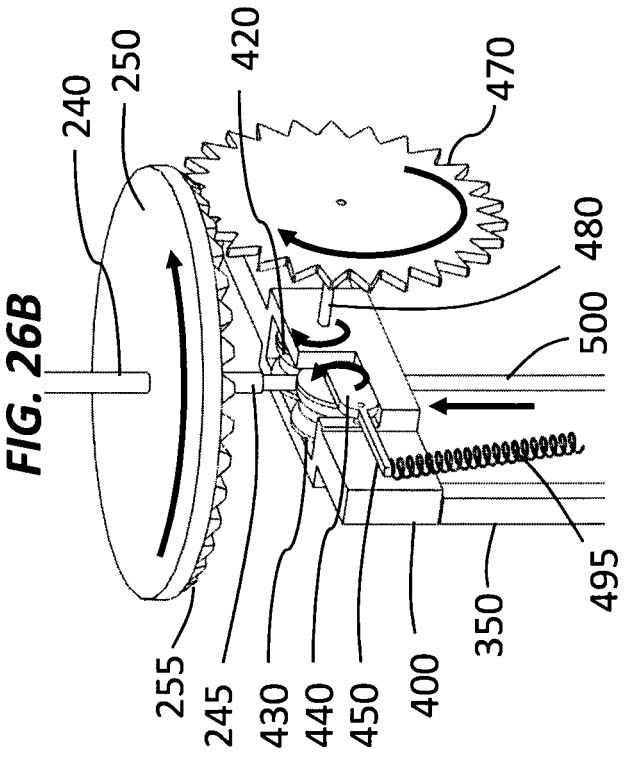


FIG. 26B

FIG. 28B

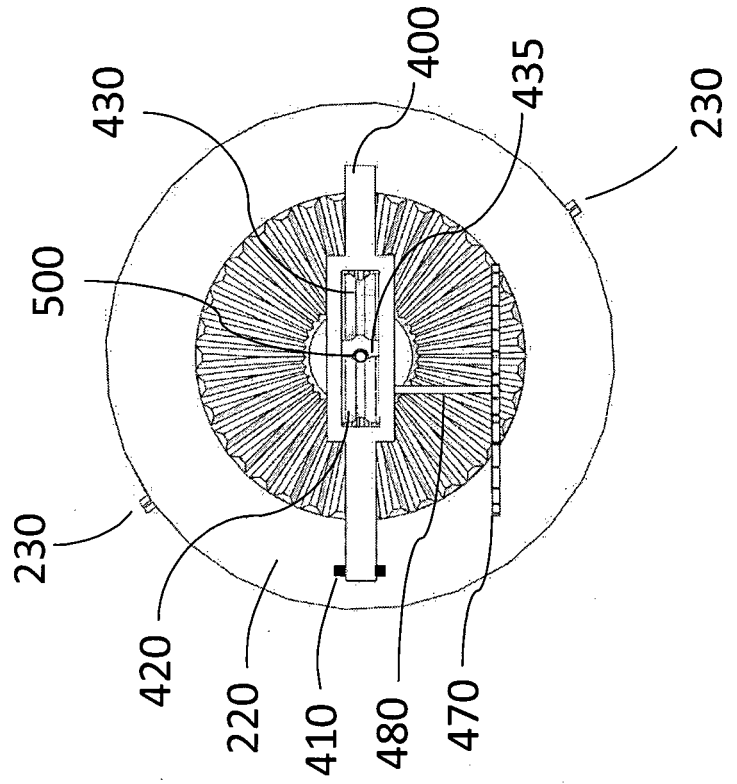


FIG. 28A

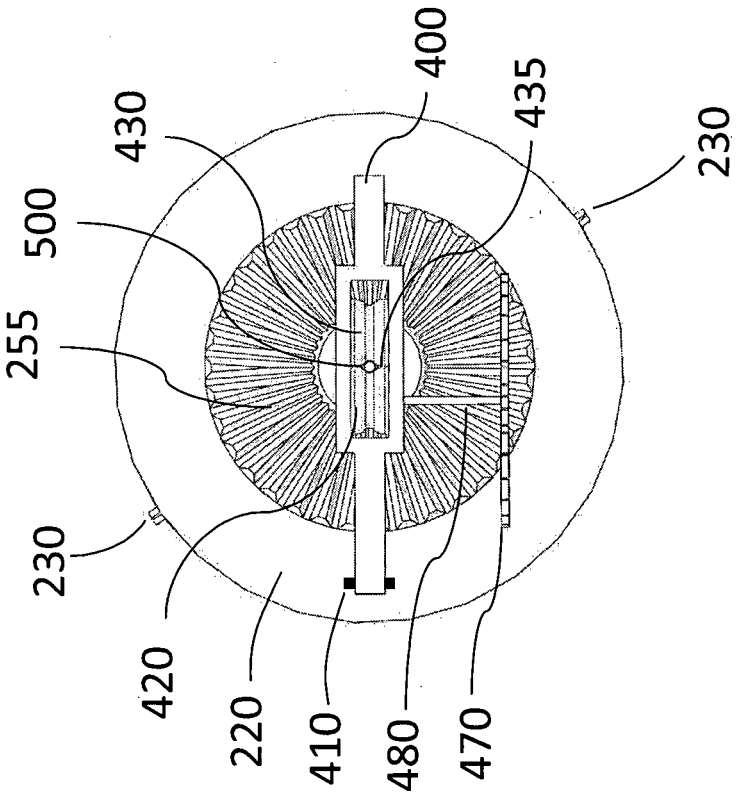


FIG. 29B

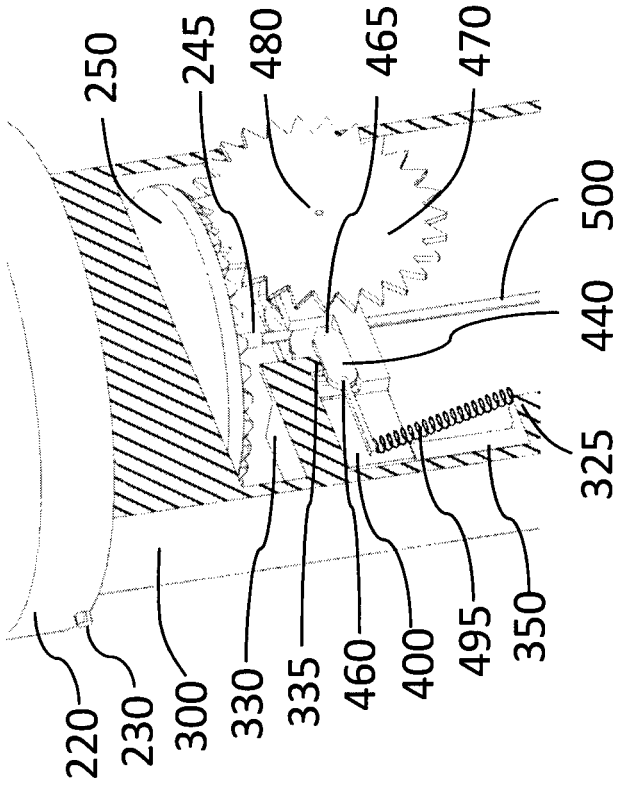


FIG. 29A

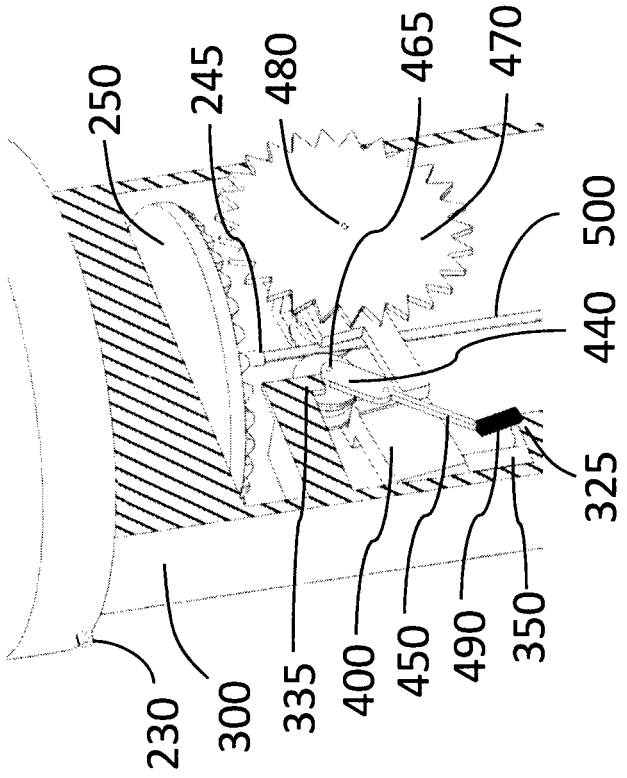
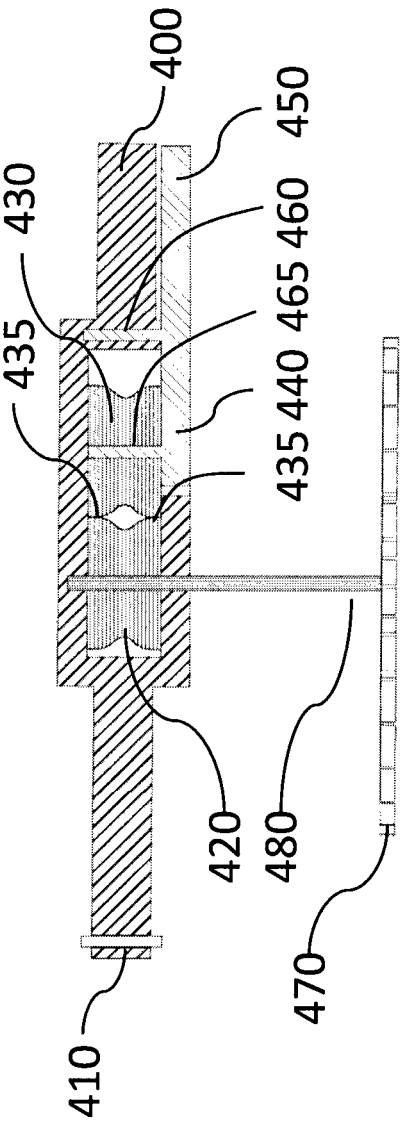
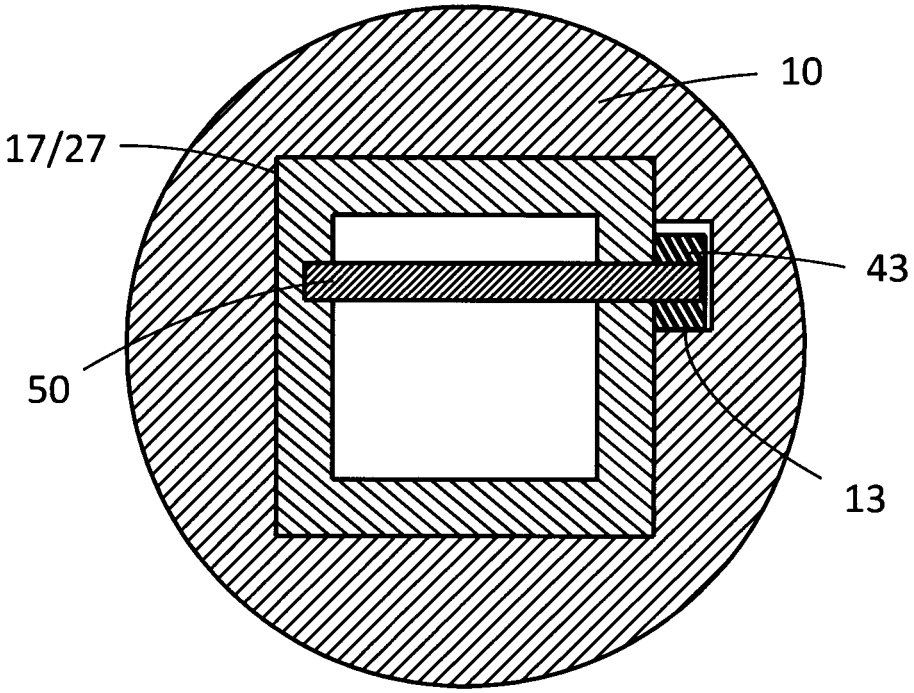


FIG. 30





Alt. D-D

FIG. 31

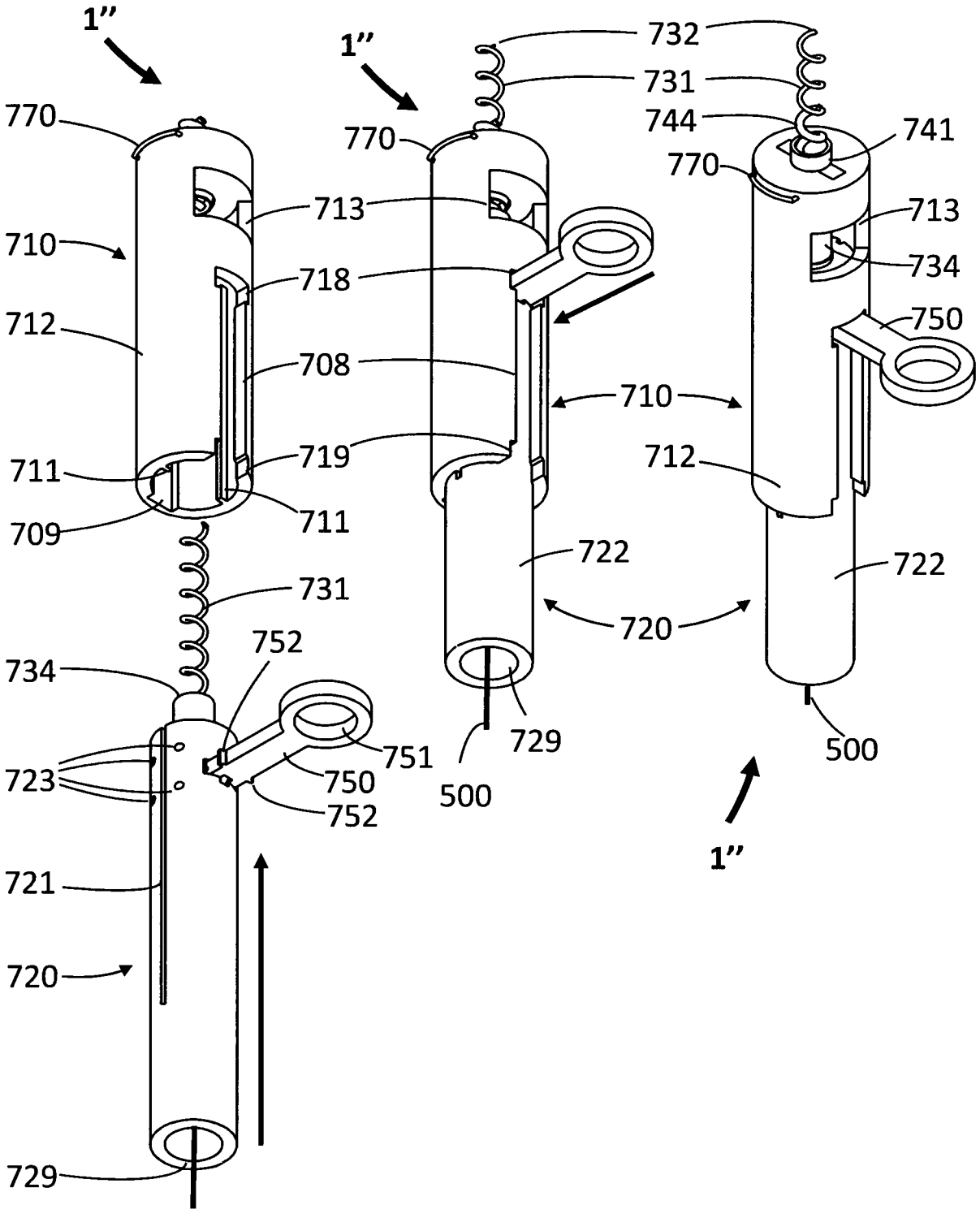


FIG. 32A FIG. 32B FIG. 32C

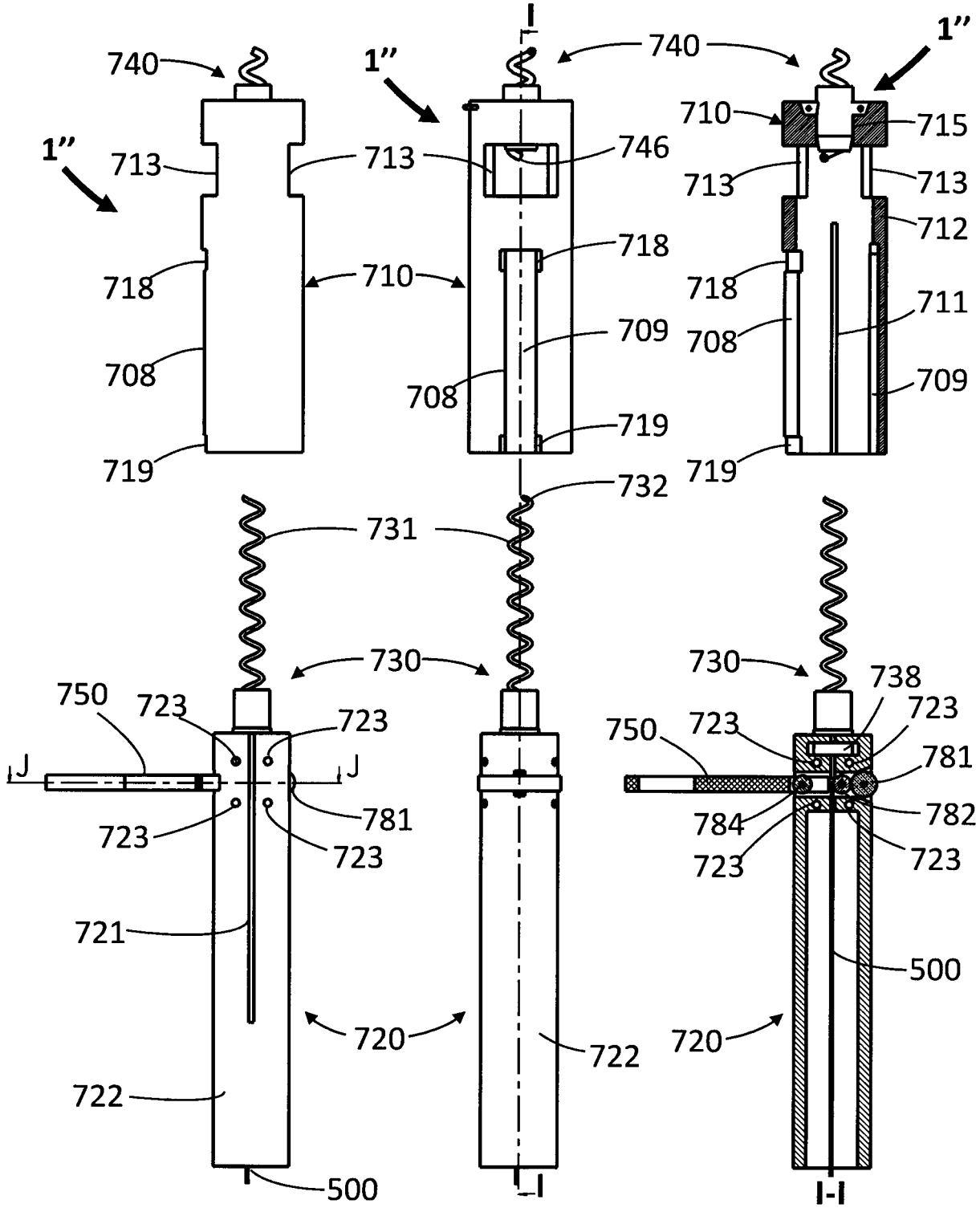


FIG. 33A FIG. 33B FIG. 33C

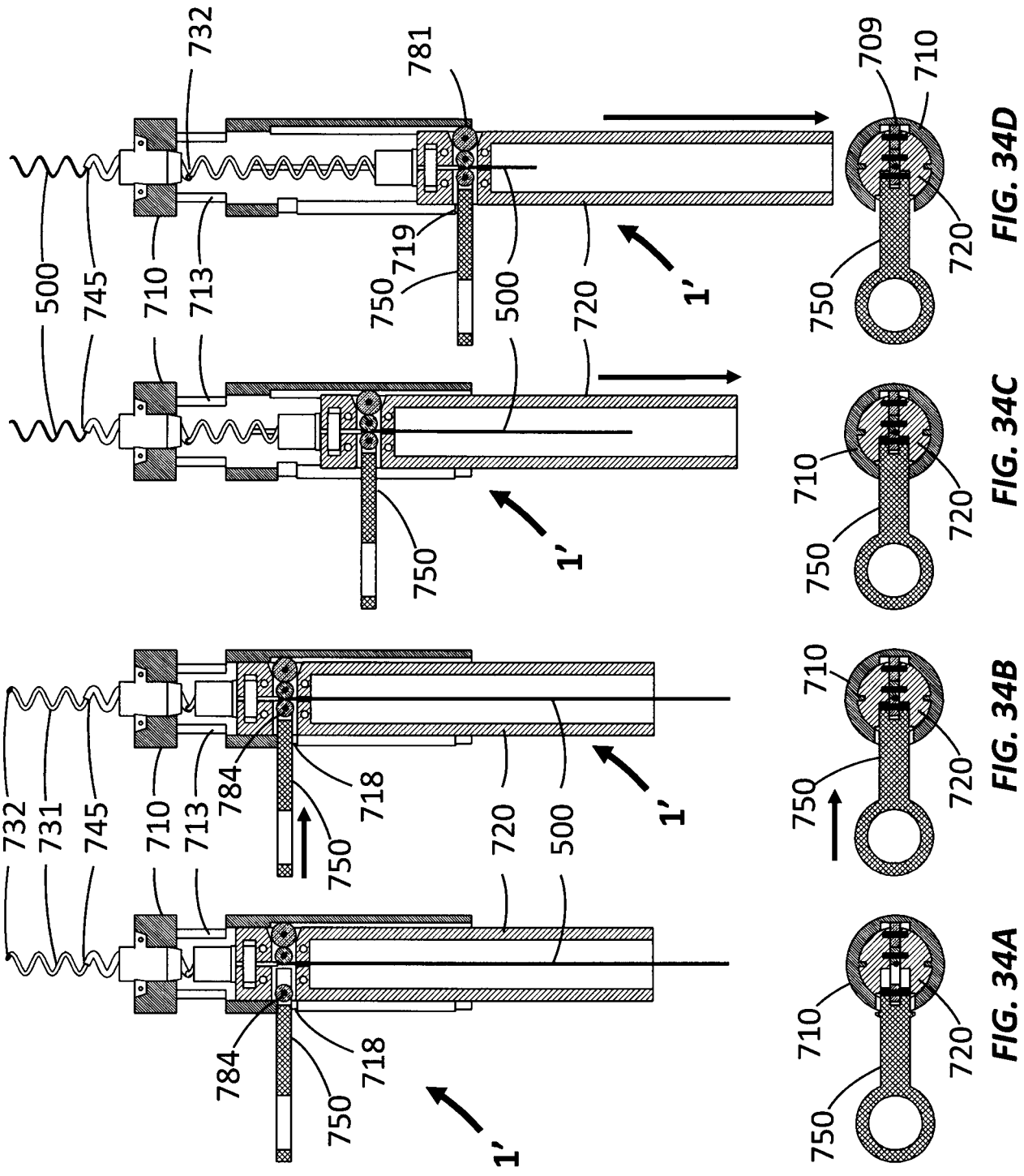


FIG. 34A FIG. 34B FIG. 34C FIG. 34D

FIG. 35A

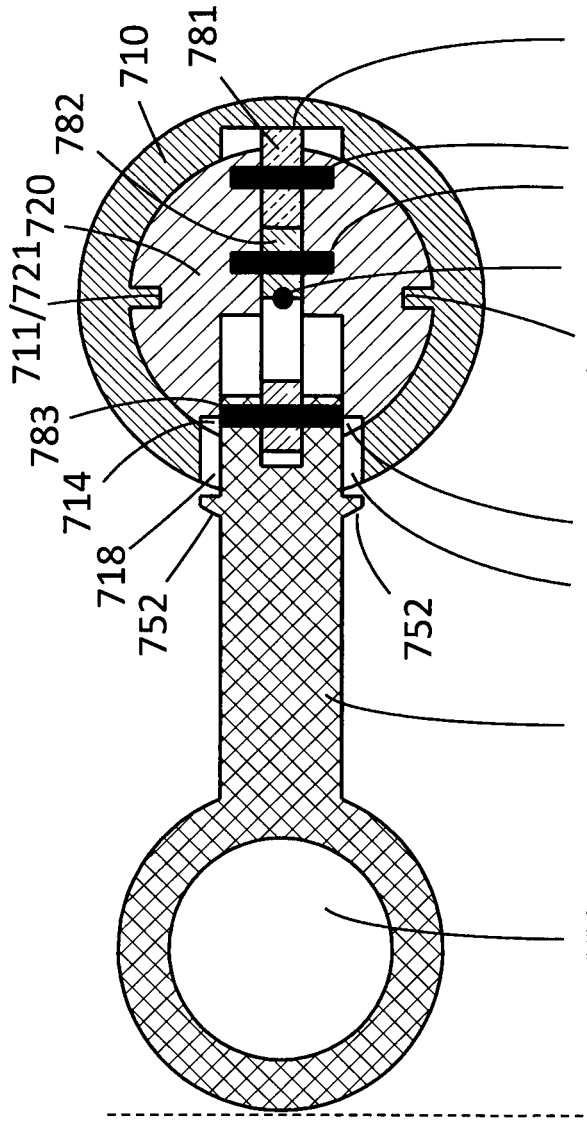
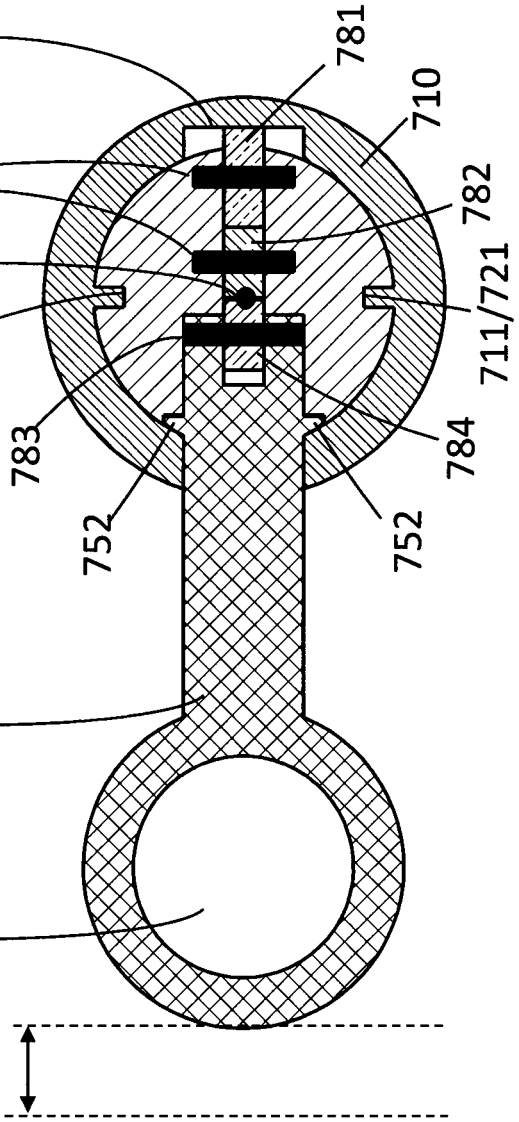


FIG. 35B



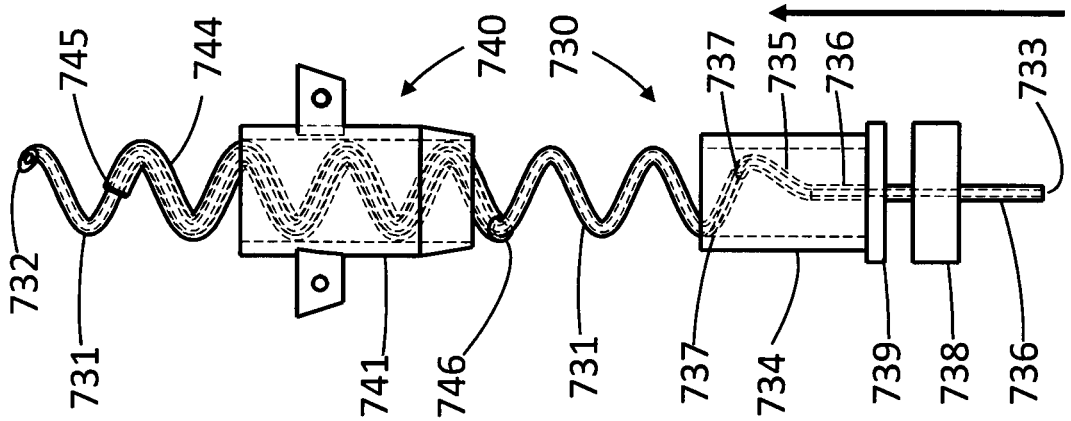


FIG. 38

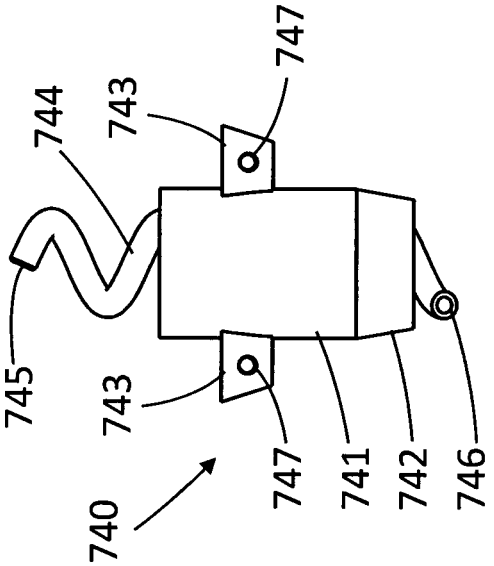


FIG. 37A

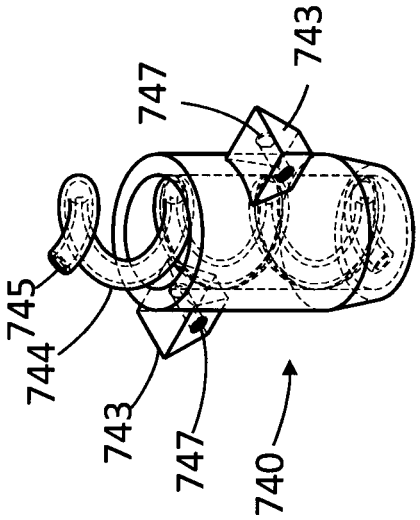


FIG. 37B

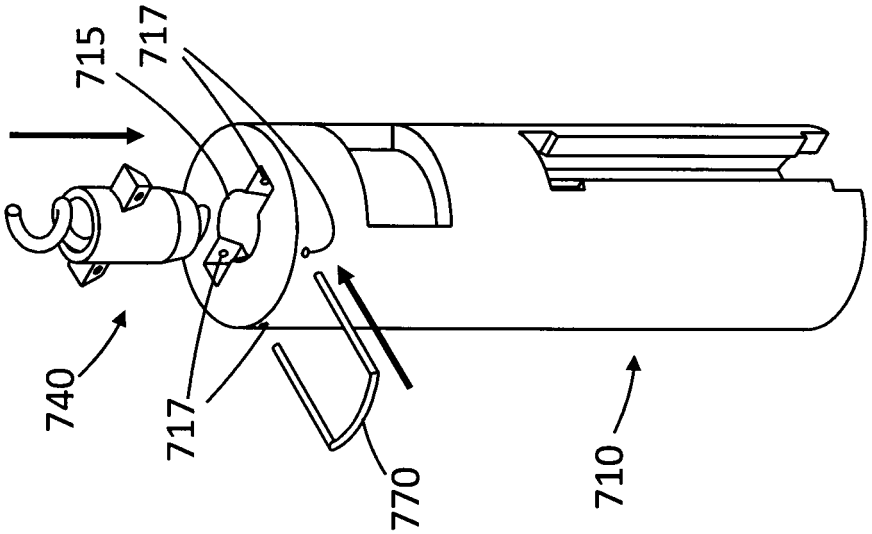


FIG. 36

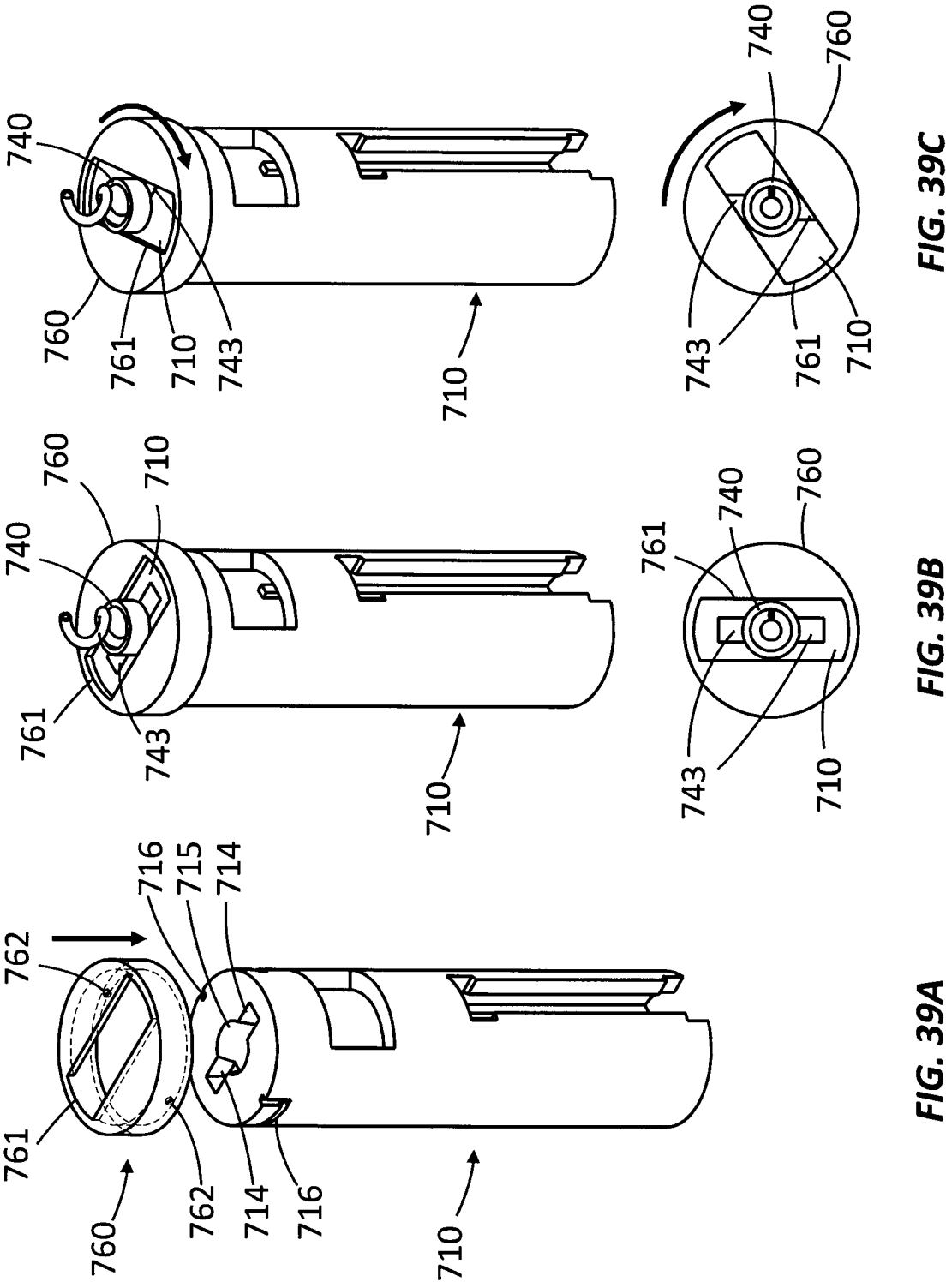
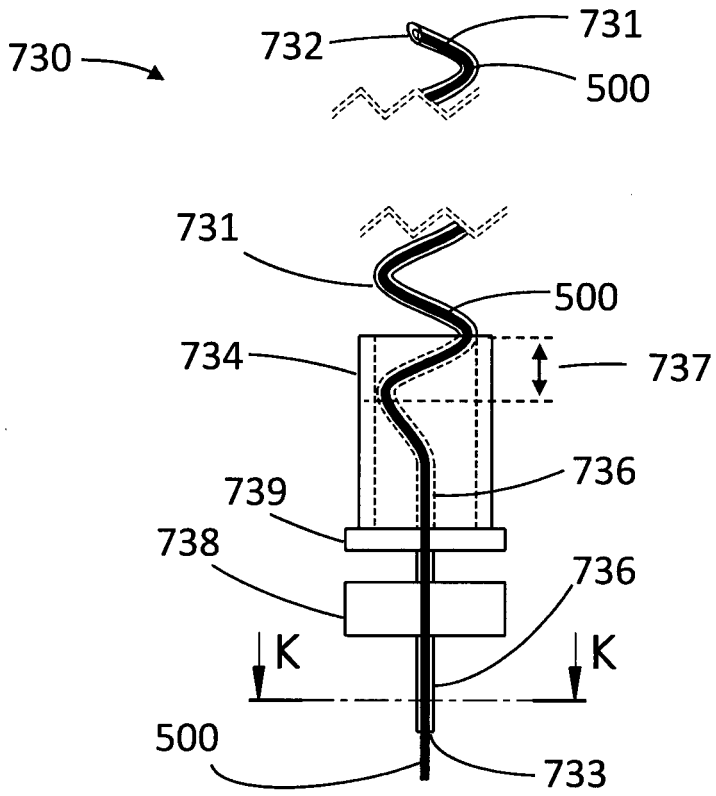
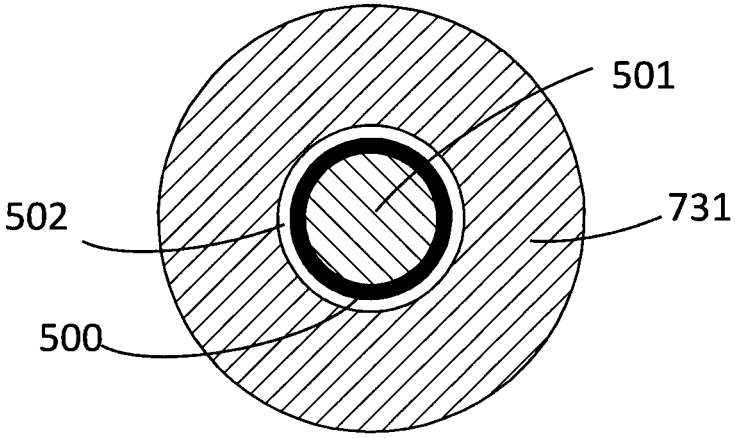


FIG. 39C

FIG. 39B

FIG. 39A





K-K
Scale 50 : 1

FIG. 40

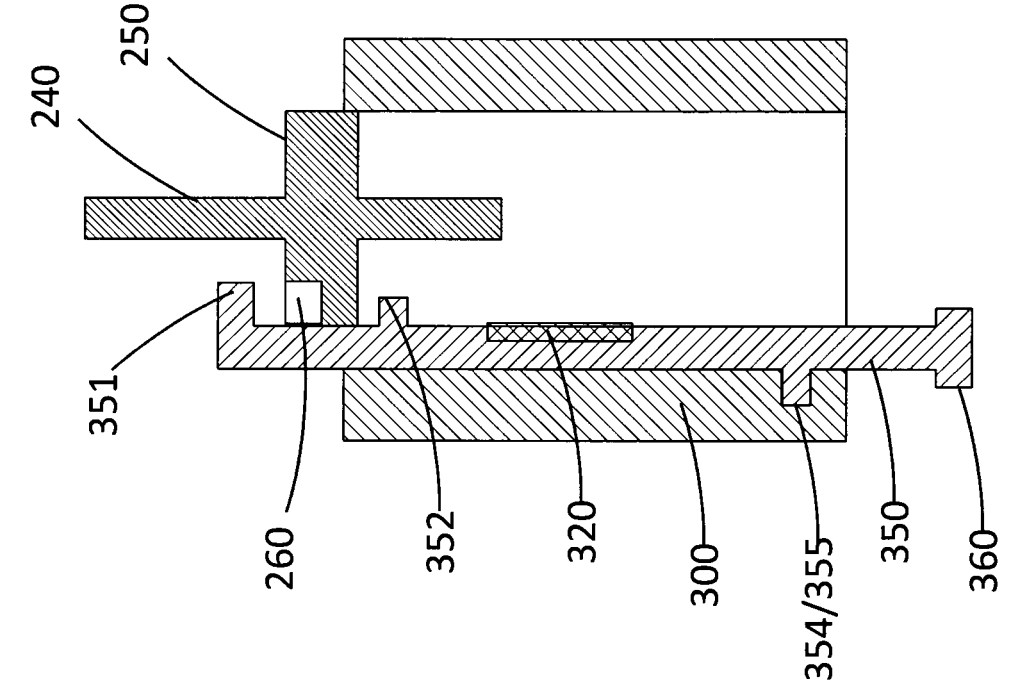


FIG. 41B

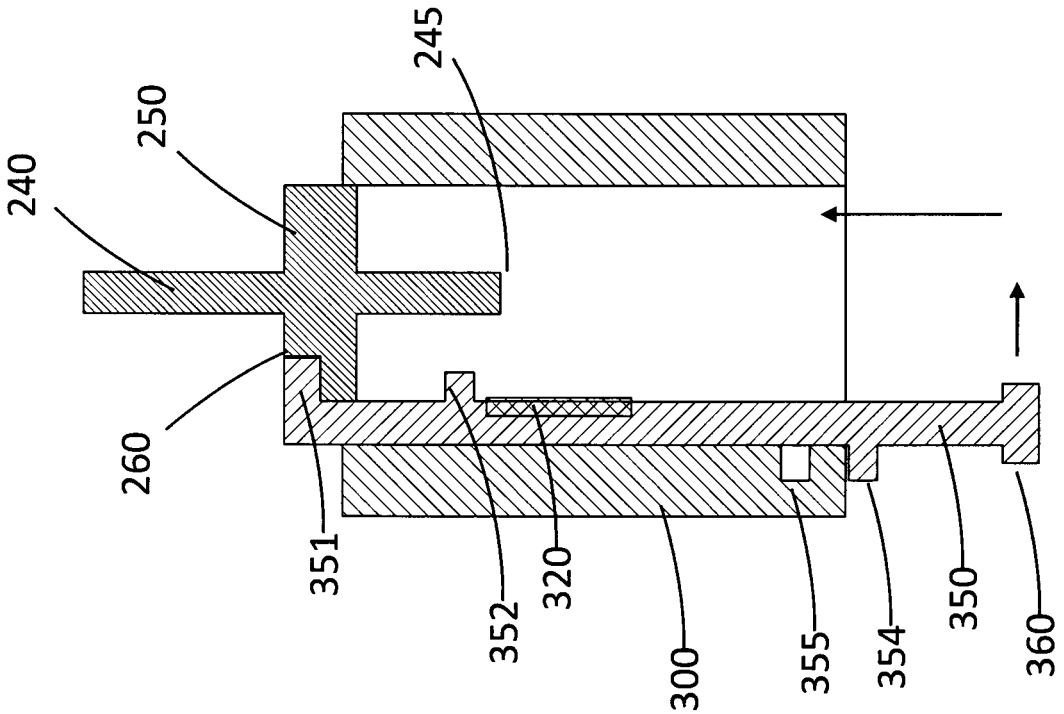


FIG. 41A

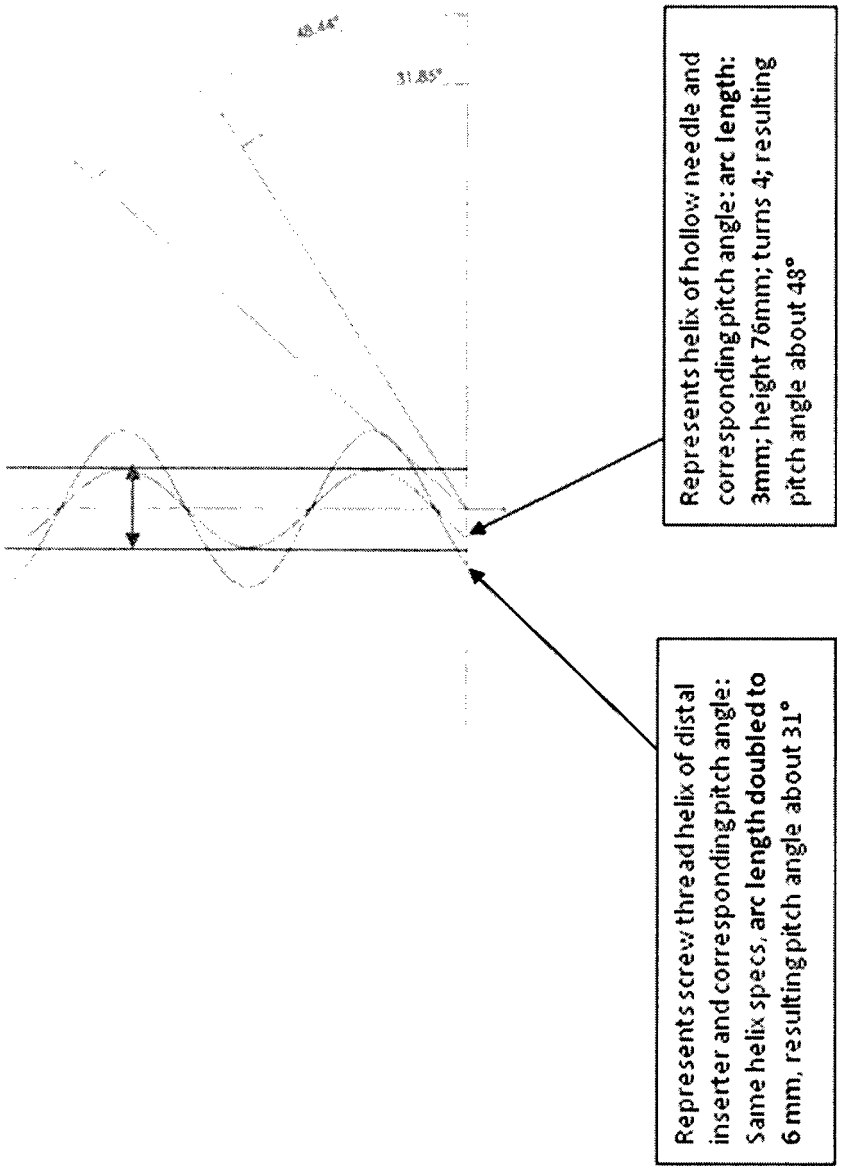

Represents helix of hollow needle and corresponding pitch angle: arc length: 3mm; height 76mm; turns 4; resulting pitch angle about 48°
Represents screw thread helix of distal inserter and corresponding pitch angle: Same helix specs, arc length doubled to 6 mm, resulting pitch angle about 31°

FIG. 42

Needle	Nominal Outer Diameter		Nominal Inner Diameter		Nominal Wall Thickness	
Gauge	Inches	Mm	Inches	Mm	inches	mm
11	0.12	3.048	0.094	2.388	0.013	0.33
12	0.109	2.769	0.085	2.159	0.012	0.305
13	0.095	2.413	0.071	1.803	"	"
14	0.083	2.108	0.063	1.6	0.01	0.254
15	0.072	1.829	0.054	1.372	0.009	0.229
16	0.065	1.651	0.047	1.194	0.009	0.229
17	0.058	1.473	0.042	1.067	0.008	0.203
18	0.05	1.27	0.033	0.838	0.0085	0.216
19	0.042	1.067	0.027	0.686	0.0075	0.191
20	0.03575	0.9081	0.02375	0.603	0.006	0.1524
21	0.03225	0.8192	0.02025	0.514	"	"
22	0.02825	0.7176	0.01625	0.413	"	"

FIG. 43

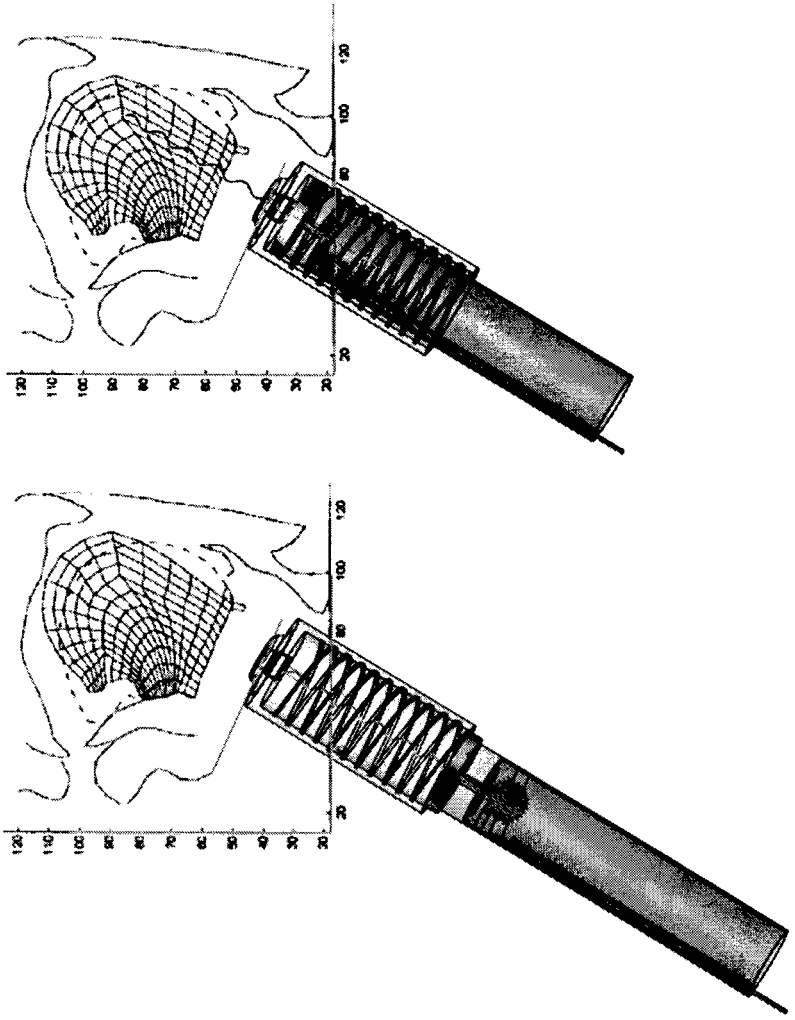


FIG. 44

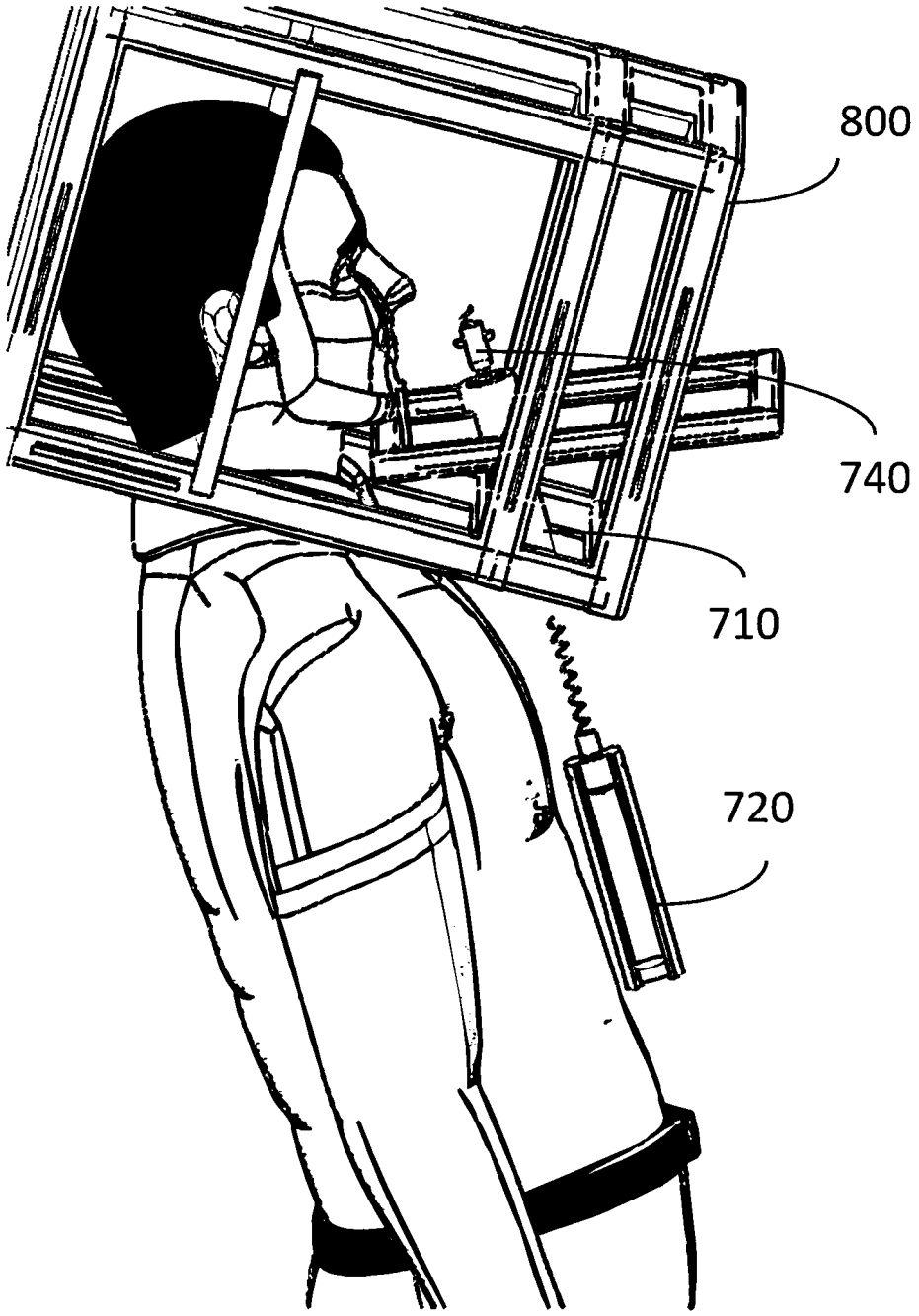


FIG. 45

专利名称(译)	螺旋插入器		
公开(公告)号	EP2646105A2	公开(公告)日	2013-10-09
申请号	EP2011808922	申请日	2011-11-30
[标]申请(专利权)人(译)	FUGLISTER费边HERMANN城市		
申请(专利权)人(译)	Füglister，费边HERMANN城市		
当前申请(专利权)人(译)	Füglister，费边HERMANN城市		
[标]发明人	FUGLISTER FABIAN HERMANN URBAN		
发明人	FÜGLISTER, FABIAN HERMANN URBAN		
IPC分类号	A61N1/04 A61N1/05 A61B17/34 A61M37/00 A61N1/36 A61B17/06 A61B17/062		
CPC分类号	A61B17/06066 A61B17/062 A61B17/3468 A61B2017/06052 A61B2017/06076 A61N1/0526 A61N1/0573 A61N1/3601 A61N2001/0578 A61N1/36078		
优先权	61/417937 2010-11-30 US		
其他公开文献	EP2646105B1		
外部链接	Espacenet		

摘要(译)

提供了一种用于将插入物螺旋插入软组织的方法和设备。插入器由壳体组件，空心螺旋针组成;以及匹配的第一和第二准双曲面齿轮。在其基本形式中，该装置包括壳体组件，中空螺旋插入件引导件，螺旋插入件驱动器和引导件移除装置。中空螺旋插入引导件通过壳体组件保持功能关系，并且适于装载有用于与其一起螺旋输送到软组织中的插入件。螺旋插入驱动器驱动螺旋插入导向器旋转并平移到软组织中。当插入件存在于插入引导件内时，引导件移除装置移除插入件引导件，同时将插入件留在其在软组织中的预期植入位置。该方法和设备将可植入构件螺旋地插入软组织中，从而在这种组织变形时更好地将可植入构件固定在软组织中。