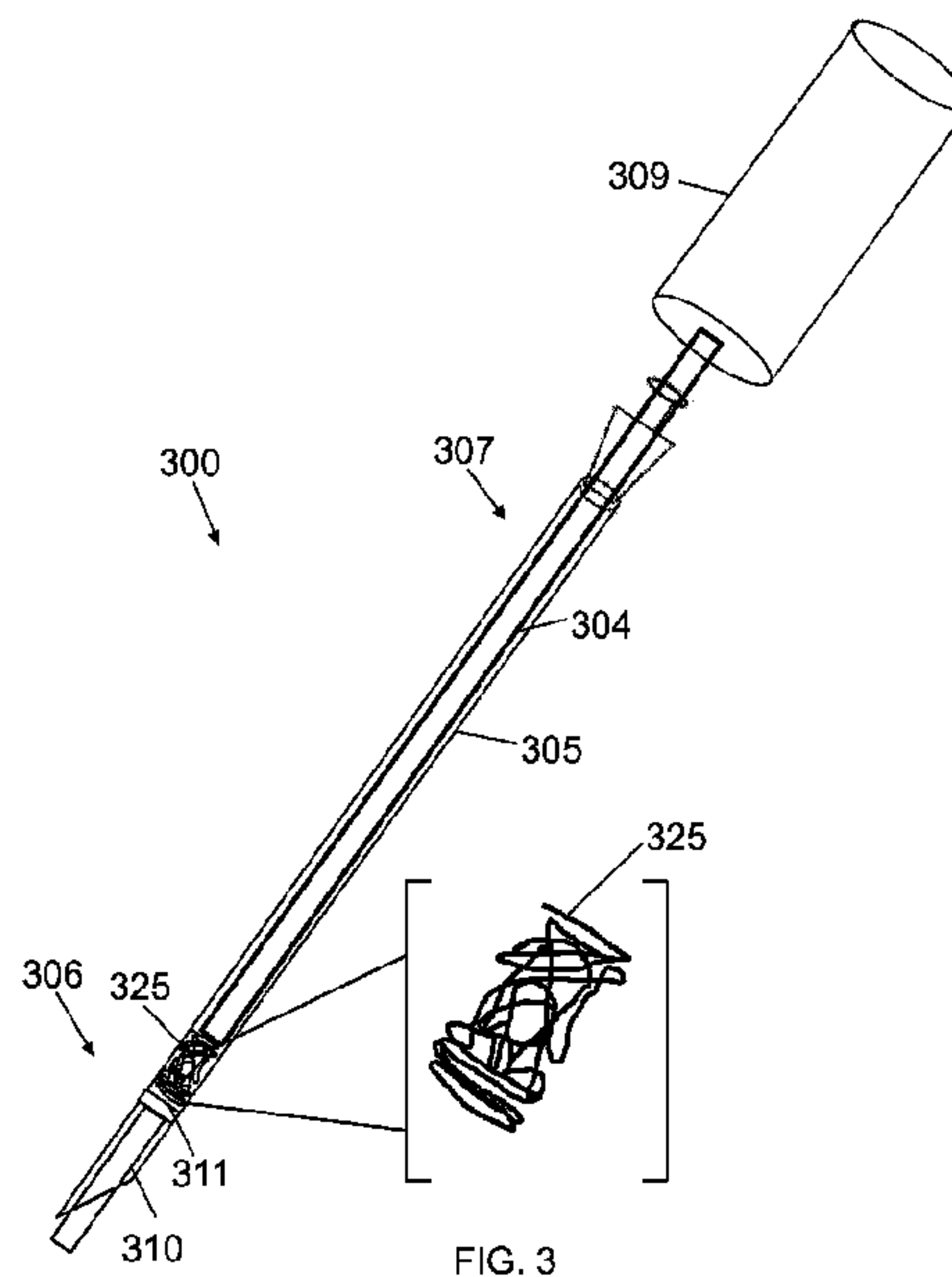




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(54) **Titre : MARQUEUR, DISPOSITIF DE FABRICATION D'UN MARQUEUR ET PROCEDE DE MARQUAGE D'UN MARQUEUR**
(54) **Title: MARKER ELEMENT, DEVICE FOR MAKING A MARKER ELEMENT, AND METHOD FOR MAKING A MARKER ELEMENT**



(57) **Abrégé/Abstract:**

Disclosed are devices, kits and methods for forming a marker element including, in aspects, a tube having a longitudinal direction, a base element received in a first end of the tube, a wire receiving portion at a second end of the tube, a force applicator receivable within the second end of the tube, the force applicator being configured to apply force to a received wire in the longitudinal direction of the tube to deformably compress the received wire to a selected length relative to the longitudinal direction of the tube. Also disclosed is a marker delivery device having a tube, a marker element preformed within the tube, and an actuator element receivable in the tube to move the marker element from the tube into a tissue site.



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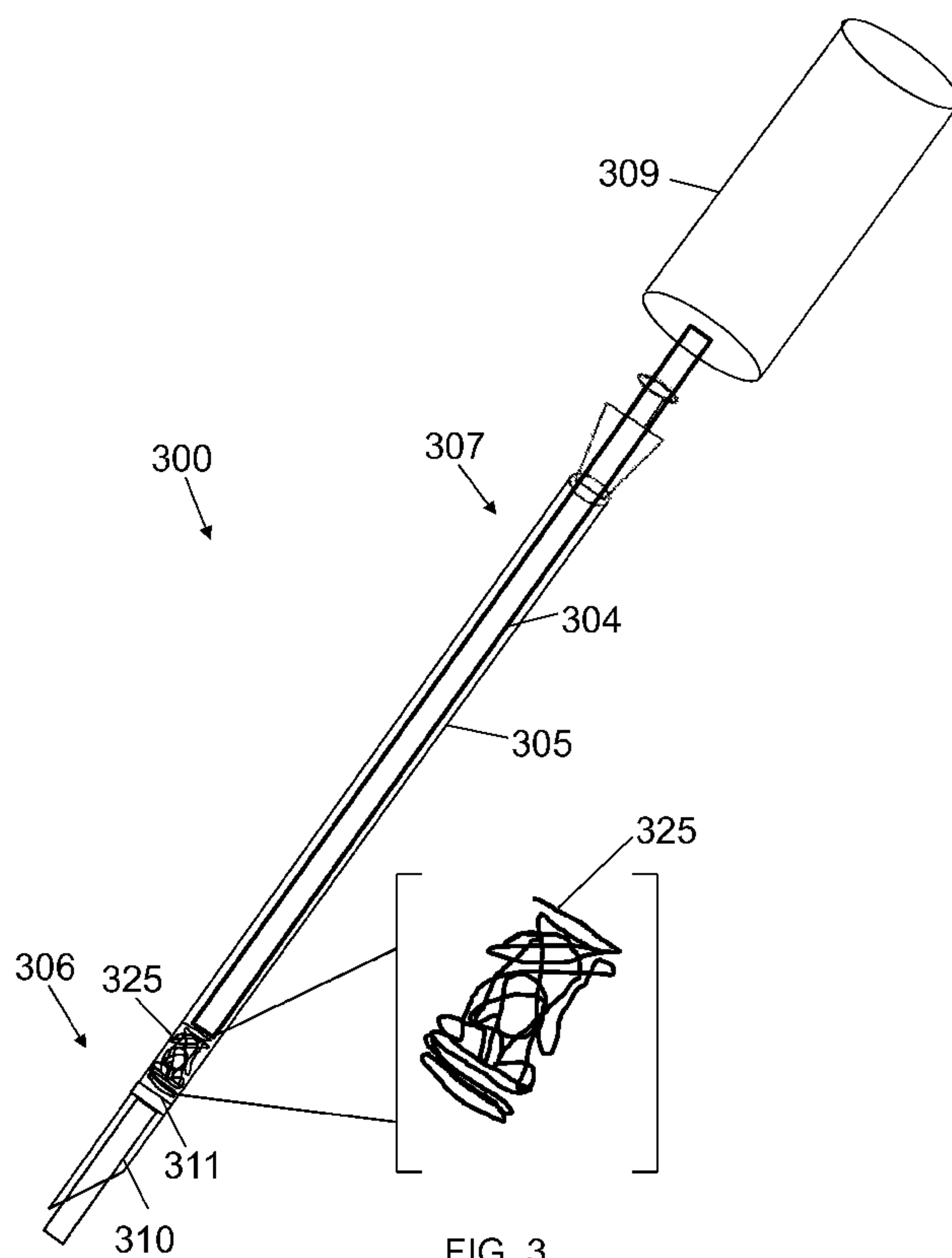
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(54) Title: MARKER ELEMENT, DEVICE FOR MAKING A MARKER ELEMENT, AND METHOD FOR MAKING A MARK-
ER ELEMENT

(57) Abstract: Disclosed are devices, kits and methods for forming a marker element including, in aspects, a tube having a longitudinal direction, a base element received in a first end of the tube, a wire receiving portion at a second end of the tube, a force applicator receivable within the second end of the tube, the force applicator being configured to apply force to a received wire in the longitudinal direction of the tube to deformably compress the received wire to a selected length relative to the longitudinal direction of the tube. Also disclosed is a marker delivery device having a tube, a marker element preformed within the tube, and an actuator element receivable in the tube to move the marker element from the tube into a tissue site.

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MARKER ELEMENT, DEVICE FOR MAKING A MARKER ELEMENT, AND METHOD FOR MAKING A MARKER ELEMENT

This application claims priority to U.S. Patent Application No. 14/286,484, filed May 23, 2014, entitled, "MARKER ELEMENT, DEVICE FOR MAKING A MARKER ELEMENT, AND METHOD FOR MAKING A MARKER ELEMENT," which is hereby expressly incorporated by reference herein in its entirety.

Field of the Invention

[0001] Aspects of the present invention relate to methods and devices for making a marker element and a marker element made thereby. More particularly, aspects of the invention pertain to a tissue marker, and a device and method for making a tissue marker within a delivery device, and a method for making and/or assembling a kit for marking a tissue location.

Background of the Invention

[0002] Markers are often used in the medical field to indicate a location where tissue (e.g., from a tumor) has been collected from a patient. The marker, and therefore the tissue collection site, can be subsequently located using imaging techniques like x-ray, ultrasound, or magnetic resonance imaging (MRI).

[0003] A variety of markers and devices for marking a tissue location are available in the medical field. Typically the markers are pre-fabricated in an assortment of shapes and sizes, and then the markers are delivered to a tissue location using a delivery device.

[0004] For example, U.S. Patent No. 6,575,991 describes a device for percutaneous marking of a lesion. The device includes a cannula and a stylet having a shaft and a base. In use, the stylet shaft extends through a guide passage and into the interior of the cannula, while the stylet base remains outside of the cannula. The device further includes a plunger configured to move the stylet within the cannula and eject a marker into a lesion site. The marker is pre-shaped prior to being loaded into a marker recess of the cannula. The marker has one of several shapes, including a spiral, star-burst, y-shape and horseshoe shape. However, because the marker is pre-fabricated outside of the cannula, it must be sized to slide within the inner passage. Therefore, the marker is not specially sized and shaped for a particular cannula, nor does the marker fit snugly into the end of the cannula, for example. The marker thus may slide within the cannula and slip out before it can be properly injected into a tissue site. In addition to having a potentially disadvantageous size, the shape of the marker may cause it to catch on or become tangled with the stylet, thereby preventing or interfering with the injection.

[0005] Another device for marking tissue within a human body is described in U.S. Patent No. 6,228,055. The device includes a marker and an apparatus for delivering the marker to a location within the human tissue. The apparatus includes a tube that is guided to the tissue location. In one embodiment, a second region of the tube includes a forming die, which forms the marker into a predetermined shape, such as a helix. An important feature of this invention is the ability to use markers having a variety of shapes in order to identify different locations in a tissue. However, the markers are either prefabricated, then inserted into a lumen, or a

special die is incorporated into each delivery device and used to form the marker. As such, unnecessary steps and components are required to make and use the device, so it is unnecessarily costly.

[0006] In general, markers that are prefabricated then inserted into a lumen or cannula according to methods of the related art are costly. These approaches typically require machining processes that are designed for very small parts with very tight tolerances, and both of those items tend to drive costs higher.

In addition, one way to prevent a marker from slipping out of an end of a device is to plug the end with a biocompatible substance, for example, bone wax. Another way to prevent the marker from slipping out is to use a spacer between the plastic hubs of the cannula and the stylet, so that, before use, the marker is able to move in between the bone wax and the stylet, but not outside of those bounds. When a doctor or other user is ready to deliver the marker, the spacer is removed and the marker and bone wax are then pushed into the patient. However, the use of bone wax introduces another foreign material into the tissue site, which may increase the risk of potential infections or adverse events.

[0007] There is a need in the art for a devices, kits and methods of making a marker element that is less costly than known devices and methods. In one aspect, the marker element should be formed within the delivery device so that it is uniquely shaped and sized for a particular device to provide seamless and reliable delivery of the marker element to a tissue location.

SUMMARY OF THE INVENTION

[0008] A device for forming a marker element, the device comprising: a tube having a longitudinal direction; a base element received in a first end of the tube; a wire receiving portion at a second end of the tube; a force applicator receivable within the second end of the tube, the force applicator being configured to apply force to a received wire in the longitudinal direction of the tube to deformably compress the received wire to a selected length relative to the longitudinal direction of the tube.

[0009] A kit for forming a marker element, the kit comprising: a tube having a longitudinal direction; a base element receivable in a first end of the tube; a wire receivable in a second end of the tube; a force applicator receivable within the second end of the tube, the force applicator being configured to apply a compression force to the wire in the longitudinal direction of the tube; and an actuator element receivable within the second end of the tube, the actuator element being configured to apply an actuation force to a marker element formed by compression of the wire.

[0010] A marker delivery device, comprising: a tube having a longitudinal direction; a marker element preformed within the tube, the marker element fixedly positioned near a first end of the tube; and an actuator element receivable in a second end of the tube, the actuator element configured to move the marker element from the first end of the tube into a tissue site.

[0011] A method of making a marker element, comprising: receiving a base element in a first end of a tube; receiving a wire in a second end of the tube; and

applying a force to an end of the wire, wherein the wire is compressed in a longitudinal direction of the tube to a shape corresponding to a selected length and constrained in outer shape by the tube so as to form a marker element.

[0012] A method of making a kit for marking a tissue, comprising: receiving a base element in a second end of the tube; receiving a wire in a first end of the tube; applying a force to the wire at the first end of the tube using a force applicator, wherein the force compresses the wire to a predetermined length of the tube to form the marker element within the tube; removing the force applicator from the tube and removing the base element, wherein the marker element is fixed near the second end of the tube by a friction force greater than a weight of the marker element; providing an actuator element receivable in the first end of the tube; and packaging the actuator element, the tube and the marker element together in a sterile material.

[0013] Additional advantages and novel features in accordance with aspects of the invention will be set forth in part in the description that follows, and in part will become more apparent to those skilled in the art upon examination of the following or upon learning by practice thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Various example methods and apparatuses in accordance with aspects of the present invention will be described in detail, with reference to the following figures, wherein:

[0015] FIG. 1 illustrates aspects of an apparatus for making a marker element, according to various aspects of the present invention;

[0016] FIG. 2 illustrates aspects of an apparatus for making a marker element, according to various aspects of the present invention;

[0017] FIG. 3 illustrates aspects of an apparatus for making a marker element, according to various aspects of the present invention;

[0018] FIG. 4 illustrates aspects of an apparatus for making a marker element, according to various aspects of the present invention;

[0019] FIG. 5 provides a flow chart of a method for making a marker element within a marker delivery apparatus, according to various aspects of the present invention;

[0020] FIG. 6 provides a flow chart of a method for making a marker element within a marker delivery apparatus, according to various aspects of the present invention; and

[0021] FIG. 7 illustrates aspects of a kit for delivering a marker element to a tissue, according to various aspect of the present invention.

DETAILED DESCRIPTION

[0022] These and other features and advantages of this invention are described in, or are apparent from, the following detailed description of various example aspects.

[0023] Referring to FIG. 1, in one aspect, the marker delivery apparatus 100 includes a tube 105 having a first end 106 and a second end 107. It should be noted that the terms “first end” and “second end” will be used consistently throughout the disclosure and claims to identify an end of an element (e.g., the wire 120, the base element 110, the force applicator 204, etc.) that is closest to the first end 106 or the second end 107, respectively. The tube may include, for example, a needle having a lumen, a cannula, or a trocar of any type suitable known for delivering a marker element or other items (e.g., a surgical device, medicaments) to a tissue site. In one aspect, an outer diameter of the tube is about the same or less than a diameter of a biopsy site.

[0024] The tube 105 may have a handle member 115 at the second end 107 for holding the tube 105. In one aspect, the handle member 115 includes an opening 116 in communication with the interior space of the tube 105, the opening 116 being configured to receive a wire 120 in a longitudinal direction of the tube 105. As will be described in more detail below, the wire 120 may be compressed to form a marker element.

[0025] In one aspect, the wire has a suitable length, diameter, malleability, tensile strength, yield strength, elongation properties and breakage properties to undergo compression to make the marker element. For example, the wire may have a length of about 1.5 inch to about 20 inch (e.g., 5 inch), a diameter of about 0.001 to 0.100 inch (e.g., about 0.006 inch), a tensile strength of about 18,000 to 25,000 psi (e.g., 21,000 psi), a yield strength of about 9,000 to 15,000 psi (e.g., 12,000 psi), an elongation at break of about 25% to 35% (e.g., 29%), and a breaking load of about

250 to 300 grams (e.g., 270 grams). The wire may also be in accordance with the chemical section of the ASTM-F-72 standard for gold.

[0026] The marker element may be formed from a wire having a high acoustic impedance compared to the tissue site and, optionally, may be radio-opaque. Suitable wire materials include, but are not limited to, biocompatible materials, such as gold, titanium, chromium, cobalt, stainless steel, silver, platinum, tantalum, palladium and alloys thereof. In one aspect, the wire may have a purity of 10K, 14K, 18K, 21K or 24K gold. Gold may be particularly be useful as a marker material for some applications of the technology because it is visible by imaging techniques, such as x-ray, ultrasound, or MRI, and is highly bio-compatible. Gold is also useful because it provides a smaller MRI artifact, which aids physicians in viewing the area directly around the marker. Other metals may have larger artifacts and may obscure areas directly around the marker. Additionally, composite materials, including one or more of the aforementioned metals and a polymer, for example, polyetherketoneketone, polyethylene, polypropylene, polyurethane, polytetrafluoroethylene, polyvinyl-chloride, polyamides, and polycarbonate may also be used to form the compressible, malleable wire 120. In other aspects, the wire 120 may include one or more of the aforementioned polymers.

[0027] In other aspects, the wire 120 may have a cross-section that is circular, ovular, rectangular, triangular, trapezoidal, or any other polygonal shape (e.g., star-shaped). The wire 120 may also be braided, twisted, flat or of any other shape or configuration suitable for compression within the tube to form a marker element.

Moreover, the cross-section, shape and/or configuration of the wire 120 may be selected to optimize bending of the wire and formation of the marker element.

[0028] A base element 110 may be configured for insertion into the first end 106 of tube 105 as shown in FIG. 1. The base element 110 may be constructed of any suitable material, for example, a polymer, a metal or a combination of the two. In one aspect, the base element 110 may include an end element 111 configured to seal the first end 106 of the tube 105 and to provide a base against which the wire 120 is compressed. If an end element 111 is not incorporated, the base element 110 may be sized slightly smaller (e.g. about 0.0001 to about 0.001 inch) than the inner diameter of the tube 105, so that it is able to be slidably received within the tube 105. In another aspect, the base element 111 may comprise a soft material, such as silicone, rubber, or other polymer that is configured to slightly deform during compression of the wire 120 and formation of the marker element.

[0029] A force applicator 204, (e.g., a rod), may be used to compress (or crumple, for example) the wire 120 within the tube 105. An example of such a force applicator 204 is shown in FIG. 2. In one example aspect, the force applicator 204 may have a handle element 209 at a second end for gripping or holding the force applicator 204. The handle element 209 may also be in communication with an electrically driven press (not shown), hydraulic mechanism (not shown) or other compression mechanism configured to move the force applicator 204 in and out of the inside portion of the tube 105, as would be readily understood by those of skill in the art. As will be described in more detail below, the force applicator 204 may be configured to compress the wire 120 to a selected length of the tube, for example, so

that the compressed wire 120 (i.e., the resulting marker element) is about 3 mm as measured between the a second end of the base element 110, 111 and a first end of the force applicator 204, thereby forming the marker element. In various aspects, the force applicator 204 may be formed of a metal or a polymer material, or a combination thereof. The force applicator 204 may need to have a sufficient hardness to compress the wire 120 without breaking.

[0030] In another aspect, the force applicator 204 may have a similar shape to the tube 105, and the size of the force applicator 204 may be such that when inserted into the tube 105, there is a clearance of about 0.0005 to about 0.003 inches, preferably about 0.001 to about 0.002 inches, between the outside surface of the force applicator 204 and the inside surface of the tube 205. For example, if the tube 105 is cylindrical and the force applicator 204 is cylindrical, the diameter of the force applicator 204 may also be about 0.001 to about 0.002 inches smaller than the inside diameter of the tube 105. If the tube 105 and force applicator 204 have an elliptical cross-section, for example, then the clearance between the outside surface of the force applicator 204 and the inside surface of the tube 105 may be about 0.001 to about 0.002 inches. This clearance ensures adequate compression of the wire 120 and optimal formation of the marker, as will be further explained below. Moreover, the clearance should generally not be too small, or the force applicator 204 may not be readily moveable within the tube 105. Also the force applicator 204 generally should not be too great, or it will not compress the wire 120 from its second end (e.g., the force applicator 204 may slip to one side or another of the wire 120). Therefore, the inventors have found that a force applicator 204 sized so that there is

a clearance of about 0.001 to about 0.002 inches is particularly useful for compression of the wire 120 for some applications of the technology.

[0031] In FIG. 3 the force applicator 304 is shown inserted into the tube 305 after compressing the wire to a predetermined length of the tube 305, so as to form the marker element 325. As will be appreciated by those of ordinary skill in the art, a marker element 325 formed in a particular tube 305 may differ from another marker element 325 formed in a different tube 305, even though the wire and tube may be of the same or similar size and material. Thus, because of 1) the mechanical properties of each wire 120 used to form the marker element 325, 2) the relative size of the wire 120 to the tube 305, and 3) the physical placement or location of the wire 120 within the tube 305 prior to compression, a first marker element formed in a first tube, may differ from a second marker element formed in a second tube. As will be appreciated by those skilled in the art, for example, a first wire will not bend in exactly the same manner as a second wire when undergoing compression by the force applicator 304 in a first tube as compared to a second tube. For example, if a first wire is placed close to an inside surface of a first tube and a second wire is placed in the middle of a second tube, this placement will affect how the wire bends. It is an aspect of the present invention that such placement does not need to be controlled, which reduces the time and cost associated with forming a marker element 325.

[0032] The marker element 325 depicted in FIG. 3 is just one example of how the wire 120 may bend from compression by the force applicator 304 to form the marker 325. In one aspect, the first end of the wire 120 may initially coil during

compression and at the end of compression, for example, the second end of the wire 120 may be compressed flat. While multiple marker elements 325 formed using a method and/or apparatus in accordance with aspects of the present invention may differ, all marker elements 325 (e.g., 325a, 325b, etc.) formed in respective tubes 305 (e.g., 305a, 305b) may have common characteristics. For example, a marker element 325 may be about 2 mm to about 5 mm in length, preferably about 3 mm in length, as measured between the second end of the base element 110, 111 (i.e., the inside face of end element 111) and the first end of the force applicator 304. More specifically, the force applicator 304 may be sized so that it will stop compression of the wire when the first end of the force applicator 304 is at a predetermined distance from the second end of the base element 110.

[0033] A positive stop may be provided between the applicator and the fixture. In this case, the handle of the applicator may be sized such that it encompasses or partially encompasses the receiving element 406 and contacts the fixture so that it cannot be pushed down any further. At the point of contact, the applicator rod may be in the appropriate position to create a marker of the desired size.

[0034] A control mechanism, electronic or hydraulic, for example, may be provided, where the travel of the applicator is monitored by a feedback loop, and, when the applicator travels the prescribed distance to create a marker of a certain size, the control mechanism stops the travel of the applicator and returns it to the home position.

[0035] Moreover, a total mass of wire used to form a particular marker element 325 (e.g., 325a, 325b) may be the same or similar for each particular marker element 325 formed by the method and apparatus of the present invention. For example, an 18 gauge, 18 karat gold wire may have a length of about 10 inches and a 12 gauge, 18 karat gold wire may have a length of about 2.5 inches, the total mass of marker element 325 produced from each wire is approximately the same. In one example aspect, the total mass of wire received to form the marker element may be about 1 g to about 10 g (e.g., about 4 g).

[0036] In addition, the resulting marker element 325 may have a general shape consistent with the inside shape of the tube 305. For example, in the case of a cylindrical tube, the resulting marker element 325 may be generally cylindrical in shape. It will be appreciated that during longitudinal compression, the wire may bend in a radial direction, as well. Thus, during compression, the wire may exert a force against the inside surface of the tube 305 so that the resulting marker element 325 is shaped and sized to fit snugly within the particular tube 305 and is held in place near the first end 306 of the tube 305. Thus, when the base element 310, 311 and force applicator 304 are removed, the marker element 325 may remain in place. For example, the friction force required to move the marker element 325 in the tube 305 may be greater than the weight of the marker element 325, which prevents undesired sliding of the marker element within the tube 305.

[0037] Another characteristic of the marker element 325 may be the formation of open spaces within the general structure as a result of the random bending of the wire. For example, as shown in FIG. 3, the wire may be compressed to form a

generally cylindrical structure having open spaces formed between the bends in the wire. Therefore, when implanted in a tissue, the open spaces of the marker element 325 may be filled by growing tissue, which ensures the marker element 325 will remain in place.

[0038] In other aspects, the size of tube 305 (e.g., length and diameter) may differ between one patient and another, depending, for example, on the type of procedure, location of tissue extraction, size of the patient and/or weight of the patient. Therefore, the length and diameter of the force applicator 304 may also differ, depending on the circumstances. Nonetheless, the marker element 325 may generally be about 2 mm to about 5 mm in length, preferably about 3 mm in length, and the force applicator 304 may be sized to have a clearance of about 0.0005 to 0.003 inch, preferably about 0.001 to 0.002 inches, between its outer surface and the inner surface of the tube 305. It should be noted that the depiction of the force applicator 304 in tube 305 in FIG. 3 is merely for illustrative purposes. In one aspect, the outside diameter of the force applicator 304 may be very proximally close to the inner surface of the tube 304, for example, when the clearance is 0.0005 to 0.003 inch. In addition, the resulting marker element 325 may have the same or similar characteristics to as described above.

[0039] In other aspects of the invention, a fixture 401 may be used to aid in the compression of the marker element, as shown in FIG. 4. A tube 405 may be inserted into the fixture 400 having incorporated therein a base element (not shown in FIG. 4) that is movable in and out of the first end (not shown in FIG. 4) of the tube 405 via an element 402, such as a set screw, located at a base of the fixture 400. In

one aspect, element 402 holds the base element in place. If the base of the fixture 401 is removable for access to the base element. In some variations, the height of the base element may then be adjusted by loosening the screw and moving the base element up or down a certain amount. When the desired height is reached, the screw may be tightened again, such as to hold the base element in place.

[0040] In an example aspect, the fixture 400 may be configured to hold the tube 405 vertically as shown in FIG. 4. Vertically orienting tube 405 may provide for easier manufacturing, for example, in that the first end of wire 120 may be inserted through the second end of tube 405, and then released, such that gravity pulls wire 120 down until it contacts the base element. A horizontally oriented fixture would not provide similar manufacturing ease. The force applicator 404 may then be inserted into the tube 405 to compress the wire (not shown) and form the marker element (not shown). The fixture 400 may include extender elements 401, 403, for example, that may be affixed to the receiving element 406 of the fixture 400, where the extender elements 401, 403 are used to hold longer tubes 405. Consequently, longer force applicators 404 may also be used.

[0041] In another aspect, the fixture shown in FIG. 4 may create one marker element at a time; however, a larger scale fixture may also be used. A larger scale fixture may be configured to hold multiple tubes, for example. In another example for an automated process, the larger scale fixture may be moveable beneath a force applicator or multiple force applicators. When aligned with a tube, the force applicator(s) may be lowered to compress the corresponding wire(s) and then raised to remove the force applicator(s) from the tube(s). After compression in a first tube,

the fixture may then translate one space, for example, so that a second tube may be aligned with the force applicator for compression.

[0042] It should be noted that the length of the force applicator 204, 304, 404 may be sized to stop compression at a predetermined length of the tube 105, 305, 405 to form the marker element (e.g., the force applicator may be shorter than the tube). In this instance, the base element 110, 111 may be sized to slide into a first end 106 of the tube at a (repeatable) predetermined length (e.g., so that there is a predetermined length between the end of the force applicator and the base element).

[0043] Although the force applicator 304, 404 may be manually pushed into tube 305, 405 using handle 309, 409 to form the marker element, in one aspect, a compression mechanism (e.g., an electrically driven press or hydraulic mechanism) may be used. In an automated process, a robot or other mechanism employed to lower the force applicator, may be controlled based on, for example, the lowering rate of the force applicator and elapsed time, a detection sensor or sensors configured to detect height, or by any other suitable means known to those of skill in the mechanical processing arts.

[0044] Aspects of a method of making a marker element 500 according to the present invention are described with reference to FIG. 5. The method 500 may optionally include, at 505 providing a tube (e.g., tube 105, 305, 405 as described in reference to FIGs. 1, 3 and 4 above). In one aspect, at 505 providing the tube comprises receiving the tube in a fixture (e.g., 400 of FIG. 4) for supporting the tube. The fixture may be configured to support the tube in a vertical orientation, for

example, as shown in FIG. 4. In another aspect, the base element (e.g., element 110, 310 of FIGs. 1, 3) may be coupled to an element of the fixture.

[0045] The method may further include at 510 receiving a base element (e.g., element 110, 310 of FIGs. 1, 3) in a first end (e.g., end 106, 306 of FIGs. 1, 3) of a tube, where the base element seals the first end of the tube and provides a base against which the wire (e.g., wire 120, 320 of FIGs. 1, 3) is compressed. The base element may be configured to position a second end of the wire at a predetermined position near the first end of the tube, for example.

[0046] At 515, the method includes receiving a wire in a second end of the tube, where the wire is as described above with reference to FIGs. 1 and 3, for example. The wire may be on a spool and inserted into the second end of the tube while still on the spool, for example. The wire may then be cut to a selected length so that the density of wire used to make, for example, a first marker element and a second marker element that is the same or very similar. The wire may also be cut to different lengths, for example, to create a first marker element and a second marker element having densities that are significantly different. In one aspect, the spool may be automated to dispense and cut the wire to a predetermined length. In another aspect, the wire may be cut to a selected length before insertion into the tube. As discussed with respect to FIG. 1, the wire may be malleable and comprise a suitable material resistant to foreign body reactions. In example aspects, the wire may be gold, and, particularly for some applications of the technology, annealed gold.

[0047] At 520, the method includes applying a force to a second end of the wire using a force applicator, wherein the force compresses the wire in a longitudinal direction of the tube to a predetermined length of the tube to form the marker element within the tube. In one aspect, the width or diameter of the force applicator may be less than an inner width or diameter of the tube so as to provide clearance, as discussed above with reference to FIGs. 1 and 3. In another aspect, the width or diameter of the force applicator may be greater than the width or diameter of the wire. Applying a force at 512 may further include one or more of moving a device coupled to the force applicator, activating an electrically driven mechanism configured to move the force applicator, and/or activating a hydraulic mechanism configured to move the force applicator.

[0048] Aspects of a method of making or assembling a kit for marking a tissue are described with reference to FIG. 6. Like the method 500 of FIG. 5, method 600 of FIG. 6 includes providing a tube 605 (optionally), receiving a base element in a first end of the tube 610, receiving a wire in a second end of the tube 615, applying a force to the wire at the second end of the tube using a force applicator, wherein the force compresses the wire to a predetermined length of the tube to form the marker element within the tube 620, and removing the force applicator from the tube 625.

[0049] In other aspects, method 600 may include at 625 removing the base element from the tube. In one aspect, after compression and removal of the base element, the marker element may remain fixed near the first end of the tube such as by a friction force greater than a weight of the marker element.

[0050] With reference to the method of FIG. 6 as applicable to the example kit of FIG. 7, at 630, the method 600 includes providing an actuator element (e.g., element 719 of FIG. 7) receivable in the second end 707 of the tube 705. In one aspect, a first end of the actuator element 719 may form a sharp tip 718, like a needle or stylet, which may assist in moving the marker element 725 from the tube 705 and into a tissue site (not shown). In another aspect, the tip may be flat (not shown). In yet another aspect, the actuator element, like the force applicator (discussed above), is sized so that there is a clearance of about 0.0005 to about 0.003 inch (e.g., about 0.001 to 0.002 inch) between the outer diameter of the actuator element and the inner diameter of the tube. In addition, the tissue site may be or include the site of a biopsy or surgical incision.

[0051] In another aspect, method 600 as applied to the kit of FIG. 7 may further include at packaging the actuator element 719, the tube 705 and the marker element 725 together in a sterile material 730 to form a kit 700. The sterile material 730 may be any suitable material that is typically used for packaging sterile equipment used in the medical field, for example.

[0052] While aspects of this invention have been described in conjunction with the example features outlined above, various alternatives, modifications, variations, improvements, and/or substantial equivalents, whether known or that are or may be presently unforeseen, may become apparent to those having at least ordinary skill in the art. Accordingly, the example aspects of the invention, as set forth above, are intended to be illustrative, not limiting. Various changes may be made without departing from the spirit and thereof. Therefore, aspects of the invention are

intended to embrace all known or later-developed alternatives, modifications, variations, improvements, and/or substantial equivalents.

CLAIMS

What is claimed is:

1. A device for forming a marker element, the device comprising:
a tube having a longitudinal direction;
a base element received in a first end of the tube;
a wire receiving portion at a second end of the tube;
a force applicator receivable within the second end of the tube, the force applicator being configured to apply force to a received wire in the longitudinal direction of the tube to deformably compress the received wire to a selected length relative to the longitudinal direction of the tube.
2. The device of claim 1, wherein an outer diameter of the tube is about the same or less than a diameter of a biopsy site in which a marker element is to be emplaced.
3. The device of claim 1, comprising a separable fixture configured to receive the tube.
4. The device of claim 3, wherein the fixture is configured to support the tube in an approximately vertical orientation so that the second end of the tube is configured to protrude from a top end of the fixture.
5. The device of claim 3, wherein the base element is coupled to the fixture.

6. The device of claim 1, wherein the base element is configured to position an end of the received wire near the first end the tube.
7. The device of claim 1, wherein the base element is configured to position the end of the received wire about 2 to 5 mm from the first end of the tube.
8. The device of claim 1, wherein a clearance between an outer diameter of the force applicator and an inner diameter of the tube is about 0.0005 to 0.003 inches.
9. The device of claim 8, wherein a clearance between an outer diameter of the force applicator and an inner diameter of the tube is about 0.001 to 0.002 inches.
10. The device of claim 1, comprising a marker element formed of a compressed received wire.
11. The device of claim 10, wherein the marker element is constrained to one or more dimensions within the tube so as to be constrained between the base element and an end of the force applicator.
12. The device of claim 11, wherein the constrained length of the marker element is about 2 to 5 mm.

13. The device of claim 12, wherein the constrained length of the marker element is about 3 mm.
14. The device of claim 10, wherein the marker element has an outer shape limited by a shape of an inner surface of the tube.
15. The device of claim 10, wherein the marker element comprises a plurality of open spaces configured to receive tissue in-growth.
16. The device of claim 10, wherein the marker element has a cylindrical outer surface shape with a plurality of open spaces.
17. The device of claim 10, wherein the marker element comprises a mass of total received wire of about 1 g to about 10 g.
18. A kit for forming a marker element, the kit comprising:
- a tube having a longitudinal direction;
 - a base element receivable in a first end of the tube;
 - a wire receivable in a second end of the tube;
 - a force applicator receivable within the second end of the tube, the force applicator being configured to apply a compression force to the wire in the longitudinal direction of the tube; and

an actuator element receivable within the second end of the tube, the actuator element being configured to apply an actuation force to a marker element formed by compression of the wire.

19. The kit of claim 18, comprising a separable fixture configured to receive the tube.

20. The kit of claim 18, wherein the base element is configured to position an end of the wire near the first end the tube.

21. The kit of claim 18, wherein the wire comprises a metal selected from a group consisting of gold, titanium, chromium, cobalt, stainless steel, silver, platinum, tantalum and alloys thereof.

22. The kit of claim 18, wherein the wire comprises annealed gold.

23. The kit of claim 18, wherein the wire has a length of about 1.5 to 20 inch, a diameter of about 0.004 to 0.100 inch, a tensile strength of about 18,000 to 25,000 psi, a yield strength of about 9,000 to 15,000 psi, an elongation at break of about 25% to 35%, and a breaking load of about 250 to 300 grams.

24. The kit of claim 18, wherein the base element when received in the tube is configured to position an end of the wire at a predetermined length from the first end

of the tube and wherein the force applicator is configured to stop compression of the wire at a predetermined distance from the base element.

25. The kit of claim 24, wherein the predetermined distance is about 3 mm.

26. The kit of claim 18, wherein the actuator element is configured to move the marker element from the tube and into a tissue site.

27. A marker delivery device, comprising:

a tube having a longitudinal direction;

a marker element preformed within the tube, the marker element fixedly positioned near a first end of the tube; and

an actuator element receivable in a second end of the tube, the actuator element configured to move the marker element from the first end of the tube into a tissue site.

28. The device of claim 27, wherein the tube is configured to receive a base element in the first end of the tube to form a base on which the marker element is preformed.

29. The device of claim 28, wherein the tube is configured to receive a deformably compressible wire in the second end of the tube, an inner surface of the tube being

configured to exert an opposing force against the wire during compression of the wire to shape the wire and thereby preform the marker element.

30. The device of claim 27, wherein the tube is configured to receive a force applicator in the second end of the tube, the force applicator being configured to compress a wire to preform the marker element within the tube.

31. The device of claim 27, wherein the tube is configured to receive a base element in the first end of the tube, a wire in the second end of the tube and a force applicator in the second end of the tube, wherein the force applicator is configured to compress the wire between the base element and the force applicator to preform the marker element.

32. The device of claim 33, wherein the marker element is preformed to a length and dimensions within the tube between the base element and the force applicator.

33. A method of making a marker element, comprising:
receiving a base element in a first end of a tube;
receiving a wire in a second end of the tube; and
applying a force to an end of the wire, wherein the wire is compressed in a longitudinal direction of the tube to a shape corresponding to a selected length and constrained in outer shape by the tube so as to form a marker element.

34. The method of claim 33, wherein a clearance between an outer diameter of the force applicator and an inner diameter of the tube is about 0.001 to 0.002 inches.
35. The method of claim 33, wherein applying a force comprises activating a compression mechanism selected from the group consisting of a lever coupled to the force applicator, an electrically driven press and a hydraulic mechanism, wherein the compression mechanism is configured to move the force applicator.
36. A method of making a kit for marking a tissue, comprising:
- providing a tube;
 - receiving a base element in a second end of the tube;
 - receiving a wire in a first end of the tube;
 - applying a force to the wire at the first end of the tube using a force applicator, wherein the force compresses the wire to a predetermined length of the tube to form the marker element within the tube;
 - removing the force applicator from the tube and removing the base element, wherein the marker element is fixed near the second end of the tube by a friction force greater than a weight of the marker element;
 - providing an actuator element receivable in the first end of the tube; and
 - packaging the actuator element, the tube and the marker element together in a sterile material.

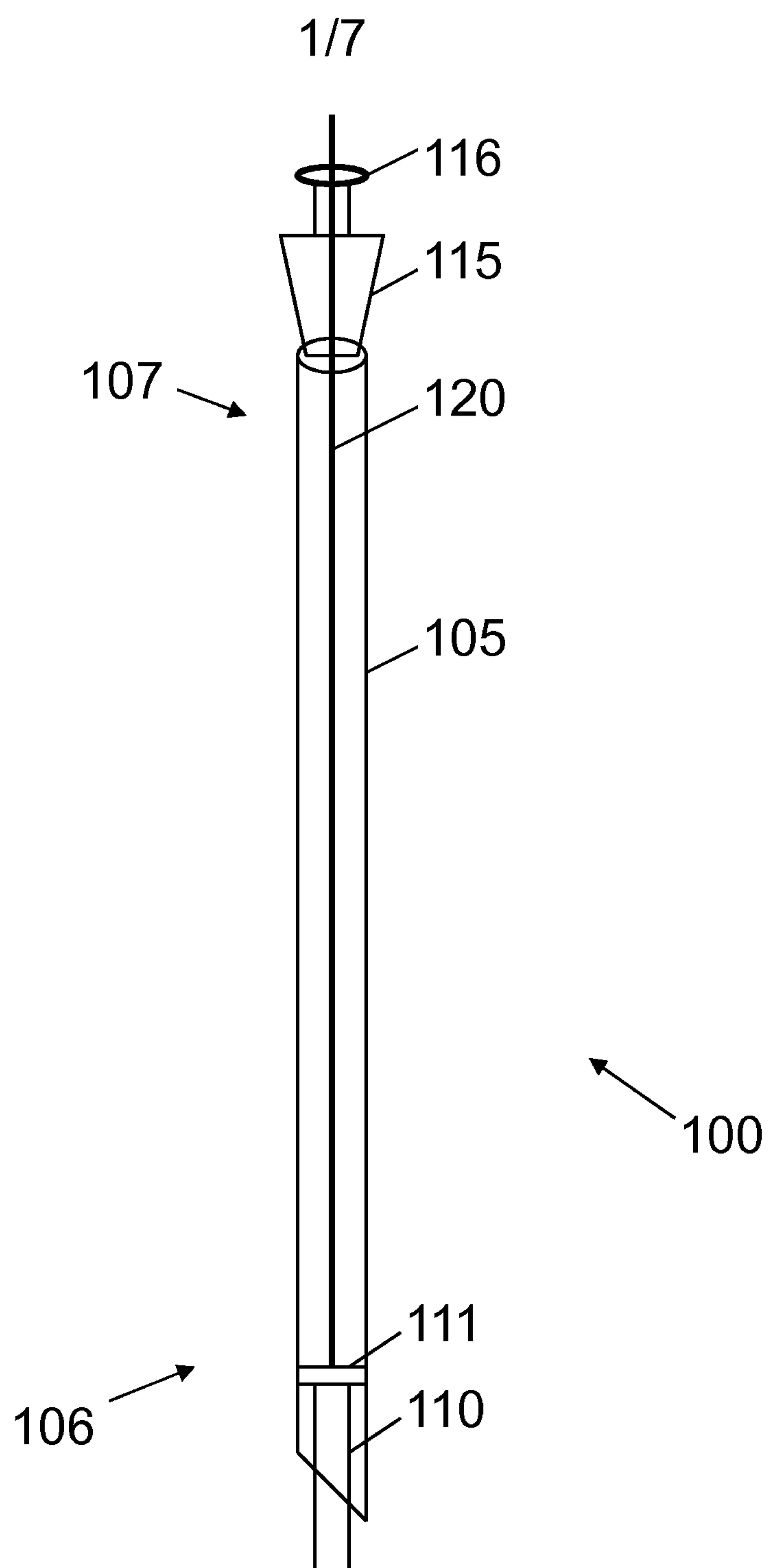


FIG. 1

2/7

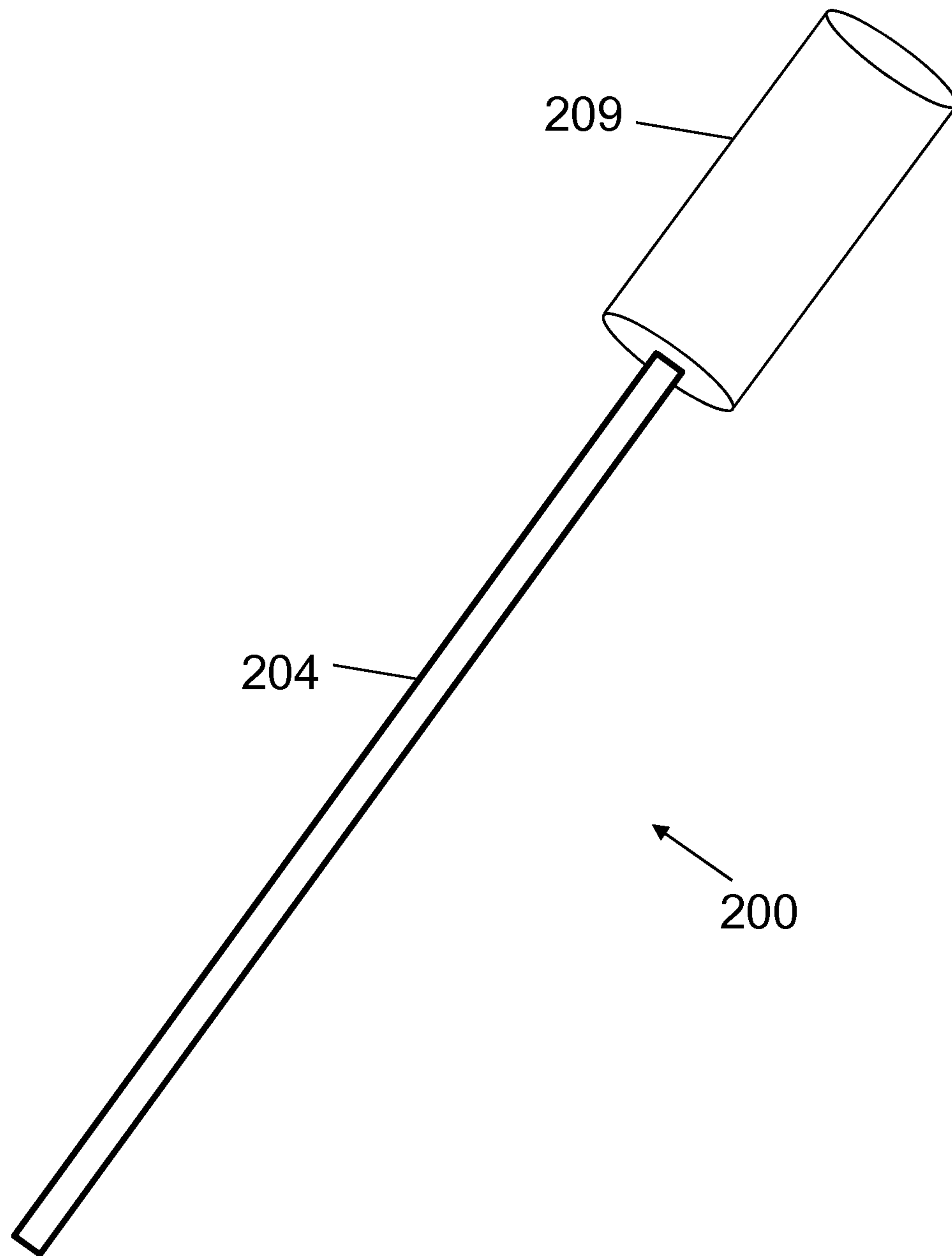
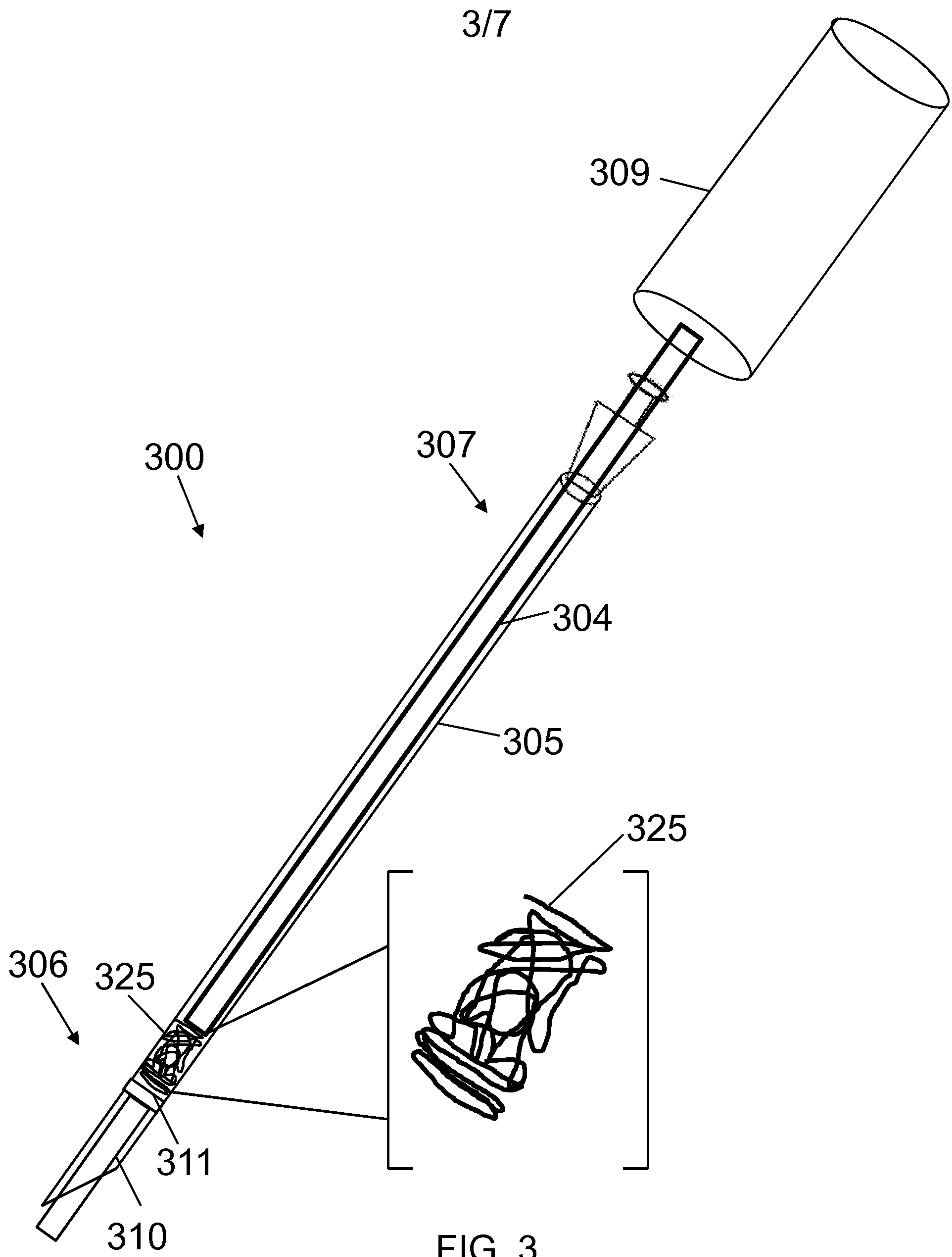


FIG. 2



4/7

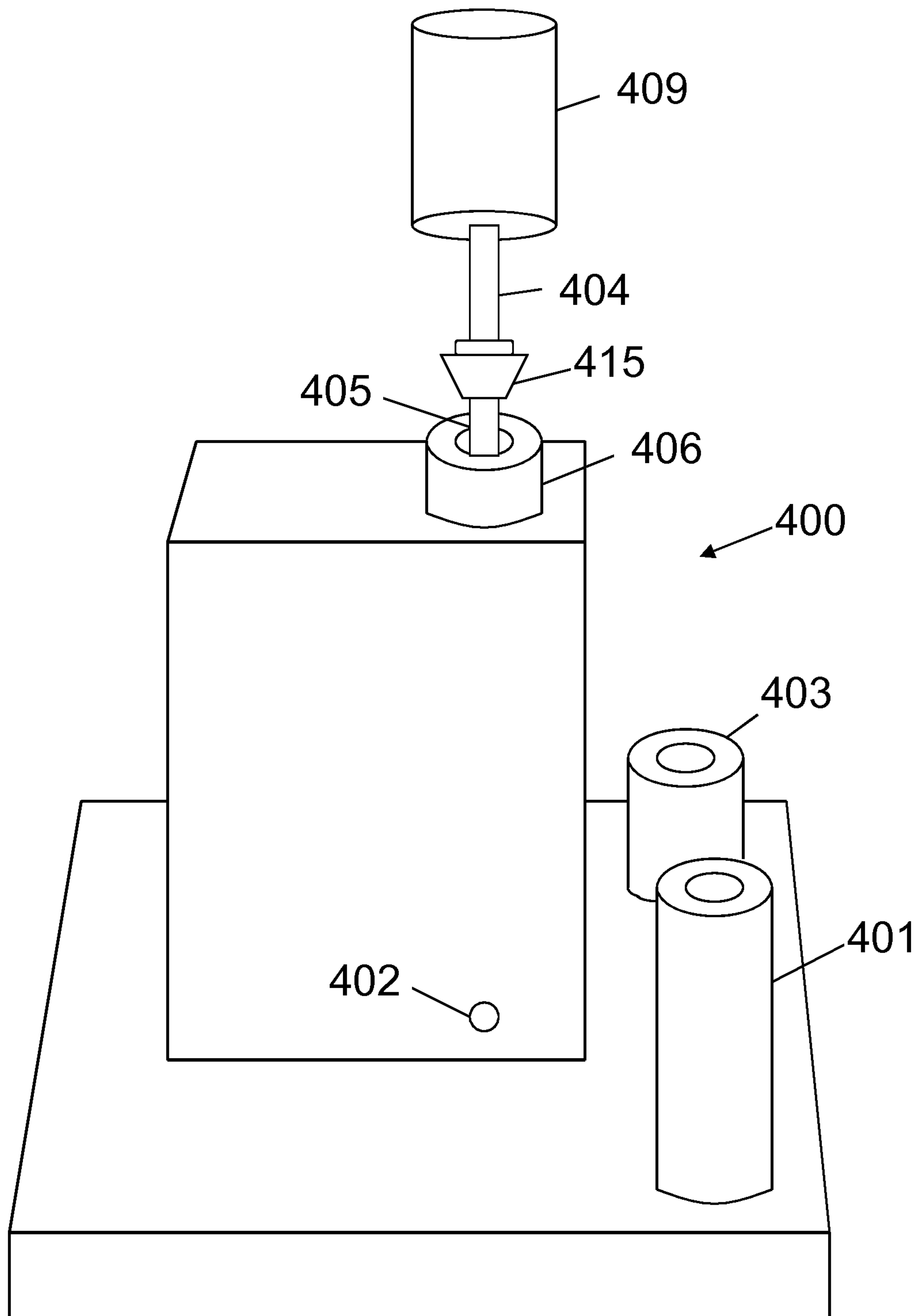


FIG. 4

5/7

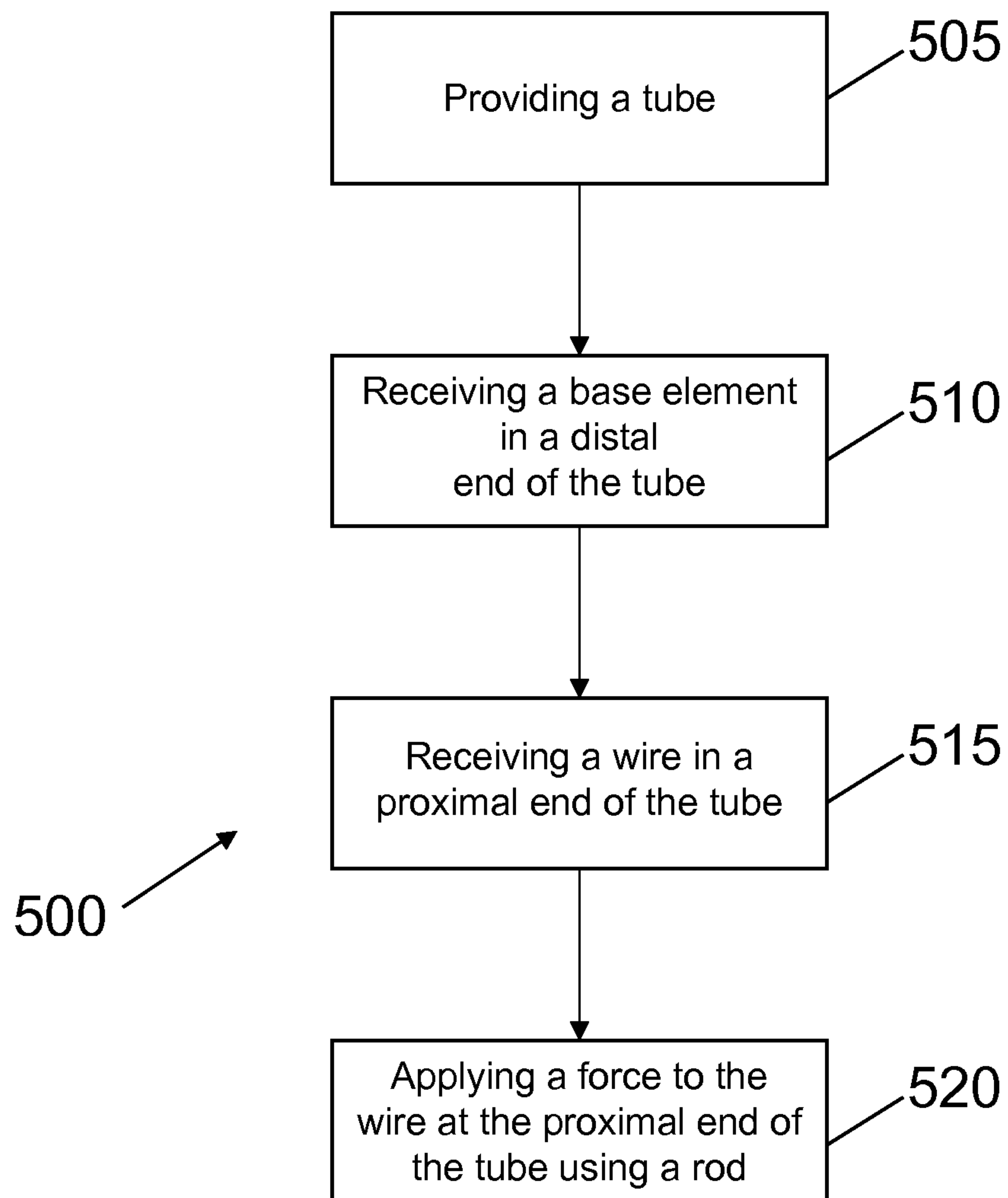


FIG. 5

6/7

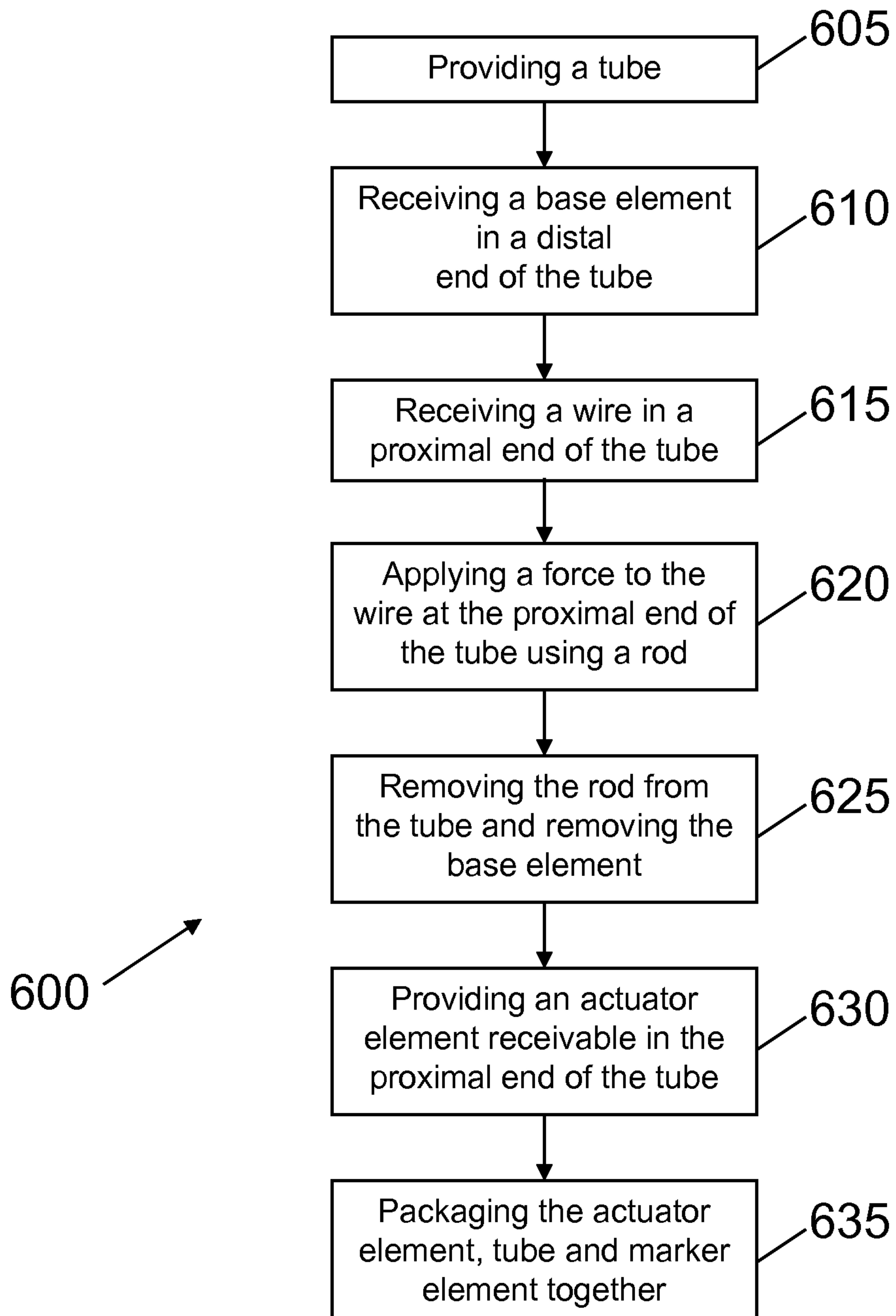


FIG. 6

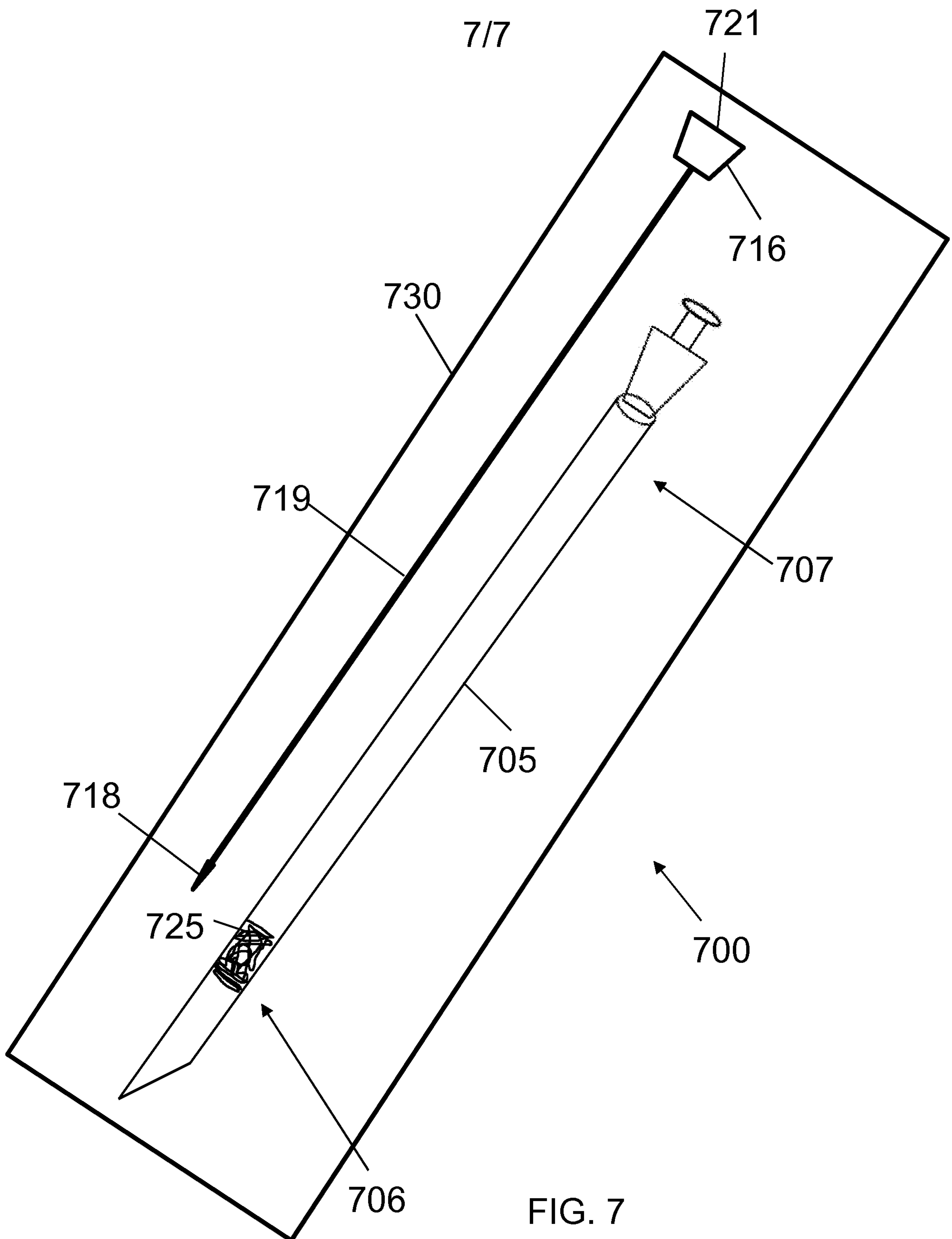


FIG. 7

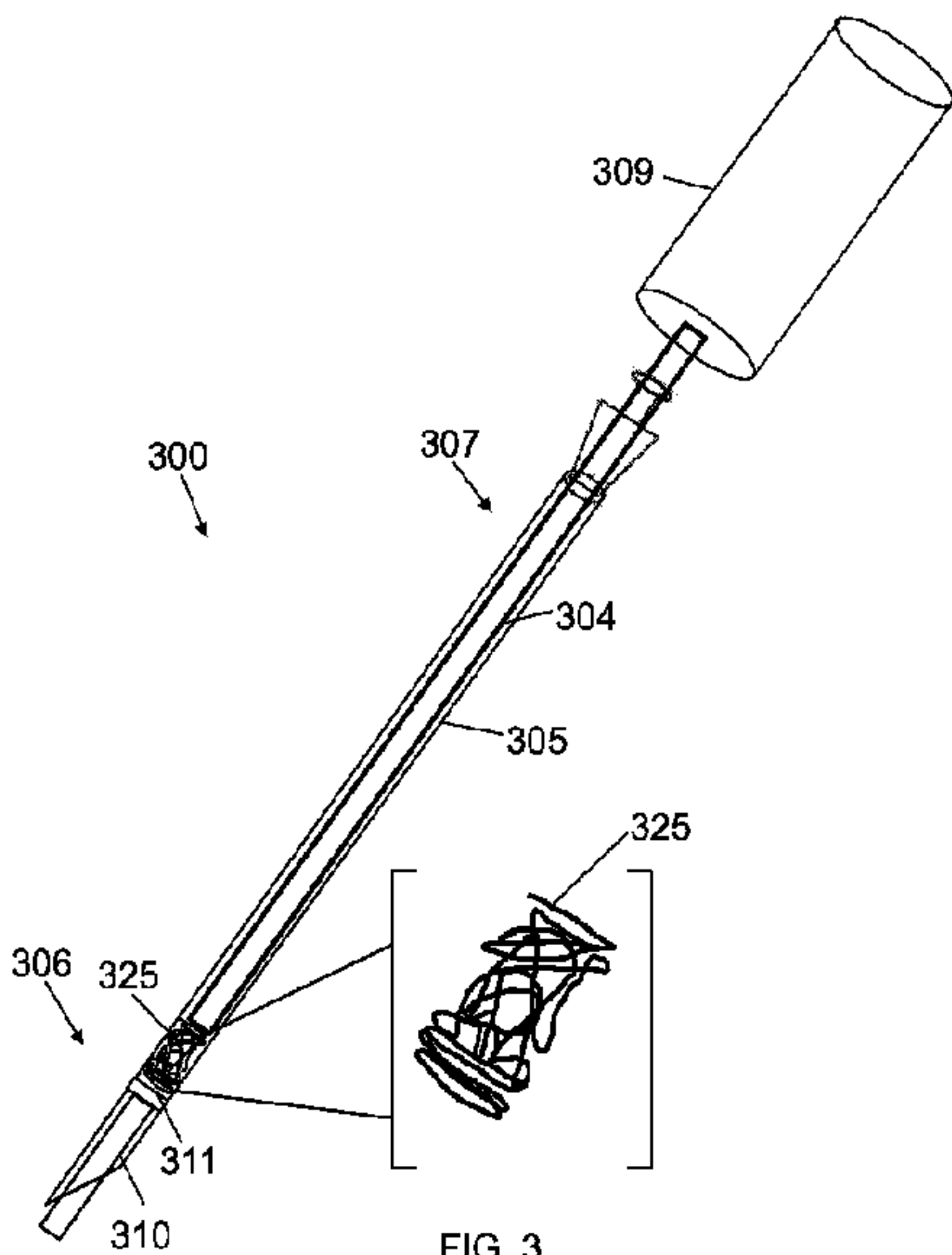


FIG. 3