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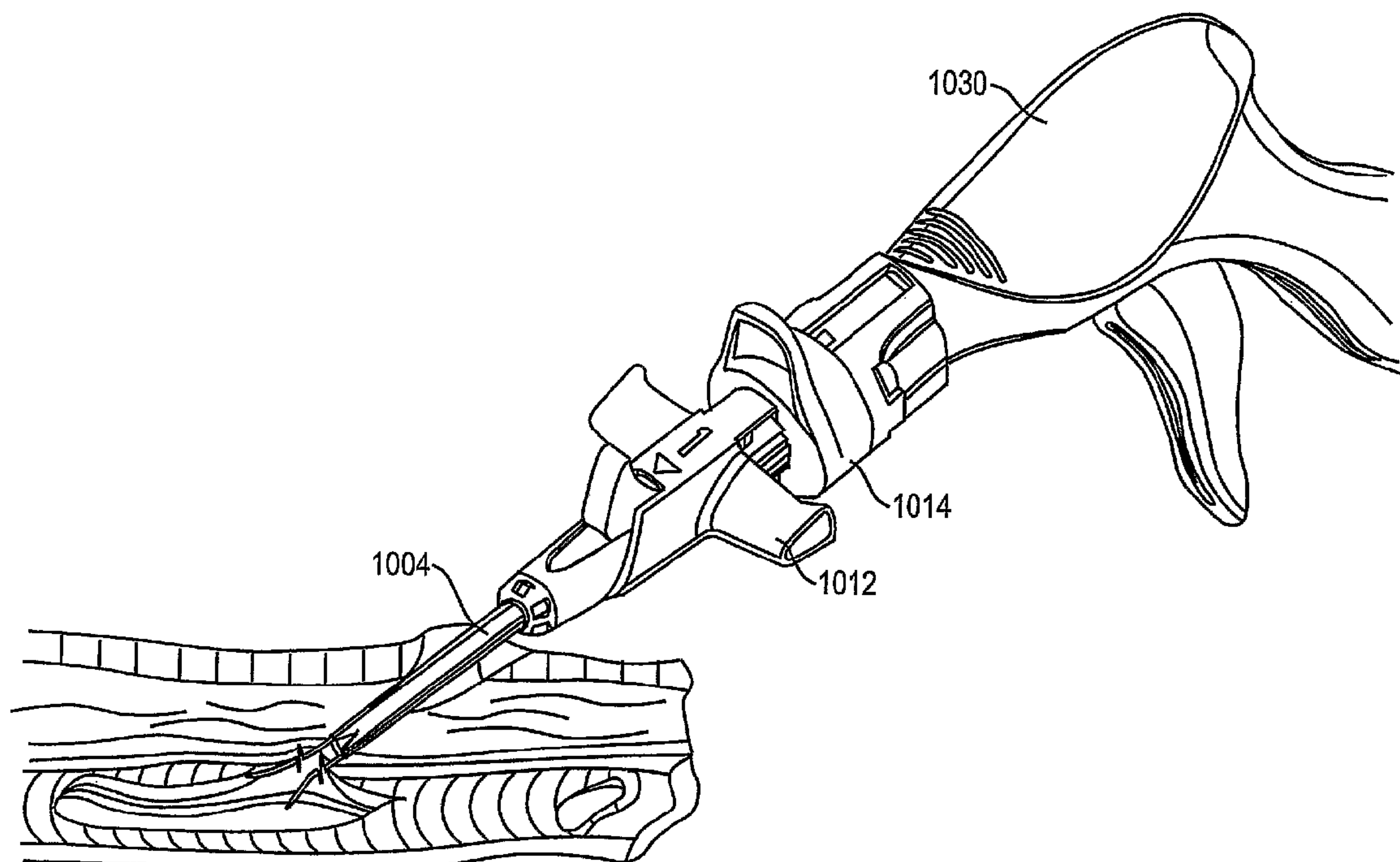
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(54) Titre : **METHODES ET SYSTEMES DE GESTION DE SITE DE PLAIE AVANCES**

(54) Title: **ADVANCED WOUND SITE MANAGEMENT SYSTEMS AND METHODS**



(57) **Abrégé/Abstract:**

An introducer comprises a sheath, a guide rod, and at least one wire stabilization guide. The guide rod is sized to fit within the inside diameter of the sheath. The guide rod has at least one slot along its length for releasably holding the wire stabilization guide. One or more wire stabilization guides are coupled to the sheath. In one exemplary embodiment, the wire stabilization guides are inserted into a wound site and are dimensioned so as to cause an outward stretching force on the wound site. In another embodiment, the wire stabilization guides may form a loop, so that when the sheath is approximated to a wound site, the loop is approximated to tissue surrounding the wound site to hold the sheath approximately centered on the wound site. In other embodiments, the wire stabilization guides may include a retention device to hold the sheath approximate to the wound site.



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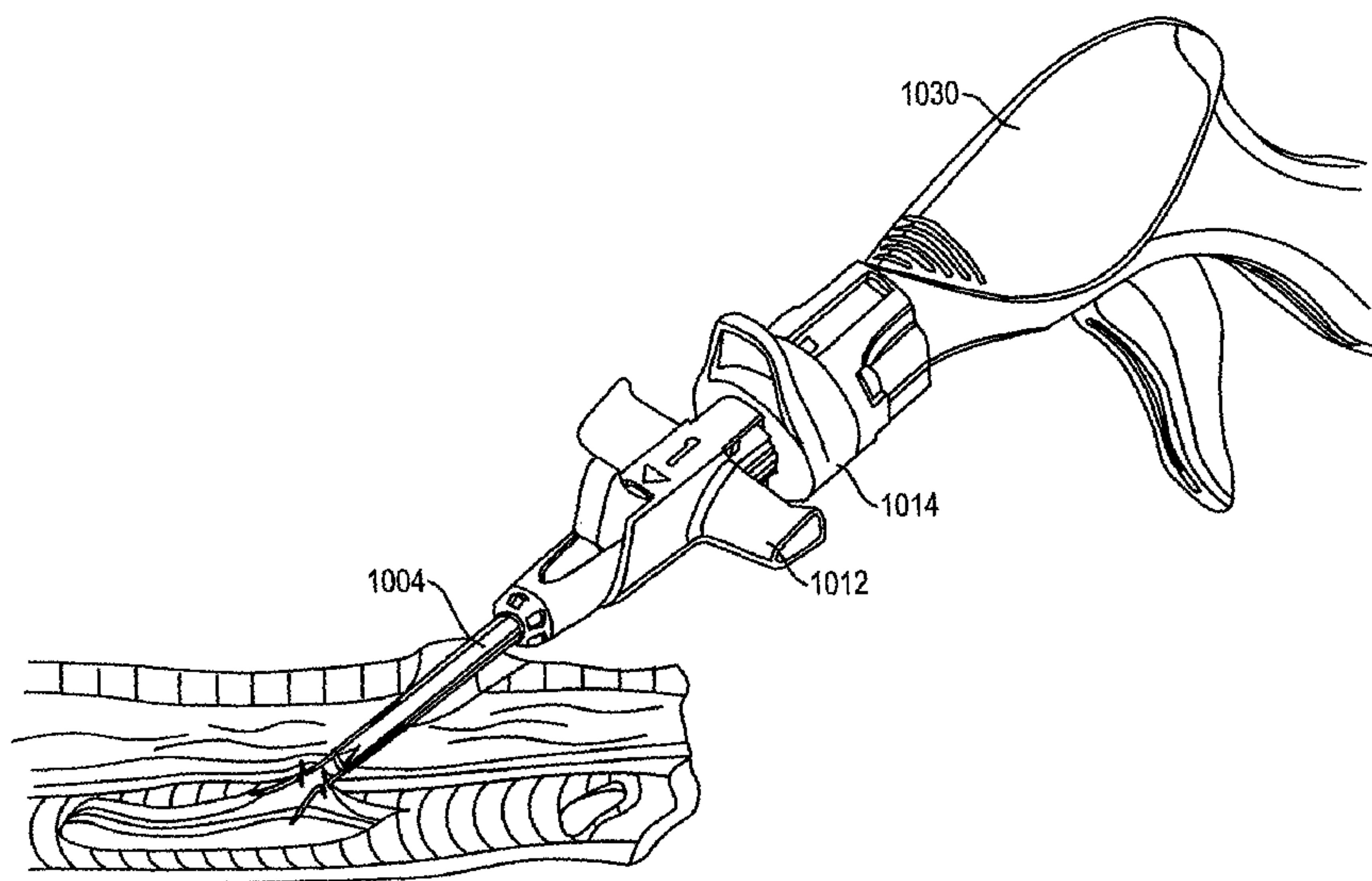
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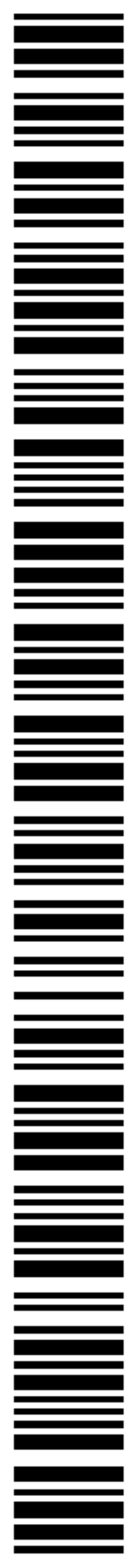
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(57) Abstract: An introducer comprises a sheath, a guide rod, and at least one wire stabilization guide. The guide rod is sized to fit within the inside diameter of the sheath. The guide rod has at least one slot along its length for releasably holding the wire stabilization guide. One or more wire stabilization guides are coupled to the sheath. In one exemplary embodiment, the wire stabilization guides are inserted into a wound site and are dimensioned so as to cause an outward stretching force on the wound site. In another embodiment, the wire stabilization guides may form a loop, so that when the sheath is approximated to a wound site, the loop is approximated to tissue surrounding the wound site to hold the sheath approximately centered on the wound site. In other embodiments, the wire stabilization guides may include a retention device to hold the sheath approximate to the wound site.



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ADVANCED WOUND SITE MANAGEMENT SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present invention is a continuation-in-part of application Serial No. 09/915,107, filed July 25, 2001; which is a continuation-in-part of application Serial No. 09/884,782, filed June 19, 2001; which is a continuation-in-part of application Serial No. 09/658,786, filed September 11, 2000, now U.S. Patent No. 6,322,580; which claims benefit of U.S. Provisional application Serial No. 60/230,234, filed September 1, 2000; and all assigned to the same assignee.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a wound site management, for use during and after an invasive medical procedure. More specifically, the present invention relates to wound site management techniques and methodology for diagnostic and interventional procedures occurring at a wound site, for example, a puncture made in the wall of an artery or vein during a medical procedure. The puncture may be the result of a catheter-based intervention, although any puncture is contemplated, accidental or intentional. The present invention has particular utility for use in and around the femoral, radial, and brachial arteries after coronary/cardiac procedures. Other utilities include soft-tissue anchoring, tendon and artery joining, vessel anastomosis, meniscal repair, thoracic lung closure, heart repair, endoscopic procedures, esophageal repair, laparoscopy, skin/epidermal wound closure and general tissue closure.

2. Description of Related Art

Catheters/catheterization procedures are well known, and typically involve insertions through the femoral artery for diagnosis or to treat cardiovascular and /or peripheral vascular diseases. After a diagnostic or interventional catheterization, the puncture formed by the catheter must be closed. The puncture opening in the artery typically ranges from 5F for a diagnostic procedure to 610F for an interventional procedure. Traditionally, intense pressure has been applied to the puncture site for at least 30-45 minutes after removal of the catheter. Other approaches include the use of a thrombotic or collagen plug or slurry, and/or other suturing methodologies for sealing the puncture. Patients who have had a femoral puncture are then required to remain at bed rest, essentially motionless and often with a heavy sandbag placed on their upper legs, for several hours to ensure that the bleeding has stopped. This

1 traditional method of hemostasis following femoral artery access has many inadequacies.
2 When a blockage is removed during a procedure, the patient quickly feels better and they
3 often have more energy than they have had in years, but they must remain motionless for
4 several hours. The weight of the sandbag on the femoral artery often causes the lower leg to
5 tingle or go numb. The recovery time from the medical procedure may be as little as ½ hour,
6 but the recovery time from the wound can exceed 24 hours. The longer the recovery time,
7 the more expensive the procedure becomes, the greater the patient discomfort, and the greater
8 the risk of complications.

9 BRIEF DESCRIPTION OF THE DRAWINGS

10 Figures 1-3 are isometric views of one embodiment of the staple of the present
11 invention in formed, opened and deployed positions, respectively;

12 Figure 3A depicts an isometric view of alternative staple of the embodiment of
13 Figures 1-3;

14 Figures 4-6 are isometric views of another embodiment of the staple of the present
15 invention in formed, opened and deployed positions, respectively;

16 Figure 7 depicts one embodiment of the stapler of the present invention;

17 Figure 8 is an isometric view of the distal tip of the stapler of Figure 7 adapted to hold
18 and deploy the staple of Figures 1-6;

19 Figures 9A-11B are isometric views of the cooperative movement of the distal tip of
20 the stapler and the staple of the present invention;

21 Figures 12-15 are isometric views of an exemplary staple deployment mechanism of
22 the stapler of the present invention;

23 Figures 16 and 17 are isometric views of another exemplary staple deployment
24 mechanism of the stapler of the present invention;

25 Figures 18-26 depict various views of a first exemplary introducer of the present
26 invention;

27 Figures 27-32, 39 and 39A depict various views of a second exemplary introducer of
28 the present invention;

29 Figures 35 and 36 depict isometric views of a third exemplary introducer of the
30 present invention;

31 Figures 20A, 33, 34, 37 and 38 are isometric views of blood marking devices and
32 methods of the introducer of the present invention;

33 Figures 40-59 depict a fourth exemplary introducer of the present invention; and

34 Figures 60-66 depict a fifth exemplary introducer of the present invention.

1 Detailed Description of the Invention

2 Tissue Staple

3 In one aspect of the present invention, a staple is provided to close a tissue wound
4 after a medical procedure. Although the preferred use of the staple of the present invention is
5 to close an artery or vein following a diagnostic or interventional procedure, it should be
6 recognized at the outset that the staple may be used for general tissue repair, not just limited
7 to vascular repair. It will be appreciated throughout the following description that the staple
8 of the present invention can be formed of any biocompatible and/or bioabsorbable materials,
9 including, for example, Titanium (and Titanium alloys), stainless steel, polymeric materials
10 (synthetic and/or natural), ceramic, etc. It will also be apparent from the following
11 description that the staple of the present invention is preferably formed of a deformable
12 material (such as those listed above) that undergoes plastic deformation (i.e., deformation
13 with negligible elastic component.) As a general overview, the staple of the present
14 invention undergoes two positions of deformation: a first position to extend the distal ends of
15 the prongs of the staple outwardly to grab a greater amount of tissue (and also to grab tissue
16 away from the wound locus), and a second position to move the prongs inwardly to close the
17 wound.

18 Figures 1, 2 and 3 depict one embodiment of staple 10 of the present invention.
19 Figure 1 is the staple in its formed position, Figure 2 is the staple just prior to deployment
20 into tissue with the prongs extended outwardly, and Figure 3 is the staple closed around
21 tissue. The staple 10 of this embodiment comprises a plurality of prongs 12A-12D and a
22 plurality of tabs 14A-14D, arranged about a centerline axis 100. Common portions, or
23 shoulders 16A-16D are formed where the tabs meet the prongs. Each shoulder is common to
24 both the prong and the tab and is generally defined by a relatively flat portion generally
25 orthogonal to the centerline axis. Shoulders 16A-16D may be viewed as an extension of each
26 prong, bent inwardly toward the centerline axis. Each of these features of the staple 10 of
27 this embodiment is detailed below.

28 In the formed position (Figure 1), prongs 12A-12D extend generally parallel to central
29 axis 100, as shown. At the distal end of each prong, tapered points 18A-18D is formed to
30 extend inwardly toward the centerline axis 100. At the proximal end, shoulders 16A-16D
31 meet at prongs 12A-12D, respectively. Tabs 14A-14D are generally U-shaped, and are
32 formed between each prong. The proximal portions of each tab are joined at consecutive
33 shoulders, as shown. Each proximal portion of the U (i.e., each "leg" of the U-shape tab)
34 extends first generally outward from the shoulder, and second bends inwardly and distally

1 toward centerline axis 100, connecting together nearest the centerline axis to form the U
2 shape. The U-shape defines slots 20A-20D within each tab having a base positioned at the
3 bottom thereof.

4 Referring specifically to Figure 2, the staple 10 is deformed so that prongs 12A-12D
5 extend outwardly from the centerline axis, prior to deployment into tissue. It is advantageous
6 to extend the prongs outwardly as shown so as to grasp a large portion of tissue, and so that
7 insertion of the prongs into the tissue occurs at a locus away from the wound site, thereby
8 providing a more consistent wound closure (by closing the wound with more of the
9 surrounding tissue) and ensuring complete (or near complete) closure of the wound. To
10 deform the staple into the position shown in Figure 2, a force F_1 is applied to tabs 14A-14D,
11 as shown in relief in Figure 2A. Force F_1 is generally outward (from the centerline axis) and
12 proximal to the top of the staple, as shown in relief in Figure 2A. This force causes the tabs
13 to move outward from the centerline axis 100. The outward movement of the tabs causes the
14 shoulder portions to pivot roughly about the juncture between the shoulder and the prong
15 (i.e., at the outer portion of the shoulder), causing the inner portions of the shoulders to move
16 inwardly toward the centerline axis and distally. Since the prongs are attached to the outer
17 portion of the shoulders, the movement of the shoulders in this manner causes the prongs to
18 move outwardly. Thus, the cross-sectional diameter of the staple gets larger at the distal end
19 (with respect to the cross-sectional diameter of the formed staple of Figure 1). Note that the
20 movement of the prongs is generally greater at the distal portions thereof than at the proximal
21 portions thereof. In other words, movement of the prongs as shown in Figure 2 is pivoted
22 from the shoulder, thus producing a staple with outwardly extending prongs. For
23 completeness, it should be noted that a holding force may be applied downwardly (i.e.,
24 substantially parallel to the centerline axis) against the base of the slots 20A-20D to hold the
25 staple in place. Also, it is preferred that these forces are simultaneously applied to each tab
26 of the staple to produce uniform deformation of each prong of the staple. As mentioned
27 above, it is preferable that the plastic deformation of the staple is semi-permanent, so that the
28 staple does not tend to return to the shape depicted in Figure 1 (i.e., non-elastic deformation).
29 Deformation of the staple into this position will be described in greater detail below in
30 reference to the preferred stapler device of the present invention.

31 Figure 3 depicts the staple 10 in a closed position. The closed position, as stated
32 herein generally means that the prongs of the staple are moved inwardly toward each other.
33 Although Figure 3 depicts the tapered tip portions of the prongs meeting generally in the
34 vicinity of the centerline axis, however, it should be understood that the term "closed" or

1 “deployed” as used in reference to the staple need not necessarily mean this precise
2 configuration. It may be required (or desirable) for some procedures to move the prongs
3 inwardly toward each other to a greater or lesser extent than as depicted in Figure 3. To
4 draw the staple into the closed position depicted in this Figure, a force F_3 is applied to the
5 inner surfaces 30A-30D of the shoulders. This force is generally orthogonal to the centerline
6 axis, and the angle between each force approximates the angle between the inner surfaces
7 30A-30D (which, in the staple of this embodiment is approximately 90 degrees). This force
8 causes the slots 20A-20D to spread apart and urges the shoulders outwardly. Movement in
9 this manner also causes the shoulders to move outwardly and proximally. Proximal
10 movement of the shoulders causes the prongs to move toward each other. Opposite to the
11 movement of Figure 2, deformation shown in Figure 3 results in an expanded cross-sectional
12 diameter of the proximal end of staple, and a diminished cross-sectional diameter of the distal
13 end of the staple (with respect to the formed staple of Figure 1 and the deformed staple of
14 Figure 2). Again, deformation of the staple 10 into this position will be described in greater
15 detail below in reference to the preferred stapler device of the present invention.

16 For certain tissue application, it may be desirable that the staple of the present
17 invention is deployed into tissue such that the prongs do not fully pierce through the tissue,
18 but rather grasp and hold the tissue together. For example, for vascular closure applications it
19 may be desirable that the tissue piercing tapered ends not enter the bloodstream, but rather
20 pierce into the tissue and stop short of piercing through the tissue wall. To that end, and
21 referring to Figure 3A, the staple 10' of the present invention can be adapted with tissue stops
22 32A-32D. Preferably, tissue stops 32A-32D are located along the length of each prong, and
23 positioned from the distal tip of the prong to permit the tapered ends to pierce tissue, but not
24 pierce all the way through the tissue. Accordingly, the position of the stops 32A-32D along
25 the length of the prongs is selected to facilitate tissue grabbing (but not complete tissue
26 piercing) and can vary from application to application.

27 Figures 4-6 depict another embodiment of a staple 50 of the present invention. Figure
28 4 is the staple in it's formed position, Figure 5 is the staple just prior to deployment into
29 tissue with the prongs extended outwardly, and Figure 6 is the staple closed around tissue.
30 Similar to the first embodiment, the staple 50 of this embodiment comprises a plurality of
31 prongs 52A-52D arranged about a centerline axis 100. A shoulder 56A-56D is provided and
32 is generally defined by a relatively flat surface, generally orthogonal to centerline axis.
33 Shoulders 56A-56D may be viewed as an extension of each prong, bent inwardly toward the
34 centerline axis. In this embodiment, webs 54A-54D are connected to and between each

1 prong, and are formed to extend inwardly from each prong toward the centerline axis,
2 creating a U shape generally orthogonal to the centerline axis (as opposed to the previous
3 embodiment in which the U-shaped tab is positioned generally parallel to the centerline axis).
4 Each of the features of the staple 50 of this embodiment is detailed below.

5 In the formed position (Figure 4), prongs 52A-52D extend generally parallel to central
6 axis 100, as shown. At the distal end of each prong, tapered points 58A-58D are formed to
7 extend inwardly toward the centerline axis 100. At the proximal end, shoulders 56A-56D
8 meet at prongs 52A-52D, respectively. Web portions (webs) 54A-54D are generally U-
9 shaped, and are formed between each prong extending inwardly toward the centerline axis.
10 As shown, webs connect the prongs at a position distal to the shoulders. The precise position
11 of the webs is determined by the desired extent to which the prongs are extended outwardly,
12 and the extent to which the web curves inward toward the centerline axis. The space
13 between the shoulders and the web portions defines a slot 60A-60D.

14 Referring specifically to Figure 5, the staple 50 is deformed so that prongs 52A-52D
15 extend outwardly from the centerline axis, prior to deployment into tissue. As with the
16 previous embodiment, it is advantageous to extend the prongs outwardly as shown so as to
17 grasp a large portion of tissue, and so that insertion of the prongs into the tissue occurs at a
18 locus away from the wound site, thereby providing a more consistent wound closure (by
19 closing the wound with more of the surrounding tissue) and ensuring complete (or near
20 complete) closure of the wound. To deform the staple into the position shown in Figure 5, a
21 force F_1 is applied to webs 54A-54D, as shown in relief in Figure 5A. Force F_1 is generally
22 outward from the centerline axis and causes the webs to deform outwardly, i.e. straightening
23 the bend of the web by moving the centermost point of the web outwardly. By deformation
24 of the web portions in this manner, the prongs move outwardly. Thus, the cross-sectional
25 diameter of the staple gets larger at the distal end (with respect to the cross-sectional diameter
26 of the formed staple of Figure 4). Note that the movement of the prongs is generally greater at
27 the distal portions thereof than at the proximal portions thereof, thus producing a staple with
28 outwardly extending prongs. For completeness, it should be noted that a holding force may
29 be applied downwardly (i.e., substantially parallel to the centerline axis) against the top of the
30 webs in slots 60A-60D to hold the staple in place. Also, it is preferred that these forces are
31 simultaneously applied to each web of the staple to produce uniform deformation of each
32 prong of the staple. As mentioned above, it is preferable that the deformation of the staple is
33 plastic, so that the staple does not tend to return to the shape depicted in Figure 4.

1 Deformation of the staple into this position will be described in greater detail below in
2 reference to the preferred stapler device of the present invention.

3 Figure 6 depicts the staple 50 in a closed or deployed position. The closed position,
4 as stated herein generally means that the prongs of the staple are moved inwardly toward
5 each other. To draw the staple into the closed position depicted in this Figure, a force F_3 is
6 applied to the inner surfaces 62A-62D of the shoulders. This force is generally orthogonal to
7 the centerline axis, and the angle between each force approximates the angle between the
8 inner surfaces 62A-62D about the centerline axis (which, in the staple of this embodiment is
9 approximately 90 degrees). This force urges the shoulders outwardly. Note that shoulders
10 can only extend outwardly as far as the web portions will permit. Outward movement of the
11 shoulders causes the prongs to move toward each other, since, there is a general pivot about
12 the web portions. Opposite to the movement of Figure 5, deformation shown in Figure 6
13 results in an expanded cross-sectional diameter of the proximal end of staple, and a
14 diminished cross-sectional diameter of the distal end of the staple (with respect to the formed
15 staple of Figure 4 and the deformed staple of Figure 5). Again, deformation of the staple 50
16 into this position will be described in greater detail below in reference to the preferred stapler
17 device of the present invention.

18 In either embodiment described above, it should be evident that although the Figures
19 depict four each of the prongs, tabs and shoulders, this should be only be considered
20 exemplary. It may be desirable to adapt the staple 10 or the staple 50 with more or fewer
21 prongs, tabs and shoulders for a given application. Also, it is not necessary that each prong is
22 the same length, or that each prong has the same overall dimensions. In alternative
23 embodiments, the entire staple, or selected portions thereof can be alternatively fashioned
24 from an elastic or shape memory (e.g., nitinol, and/or other elastic materials, including for
25 example temperature dependant shape memory materials) material thereby permitting elastic
26 deformation from the a static closed position to an expanded position and then elastically
27 close about the wound. Also, the embodiment of Figures 4-6 can be adapted with a tissue
28 stop positioned along the length of the prong, as shown in Figure 3A.

29 Stapler Device

30 Another aspect of the present invention is a stapler device to deploy the staple 10 of
31 Figures 1-3, the staple 10' of Figure 3A, and the staple 50 of Figures 4-6. As a general
32 overview, the stapler of the present invention includes a distal tip for holding and deploying a
33 staple, and an actuator mechanism to cause a staple, or at least the tissue piercing portions of
34 a staple, to expand outwardly and then close about a wound. The stapler of the present

1 invention facilitates one object of the present invention to ensure that the staple closes a
2 greater amount of tissue as compared with conventional stapling mechanisms. The following
3 description will detail various exemplary mechanisms to accomplish this goal, but it should
4 be recognized that numerous alternatives will be readily apparent to those skilled in the art,
5 and all such alternatives are to accomplish these objectives are deemed within the scope of
6 the present invention.

7 Figure 7 depicts an isometric view of one embodiment of a stapling device 100 of the
8 present invention. The device generally includes an actuation mechanism 104 and a distal tip
9 102. Figure 8 is a more detailed view of the distal tip 102 of the stapler device 200. The
10 distal tip preferably comprises an inner rod member 110 slidable within an outer sleeve 112.
11 Rod 110 includes a flared or mandrel portion 114. Mandrel 114 also includes slots 118A-
12 118D, which in use are aligned with fingers 116A-116D. Fingers 116A-116D mate with slots
13 20A-20D and 60A-60D of the staple 10 and 50, respectively. Preferably, rod 110 is
14 removable for staple attachment thereto, where a staple is positioned between the mandrel
15 and the sleeve. The mandrel, as will be described below, is responsible for the forces
16 generated on the staple.

17 Figures 9, 10A, 10B, 11A and 11B depict the working relationship between the staple
18 10' and/or 50 of the present invention and the mandrel 114/sleeve 112 of the stapler
19 mechanism 200. In Figure 9A, the staple 10' is placed between the mandrel 114 and sleeve
20 112. Slots 20A-20D of the staple engage fingers 116A-116D of the sleeve. The prongs 12A-
21 12D of the staple are dimensioned so as to fit over the mandrel, and tabs 14A-14D are
22 dimensioned so as to fit over the rod 110, as shown. Similarly, for the staple 50 shown in
23 Figure 9B the staple 50 engages the mandrel 114 and sleeve 112 (not shown). This is a static
24 position, as no forces are applied to the staple to cause deformation. In Figure 10A, the staple
25 10' is urged into the first deformed position (of Figure 2) by the relative movement of the
26 rod/mandrel and the sleeve. As shown, the mandrel is urged proximally. As the mandrel
27 moves, the tabs of the staple meet the narrowest part of the mandrel. Further movement
28 forces the tabs to move outwardly, causing the prongs to likewise move outwardly (as
29 described above with reference to Figure 2). Once the tabs clear the mandrel, outward
30 movement of the tabs and prongs ceases. Similarly, in Figure 10B, the movement of the
31 mandrel forces webs to extend outwardly causing the prongs to extend outwardly (as
32 described above with reference to Figure 5). Once the webs clear the mandrel, outward
33 movement of the prongs ceases. Figure 11A depicts final deployment of the staple into
34 tissue. As the mandrel is drawn further proximally and once the tabs have cleared the

1 mandrel, the shoulders (not shown) are spread outward, forcing the prongs to move together
2 (toward the centerline axis) and closing tissue therebetween. Figure 11B depicts the same
3 actuation, but for the staple 50 of Figures 4-6.

4 Figures 12-15 depict an exemplary actuator mechanism 104, showing the relative
5 motion of the sleeve 112 and the mandrel rod 110. The mechanism includes a cam 408
6 movable in a linear motion along a slot 412. Movement of the cam can be manual or through
7 an electronically controllable motor (not shown). The cam 408 has lobes 408A and 408C
8 located on a first side of the cam 408 and a lobe 408B located on a second and opposing side
9 of the cam 408. A first cam follower 418 is coupled to the mandrel rod 110, and is selectably
10 engagable with lobes 408A and 408C. A second cam follower 416 is coupled to the sleeve
11 112, and is selectably engagable with lobe 408B. Figure 12 depicts that neither cam follower
12 is in contact with the lobes, and is indicative of an initial position of the mechanism.

13 Figure 13 depicts the mechanism 104 in a position to expand the staple between the
14 mandrel 114 and the sleeve 112, as shown in Figure 9A. As cam 408 is moved (as indicated
15 by the arrow), lobe 408A urges cam follower 418 along slot 426. The mandrel rod 110 is
16 moved proximally, causing the prongs to extend outwardly (as shown in Figure 2 and 5) as a
17 result of the force of the mandrel 114 on the tabs or the web portions. With further movement
18 of the cam 408 (Figure 14), lobe 408B now urges cam follower 416 to move distally, thereby
19 moving the sleeve distally relative to the mandrel rod and causing further expansion of the
20 prongs and causing the staple to move distally. Finally, in Figure 15, the cam is urged yet
21 further and cam follower 418 is urged by lobe 408C causing the mandrel and mandrel rod to
22 extend further proximally. This relative movement between the cam rod and the sleeve
23 causes the mandrel to apply a force to the shoulder portions of the staple, in turn causing
24 inward movement of the prongs. Lobe 408C causes closure of the prongs and decouples the
25 staple from the mandrel. This is the fully deployed staple movement.

26 Figures 16 and 17 show an alternative cam mechanism. Similar to the previous
27 example, cam 608 is urged in a direction indicated by the arrow to cause relative motion
28 between the mandrel rod and the sleeve. Lobes 608A and 608B are located on opposite sides
29 of cam 608. As the cam 608 is moved along slot 612, the lobe 608A urges a cam follower
30 618 in a linear motion along a slot 626. This urges the cam follower 618 proximally. The
31 cam follower 618 is coupled to a mandrel rod 604. This deforms staple 10/50 in the second
32 configuration (see Figure 2 or 5). As the cam 608 is urged further, the cam follower 618
33 moves distally to stay in contact with the lobe 608A. This urges mandrel rod 604 distally.
34 The same movement of the cam 608 urges lobe 608B to urge cam follower 616 distally. The

cam follower 616 is coupled to a sleeve 606. This urges sleeve 606 distally. The downward slope of lobe 608A is parallel with upward slope of lobe 608B so the mandrel rod 604 and the sleeve 606 move distally in unison and the staple is advanced into the tissue. The movement of the cam follower 618 down the slope of lobe 608A then ceases while the movement of cam follower 616 continues up the slope of lobe 608B, the staple 10/50 is deformed into the closed or deployed configuration (see Figure 3 or 6). Springs 614 and 650 can be provided to return cam followers 616 and 618, respectively, to an initial position. Of course an additional spring can be provided in slot 612 to move cam 608 back to an original position.

Alternatively, the actuation mechanism can include a rotating drum (not shown) to replace the cam 408 and 612. The drum may be adapted with lobes formed thereon, similar to lobes 408A-408C and 608A-608B, respectively. Other alternatives may include a rotating screw having a variable width in accordance with lobes 408A-408C or 608A-608B to actuate the mandrel rod and/or sleeve. Of course, instead of the cam mechanisms depicted in the Figures, direct linkage may be used to actuate the mandrel rod and/or sleeve.

Wound Site Management

1. First Exemplary Introducer

Figures 18-26 depict one exemplary structural and procedural embodiment of wound site management during and after a medical procedure, such as angioplasty. Figure 18 depicts a conventional tubular sheath 500 extending through the skin, soft tissue and the puncture in the vessel wall of a patient. Typically, the sheath 500 is left in place following a completed medical procedure. To start the stabilization process of the wound site, the doctor inserts a flexible guide wire 502 through an opening 504 in the end of the dilator 500. Figure 19 shows removal of the sheath 500 from the wound site after the guide wire 502 is properly inserted through the skin and into the artery.

To facilitate efficient and effective wound closure, another aspect of the present invention provides an introducer formed to stretch the wound site.. Figure 20 depicts an exemplary introducer 510 of the present invention, and continues the process from Figures 18 and 19 where the introducer 510 slides over the guide wire 502 until a portion of the dilator 520 is placed into the artery. Details of the introducer 510 are disclosed below.

Figure 20 depicts the introducer 510 inserted over the guide wire 502 (already in the artery) and into the artery. The introducer is comprised of a hollow elongated guide sheath 512 and dilator 520. Referring to Figure 20A, the doctor urges the distal end 516 of the dilator 520 into and through the guide sheath 512 (over guide wire 502)??]. A flexible distal end 516 of the dilator 520 into the wound, until the presence of fluid (blood) within the

1 blood marking lumen 540 indicates that the dilator 520 is properly positioned in the artery.
2 The blood marking lumen 540 is located at a predetermined length along the dilator 520 to
3 allow blood to flow through a cavity (lumen) 540 to alert the doctor that the dilator 520, and
4 more specifically the flexible distal end 516, is properly inserted in an artery to a desired
5 depth. The distal end 516 of the dilator may include a tapered tip portion 522 to facilitate
6 easier ingress through the skin and into the artery. An additional blood marking passageway
7 (not shown) can be included proximal to the first blood marking passageway on the dilator or
8 on the distal end of sheath 512 as precautionary indicator of the depth of the dilator. Presence
9 of blood in this additional passageway is indicative of the dilator being pressed too far and
10 into the arterial wall or into the artery. Of course, those skilled in the art will recognize that
11 the introducer 510 will include internal passageways (lumens) for blood marking and the
12 guide wire.

13 One feature of the guide sheath of this exemplary embodiment is the use of two or
14 more wire guides 514 to maintain the sheath located on the wound site, to provide
15 approximation of opposing sides of the wound, to ensure that the closure device (e.g.,
16 stapler/staple, suturing device, cauterization, etc) remains located about the wound so that a
17 closure device is properly deployed, and to provide unobstructed access to the wound site. In
18 this embodiment, wire guides 514 are formed on opposing sides of the guide sheath 512.
19 Having the wire guides 514 on opposing sides helps to ensure that not only is the distal end of
20 the sheath located on the wound site, but that the sheath is approximately centered thereon.
21 The wire guides are delivered into the artery by the dilator 520, as shown in Figures 21 and
22 26. The wire guides are removably coupled to or contained within the distal end 516 of the
23 dilator 520 and deployed into the wound, as shown in Figure 26. The wire guides can be
24 releasably held in openings or slots (not shown) on the sides of dilator. Once the dilator is
25 properly inserted into the wound to a proper depth (as indicated by the BM passageway), the
26 dilator is removed from the wound and the guide sheath. To remove the dilator 520 from the
27 guide sheath 512, the doctor (or clinician) first holds the guide sheath 512 and advances the
28 dilator 520 inward (distally) through the guide sheath 512. This decouples the wire guides
29 514A and 514B from the openings. To ensure that the wire guides 514A and 514B properly
30 decouple from the dilator 520 before the dilator is withdrawn, a mechanism is provided that
31 does not allow withdrawal until the guide rod has been inserted a predetermined distance. As
32 shown in the drawing this mechanism 530 can include a mechanism that requires a twisting
33 motion or other action prior to withdrawal. After the guide rod has been inserted the

1 predetermined distance, the doctor extracts the guide rod. This leaves the guide sheath 512
2 centered on the wound with the wire guides 514A and 514B extending inside the wound.

3 As is understood to those skilled in the vascular anatomy arts, a puncture in an artery
4 or vein has a general tendency to manifest a slit or an elongated opening generally
5 perpendicular to the length of the vessel. This is due to the circumferential (rather than
6 longitudinal) cell structure of the vascular tissue which supports radial expansion and
7 contraction of the vessel. The wire guides 514A and 514B of the present enable the wound to
8 approximate the natural state of the wound, i.e., elongated circumferentially. The sheath may
9 have a diameter approximately equal to the diameter of the opening or wound, so that the
10 distance across the wire guides 514A and 514B approximately equals the dimension of the
11 long axis of the wound, as best shown in Figure 23. Once inside the vessel, the wire guides
12 514A and 514B in this position limit movement of the sheath along the long axis, and since
13 the wound is elongated, movement along the short axis is likewise limited. In this
14 embodiment, since the wire guides 514A and 514B are disposed on opposing sides of the
15 sheath, any device inserted through the sheath will be approximately centered on the wound.
16 Additionally, the wire guides are long enough to push against the opposite vessel wall (distal
17 wall) thereby preventing the distal wall from being punctured or captured by the closure
18 device, or the vessel from being occluded by a closure activity during a closure activity at the
19 puncture site.

20 Importantly, since the wound opening tends to assume the shape shown in Figure 23
21 even in the absence of the wire guides, the opposing tissue located along the short axis tends
22 to approximate. The present invention takes advantage of this tendency. If the position of
23 the wire guides define a circumference larger than the circumference of the wound, the tissue
24 along the short axis tends to approximate more, because the tissue on the long axis is
25 stretched, thereby creating tension on the wound site. In other words, in this configuration,
26 the wire guides are dimensioned apart such that an outward force is created along the long
27 axis of the wound site, and this causes the tissue on either side of the short axis of the wound
28 to come together. It will be appreciated by those skilled in this art that the amount of tension
29 required will be tissue dependant, and thus, the overall diameter of the sheath and wire guides
30 should be sized according to the wound size and tissue strength. For example, vascular tissue
31 is relatively elastic, and can tolerate more tension than other tissues (e.g., dura-matter, duct
32 tissue, bladder tissue, etc.). The sheath and dilator of the present invention take these factors
33 into consideration and are accordingly sized for the particular tissue application.

1 However, sufficient wound site management according to the present invention does
2 not require that the wire guides stretch the wound. Rather, if the outside dimension across
3 the wire guides (i.e., the outside diameter of the sheath plus the outside diameter of both wire
4 guides) is shorter than the long axis of the elongated wound, the wire guides still serve to
5 maintain the sheath generally located (and possibly centered) on the wound. In both
6 circumstances, the wire guides ensure that a closure modality (e.g., staple) deployment is
7 more accurately centered on the wound site. As described above, when tension is created on
8 the wound site, tissue along the short axis tends to come together, and thus a certain amount
9 of tissue is available which may be advantageously grasped by the staple during closure.
10 Also, if the wound opening in the tissue is held taught by the sheath/wire guides, there is less
11 tendency for the tissue surrounding the opening to slip down into the vessel during staple
12 deployment (which would reduce the effectiveness of the closure).

13 Figure 23 also shows examples of locations S1, S2, S3, and S4 of where the prongs of
14 the staple to be inserted will line-up relative to the wound opening WO. The wire guides
15 514A and 514B are depicted disposed on opposing sides of the guide sheath 512, and more
16 specifically, the wire guides are inserted into the wound opening along the long axis of the
17 wound opening in the artery or vein, so that the wound is pulled taught along such axis.

18 Figure 22 shows the distal end of a stapler 104 with a staple 10/50 being inserted
19 through the guide sheath 512 of the introducer 510. The diameter of distal end of the guide
20 sheath 512 may be formed to expand if outward pressure is applied to inside surface of the
21 guide sheath 512. For example, slits or weakened tear seams (described below) may be
22 formed in the distal end of the guide sheath 512 to allow the diameter of the guide sheath to
23 increase when pressure is applied. Alternatively, the sheath may comprise slots on the distal
24 end to permit expansion. Figure 22A depicts a relief view of the introducer 510, and more
25 clearly depicts a slit or weakened tear seam 700. When the distal end of the stapler 104 is
26 properly inserted in the guide sheath 512, the staple can be deployed into the tissue. Figure 24
27 shows the first step of staple deployment, the process of which is described in detail above.
28 Note that in Figure 24A, the extension of the staple prongs causes the weakened tear seams or
29 slits 700A and 700B to separate. This further causes the wire guides to expand against the
30 long axis of the wound, thereby further approximating the tissue surrounding the opening.
31 The diameter formed by the prongs of the staple 10/50 is now larger than the original outside
32 diameter of the guide sheath 512. Figures 25 and 25A depict the staple fully deployed into
33 tissue, the process of which is described above. The stapler, guide sheath 512 and wire guides
34 514 can now be removed from the closed puncture site.

2. Second Exemplary Introducer

In an alternative exemplary embodiment, instead of using wire guides 514A and 514B as described above, a loop actuation wire 654 is used in conjunction with tubular stabilization guides 660A and 660B, as in the exemplary introducer assembly 510' illustrated in Figures 27-32 and 39-39A. The exemplary introducer assembly 510' comprises a guide rod 670 and a guide sheath 662. The guide rod 670 is similar to the dilator 520 of the previous embodiment, and may comprise a flexible tip portion that is inserted into the artery. Accordingly, dilator and guide rod, as used herein may be considered equivalent devices and the terms used interchangeably. As before, during use, the introducer assembly is slidably disposed about a central guide wire 502. The guide sheath 662 includes a plurality of wire stabilization guides 660 (shown as 660A and 660B in Figure 30), which may be integrated into the guide sheath 662, or alternatively, be formed separately and coupled thereto. The wire stabilization guides 660 generally comprise tubular members disposed around the outside diameter of the sheath, and the loop actuation wire is threaded into each stabilization guide, leaving end portions 656 and 657. A portion of each wire stabilization guide extends from the distal end of the sheath. Guide sheath 662 is a tubular member with an inside diameter dimensioned to slide over the guide rod 670. It is equally contemplated that the guide sheath has an oval or non-circular cross-sectional shape. The sheath further includes one or more slits or weakened tear seams 686 to provide controlled expansion of portions of the guide sheath, as will be detailed below.

The guide rod 670 is a tubular member and includes at least one slot 682 formed therein for releasably holding the loop actuation wire 654. As shown in Figure 27, the guide rod has a main tubular body dimensioned to fit inside the guide sheath and has a tapered end 800 having an opening 802 at the tip to accept the central guide wire. To releasably hold the actuation wire, at least one longitudinal slot (or slit) 682 may be formed in the guide rod 670 along its length. To permit temporary holding and controlled release of the loop actuation wire 654, the width of the longitudinal slot (or slit) 682 at the surface of the guide rod 670 may be less than the outside diameter of the stabilization guides 660 or the loop actuation wire 654, so that the stabilization guide and/or loop actuation wire 654 is held within the slot (as shown in Figure 27) until released by the sliding action of the sheath over the guide rod, as described below. The loop actuation wire and/or wire guides can be held in a slot or slit formed in the guide rod (which may define a separate lumen structure in the guide rod), or alternatively the slot can be formed with a diameter less than the width of the wire or wire stabilization guide to permit the wire or wire stabilization guide to friction fit into the slot.

1 As shown in Figures 27-29, the slot 682 may be bounded by a pair of recessed areas 658,
2 659, so that, for example, the wire guides do not catch on tissue as the guide rod is inserted
3 and removed from an artery or vein. Alternatively, instead of defined slots formed in the
4 guide rod, slits (not shown) may be formed in the material of the rod such that the loop
5 actuation wire 654 is releasably held to the guide rod in a friction fit manner, and released
6 from the guide rod in a similar manner as described above.

7 In this configuration, one end portion 656 of the loop actuation wire 654 is threaded
8 inwardly into one end of the slot 682 at the first recessed area 658 and back outwardly from
9 the slot 682 at the second recessed area 659 in the guide rod 670. Similarly, the other end
10 portion 657 of the loop actuation wire 654 may be threaded through a second slot (not
11 shown), which may optionally include a set of recessed areas (not shown) on the opposing
12 side of the guide rod 670, or elsewhere along its length. The slot 682 may be located along
13 the length of the guide rod 670. For example, as shown in Figures 27-32, the slot 682 is
14 located along a line parallel to the central axis of the guide rod 670. Of course, it is not a
15 requirement of the present invention that the slot be formed in this manner, nor that the slot
16 include recessed areas at its ends. As used herein with reference to the location of the slot(s)
17 682 and/or recessed areas 658, 659, the phrase "along the length of the guide rod" or "along
18 its length" may mean generally longitudinally along the central axis of the guide rod, or may
19 alternatively mean a slot formed in any orientation, since the slot and/or recessed areas 658,
20 659 serve to releasably hold the wire stabilization guides 660 and/or ends 656, 657 of the
21 loop activation wire in place, and one of any number of configurations of slot 682 and/or
22 recessed areas 658, 659 may suffice.

23 While not necessary to provide operability to the present invention, an opening 804
24 within the guide rod may be provided to expose a portion of the central guide wire 502. The
25 central guide wire 502 can then be placed over the loop portion 680 of the loop actuation wire
26 654 to secure the loop to the guide rod until the central guide wire is removed.

27 The foregoing assumes that the wire forming the loop has a generally circular cross
28 section. However, alternatively other wire shapes may be used, in which case the wire
29 stabilization guides 660 and slot 682 may be mated with the wire 654, in which case the end
30 portions 656, 657 would comprise one or more appropriate corresponding mating
31 components.

32 Figures 39 and 39A depict cross-sectional views of the guide rod 670 of this
33 exemplary embodiment. The guide rod 670, as depicted in Figure 40, includes a plurality of
34 lumens: 802, 804, 806 and 808. Lumens 808 and 806 are included as a blood marking

1 passageway (described herein) and a wire guide passageway, respectively. Lumens 806 and
2 808 are shown adjacent one another, but these lumens could also be formed coaxial with on
3 another (e.g., the wire guide lumen inside of the blood marking lumen). Lumens 802 and 804
4 releasably hold the loop actuation wire therein, and run along the length of the guide rod, for
5 example, as shown in Fig. 27. Lumens 802 and 804 are shown on opposing sides of the
6 guide rod. But it is equally contemplated that the lumens need not be disposed at opposition,
7 but rather may be formed at any angle with respect to one another. A slit 810 may be
8 provided such that the loop actuation wire is held in lumen 802/804 until outward pressure
9 forces the wire to "pop" out of the slit 810. To that end, the material surrounding the slit may
10 comprise material of reduced durometer (with respect to the rest of the guide rod) such that
11 the actuation wire can slide into and out of the lumen. Alternatively, instead of a slit, a slot
12 may be formed as depicted in Figure 39A. The slot 812 is defined by truncated lobes 814 and
13 816. Lobes 814 and 816 may also comprise material of reduced durometer with respect to
14 the remaining portions of the guide rod. Slot 812 can be dimensioned for a particular gage
15 wire inserted therein. Although lumens 804 and 802 are depicted as having generally circular
16 cross-sectional shapes, the present invention equally contemplates other shapes, as may be
17 dictated by the cross-sectional shape of the loop actuation wire (although the cross sectional
18 shape of the wire stabilization guide, loop actuation wire and the lumen need not match).

19 The use of the foregoing described exemplary introducer 510' will now proceed with
20 reference to Figures 27-32. As Figure 27 illustrates, the introducer 510' is initially inserted
21 into the percutaneous puncture over the central guide wire 502 (already in the artery), which
22 tracks into the puncture site, and is inserted into the artery. Once it has been determined that
23 the distal end of the guide sheath 662 has reached the approximate location of the artery or
24 venous outer wall (via blood marking described herein, or other depth-measuring or locating
25 method known in the art), the central guide wire 502 may be removed from the introducer
26 assembly 510', as shown. As shown in Figure 28, removing the central guide wire 502
27 allows the loop activation wire 654 to be released from the guide rod 670 through the
28 longitudinal slots (or slits) 682 within the guide rod 670. This is accomplished by
29 withdrawing the guide rod 670 from the guide sheath 662 as shown in Figures 28 and 29.
30 Removing the guide rod from the guide sheath forces the wire stabilization guides 660 (and
31 the loop activation wire within) out of the slots 682 defined in the guide rod by virtue of the
32 force of the end of the sheath on the wire stabilization guides as the guide rod slides
33 proximally out of the sheath, whereupon the loop actuation wire 654 and wire stabilization

1 guides 660 are released to form an open loop, as shown in Figure 29. The guide rod 670 may
2 then be completely withdrawn from the guide sheath 662.

3 As Figures 30 and 31 illustrate, the stabilization guides 660 may be secured and
4 actuated by pulling the loop actuation wire 654 at one or both end portions 656, 657 until the
5 distal ends of the stabilization guides 660A and 660B approximate to form a stabilized loop
6 portion 680. Slits or weakened tear seams 686 may be formed in the distal end of the guide
7 sheath 662 to allow the diameter of the guide sheath 662 to increase when an outwardly radial
8 force is applied to the distal end of the guide sheath 662, for example by the expansion of the
9 loop portion by the loop actuation wire 654 depicted in Figure 31. The foregoing action
10 provides opposing forces outwardly to the central axis of the guide sheath 662, thereby
11 causing the end of the guide sheath 662 to separate at its slits 686 (or weakened tear seams).
12 Additional clearance for the expansion of a closure device (not shown) within the guide
13 sheath 662 is thus provided. Furthermore, the tissue that is stretched by the stabilization
14 guides 660A and 660B is caused to slide along the newly ramped angles of the stabilization
15 guides 660A and 660B (i.e., the angle created at the junction between the guides 660A and
16 660B and the distal end of the sheath), thereby urging tissue against the distal end of the
17 guide sheath 662. The foregoing action aids in retaining the guide sheath 662 within the
18 puncture against the vessel. The closure modality (e.g., a staple, as described hereinabove)
19 may next be delivered. As shown in Figure 32, tension may then be applied to a single end
20 657 of the loop actuation wire 654 until the wire 654 is completely removed from the
21 stabilization guides 660A and 660B, thereby freeing the distal ends of the stabilization guides
22 660A and 660B allowing them to slide out of the vessel puncture on either side of the closure
23 device (not shown). Finally, the guide sheath 662 assembly may be removed from the
24 puncture site.

25 The wire stabilization guides 660A and 660B depicted in Figures 30-32 are generally
26 formed as tubular structures having an inside diameter sufficient to pass the wire ends 656,
27 657 therethrough. The guides 660A and 660B are drawn together (Figure 31) to form the
28 loop. As a general matter, the wire stabilization guides 660A and 660B in combination with
29 the loop activation wire 654 add to the stiffness of the combined area (680), since it is
30 intended that the closure of the guides causes sufficient outward force to expand the tissue
31 surrounding the wound site in a manner described in detail above. Also, this force may be
32 sufficient to expand the sheath radially by opening the slits or weakened tear seams. Note
33 that the Figures depict wire guide 660A longer than 660B, however, it is not essential that the
34 lengths of the wire guides are as depicted. Rather, the lengths may be selected to be equal or

1 non-equal without departing from the present invention. The positions of the wire guides
2 660A and 660B are depicted on opposing sides of the sheath. While this arrangement will
3 provide a more accurate centering of the sheath on the wound site, it is contemplated herein
4 that for certain procedures centering on the wound site may not be necessary, critical, or
5 accurate, and thus, the positions of the wire stabilization guides can be at locations about the
6 sheath other than at opposition.

7 Note also that in the description of the slots in the guide rod to releasably hold the
8 wire stabilization guides, the slots are formed in a location most convenient for placing the
9 wire guides into the slots. Also, the slots may be defined such that one slot releasably holds
10 the wire stabilization guide with the wire inserted therethrough, and the other slot is
11 dimensioned to releasably hold just the wire (as may be the case when the lengths of the wire
12 stabilization guides differ).

13 Thus, a single or multi-lumen sheath device may be stabilized in direct approximation
14 to an arterial, venous or other lumenal puncture. Advantageously, the foregoing described
15 devices and methodologies allow the positioning of a closure modality centered over such a
16 puncture. The foregoing described introducer assembly 510' allows the distal end of the
17 sheath 662 through which the closure device is introduced to be drawn against the artery, vein
18 or other lumen, thereby aiding in sealing the puncture site to prevent leakage, as well as
19 stabilizing the sheath 662 directly over the wound site.

20 3. Third Exemplary Introducer

21 As Figures 35 and 36 illustrate, in another embodiment, the foregoing described
22 stabilization loop portion may be replaced with a stabilization loop portion 680' comprising a
23 loop actuation wire 654 having at least one reinforced section 666. The reinforced section
24 may comprise an area of increased material or combination of materials, e.g., a section of the
25 actuation wire 654 or stabilization guide 660A and/or 660B with greater individual or
26 combined rigidity. In this configuration, the location of the reinforced section 666 may be
27 manipulated with respect to the wound site to control the shape of the stabilization loop
28 portion 680'. The stabilization guides 660A and 660B may be secured and actuated by
29 pulling the loop actuation wire 654 at one or both end portions 656, 657 until the distal ends
30 of the stabilization guides 660 approximate to form a stabilization loop portion 680' which
31 comprises the reinforced section 666, the central axis of which is generally perpendicular to
32 the central axis of the guide sheath 662, thereby providing opposing forces outwardly
33 perpendicular to the central axis of the guide sheath 662 and causing the end of the guide
34 sheath 662 to separate at its slits 686. As shown in Figure 36, the loop portion and reinforced

1 section forms a shape with the general appearance of a coat hanger. Additional clearance for
2 the expansion of a closure device (not shown) within the guide sheath 662 may likewise be
3 provided.

4 As in the previously described embodiment, the tissue which is stretched by the
5 stabilization guides 660A and 660B is caused to slide along the newly ramped angles of the
6 stabilization guides 660A and 660B and be forced against the distal end of the guide sheath
7 662. The foregoing action aids in retaining the guide sheath 662 within the puncture against
8 the vessel. The closure modality (e.g., a staple, as described hereinabove) may next be
9 delivered. As shown in Figure 32, tension may then be applied to a single end 657 of the
10 loop actuation wire 654 until the wire 654 is completely removed from the plurality of
11 stabilization guides 660, thereby freeing the distal ends of the stabilization guides 660 and
12 allowing them to slide out of the vessel puncture on either side of the closure device (not
13 shown). Finally, the guide sheath 662 assembly may be removed from the puncture site.

14 4. Fourth Exemplary Introducer

15 Figures 40-45 depict another exemplary embodiment of the introducer of the present
16 invention. In this embodiment, the wire stabilization guides are modified to include
17 intraluminal support for procedures being performed at the vascular puncture site such as
18 closure of the puncture or an anastomosis procedure. Figure 40 depicts a similar introducer
19 as is shown in Figures 27-32, except in this exemplary embodiment the wire stabilization
20 guides 660A and 660B comprise a retention device 820 formed along a portion of the guide.

21 The tissue retention device 820 is generally provided herein to secure the distal end of
22 the sheath to the tissue, e.g., to the arterial wall about the wound site. Deployment of the
23 retention device is depicted in Figures 41-45. As in the previous embodiments, the wire
24 stabilization guides 660A and 660B are deployed by moving the guide rod 670 with respect
25 to the sheath 662. The retention device 820 is formed along the length of the wire
26 stabilization guide at a predetermined distance from the end of the sheath. One utility of the
27 retention device 820 is to ensure the sheath 662 remains located on the wound site, so a
28 predetermined distance of the retention device from the end of the sheath may be chosen, for
29 example, in accordance with the thickness of the tissue in which the device is deployed.
30 Figure 43 depicts the sheath, stabilization guides and retention devices in a deployed position.
31 In this exemplary embodiment, the retention devices 820 formed on each stabilization guide
32 secures the sheath to the arterial wall to prevent transverse movement of the sheath with
33 respect to the wound site.

1 The retention device 820 of this embodiment is essentially an expanding portion of
2 the wire stabilization guide. To that end, Figures 42, 43 and 44A depict the retention device
3 deployed into the expanded position. The retention device 820 is formed by a split 822 on
4 each side of the stabilization guide 660. The loop actuation wire is affixed to the wire
5 stabilization guide, for example, at point 824. To deploy the retention device, the (656
6 and/or 657) of the wire are pulled proximally, thus causing the distal end of the wire
7 stabilization guide to be drawn proximally, and causing the retention device to compress and
8 buckle at the split sections (by placing a tensile load on the stabilization guide). To release
9 the retention device, the wire is moved distally, thereby releasing tension on the stabilization
10 guide, as shown in Figure 45.

11 Returning again to Figure 44A and 44C, compression on the stabilization guide to
12 form the retention device may also be used to expand the distal tip of the sheath at the slits or
13 weakened tear seams 686, as shown in the relaxed position (Figure 44B) and expanded
14 position (Figures 43A and C). Optionally, the stabilization guides 660A and/or 660B may be
15 of a more rigid nature and preformed in the configuration shown in Figure 44 B. Drawing the
16 stabilization guides 660A and/or 660B in a proximal direction would cause an expansion of
17 the distal tip of the sheath (Figure 44 C).

18 Figures 46-48 depict yet another exemplary embodiment of the introducer of the
19 present invention. This embodiment is similar to the embodiment of Figures 27-32 and
20 Figures 35 and 36, except in this exemplary embodiment the loop actuation wire comprises a
21 retention device 820 formed along a portion of the guide. In this embodiment, the loop
22 actuation wire forms a single loop, with a retention device 820 positioned on one or both wire
23 stabilization guides adjacent the sheath. Other features depicted in the Figures are the same
24 as the previous embodiment, described above.

25 Figures 49-57 depict numerous exemplary embodiments of the retention device of the
26 present invention. The retention device 820 in each of the figures is depicted in partial cut-
27 away view, showing the stabilization guide 660 and wire 654. Figure 49A and 49B depict
28 detailed views of the retention device 820 of the previous embodiment in the relaxed (static)
29 and deployed positions, respectively. In Figure 50, the retention device 820' comprises a
30 tubular member with a hollowed out notch portion (or skive) 824 formed along the length
31 thereof. Compression of the tubular member causes the material opposite the notch to
32 collapse thereby forming the retention device (Figure 50B). In Figure 51, the retention
33 device 820'' comprises a tubular member with a plurality of filaments 826 that fold (upon
34 compression) to form the retention device. In this case, a small loop is formed.

1 Alternatively, a buckle (not shown) is formed having a U-shape that does not form a
2 complete loop. In Figure 52, retention device 820''' comprises a tubular member with
3 generally symmetrical notches (or skive) on either side, 840 and 842, with slots emanating
4 from the notches which overlap approximately midway between the notches. The slots
5 overlap forming a through-hole approximately equal to the inside diameter of the tube. The
6 cross section of the tube in the area of the slot is that of a U-shaped beam. Compression
7 causes the tubular member to fold at the notched sections 840 and 842, fulcruming on the
8 wire at the location where the slots overlap, as shown in Figures 52B and 52C.

9 Figure 53 depicts yet another exemplary embodiment of a retention device 900 that is
10 similar to the example shown in Figure 51, except the retention device 900 comprises a
11 single strand member 902 between a stationary member 904 and a moveable member 906.
12 The moveable member 906 is moved over the wire guide 660 towards the stationary member
13 904 buckling the strand 902, as shown in Figure 53B. Similarly, in Figure 55 the moveable
14 member 906 is brought closer to the stationary member 904 to form a loop from the strand
15 902. In the retention device 900' of Figure 54, the strand 902' is disposed off-line (i.e., off
16 axis) between the stationary member 904 and the moveable member 906 (Figure 54A).
17 Movement of the moveable member 906 forms a loop as shown in Figure 54B (the loop in
18 Figure 54B is somewhat distorted as compared to the loop of Figure 55B). Figures 56A and
19 56B depict another exemplary retention device that utilizes a resiliently deformable member
20 908 that is compressed along the axis of the wire thus causing expansion of the member 908
21 in the plane substantially normal to the wire. Figure 56B depicts expansion in all direction in
22 the plane normal to the wire, however, the expansion in all directions is not necessary.
23 Figures 57A and 57B depict an expanding mesh retention device 910. In this embodiment,
24 mesh is formed by a plurality of individual strands which expand outwardly upon
25 compression (as indicated by the arrows).

26 In the embodiments of Figures 40-57, the retention device of the present invention
27 may be viewed as an extension or lobe formed on one or both stabilization guides, or, in the
28 case of the loop structure of Figures 46-48, the retention device may be formed on opposing
29 sides of the loop, as shown. The retention device examples of Figures 49-57 are intended to
30 apply to both the embodiments of Figures 40-45 and/or 46-48. The orientation of the
31 retention device with respect to the wire stabilization guide or loop is depicted as generally
32 perpendicular thereto, but the retention device may be formed from greater than 0 degrees to
33 less than 180 degrees from wire stabilization guide or loop and still work as intended. The
34 present invention covers all such alternatives. The orientation of the retention device with

1 respect to the wound opening is depicted, for example in Figures 43, 45 and 47, as being
2 generally perpendicular to the long axis of the wound. However, this angle is not a
3 requirement of the present invention, but rather the retention device can be disposed at any
4 angle with respect to the long axis of the wound.

5 Figures 58 and 59 depict yet another exemplary embodiment of the retention device
6 applicable to any of the devices shown in Figures 40 through 48. In this example the wire
7 guides 660A and 660B are slidably disposed within cannulated members 912, respectively,
8 on the sheath. Members 912A and 912B are attached to the sheath, as shown. This
9 configuration permits the wire guide and the retention device to be drawn proximally, i.e.,
10 closer to the distal end of the sheath. Such a slidably disposed wire stabilization feature may
11 be created with any of the retention devices represented in Figures 49 through 57, or any
12 equivalent thereof.

13 5. Fifth Exemplary Introducer

14 Referring now to Figures 60-66, a fifth exemplary introducer 1000 is depicted. The
15 introducer of this embodiment can incorporate any of the previously-described guide rod and
16 sheath devices, and further includes additional components set forth below. This
17 embodiment depicts the introducer 1000 during its use at a wound site, and thus also depicts
18 another exemplary wound site management methodology according to the invention. For
19 clarity, like components described above (for example, the sheath, dilator, wire guide,
20 retention device, stapler, staple etc.) are numbered differently in the embodiment of Figures
21 60-66 from the previous embodiments; however, it should be understood that these
22 components are interchangeable with any of the previously-described components.

23 The introducer 1000 comprises a guide rod 1002, a sheath 1004 with a transition
24 sheath 1006 covering at least the distal end of the sheath 1004, and an actuator portion 1010
25 comprising a transition sheath retractor 1012, a receiver 1014, a dilator slide 1016 and a
26 dilator handle 1018. The dilator handle 1018 is slidably disposed on the dilator slide 1016.
27 The retractor 1012 is slidably disposed on the sheath 1004 and receiver 1014 which are
28 fixedly attached. The transition sheath 1006 is provided to smooth and protect the juncture
29 between the distal end of the sheath 1004 and the guide rod 1002. The transition sheath is
30 provided so that when that portion of the device is urged through the skin and superficial
31 fascia (as depicted in Figure 60), the transition sheath reduces the tendency of snagging on
32 tissue.

33 The sheath 1004 (and transition sheath 1006), transition sheath retractor 1012,
34 receiver 1014 and dilator slide 1016 are generally tubular members that provide access

1 therethrough to the wound site at the distal end of the sheath, as will be explained below.
2 Referring now to Figure 61, once the dilator tip is within the vessel (as may be determined by
3 one or more blood marking passageways associated therewith as described herein) and the
4 distal end of the sheath is in close proximity to the vascular wound site, the transition sheath
5 is retracted to expose at least a portion of the distal end of the sheath. To do so, the sheath
6 retractor 1012 is moved proximally with respect to the receiver 1014 (as indicated by the
7 arrow). The transition sheath 1006 is attached to the sheath retractor 1012 at, for example,
8 joint 1020. The transition sheath is slidably disposed over the sheath 1004, and thus moving
9 the transition sheath in this manner exposes the distal tip 1022 of the sheath 1004.

10 In this exemplary embodiment, the dilator 1002 is housed within the actuator portion
11 1010. In Figure 62, the dilator 1002 is urged distally (i.e. further into the artery) by sliding
12 the dilator handle 1018 distally over the dilator slide 1016. Within the dilator slide, the
13 dilator 1002 abuts against the dilator handle, so that as the dilator handle is moved so does the
14 dilator. To facilitate this action, a slot 1050 is defined along the length of the slide 1016, and
15 a tab portion (not shown) of the handle 1018 extends into the slot and contacts the proximal
16 end of the dilator (also not shown) housed within the slide 1016. Moving the dilator 1002
17 distally further into the vessel also exposes the wire guides 1024 that are removably affixed
18 within the dilator (e.g., by the same manner as described in the previous embodiments). As
19 the handle 1018 is moved distally, a finger protruding from the distal surface of the handle
20 1018 and into the receiver 1014 also activates a mechanism contained within the receiver
21 1014 which causes the retention devices 1026A and 1026B (Figure 63) to be deployed within
22 the vessel. This action is effected by drawing the wires disposed within the wire guides,
23 thereby creating a retention device as is detailed above. The retention devices 1026A and
24 1026B operate to grip the inside wall of the artery and draw the sheath 1004 towards the
25 arterial wall to stabilize the wound site, in a manner described above.

26 In Figure 63, the slide 1016, handle 1018 and dilator are removed from the remaining
27 portions of the introducer. In this exemplary embodiment, the handle 1018 and slide 1016
28 are removed by drawing these components proximally from the receiver 1014. By removing
29 the dilator 1002, the retention devices 1026A and 1026B retract proximally toward the
30 sheath 1004 to grip the tissue located between the retention feet and the sheath. A retention
31 device actuator lever 1028 is provided to manually retract retention devices 1026A and
32 1026B (associated with each wire guide 1024A and 1024B, respectively).

33 Figure 64 depicts a closure device 1030 inserted into the tubular structures of the
34 receiver 1014, the sheath retractor 1012 and sheath 1004, once the dilator is removed as

1 described with reference to Figure 63. The closure device can be a stapler as set forth in the
2 description of Figures 7-17 of the present invention, or other tissue closing device such as a
3 tissue clip delivery device and/or other stapler known in the art. Figures 65 and 66 depict
4 details of staple delivery, and further details of the distal tip of the sheath. In Figure 65, the
5 stapler 1030 is inserted down through the remaining portions of the introducer to the wound
6 site. Figure 66 shows the area around the wound site in greater detail. In this exemplary
7 embodiment (and assuming the transition sheath 1006 is retracted proximally as described
8 above) the distal tip of the sheath 1004 includes a plurality of slots 1038A and 1038B. The
9 slots expose the prongs of the staple 1036 which is deployed into the tissue. Recall from the
10 above-description of the staple and stapler that the prongs of the staple are designed to
11 expand outwardly, pierce the vessel wall, and then fold inwardly to close the wound. Lever
12 1032 (Figure 65) of the stapler 1030 performs this function, and is described in detail above.
13 After the staple is deployed, the retention devices 1026A and 1026B are released, and the
14 entire device (including wire guides 1024A and 1024B) is removed.

15 6. Blood Marking

16 The following description of identifying insertion depth of a transluminal device
17 applies to any of the introducer embodiments described herein. Blood marking lumens may
18 be provided with the sheath, the guide rod (dilator), or both. Figures 33 and 34 show blood
19 marking lumens associated with the sheath 602. As shown, two "flash back" blood marking
20 lumens 689A and 689B are fixedly attached to the guide sheath 662. At the distal end of the
21 first blood marking lumen 689A is an intraluminal blood marking port 674 located at a
22 predetermined point in relation to the distal end of the sheath. The proximal end of the first
23 blood marking lumen 689A is an interluminal flashback port 684 for observing the presence
24 of blood at the intraluminal blood marking port 674. At the distal end of the second blood
25 marking lumen 689B is a blood marking port 675 located approximately at the distal end of
26 the guide sheath 662, and the proximal end of the second blood marking lumen is an
27 extraluminal flashback port 688 for observing the presence of blood at the extraluminal blood
28 marking port 675.

29 In operation, the introducer assembly is introduced into the percutaneous puncture
30 which tracks into the puncture site, as described hereinabove. The location at which the
31 guide sheath 662 has reached the approximate location of the artery or venous outer wall may
32 be identified by observing the pressurized blood flow from the internal flashback port 684,
33 which enters the internal blood marking port 674 when the internal blood marking port 674
34 has reached the inner lumen of the vessel. The absence of pressurized blood flow observed at

1 the internal flashback port 684 indicates that the guide sheath 662 has not yet reached the
2 vessel outer wall or that the internal blood marking port 674 has not reached the inner lumen
3 of the vessel. The fact that the guide sheath 662 has not entered the inner lumen of the vessel
4 may be confirmed by the absence of pressurized blood flow observed at the external
5 flashback port 688. Blood flow would enter the extraluminal blood marking port 675 only if
6 the extraluminal blood marking port 675 has reached the inner lumen of the vessel.
7 Likewise, presence of blood in this lumen indicates the guide is too far into the artery or vein.
8 The presence of pressurized blood flow at the internal flashback port 684 and absence of
9 pressurized blood flow at the external flashback port 688 indicate that the distal end of the
10 guide sheath 662 is sufficiently inserted into the wound site and adjacent to the arterial or
11 venous outer wall.

12 Figures 37 and 38 depict alternative embodiments for bloodmarking associated with
13 the dilator. Figures 37 and 38 may be considered alternative exemplary embodiments to the
14 blood marking description of Figures 20A and 39. In Figure 37, the BM lumen 540 includes
15 a sensor 700 (e.g., differential pressure transducer, flow sensor, electrodes, etc.) to detect the
16 presence of fluid or fluid flow thereon. The wiring for the sensor can be routed through the
17 lumen 540, as shown, to transmit a signal of the pressure (or presence of fluid) at the sensor
18 700. In Figure 38, an optical fiber 702 is placed in lumen 540 for direct viewing of the area
19 around BM port to identify the presence of a vascular inner lumen.

20 Thus, the foregoing-described steps provide a method for identifying the depth of
21 insertion of the transluminal device into an artery or vein based on the presence of
22 pressurized blood internal to the vessel and the absence of pressurized blood external to the
23 vessel. Alternatively, more than two blood marking points, lumens, and ports may be
24 provided to further aid in determining precisely the depth of the inserted transluminal device.
25 Furthermore, it is contemplated that the foregoing described insertion depth identifying
26 technique may have utility in other contexts, as well, and those skilled in the art will
27 recognize that the foregoing technique should not be limited to the context described
28 hereinabove.

29 As described above, the wire guide, the stabilization loop portion, or the loop
30 actuation wire may be used to cause tension against the surrounding tissue, thereby aiding in
31 approximately centering an introducer about the wound site, as well as in allowing opposing
32 sides of the tissue surrounding the wound site to approximate one another. Also, the wire
33 guides may be sized so that, when inserted into the artery they abut the opposing (distal) wall
34 of the vessel so that the proximal wall at the wound site is pushed away from the distal wall

1 to prevent the closure device from piercing the distal wall. In alternative embodiments,
2 instead of the slits or weakened tear seams of the sheath as described herein, the sheath may
3 instead comprise a helical structure that is expandable and contractable in the radial direction
4 to provide the wound site stretching and expansion for the closure device that is described
5 above. It is further contemplated that alternatives of the embodiments described above may
6 be implemented consistent with the invention for stretching the wound site and for centrally
7 locating procedures at the wound site. For example, in the above-described embodiments,
8 loop portions provide a force to the wire and the guide sheath to spread the sheath outwardly
9 and to approximate opposing portions of the wound site, as shown and described. However,
10 in still other embodiments, the guide sheath can be formed having a biasing mechanism that
11 forces the sheath into the opened or spread position as shown in Figures 31 and 36. To that
12 end, this sheath may further comprise flexible members on either side that provide the
13 aforementioned outwardly opposing forces on the tissue surrounding the wound site.

14 There are many alternatives to the foregoing description of Figures 18-66 that will be
15 apparent to those skilled in the art. For example, the wire forming the loop structure
16 described herein may be provided as a single continuous loop that is pre-threaded into the
17 wire stabilization guides. In this case, the loop is closed by pulling on the free end of the
18 wire. The wire may be snapped or cut so that it can be pulled free of the sheath and the wire
19 stabilization guides. Other modifications may be made. For example, the sheath may be
20 adapted with holding mechanisms (not shown) to hold the ends of the wire in place once the
21 doctor has pulled on the free ends to form the loop. Still other modifications may be made.
22 For example, instead of using wire in cooperation with the tubular wire stabilization guides to
23 form the loop, the present invention contemplates that this arrangement can be replaced with a
24 single elongated member (e.g. similar to the wire stabilization guide described herein) affixed
25 to the guide sheath on opposing sides so that pulling this member forms the loop as shown in
26 the drawings. In other words, the wire stabilization guide and wire described above may be
27 replaced with a single member of sufficient modulus to form the loop as set forth herein. The
28 wire described herein may comprise a tube, filament, stranded filaments, or other structures
29 that are equivalent.

30 With any of the embodiments described above, the slits or weakened tear seams
31 formed on the distal tip of the sheath (Figures 22A, 24A, 25A, 27-36, 40-48, and 66) permits
32 expansion of the distal tip to cause the wire guides to stretch the wound site, as detailed
33 above. Although the drawings have been described as having two slits or weakened tear
34 seams on opposing sides of the sheath, the present invention is not so limited. The present

1 invention could alternatively comprise a single slit or tear seam, where expansion of the distal
2 tip is caused by “buckling” of the device to cause radial expansion. Alternatively, three or
3 more slits or tear seams could be formed. In still other alternative embodiments, the sheath
4 may generally comprise an expandable distal tip. For example, the distal tip of the sheath
5 may include bellows or baffles to permit expansion thereof. Alternatively, the distal tip may
6 be formed of an elastomeric material that permits expansion in the radial direction. All such
7 alternatives are deemed within the scope of the present invention.

8 Still other modifications can be made. For example the stabilization guides have been
9 described herein as being generally tubular so that wire can be threaded therethrough.
10 However, this is only an exemplary arrangement. The stabilization guides and wire could be
11 coupled together in other configuration, for example, sliding engagement that may comprise a
12 tongue-and-groove coupling, dovetail coupling, or other arrangement that would permit
13 relative motion between the stabilization guides and the wire, while still providing
14 mechanical strength along at least one axis. Although the present invention has been
15 described in relation to particular embodiments thereof, many other variations and
16 modifications and other uses will become apparent to those skilled in the art.

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1 What is claimed is:

2 1. A medical device, comprising:

3 a tubular sheath having a plurality of spaced apart wire stabilization guides, said wire
4 stabilization guides comprising elongated tubular members having at least a portion thereof
5 extending from an end of said sheath;
6 a retention device formed on said portion of at least one wire stabilization guide extending
7 from said end of said sheath, said retention device comprising a portion of said wire
8 stabilization guide adapted to selectively expand outwardly from said wire stabilization guide
9 in at least one direction.

10 2. A device as claimed in claim 1, further comprising a guide rod sized to fit within said
11 tubular sheath and having at least one slot formed along its length, said at least one slot
12 releaseably holding one respective said wire stabilization guide.

13 3. A medical device as claimed in claim 1, further comprising wire moveably disposed
14 within said wire stabilization guides, said wire being fixed to said wire stabilization guide at a
15 point along said wire stabilization guide, wherein movement of said wire in a proximal
16 direction causes a compression of said wire stabilization guide thereby forming said retention
17 device.

18 4. A medical device as claimed in claim 3, said retention device comprises a slit on one
19 or more sides of said tubular stabilization guides and wherein said wire being drawn
20 proximally thereby compresses said retention device causing a portion of said stabilization
21 guide about said slit to expand outwardly in at least one direction.

22 5. A medical device as claimed in claim 3, said retention device comprising one or more
23 notch sections of said tubular stabilization guides and wherein said wire being drawn
24 proximally thereby compresses said retention device and causes a portion of said stabilization
25 guide about said notch to expand outwardly in at least one direction.

26 6. A medical device as claimed in claim 5, wherein said notch sections are generally
27 symmetrical on either side of said tubular stabilization guide, wherein compression of said
28 tubular stabilization guide causes folds at said notch sections.

29 7. A medical device as claimed in claim 3, said retention device comprises one or more
30 filament attached to said tubular stabilization guides and wherein said wire being drawn
31 proximally thereby compressing said retention device and causing said one or more filaments
32 to expand outwardly in at least one direction.

33 8. A medical device, comprising:

1 a tubular sheath having two wire stabilization guides, said wire stabilization guides
2 comprising an elongated tubular member having at least a portion thereof extending from an
3 end of said sheath;

4 a retention device formed on said portion of said wire stabilization guide extending
5 from said end of said sheath, said retention device comprising a portion of said wire
6 stabilization guide adapted to selectively expand outwardly in at least one direction and
7 further comprising a wire having two ends threaded into said wire stabilization guides and
8 moveably disposed within said wire stabilization guides and thus forming a loop extending
9 from said end of said sheath, said wire being fixed to each said wire stabilization guide.

10 9. A medical device as claimed in claim 8, said retention device comprises a slit on at
11 least one side of said tubular stabilization guides and wherein said wire being drawn
12 proximally thereby compressing said stabilization guides at said point where said wire is
13 fixed to said wire stabilization guides, and causing a portion of said stabilization guide about
14 said slit to expand outwardly in at least one direction.

15 10. A medical device as claimed in claim 8, said retention device comprising one or more
16 notch sections of said tubular stabilization guides and wherein said wire being drawn
17 proximally thereby compresses said retention device and causes a portion of said stabilization
18 guide about said notch to expand outwardly in at least one direction.

19 11. A medical device as claimed in claim 10, wherein said notch sections are generally
20 symmetrical on either side of said tubular stabilization guide, wherein compression of said
21 tubular stabilization guide causes folds at said notch sections.

22 12. A medical device as claimed in claim 8, said retention device comprises one or more
23 filament attached to said tubular stabilization guides and wherein said wire being drawn
24 proximally thereby compressing said retention device and causing said one or more filaments
25 to expand outwardly in at least one direction.

26 13. A medical device as claimed in claim 1, said retention device securing said sheath to
27 an arterial wall to prevent transverse movement of said sheath with respect to a wound site in
28 said arterial wall.

29 14. A medical device as claimed in claim 8, said selectively deployable extension
30 member securing said sheath to an arterial wall to prevent transverse movement of said
31 sheath with respect to a wound site in said arterial wall.

32 15. A medical device as claimed in claim 1, wherein said wire stabilization guides being
33 disposed opposite one another on said sheath approximately 180 degrees apart.

1 16. A medical device as claimed in claim 7, wherein said wire stabilization guides being
2 disposed opposite one another approximately 180 degrees apart.

3 17. A medical device as claimed in claim 1, wherein said wire stabilization guides are
4 placed into a wound site in an artery or vein such that said wire stabilization guides are
5 transverse to a long axis of said artery or vein.

6 18. A medical device as claimed in claim 7, wherein said wire stabilization guides are
7 placed into a wound site in an artery or vein such that said wire stabilization guides are
8 transverse to a long axis of said artery or vein.

9 19. A medical device as claimed in claim 17, wherein said wire stabilization guides urge
10 said wound site into an elongated configuration.

11 20. A medical device as claimed in claim 18, wherein said wire stabilization guides urge
12 said wound site into an elongated configuration.

13 21. A medical device as claimed in claim 14, wherein said loop is internal within said
14 wound site when said wire stabilization guides are placed within said wound site.

15 22. A method for stabilizing a wound in an artery or vein, said method comprising the
16 steps of:

17 approximating an elongated sheath to a wound site;

18 placing a loop activation wire into said wound site;

19 placing said loop activation wire approximate to tissue surrounding said wound site;

20 and

21 deploying a retention device extending from said loop, said retention device securing
22 said sheath to said wound site.

23 23. A method as claimed in claim 22, further comprising the step of allowing opposing
24 sides of said tissue surrounding said wound site to approximate one another.

25 24. A method as claimed in claim 22, further comprising the steps of retracting said
26 retention device and removing said loop activation wire from said wound site.

27 25. A method for stabilizing a wound site, said method comprising:

28 approximating an elongated sheath to a wound site;

29 inserting two wire stabilization guides into said wound site;

30 and deploying a retention device, said retention device securing said sheath to said wound
31 site.

32 26. A method as claimed in claim 25, further comprising the step of positioning said wire
33 stabilization guides wherein into said wound site such that said wire stabilization guides are
34 transverse to a long axis of said artery or vein.

- 1 27. A method as claimed in claim 25, further comprising the step of allowing opposing
2 sides of said tissue surrounding said wound site to approximate one another.
- 3 28. A medical device as claimed in claim 1, said sheath further comprises an expandable
4 distal tip section.
- 5 29. A medical device as claimed in claim 8, said sheath further comprises an expandable
6 distal tip section.
- 7 30. A medical device as claimed in claim 28, wherein said sheath is approximated to
8 tissue surrounding a wound site to hold said sheath approximately centered on said wound
9 site when said distal tip of said sheath expands.
- 10 31. An introducer, comprising:
11 a tubular sheath having two hollow wire stabilization guides, said wire stabilization
12 guides comprising an elongated tubular member having at least a portion thereof extending
13 from an end of said sheath;
14 a guide rod sized to fit within said tubular sheath and having slots formed along its
15 length, said slots releaseably holding said wire stabilization guides;
16 a retention device formed on said portion of said wire stabilization guide extending
17 from said end of said sheath, said retention device comprising a portion of said wire
18 stabilization guide adapted to selectively expand outwardly in at least one direction; and a
19 wire moveably disposed within each said wire stabilization guide, said wire being fixed to
20 said wire stabilization guide at a point along said wire stabilization guide that is distal to said
21 retention device.
- 22 32. An introducer as claimed in claim 31, wherein said wire being moved relative to said
23 stabilization guide to deploy said retention device.
- 24 33. An introducer as claimed in claim 31, wherein said wire being moved relative to said
25 stabilization guide to retract said retention device.
- 26 34. An introducer as claimed in claim 31, wherein said wire stabilization guides are
27 placed in a wound site formed in an artery or vein and disposed along a transverse axis
28 relative to a long axis of said artery or vein.
- 29 35. An introducer and claimed in claim 31, wherein said sheath further comprises an
30 expandable distal tip section and wherein when said sheath is approximated to a wound site
31 and a radial force is applied to the distal end of said sheath in a direction generally
32 perpendicular to the central axis of said sheath, said expandable section expands, thereby
33 increasing the diameter of said sheath.

1 36. An introducer as claimed in claim 35, wherein said sheath is approximated to tissue
2 surrounding said wound site to hold said sheath approximately centered on said wound site
3 when the diameter of said expandable section increases.

4 37. An introducer as claimed in claim 31, wherein said guide rod further comprises a first
5 and a second blood marking lumen, each said lumen having a flashback port at a first end and
6 a blood marking port at a second end, the blood marking port of the first said lumen being
7 fixedly disposed to said device at a shorter distance from a wound site than the blood marking
8 port of said second lumen; wherein the fact that the blood marking port of the first lumen is
9 adjacent to the outer wall of said artery or vein is indicated when pressurized blood flow is
10 present at the first said lumen and absent at said second lumen.

11 38. An introducer, comprising:

12 a tubular sheath having two wire stabilization guides, said wire stabilization guides
13 comprising elongated tubular members having at least a portion thereof extending from an
14 end of said sheath;

15 a guide rod sized to fit within said tubular sheath and having two slots formed along
16 its length, at least one slot releaseably holding one respective said wire stabilization guide;

17 a retention device formed on said portion of said wire stabilization guide extending
18 from said end of said sheath, said retention device comprising a portion of said wire
19 stabilization guide adapted to selectively expand outwardly in at least one direction; and

20 a wire having two ends, each said end threaded into a respective said wire
21 stabilization guide and thus forming a loop of wire from the wire protruding from said wire
22 stabilization guides extending from said end of said sheath.

23 39. A medical device, comprising:

24 a tubular sheath having two wire stabilization guides, said wire stabilization guides
25 comprising elongated tubular members having at least a portion thereof extending from an
26 end of said sheath;

27 a selectively deployable retention device extending from portion of said wire
28 stabilization guide extending from said end of said sheath, said selectively deployable
29 retention device securing said sheath to an arterial wall.

30 40. A medical device, comprising a tubular sheath having two spaced apart wire
31 stabilization guides, said wire stabilization guides comprising elongated tubular members
32 having at least a portion thereof extending from an end of said sheath, said sheath further
33 comprising an expandable distal tip section.

1 41. A medical device as claimed in claim 40, further comprising a guide rod sized to fit
2 within said tubular sheath, and having slots formed along its length, said slots releaseably
3 holding said wire stabilization guides.

4 42. A medical device as claimed in claim 40, wherein said wire stabilization guides are
5 placed within a wound site formed in an artery or vein, and said slit or weakened tear seam
6 permits expansion of said distal end of said sheath, thereby causing said wire stabilization
7 guides to stretch said wound site along the long axis of said wound site.

8 43. A medical device as claimed in claim 42, wherein stretching said wound site causes
9 tissue along opposing sides of the short axis of said wound site to approximate each other.

10 44. An introducer, comprising:

11 a tubular sheath and a transition sheath slideably disposed over at least a portion of said
12 sheath.

13 45. An introducer as claimed in claim 44, said sheath having at least two stabilization
14 guides slideably attached to said sheath, said stabilization guides having at least a portion
15 thereof extending from a distal end of said sheath.

16 46. An introducer as claimed in claim 45, said sheath transition sheath disposed over said
17 distal end of said sheath.

18 47. An introducer as claimed in claim 45, further comprising an elongated dilator
19 slideably disposed within said sheath and having a flexible tip portion extending from said
20 sheath.

21 48. An introducer as claimed in claim 47, said dilator comprising a first slot releasably holding
22 one of said stabilization guides, and a second slot releasably holding another said stabilization
23 guide.

24 49. An introducer as claimed in claim 47, said dilator comprising a central lumen
25 dimensioned to accept a wire guide therethrough.

26 50. An introducer as claimed in claim 45, said stabilization guides comprising flexible or
27 rigid elongated tubular or solid members.

28 51. An introducer as claimed in claim 50, further comprising a retention device formed on
29 said portion of said wire stabilization guide extending from said end of said sheath, said
30 retention device comprising a portion of said wire stabilization guide adapted to selectively
31 expand outwardly from said wire stabilization guide in at least one direction.

32 52. An introducer as claimed in claim 50, further comprising wire moveably disposed
33 within said wire stabilization guides, said wire being fixed to said wire stabilization guide at a
34 point along said wire stabilization guide, wherein movement of said wire in a proximal

1 direction causes a compression of said wire stabilization guide thereby forming said retention
2 device.

3 53. An introducer as claimed in claim 52, said retention device comprises a slit on at least
4 two sides of said tubular stabilization guides and wherein said wire being drawn proximally
5 thereby compressing said retention device and causing a portion of said stabilization guide
6 about said slit to expand outwardly in at least one direction.

7 54. An introducer as claimed in claim 52, said retention device comprises one or more
8 notch sections of said tubular stabilization guides and wherein said wire being drawn
9 proximally thereby compressing said retention device and causing a portion of said
10 stabilization guide about said notch to expand outwardly in at least one direction.

11 55. An introducer as claimed in claim 54, wherein said notch sections are generally
12 symmetrical on either side of said tubular stabilization guide, wherein compression of said
13 tubular stabilization guide causes folds at said notch sections.

14 56. An introducer as claimed in claim 52, said retention device comprises one or more
15 filament attached to said tubular stabilization guides and wherein said wire being drawn
16 proximally thereby compressing said retention device and causing said one or more filaments
17 to expand outwardly in at least one direction.

18 57. An introducer as claimed in claim 44, said sheath comprising slots formed at the
19 portion covered by said transition sheath.

20 58. An introducer, comprising:
21 a tubular sheath;
22 a transition sheath slideably disposed over at least a portion of said sheath; and
23 an elongated dilator slideably disposed within said sheath and having a flexible tip
24 portion extending from said sheath.

25 59. An introducer as claimed in claim 58, further comprising an actuator portion
26 connected to said sheath and said transition sheath comprising a transition sheath retractor
27 and a dilator handle.

28 60. An introducer as claimed in claim 59, wherein said dilator handle and retractor are
29 each slidably disposed on a dilator slide member, and wherein said retractor is slidably
30 disposed on the receiver/sheath assembly.

31 61. An introducer as claimed in claim 58, wherein said transition sheath is disposed over
32 the juncture between the distal end of the sheath and the flexible tip portion of the guide rod
33 extending from the distal end of said sheath.

1 62. An introducer as claimed in claim 59, wherein said transition sheath retractor causing
2 said transition sheath to slide over said sheath.

3 63. An introducer as claimed in claim 59, said sheath comprising at least two
4 tubular stabilization guides slideably attached to said sheath and having a portion thereof
5 extending from a distal end of said sheath, a retention device formed on said portion of said
6 stabilization guide extending from said end of said sheath, said retention device comprising a
7 portion of said stabilization guide adapted to selectively expand outwardly in at least one
8 direction; and a wire moveably disposed within each said stabilization guide, said wire being
9 fixed to said wire stabilization guide at a point along said wire stabilization guide; and
10 said actuator portion comprising a retention device actuator attached to said wire and
11 causing said wire to move within said stabilization guide to deploy or retract said retention
12 device and to cause said stabilization guides to slide proximally with respect to the distal end
13 of said sheath thereby moving said retention device toward the distal end of the sheath.

14 64. An introducer, comprising:
15 a sheath having an inside diameter and a distal end,
16 a dilator sized to fit within the inside diameter of the sheath,
17 a plurality of flexible wire guides having first ends and second ends, the first ends
18 coupled to the distal end of the sheath, wherein the sheath being approximated to a wound
19 site and the wire guides placed into a tissue wound site, said wire guides causing outward
20 pressure along the long axis of said wound site.

21 65. The introducer of claim 64, wherein the guide wires are coupled to the sheath in
22 geometrical opposed positions.

23 66. The introducer of claim 64, wherein the wire guides urge the wound opening into an
24 elongated configuration.

25 67. The introducer of claim 65, wherein said wound site is formed in an artery or vein and
26 at least two of said guide wires placed at opposing ends of said wound..

27 68. The introducer of claim 64, further comprising a blood marker to signal when said
28 dilator is inserted into the wound opening to a predetermined depth.

29 69. An introducer, comprising:
30 a tubular sheath, and
31 at least two flexible wire guides extending from said sheath in geometrically opposed
32 positions, said wire guide placed into a tissue wound site, said wire guides causing outward
33 pressure along the long axis of said wound site and holding said sheath approximately
34 centered on said wound site.

- 1 70. An introducer as claimed in claim 69, wherein said wound site is formed in an artery
2 or vein and said two of wire guides placed in said wound along a transverse axis relative to a
3 long axis of said artery or vein.
- 4 71. An introducer of claim 64, further comprising a dilator inserted into said tubular
5 sheath, at least a portion of said dilator being also inserted into said wound.
- 6 72. An introducer as claimed in claim 71, said dilator further comprising a fluid
7 passageway to permit fluid to flow therethrough to indicate when said dilator is inserted into
8 the wound opening to a predetermined depth.
- 9 73. An introducer as claimed in claim 71, wherein a portion of said wire guide being
10 removably attached to said dilator.
- 11 74. An introducer as claimed in claim 64, wherein said sheath having an outside diameter
12 approximately equal to the diameter of said wound.
- 13 75. A medical device, comprising:
14 a sheath having an inside diameter and a distal end,
15 and a plurality of flexible wire guides coupled to said sheath and extending from the
16 distal end of said sheath, wherein the sheath being approximated to a wound site and the wire
17 guides placed into a tissue wound site, said wire guides causing outward pressure along the
18 long axis of said wound site.
- 19 76. An introducer comprising:
20 a tubular sheath having two wire stabilization guides, said wire stabilization guides
21 comprising elongated tubular members having at least a portion thereof extending from an
22 end of said sheath;
23 a retention device formed on said portion of said wire stabilization guide extending
24 from said end of said sheath, said retention device comprising a slit on either side of said wire
25 stabilization guide wherein compression of said retention device causes said wire
26 stabilization guide to expand outwardly in at least one direction;
27 a guide rod sized to fit within said tubular sheath and having two slots formed along
28 its length, at least one slot releaseably holding one respective said wire stabilization guide;
29 a wire having two ends, each said end threaded into a respective said wire
30 stabilization guide and thus forming a loop of wire from the wire protruding from said wire
31 stabilization guides extending from said end of said sheath.
- 32 77. An introducer, comprising:

1 a tubular sheath having a wire stabilization guide, said wire stabilization guide
2 comprising an elongated tubular member having at least a portion thereof extending from an
3 end of said sheath;

4 a retention device formed on said portion of said wire stabilization guide extending
5 from said end of said sheath, said retention device comprising a slit on either side of said wire
6 stabilization guide wherein compression of said retention device causes said wire
7 stabilization guide to expand outwardly in at least one direction;

8 a guide rod sized to fit within said tubular sheath and having a slot formed along its
9 length, said slot releaseably holding said wire stabilization guide;

10 a wire having two ends, one end threaded into said wire stabilization guide, the other
11 end attached to said guide sheath, and thus forming a loop of wire from the wire protruding
12 from said wire stabilization guide extending from said end of said sheath.

13 78. An introducer comprising:

14 a tubular sheath having two wire stabilization guides, said wire stabilization guides
15 comprising elongated tubular members having at least a portion thereof extending from an
16 end of said sheath;

17 a guide rod sized to fit within said tubular sheath and having two slots formed along
18 its length, at least one slot releaseably holding one respective said wire stabilization guide;

19 a wire having two ends, each said end threaded into a respective said wire
20 stabilization guide and thus forming a loop of wire from the wire protruding from said wire
21 stabilization guides extending from said end of said sheath.

22 79. An introducer, comprising:

23 a tubular sheath having a wire stabilization guide, said wire stabilization guide
24 comprising an elongated tubular member having at least a portion thereof extending from an
25 end of said sheath;

26 a guide rod sized to fit within said tubular sheath and having a slot formed along its
27 length, said slot releaseably holding said wire stabilization guide;

28 a wire having two ends, one end threaded into said wire stabilization guide, the other
29 end attached to said guide sheath, and thus forming a loop of wire from the wire protruding
30 from said wire stabilization guide extending from said end of said sheath.

31 80. An introducer, comprising:

32 a tubular sheath having a wire stabilization guide and a passageway, said wire
33 stabilization guide comprising an elongated tubular member having at least a portion thereof
34 extending from an end of said sheath;

1 a guide rod sized to fit within said tubular sheath and having a slot formed along its
2 length, said slot releaseably holding said wire stabilization guide;

3 a wire having two ends, one end threaded into said wire stabilization guide, the other
4 end threaded through said passageway, and thus forming a loop of wire from the wire
5 protruding from said wire stabilization guide extending from said end of said sheath to said
6 passageway.

7 the first end of said wire being slidably disposed through said wire stabilization guide
8 and the loop portion of said wire disposed so that, when said sheath is approximated to a
9 wound site, said loop portion is approximates tissue surrounding said wound site to hold said
10 sheath approximately centered on said wound site.

11 81. The introducer of claim 80, wherein said loop actuation wire has a second end, said
12 second end being disposed opposite said first end with respect to said sheath.

13 82. The introducer of claim 80, wherein said loop portion urges said wound site into an
14 elongated configuration.

15 83. The introducer of claim 81, wherein said wound site is formed in an artery or vein,
16 and at least a portion of said first and said second ends are placed at opposing ends of said
17 wound site and transverse to a long axis of said artery or vein.

18 84. The introducer of claim 80, said guide rod further comprising a first blood marking
19 lumen disposed along its length to signal when said sheath is inserted into said wound site to
20 a predetermined depth.

21 85. An sheath comprising:

22 a tubular sheath, and

23 a loop actuation wire removably affixed to said sheath, said loop actuation wire
24 capable of exerting outwardly opposing forces on tissue surrounding a wound site when said
25 loop actuation wire is placed approximate to said tissue, thereby holding said sheath
26 approximately centered on said wound site.

27 86. An introducer as claimed in claim 85, wherein said tubular sheath includes at least
28 two flexible wire stabilization guides affixed substantially longitudinally along said tubular
29 sheath.

30 87. An introducer as claimed in claim 86, wherein said wound site is formed in an artery
31 or vein, and wherein said wire stabilization guides are placed in said wound site along a
32 transverse axis relative to a long axis of said artery or vein.

33 88. An introducer as claimed in claim 84, wherein said sheath further comprises a distal
34 end;

1 wherein said wound site is formed in an artery or vein;
2 wherein said introducer further comprises at least a second blood marker to signal
3 when said guide rod is inserted into the wound opening to a predetermined depth; and
4 wherein the presence of pressurized blood flow at said first blood marker and the
5 absence of pressurized blood flow at said second blood marker indicates that the distal end of
6 said sheath is adjacent to the outer wall of said artery or vein.

7 89. An introducer as claimed in claim 80, wherein said loop portion is internal within said
8 wound site when said sheath is approximated to said wound site.

9 90. A method for stabilizing a wound in an artery or vein, said method comprising:
10 approximating an elongated sheath to a wound site;
11 placing a loop activation wire into said wound site;
12 placing said loop activation wire approximate to tissue surrounding said wound site;
13 and
14 allowing opposing sides of said tissue surrounding said wound site to approximate
15 one another.

16 91. A method for stabilizing a wound site, said method comprising:
17 approximating an elongated sheath to a wound site;
18 inserting a loop activation wire into said wound site;
19 placing said loop activation wire approximate to tissue surrounding said wound site.
20

21 92. The method of claim 90, wherein said loop activation wire is placed internally within
22 said wound site in said placing step.

23 93. The method of claim 91, wherein said loop activation wire is placed internally within
24 said wound site in said placing step.

25 94. The introducer of claim 80, where said sheath further comprises tear seams formed
26 along the length thereof and wherein when said sheath is approximated to a wound site and a
27 radial force is applied to the distal end of said sheath in a direction generally perpendicular to
28 the central axis of said sheath, said tear seams are caused to tear, thereby increasing the
29 diameter of said sheath.

30 95. The introducer of claim 94, wherein said sheath is approximated to tissue surrounding
31 said wound site to hold said sheath approximately centered on said wound site when the
32 diameter of said sheath increases.

33 96. An introducer sheath comprising:

1 a tubular member having a central axis and a distal end, said distal end having a
2 plurality of tear seams;

3 wherein when said member is approximated to a wound site and a radial force is
4 applied to the distal end of said member, said tear seams are caused to tear, thereby
5 increasing the diameter of said member.

6 97. The introducer of claim 96, wherein said member is approximated to tissue
7 surrounding said wound site to hold said member approximately centered on said wound site
8 when the diameter of said member increases.

9 98. A method for stabilizing a wound site, said method comprising:
10 approximating an elongated tubular sheath to a wound site, said sheath having a
11 central axis and a distal end, said distal end having a plurality of tear seams; and
12 tearing said tear seams by applying a radial force to the distal end of said sheath
13 thereby increasing the diameter of said sheath.

14 99. The method of claim 98, wherein said sheath is held approximately centered on said
15 wound site due to the increased diameter of said sheath.

16 100. An introducer comprising:
17 a sheath comprising means for producing outwardly opposing forces,
18 wherein when said sheath is approximated to a wound site and said means for
19 producing outwardly opposing forces is activated, opposing sides of the tissue surrounding
20 said wound site are caused to approximate one another.

21 101. The introducer of claim 100, wherein when said sheath is approximated to said wound
22 site and said means for producing outwardly opposing forces is activated, said sheath is held
23 approximately centered on said wound site.

24 102. A method for stabilizing a wound site comprising:
25 approximating to a wound site the sheath of an introducer, said sheath comprising
26 means for producing outwardly opposing forces; and
27 activating said means for producing outwardly opposing forces, so as to cause
28 opposing sides of the tissue surrounding said wound site to approximate one another.

29 103. The method of claim 102, wherein when said sheath is approximated to said wound
30 site and said means for producing outwardly opposing forces is activated, said sheath is held
31 approximately centered on said wound site.

32 104. The introducer of claim 78, wherein said sheath includes at least two flexible wire
33 stabilization guides affixed substantially longitudinally along said tubular sheath; and

1 wherein said wire stabilization guides are placed in said wound site along a transverse axis
2 relative to a long axis of said wound site.

3 105. The introducer of claim 94, wherein said sheath includes at least two flexible wire
4 stabilization guides affixed substantially longitudinally along said tubular sheath; and
5 wherein said wire stabilization guides are placed in said wound site along a transverse axis
6 relative to a long axis of said wound site.

7 106. A method for determining the depth of a transluminal device with respect to a wound
8 site located at an artery or vein, said method comprising:

9 coupling at least a first and a second blood marking lumen to said device, each said
10 lumen having a flashback port at a first end and a blood marking port at a second end, the
11 blood marking port of the first said lumen being fixedly disposed to said device at a shorter
12 distance from said wound site than the blood marking port of said second lumen;

13 introducing said transluminal device into said wound site; and

14 observing said lumens until pressurized blood flow is present at the first said lumen
15 and absent at said second lumen, wherein the fact that the blood marking port of the first
16 lumen is adjacent to the outer wall of said artery or vein is indicated.

17 107. An introducer, comprising:

18 a tubular sheath having a wire stabilization guide having at least a portion thereof
19 extending from an end of said sheath;

20 a guide rod sized to fit within said tubular sheath and having a slot formed along its
21 length, said slot releaseably holding said wire stabilization guide;

22 a wire having two ends, one end slidably coupled to said wire stabilization guide, the
23 other end attached to said guide sheath, and thus forming a loop of wire from the wire
24 protruding from said wire stabilization guide extending from said end of said sheath.

25 108. A device, comprising:

26 a tubular sheath having two wire stabilization guides, said wire stabilization guides
27 comprising elongated tubular members having at least a portion thereof extending from an
28 end of said sheath; and

29 a wire having two ends, each said end threaded into a respective said wire
30 stabilization guide and thus forming a loop of wire from the wire protruding from said wire
31 stabilization guides extending from said end of said sheath.

32 109. A device, comprising:

1 a tubular sheath having a wire stabilization guide, said wire stabilization guide
2 comprising an elongated tubular member having at least a portion thereof extending from an
3 end of said sheath; and

4 a wire having two ends, one end threaded into said wire stabilization guide, the other
5 end attached to said guide sheath, and thus forming a loop of wire from the wire protruding
6 from said wire stabilization guide extending from said end of said sheath.

7 110. A device, comprising:

8 a tubular sheath having a wire stabilization guide having at least a portion thereof
9 extending from an end of said sheath; and

10 a wire having two ends, one end slidably coupled to said wire stabilization guide, the
11 other end attached to said guide sheath, and thus forming a loop of wire from the wire
12 protruding from said wire stabilization guide extending from said end of said sheath.

13 111. An introducer, comprising:

14 a tubular sheath having a wire stabilization guide having at least a portion thereof
15 extending from an end of said sheath;

16 said wire stabilization guide comprising a reinforced section disposed along at least a
17 portion of said wire stabilization guide extending from said sheath;

18 a guide rod sized to fit within said tubular sheath and having a slot formed along its
19 length, said slot releaseably holding said wire stabilization guide;

20 a wire having two ends, one end slidably coupled to said wire stabilization guide, the
21 other end attached to said guide sheath, and thus forming a loop of wire from the wire
22 protruding from said wire stabilization guide extending from said end of said sheath, wherein
23 said reinforced section causing said loop of wire to extend in a direction generally
24 perpendicular to the long axis of said guide rod and said sheath.

25 112. An introducer, comprising:

26 a tubular sheath having a wire stabilization guide, said wire stabilization guide
27 comprising an elongated tubular member having at least a portion thereof extending from an
28 end of said sheath;

29 a reinforced section disposed on a portion of said wire stabilization guide extending
30 from said sheath;

31 a guide rod sized to fit within said tubular sheath and having a slot formed along its
32 length, said slot releaseably holding said wire stabilization guide;

33 a wire having two ends, one end threaded into said wire stabilization guide, the other
34 end attached to said guide sheath, and thus forming a loop of wire from the wire protruding

1 from said wire stabilization guide extending from said end of said sheath, wherein said
2 reinforced section causing said loop of wire to extend in a direction generally perpendicular
3 to the long axis of said guide rod and said sheath.

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FIG. 1

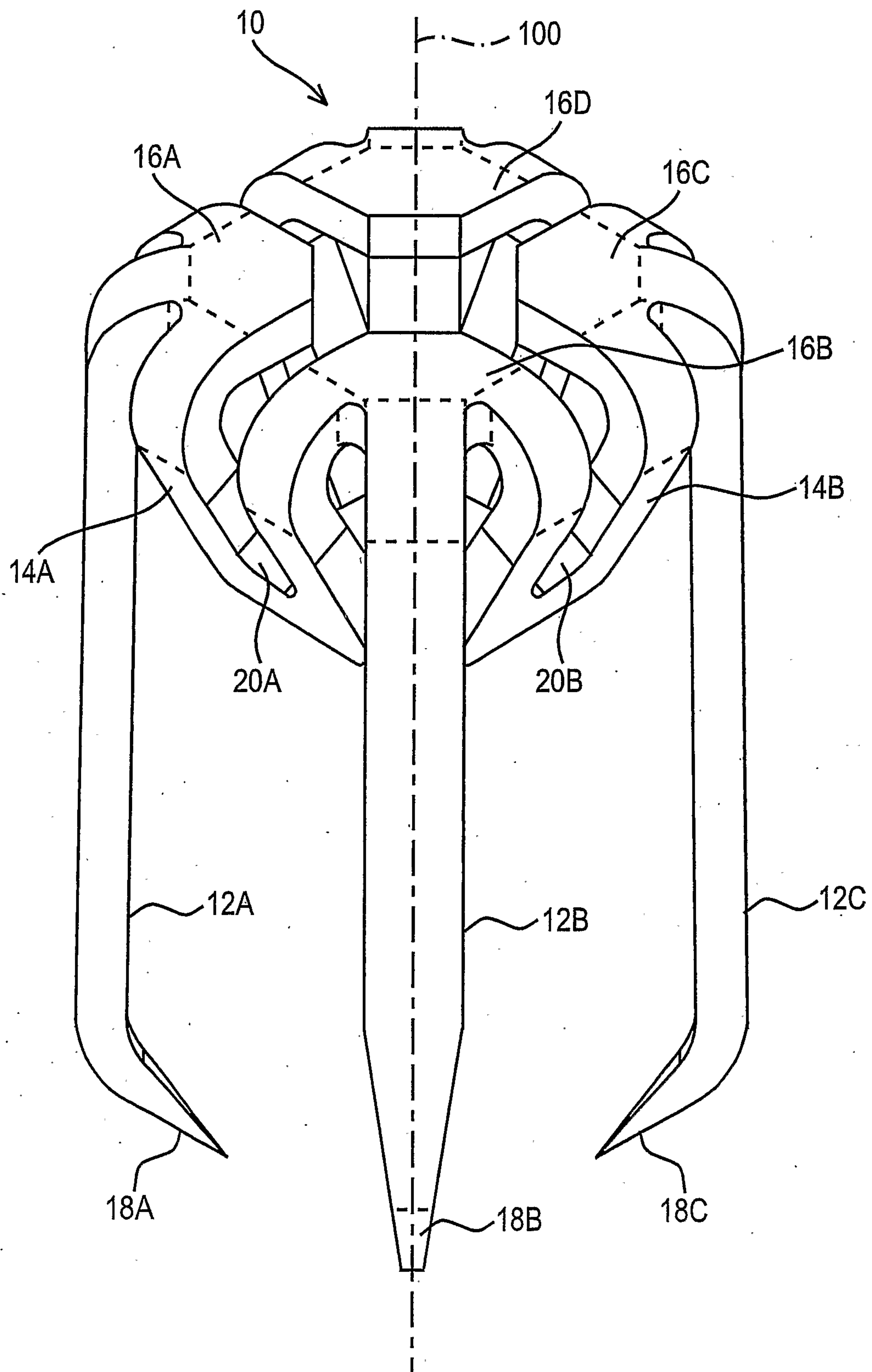
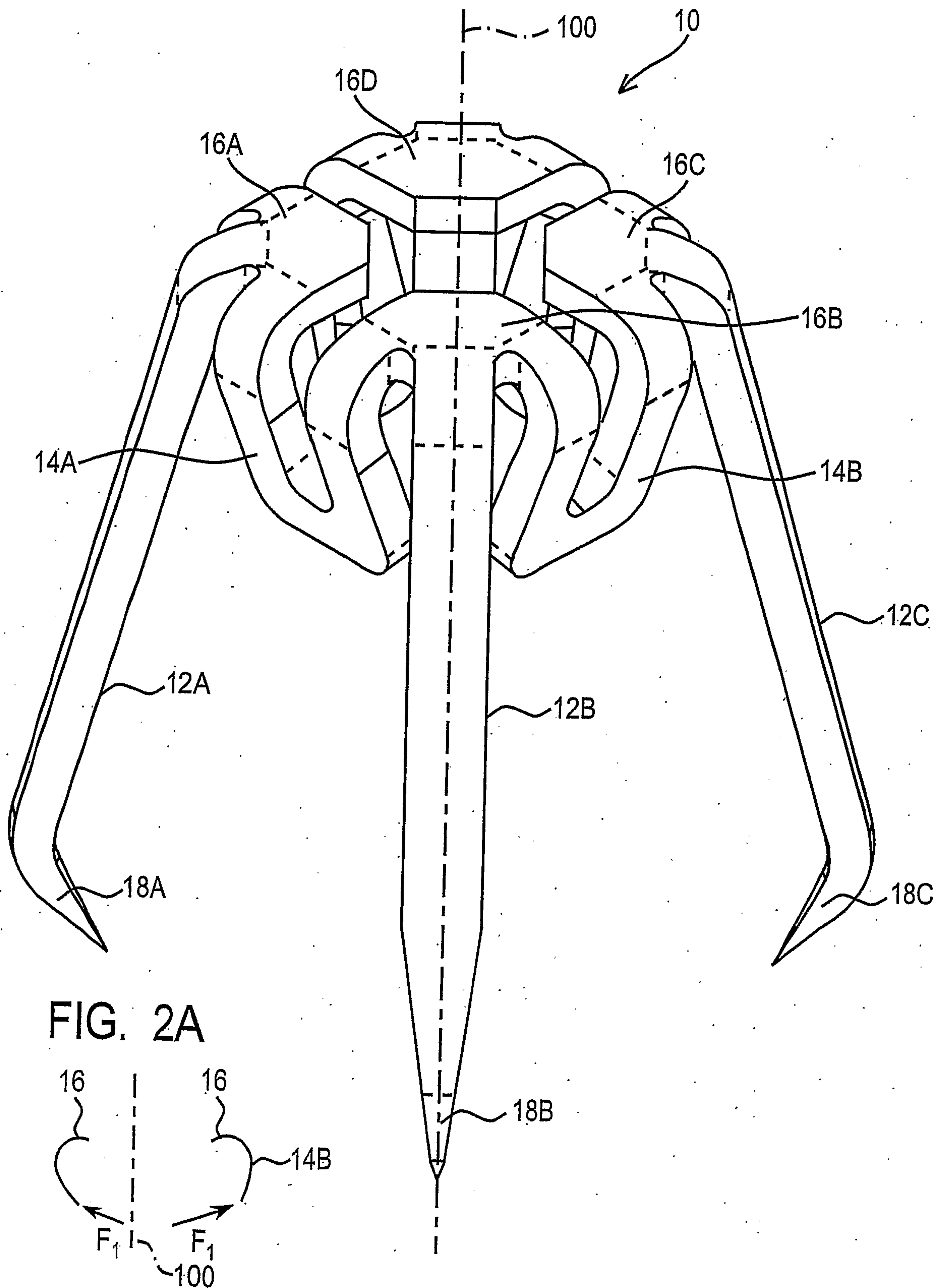
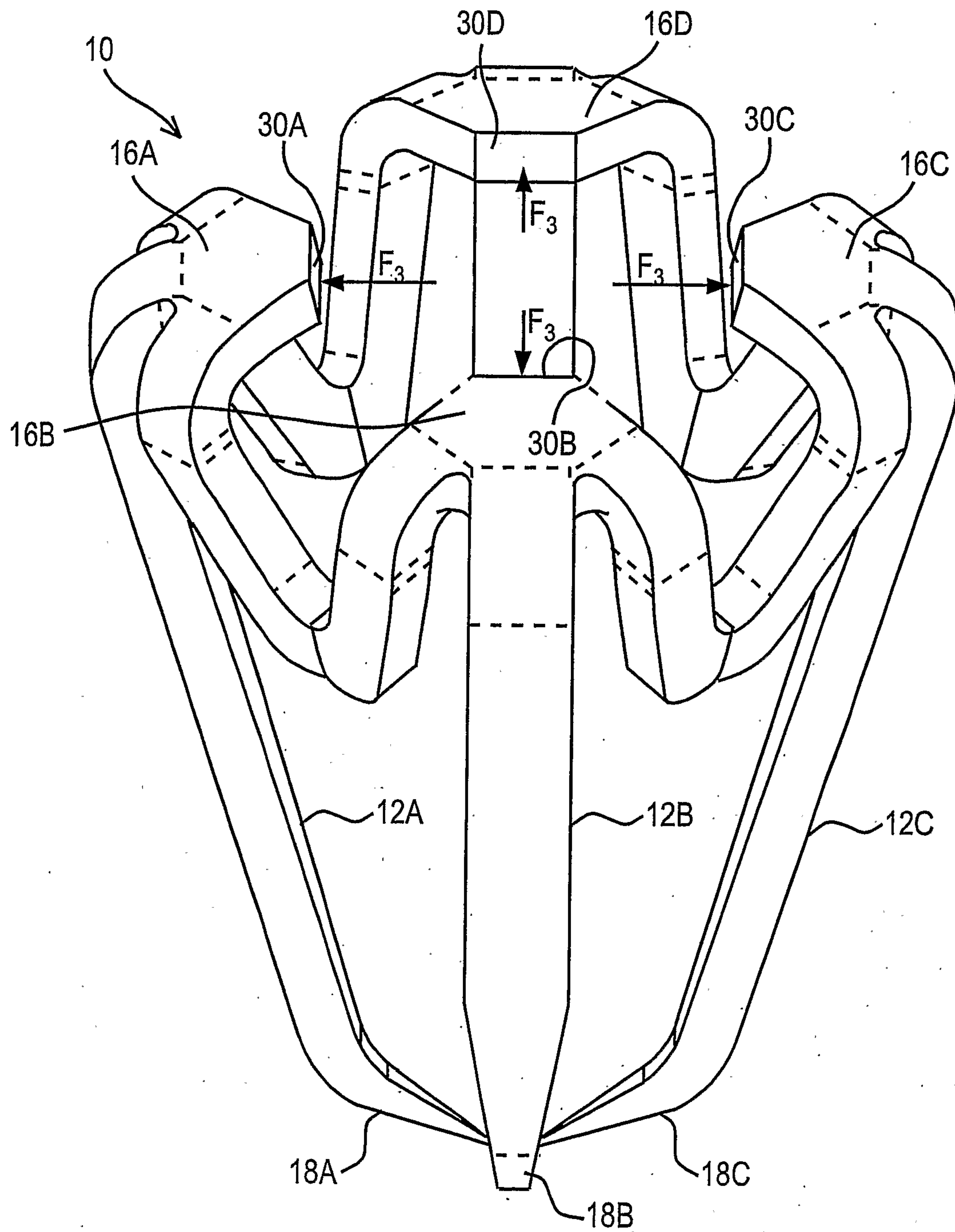


FIG. 2



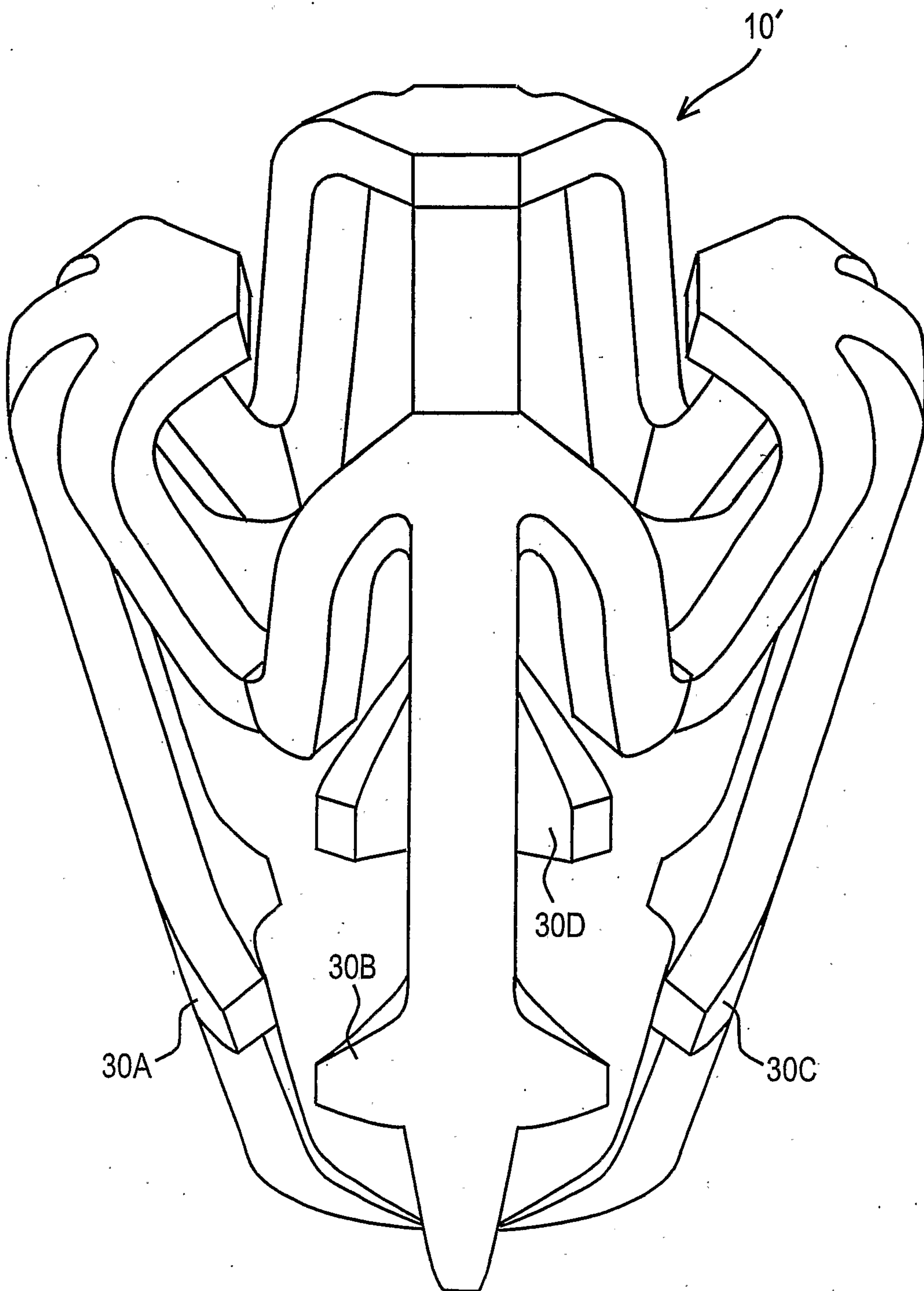
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FIG. 3



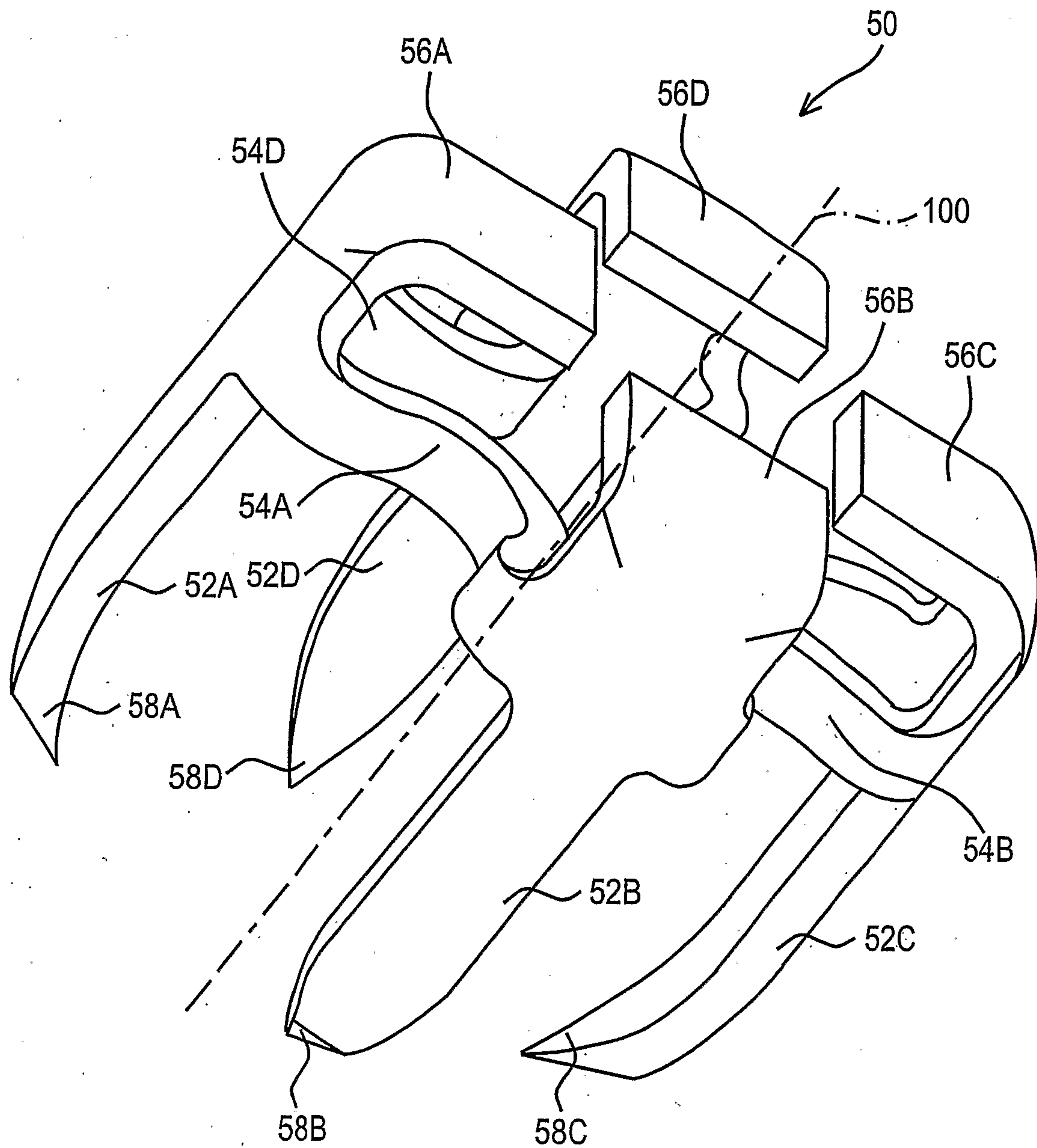
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FIG. 3A



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FIG. 4



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FIG. 5

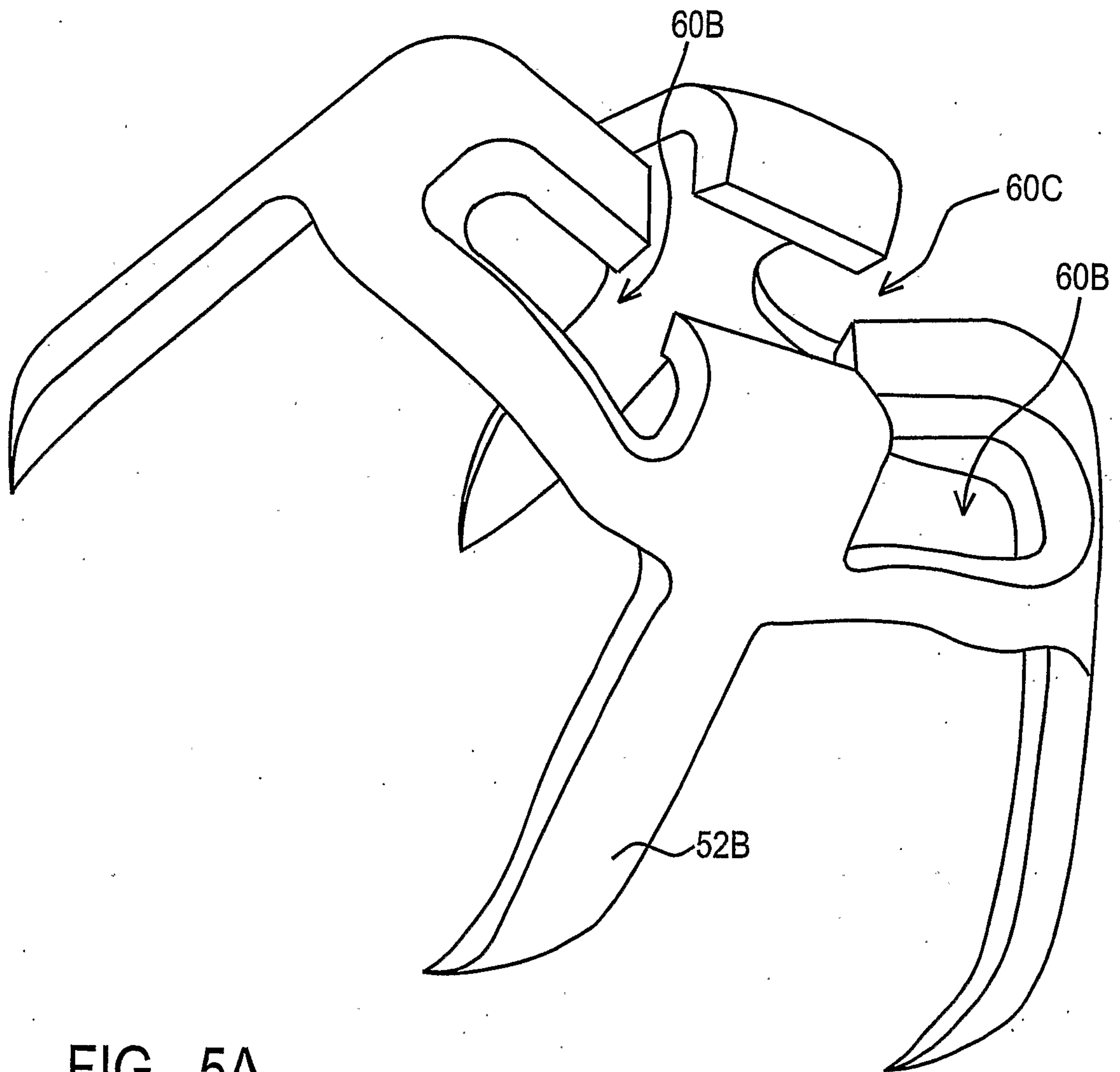
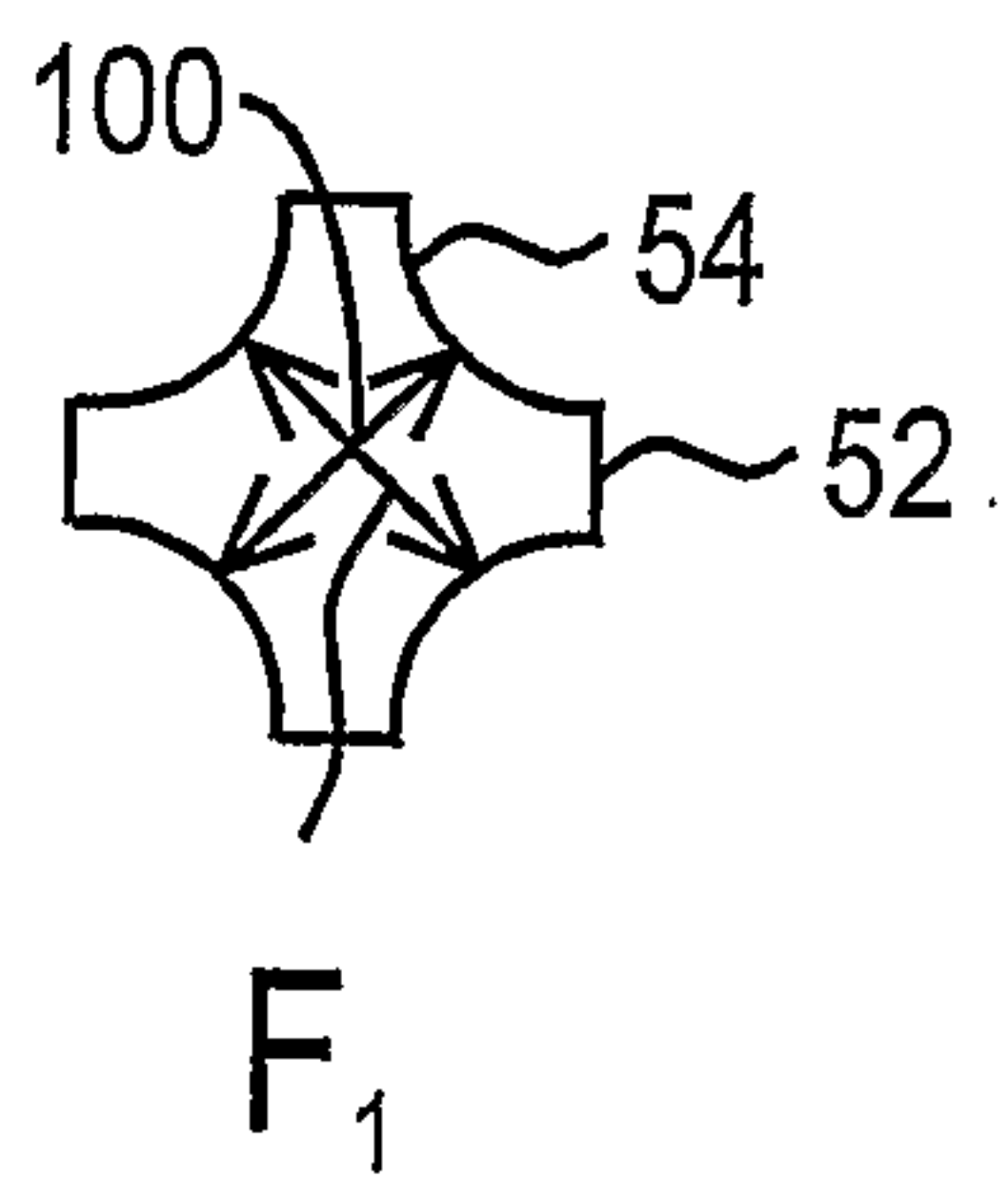
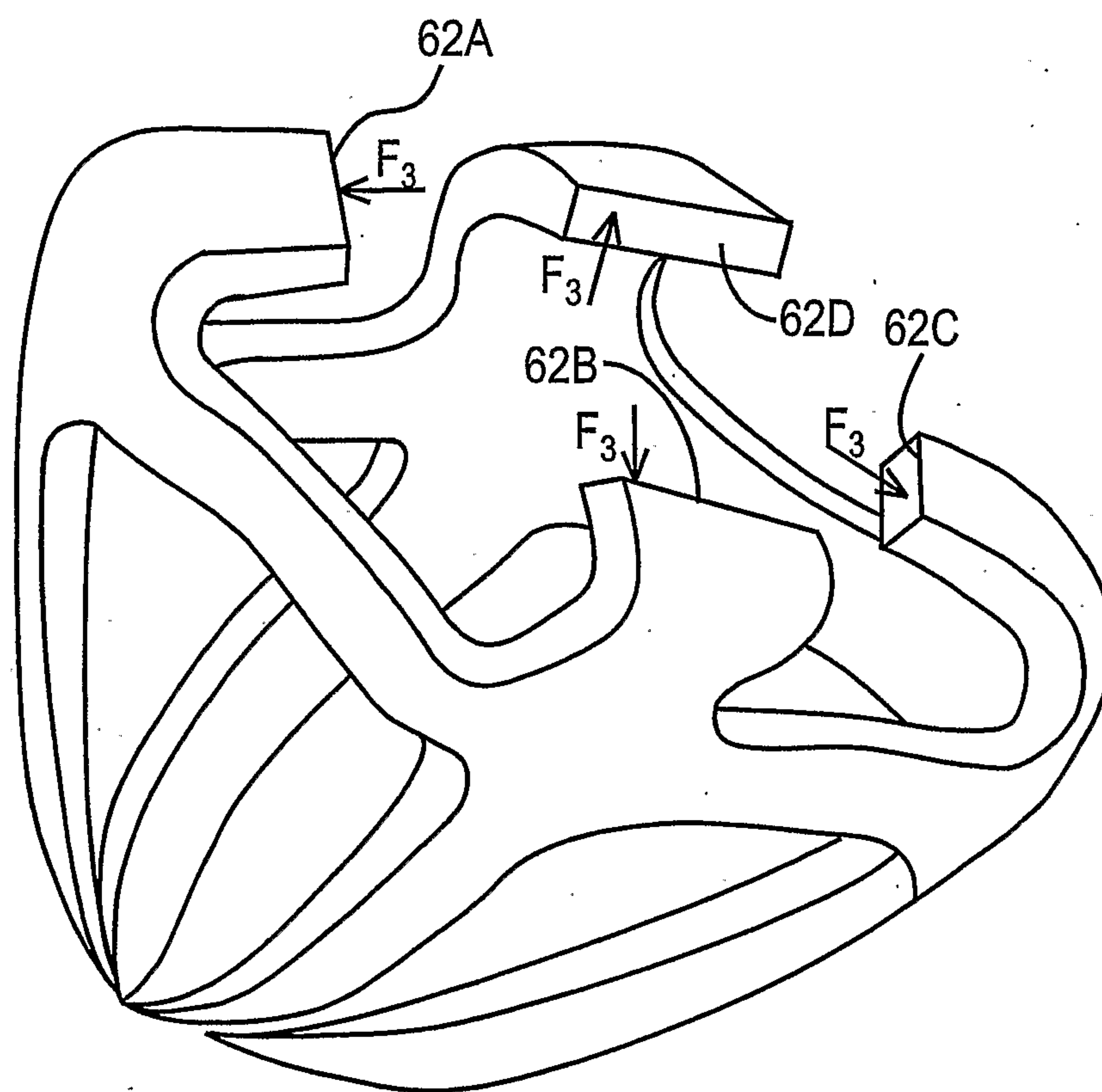


FIG. 5A

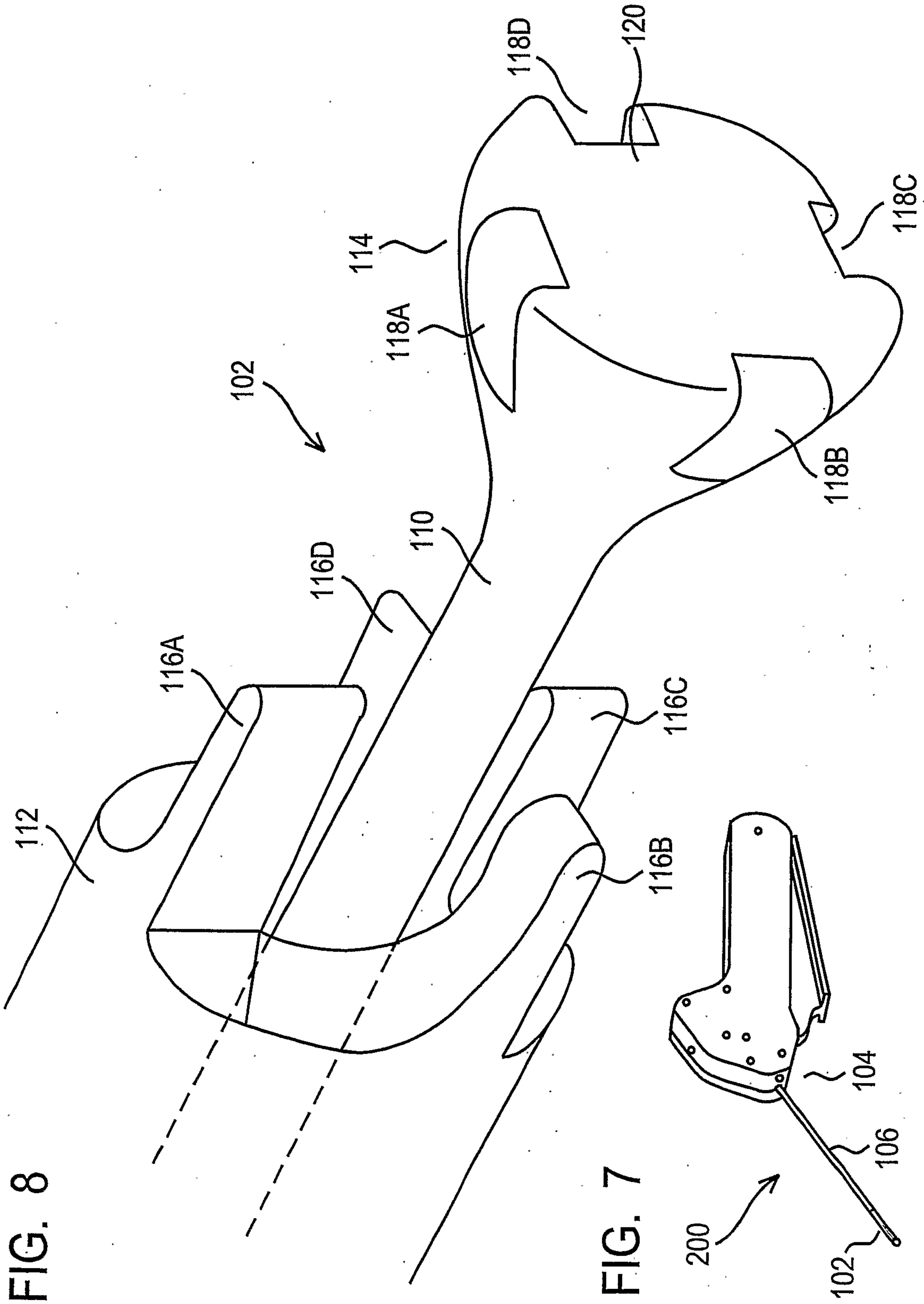


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FIG. 6



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FIG. 9A

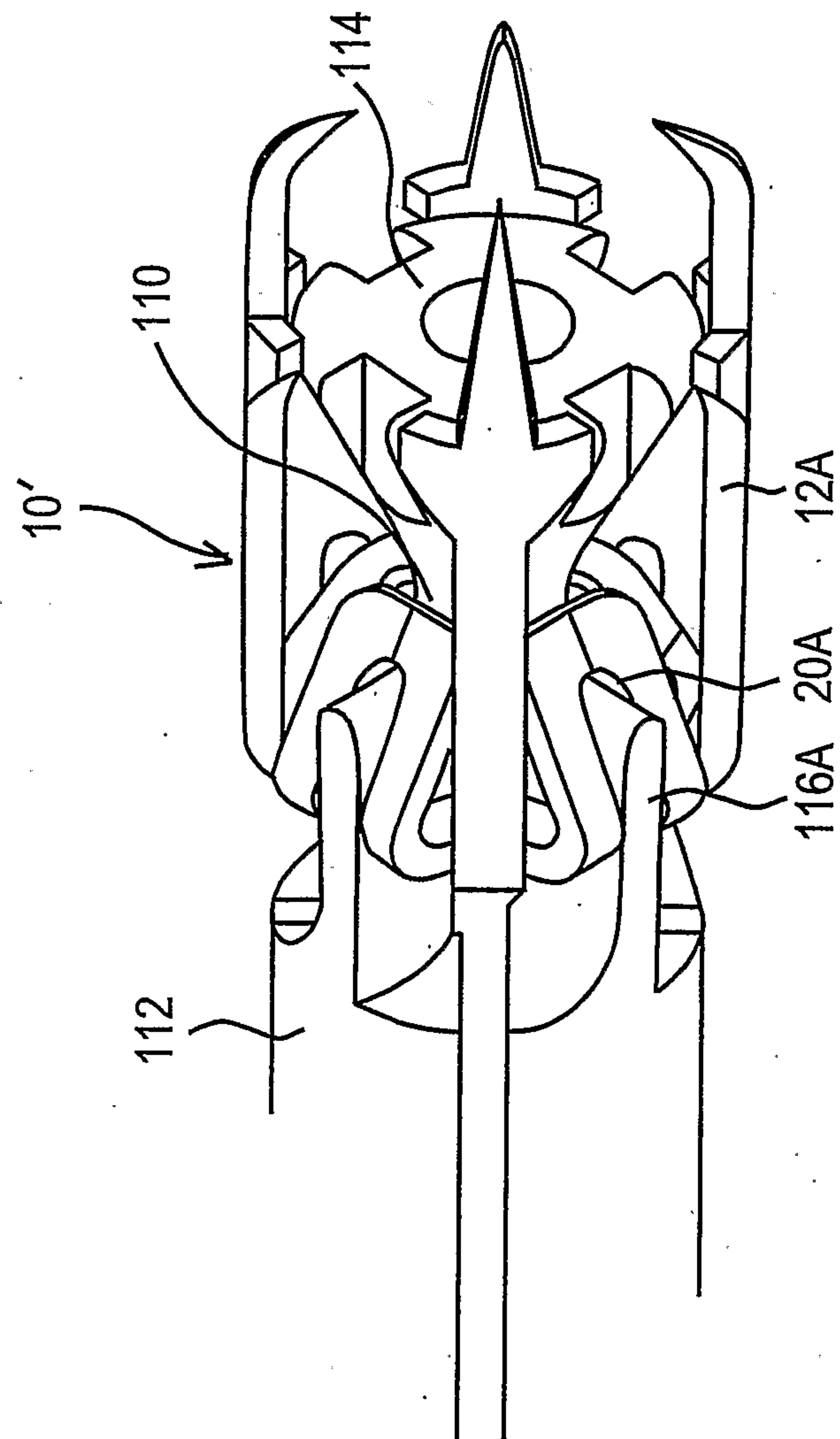
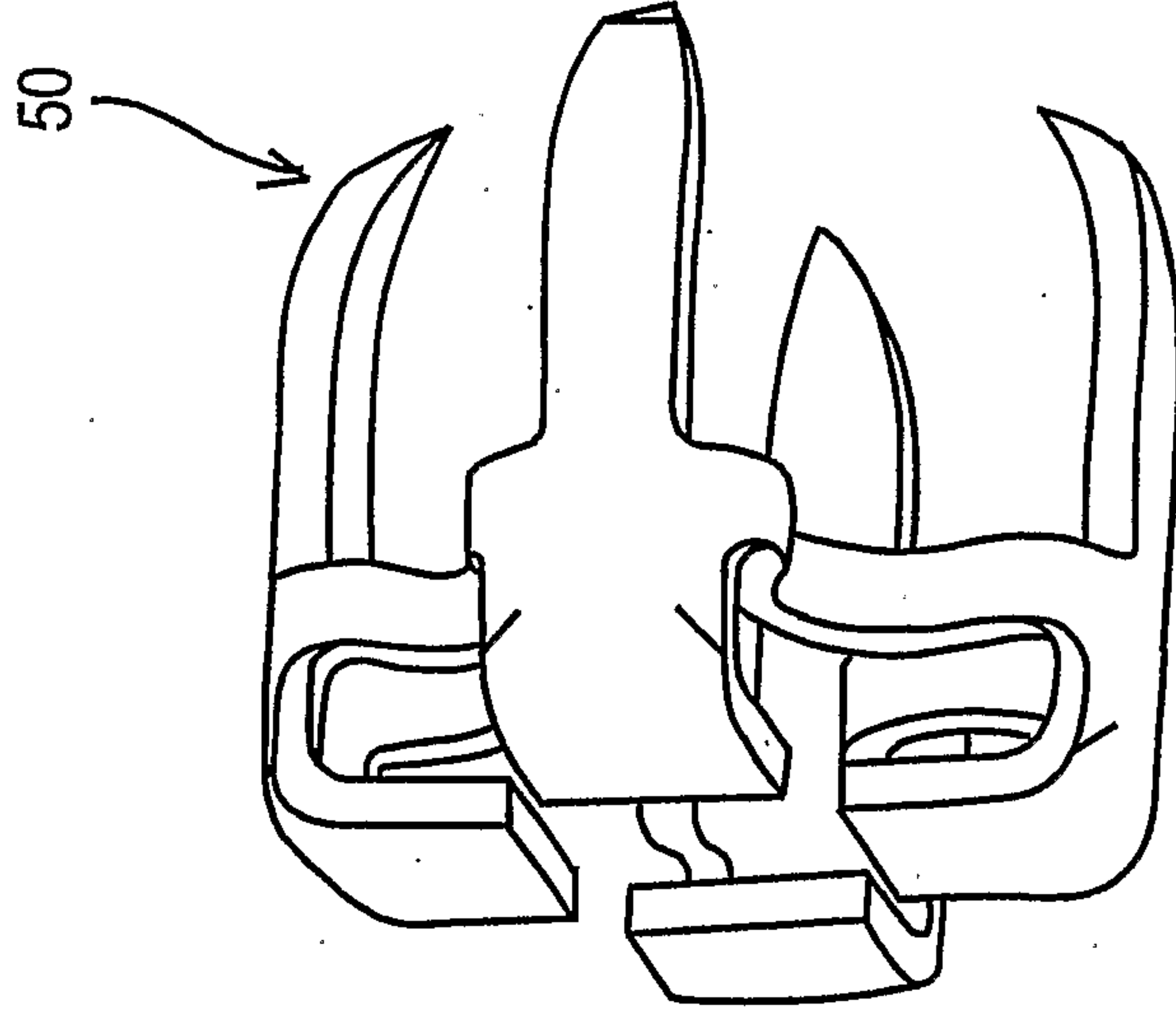


FIG. 9B



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FIG. 10B

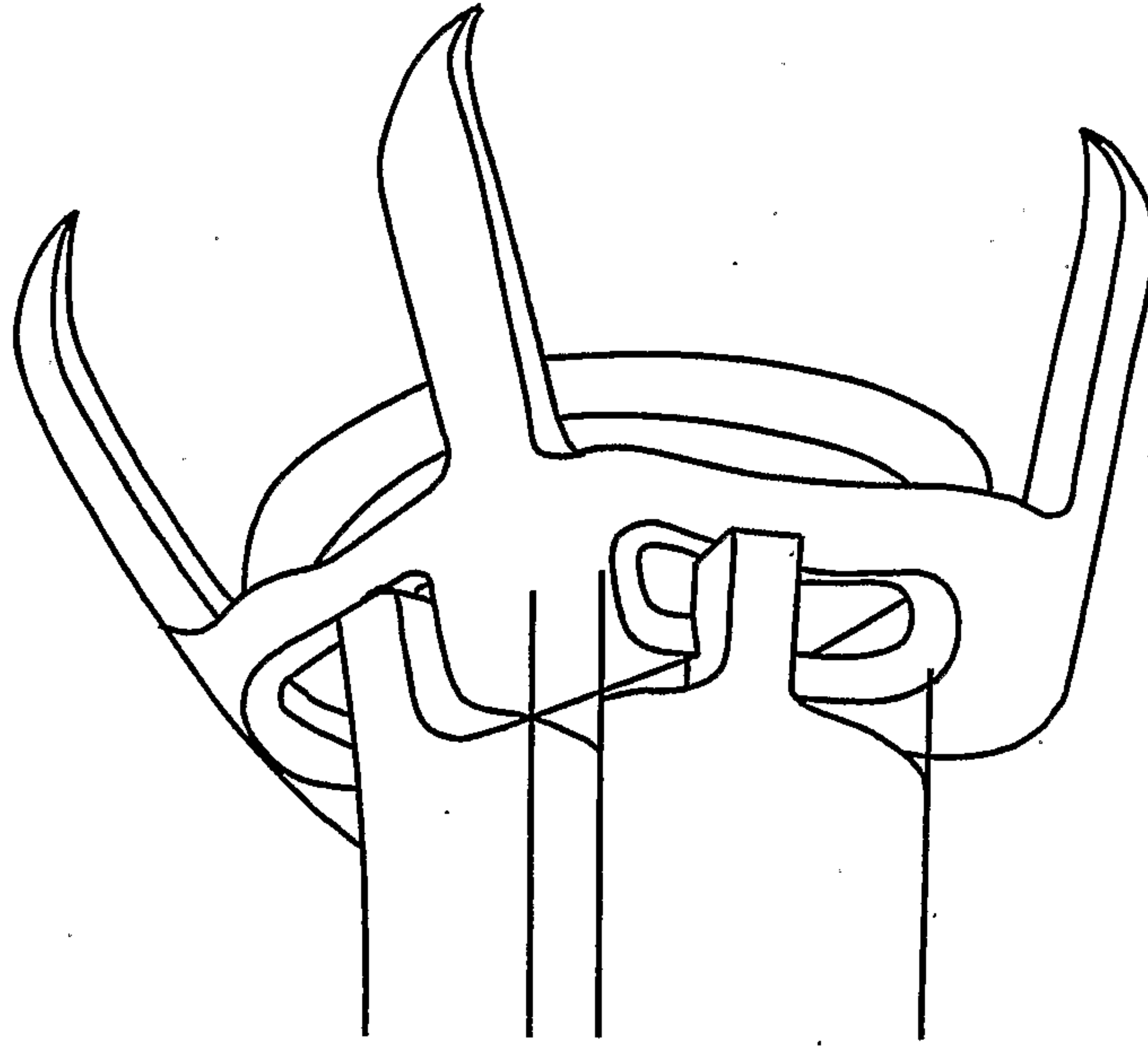
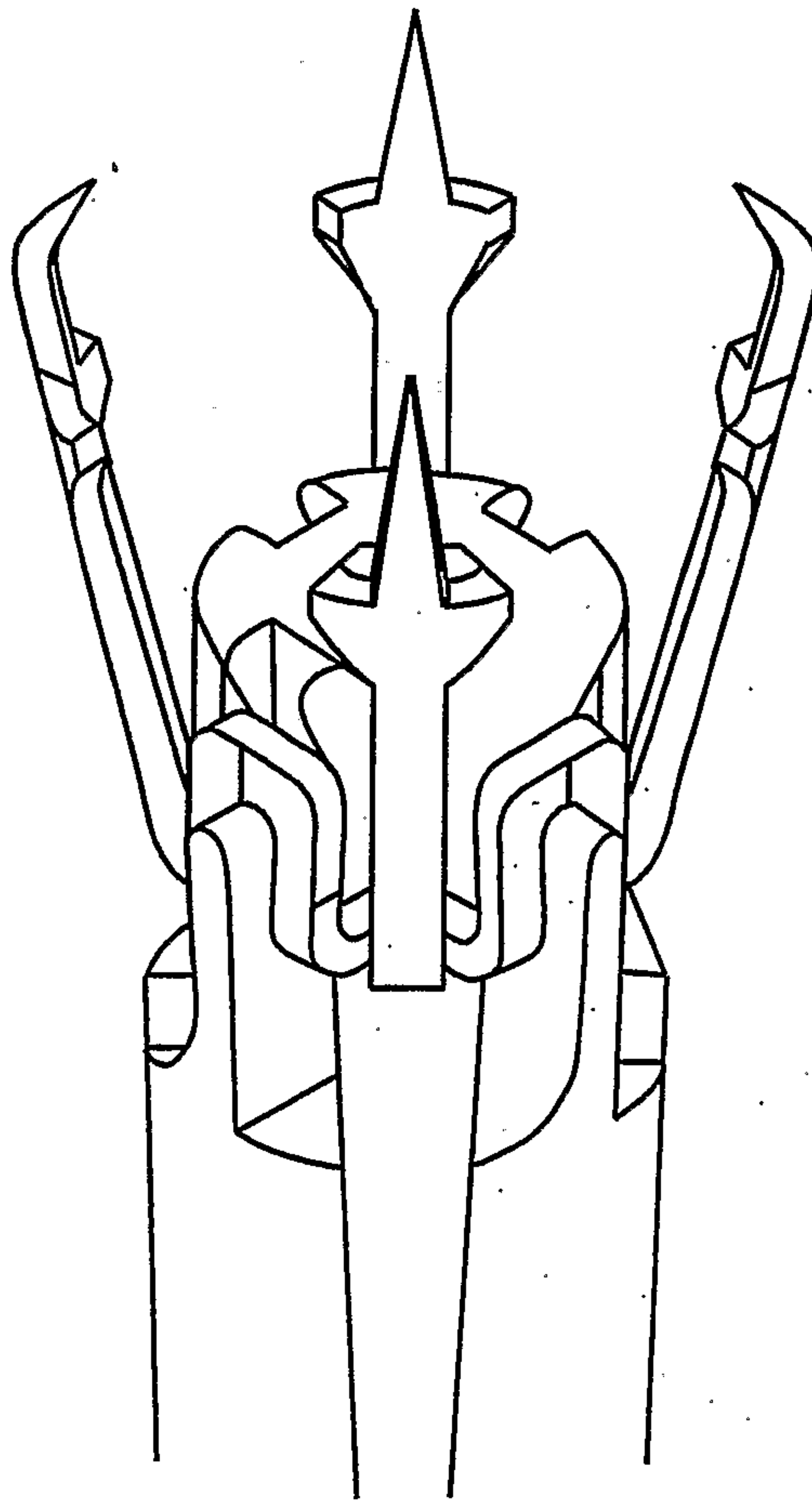


FIG. 10A



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FIG. 11B

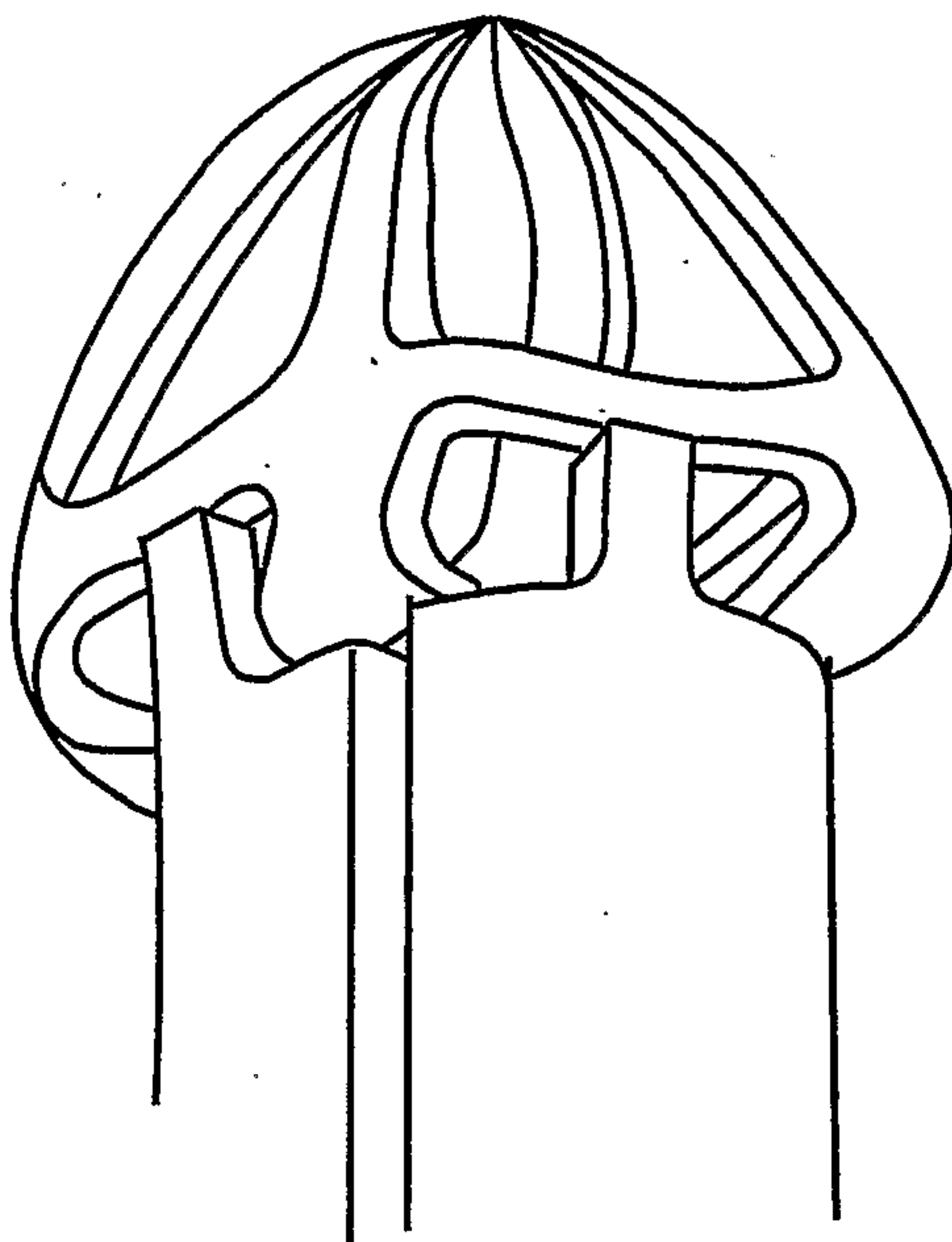
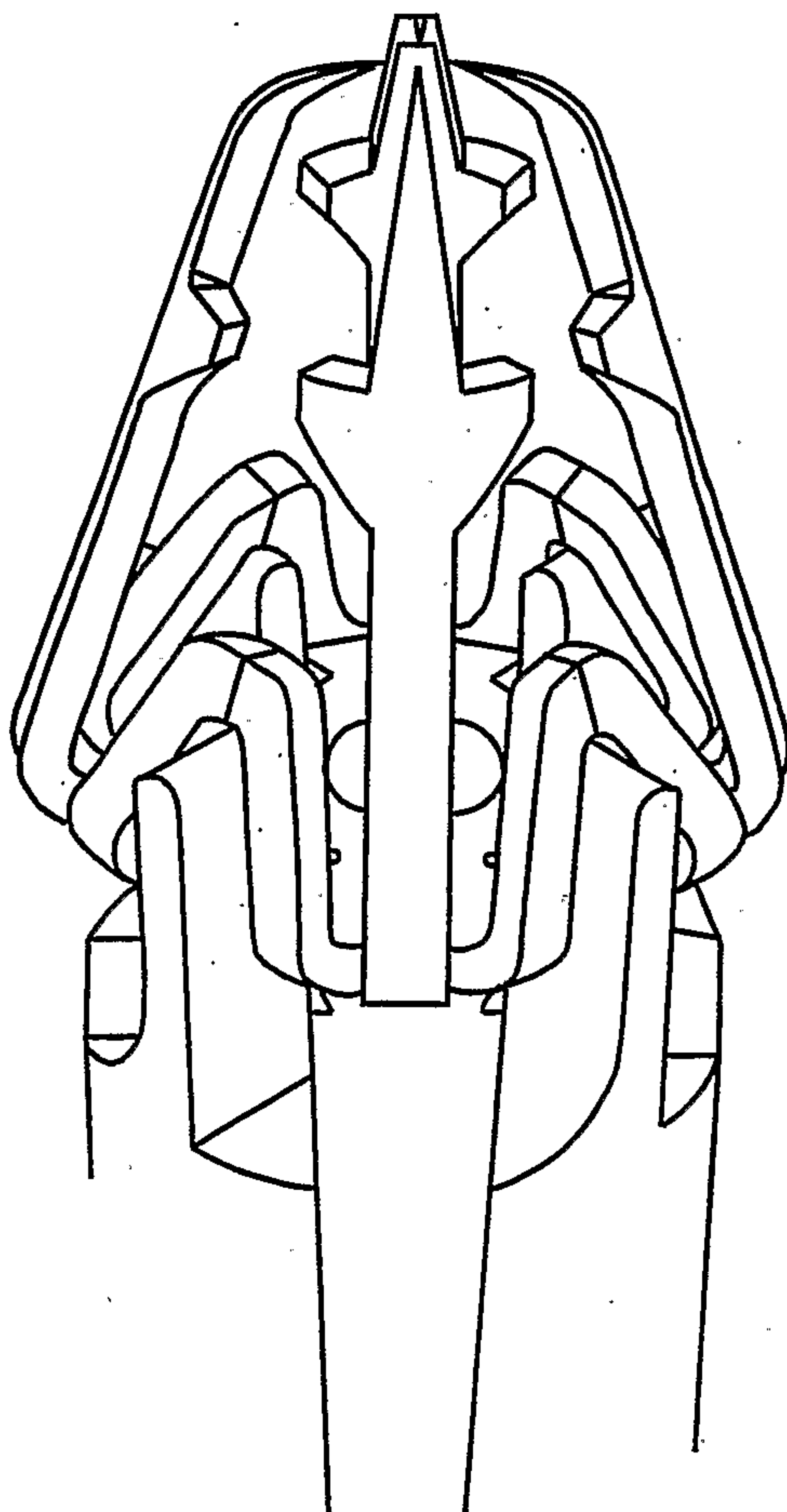
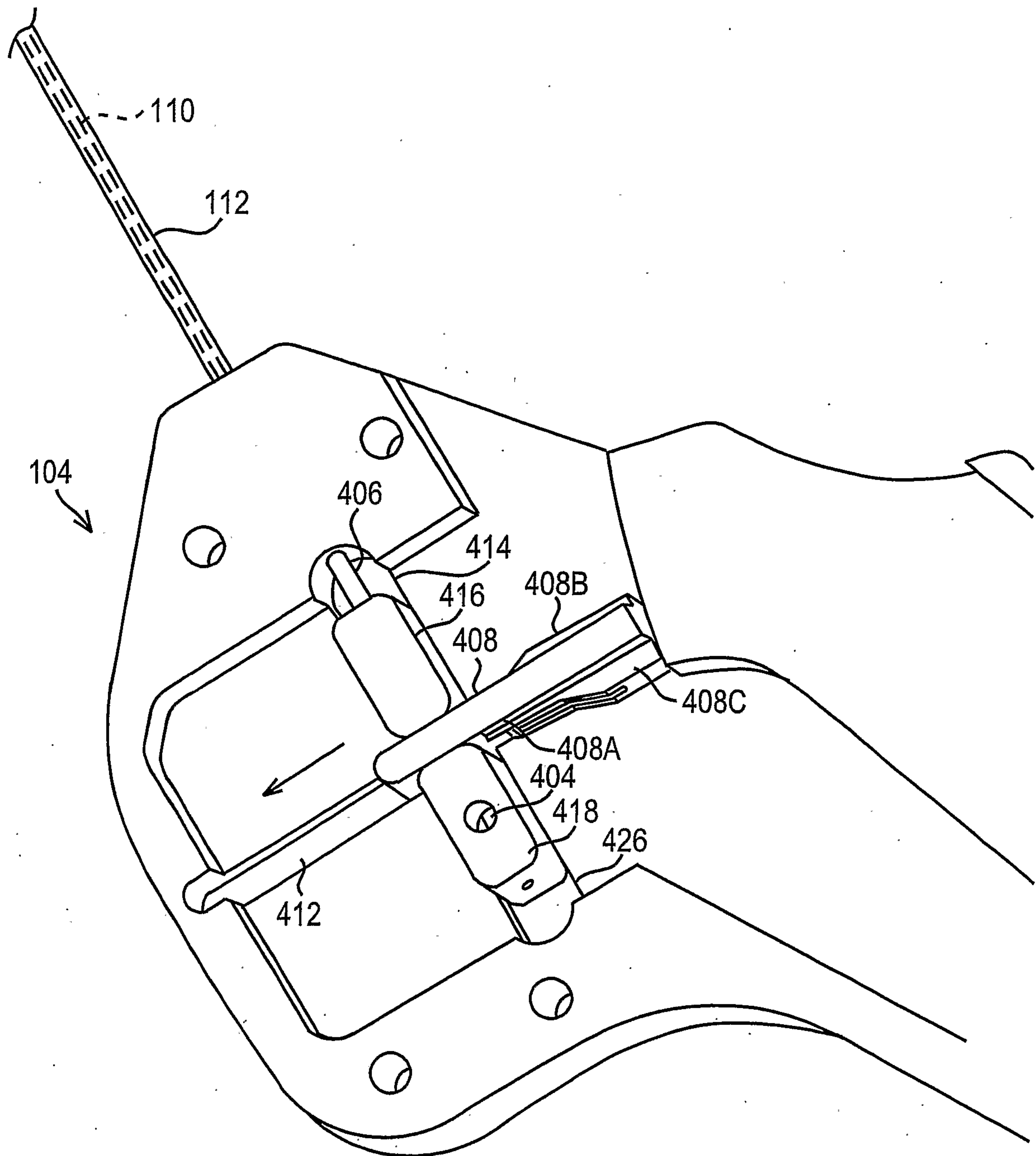


FIG. 11A



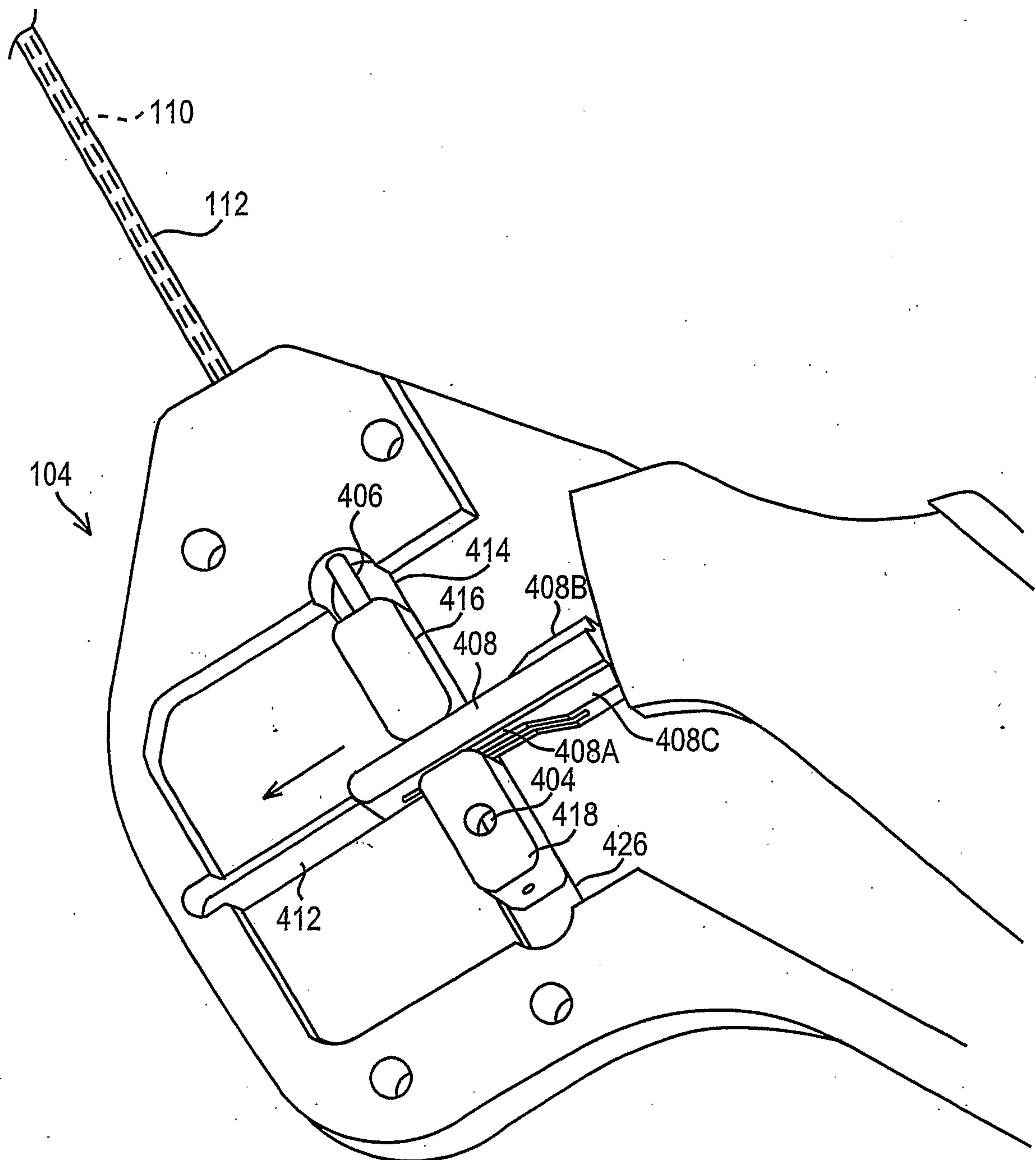
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FIG. 12



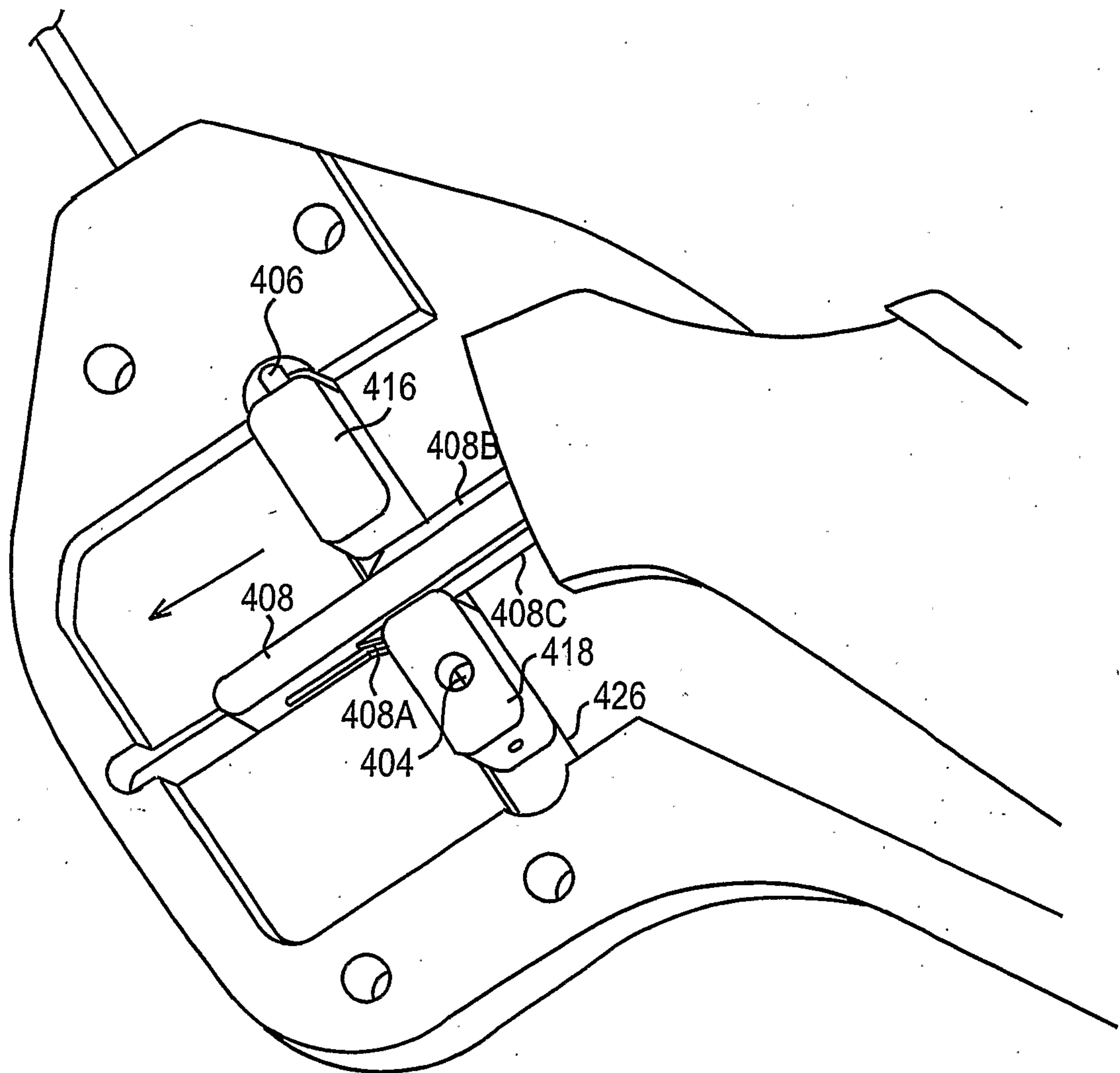
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FIG. 13



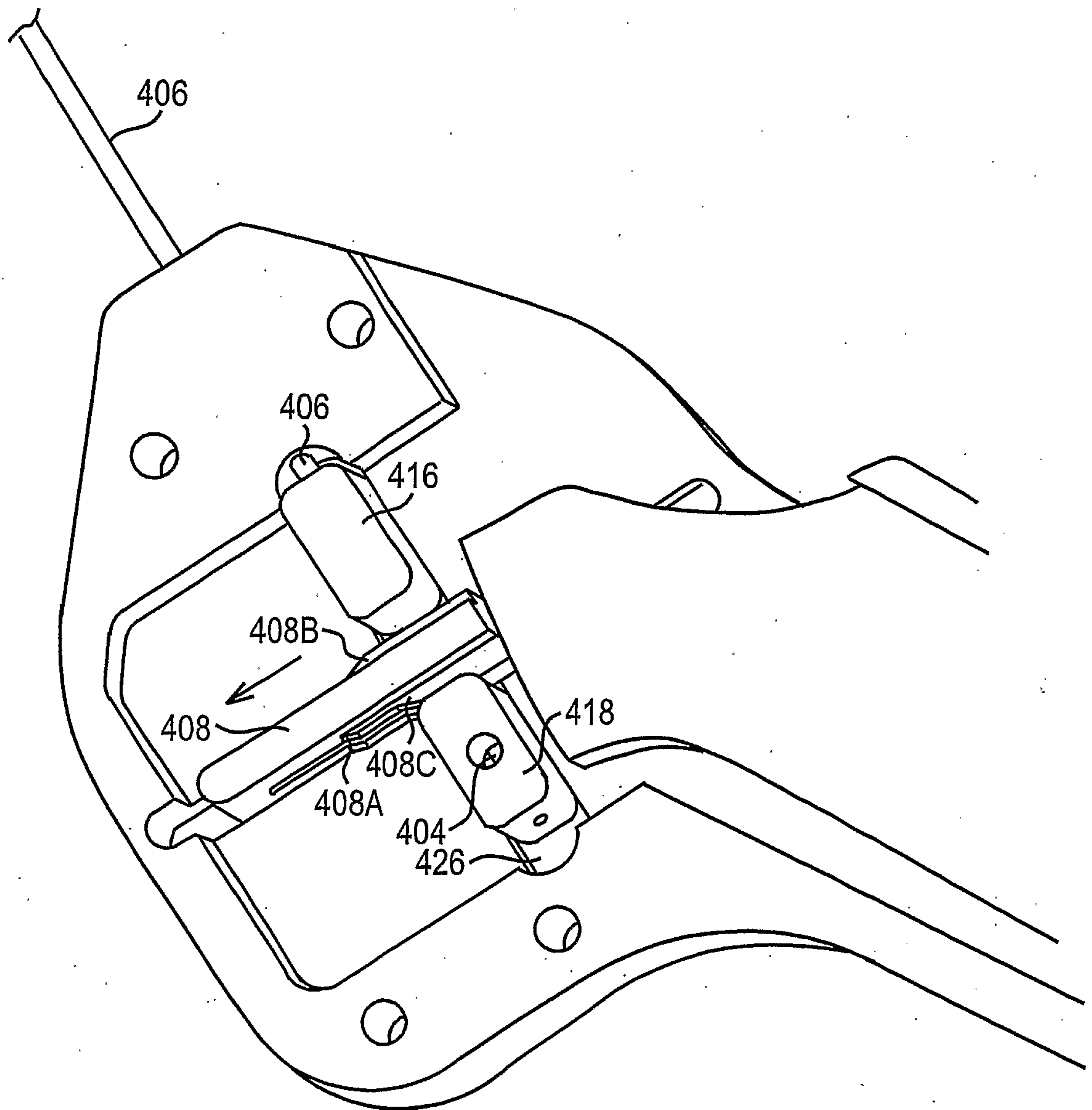
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FIG. 14



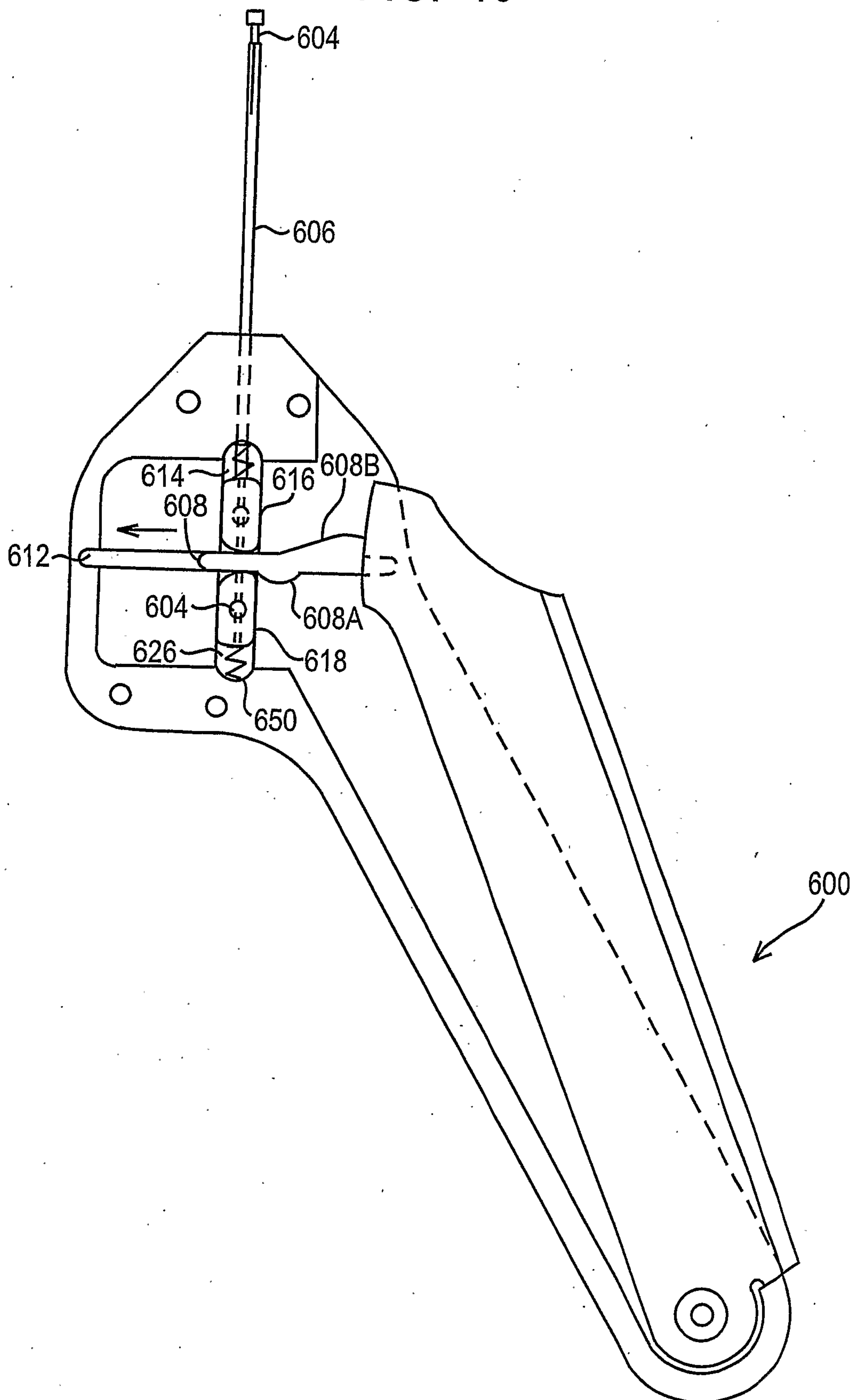
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FIG. 15



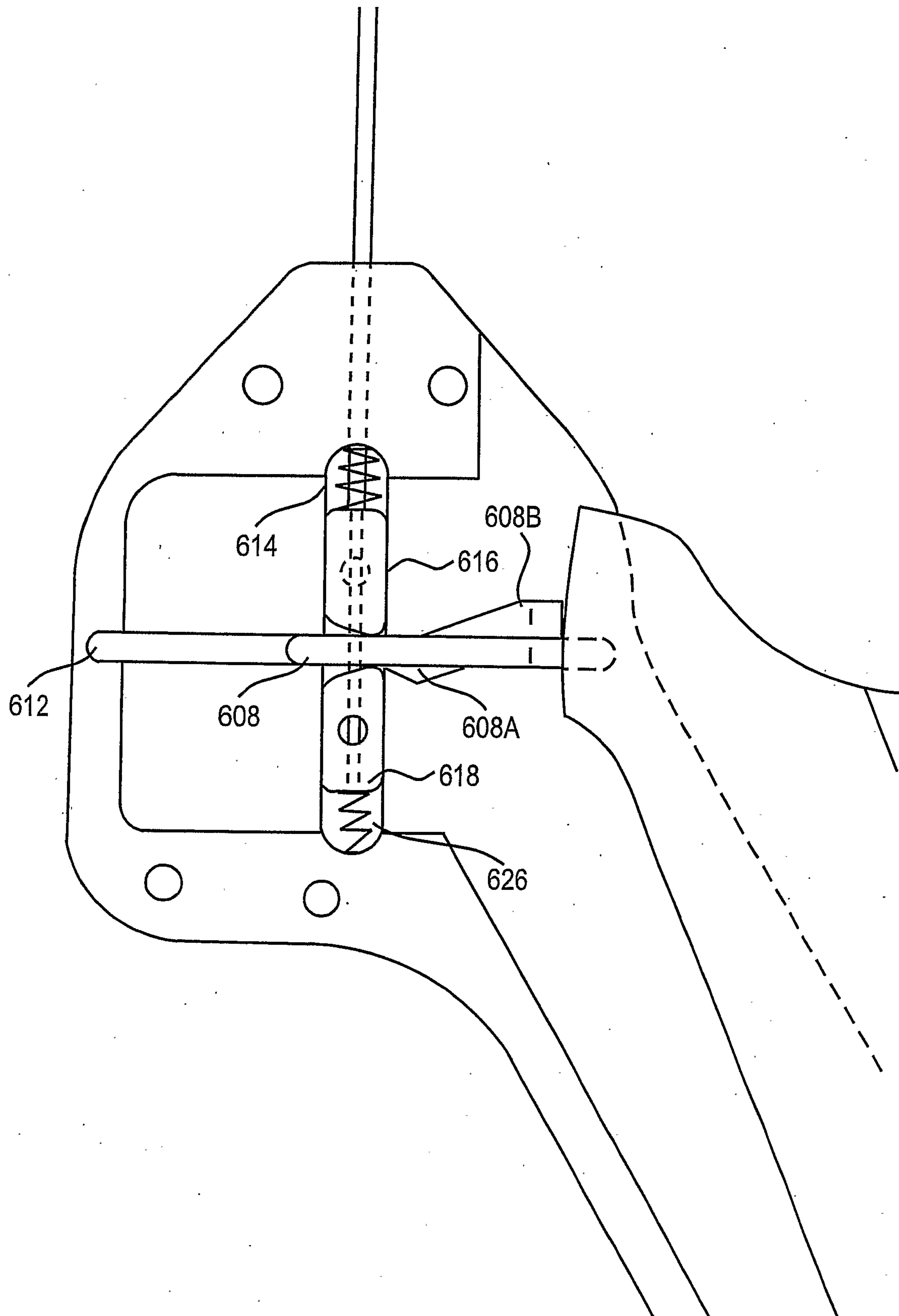
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FIG. 16



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FIG. 17



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FIG. 18

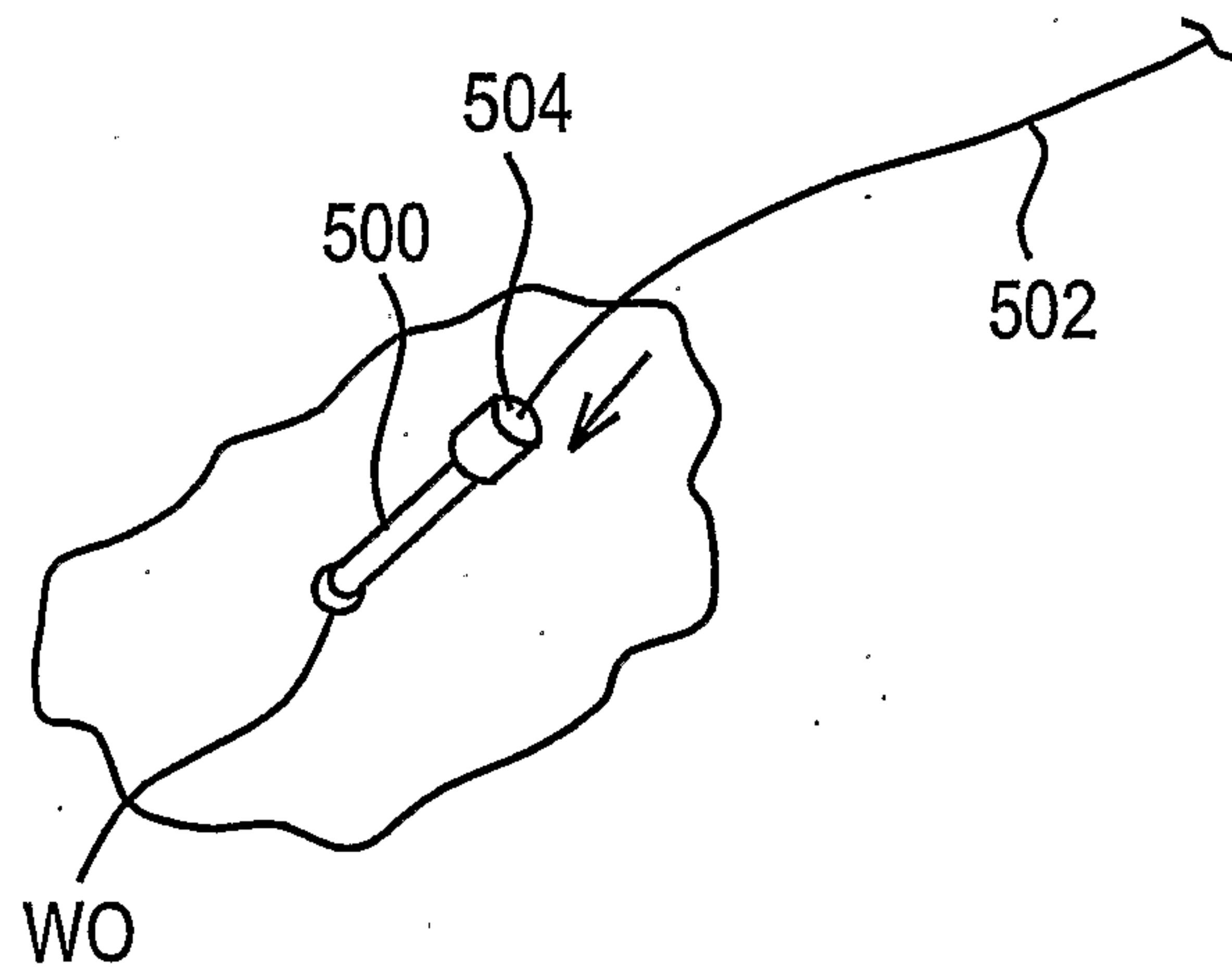


FIG. 19

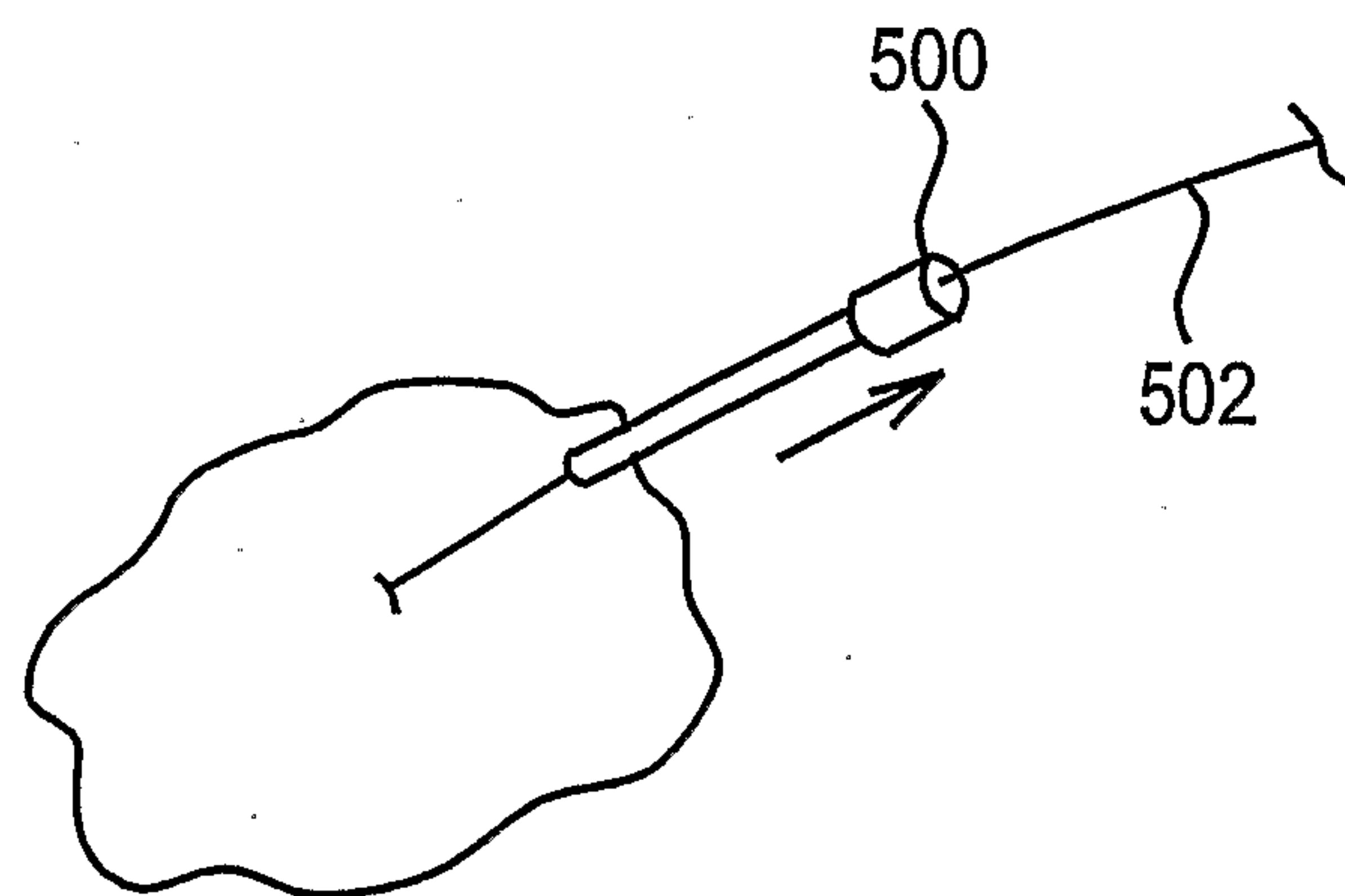
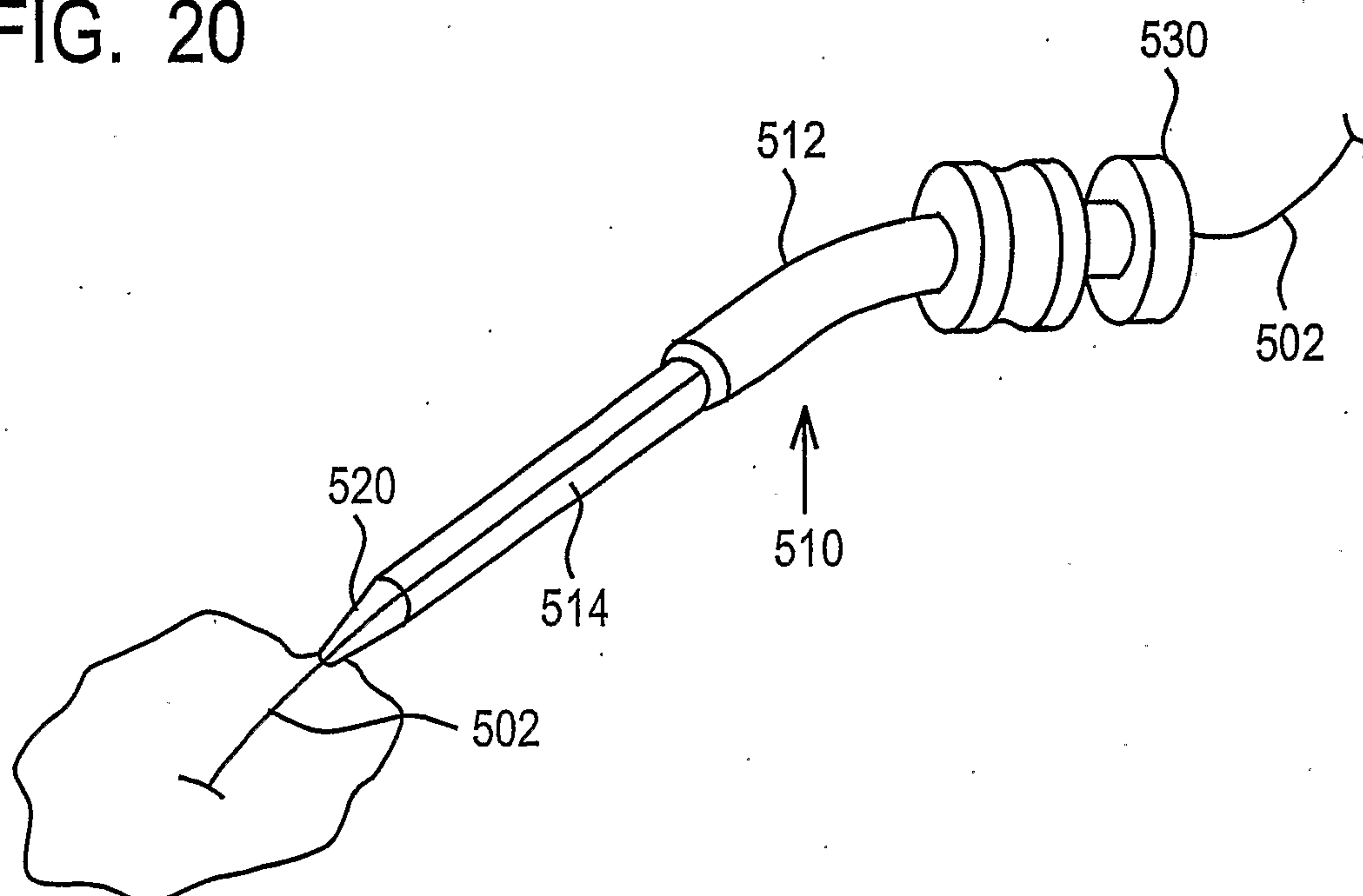
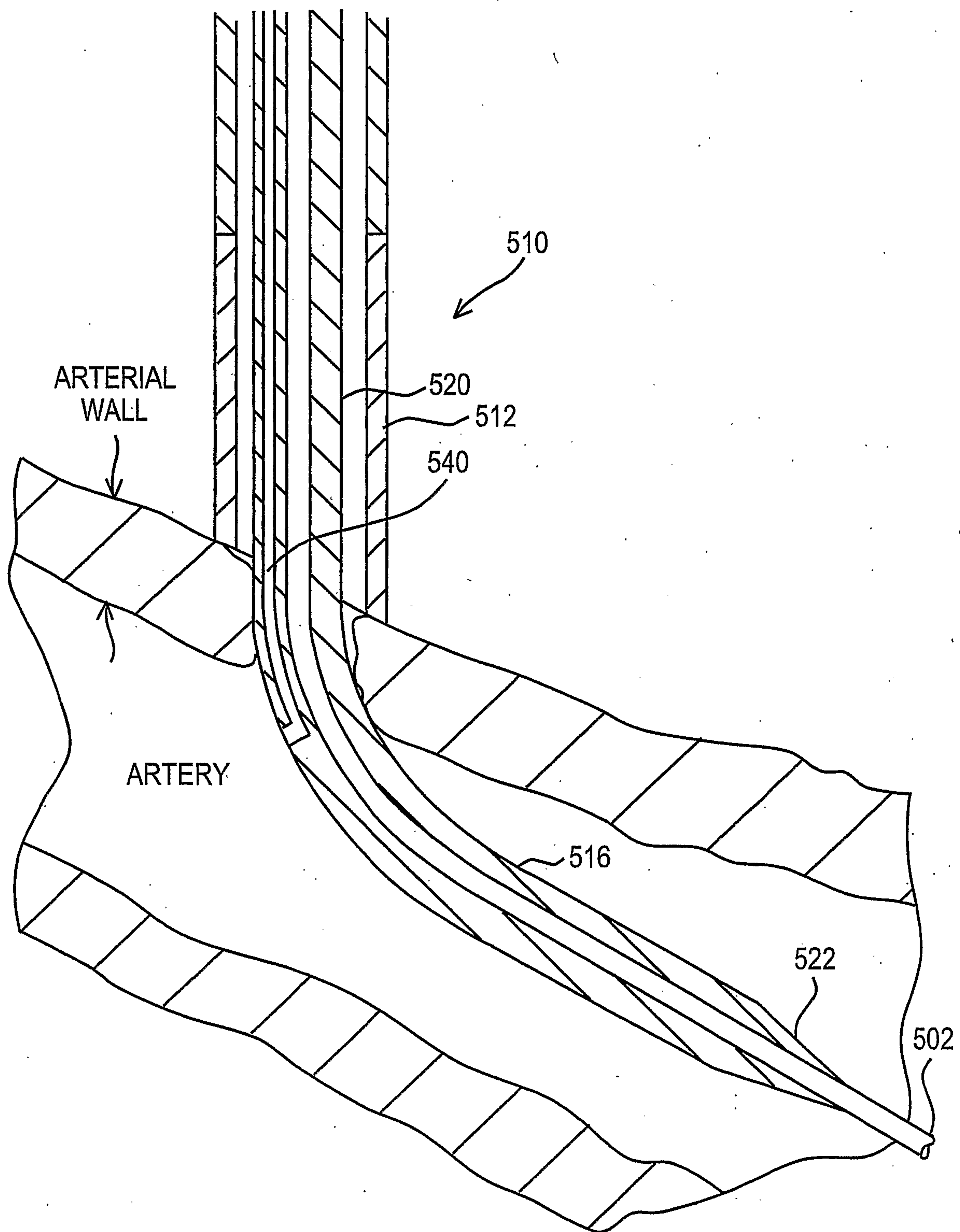


FIG. 20



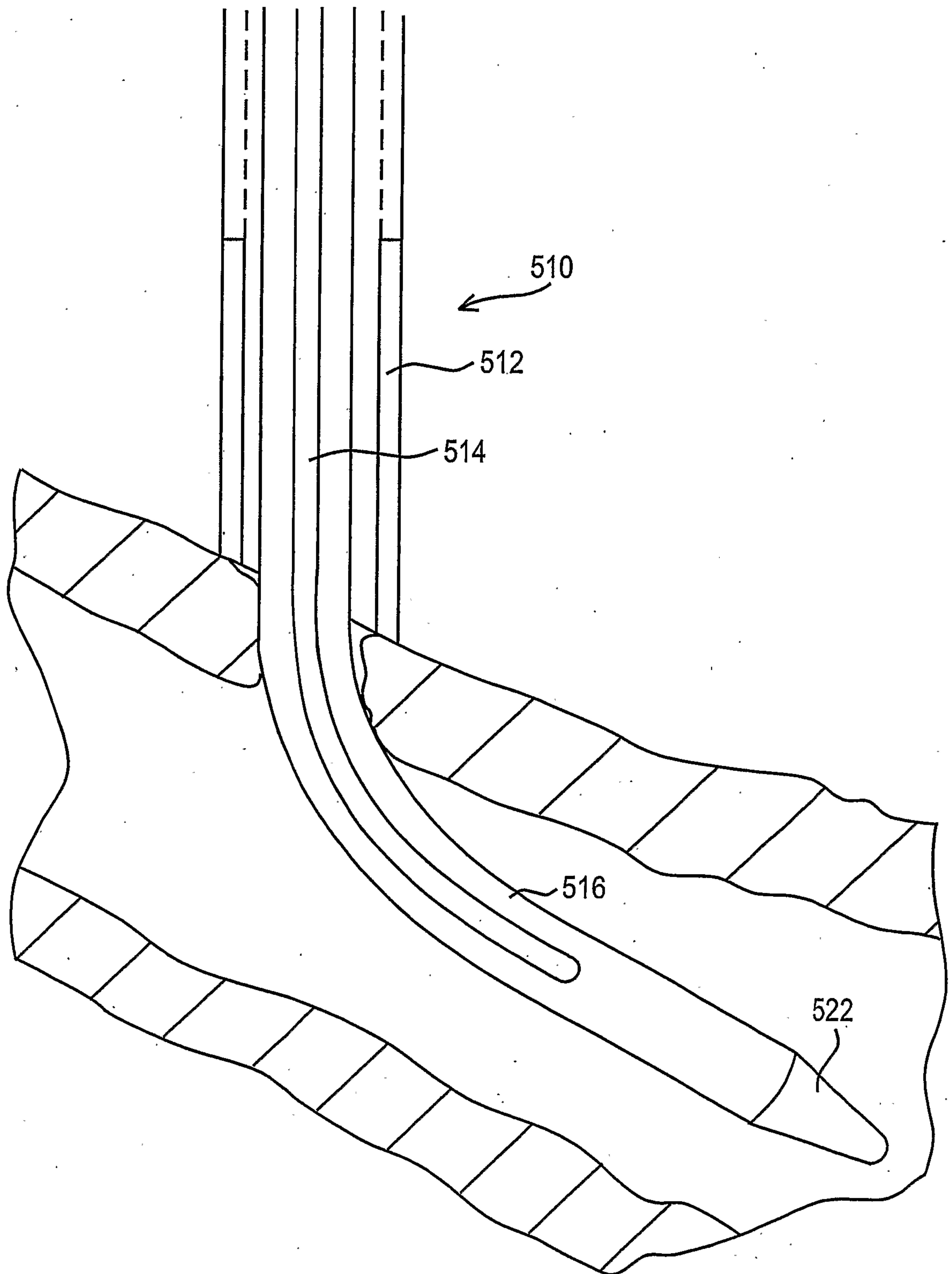
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FIG. 20A



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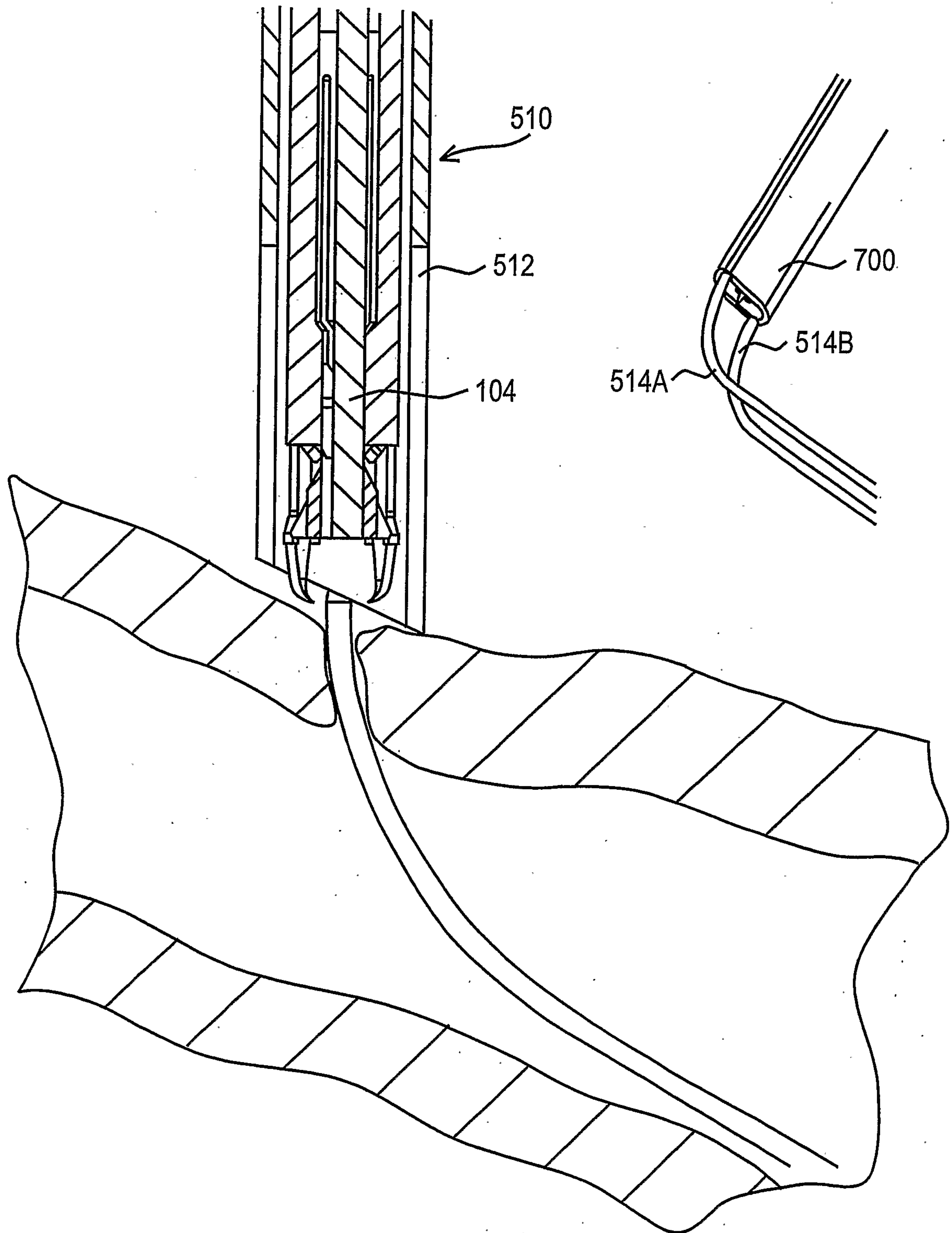
FIG. 21



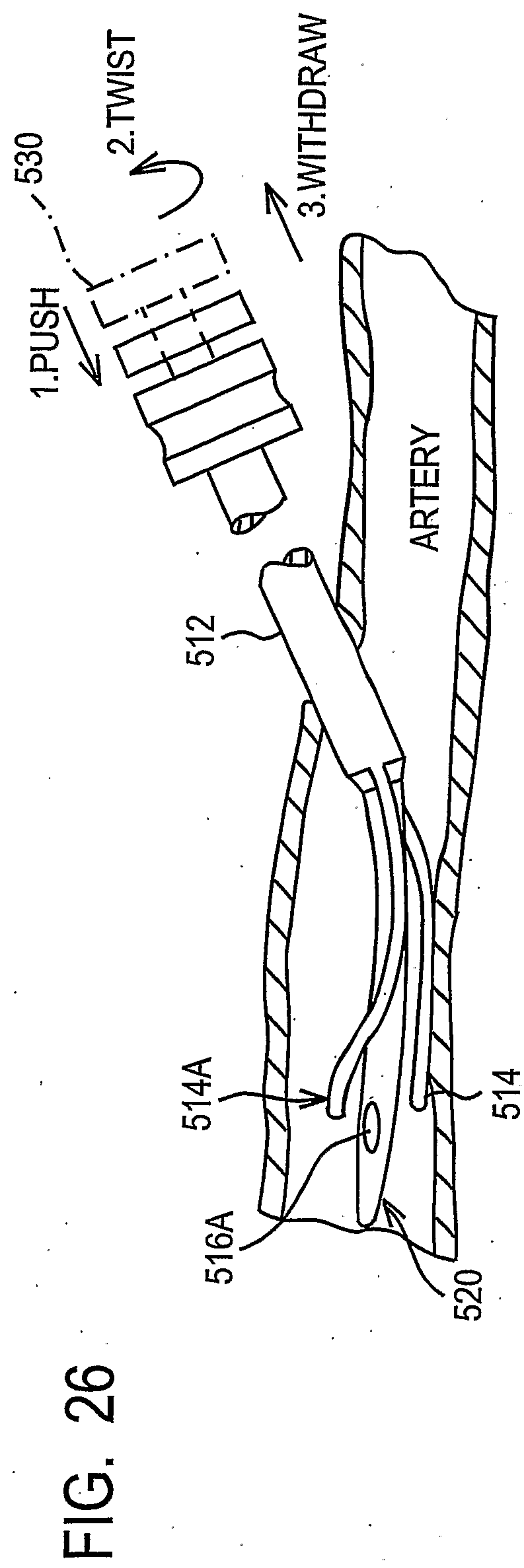
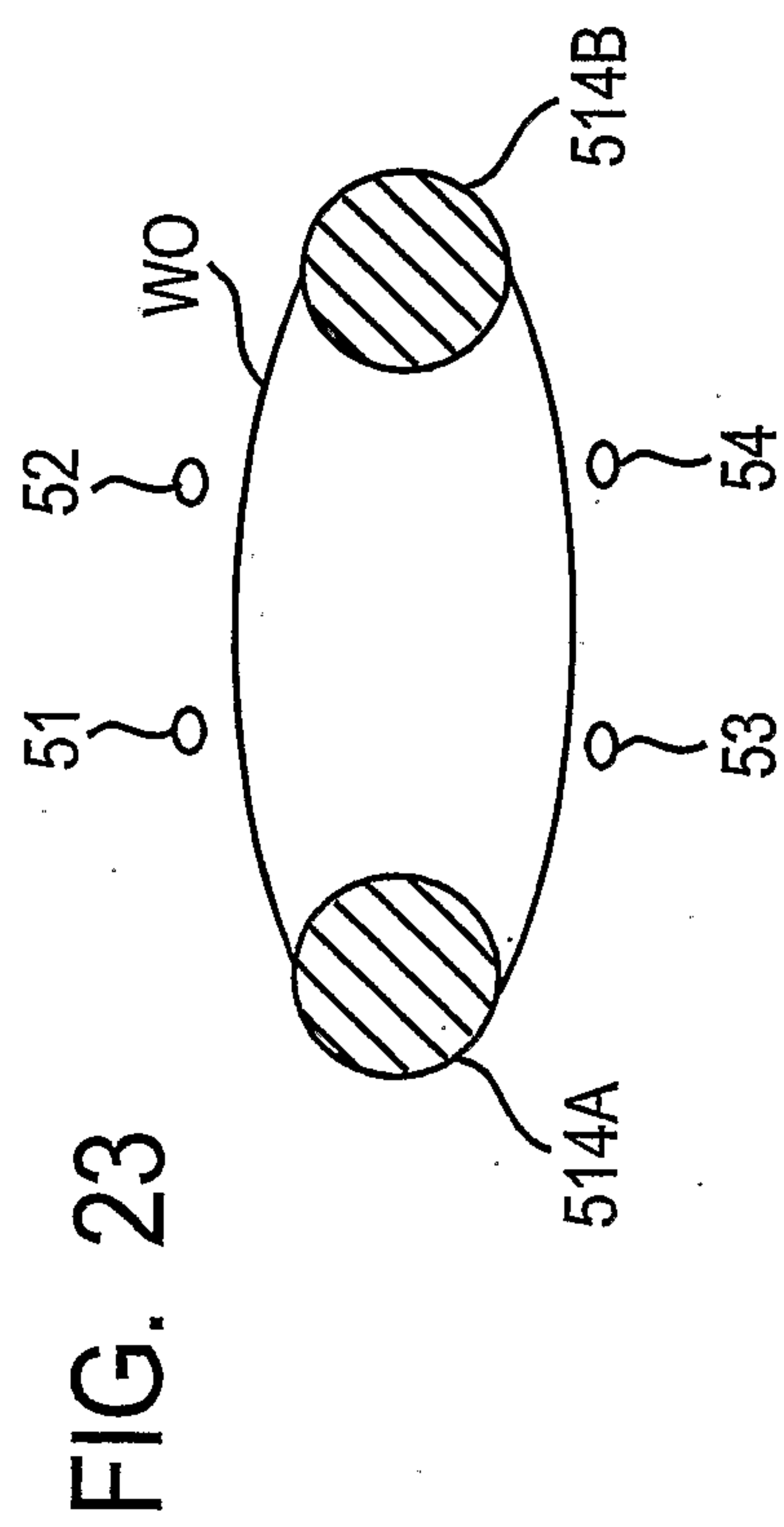
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FIG. 22

FIG. 22A



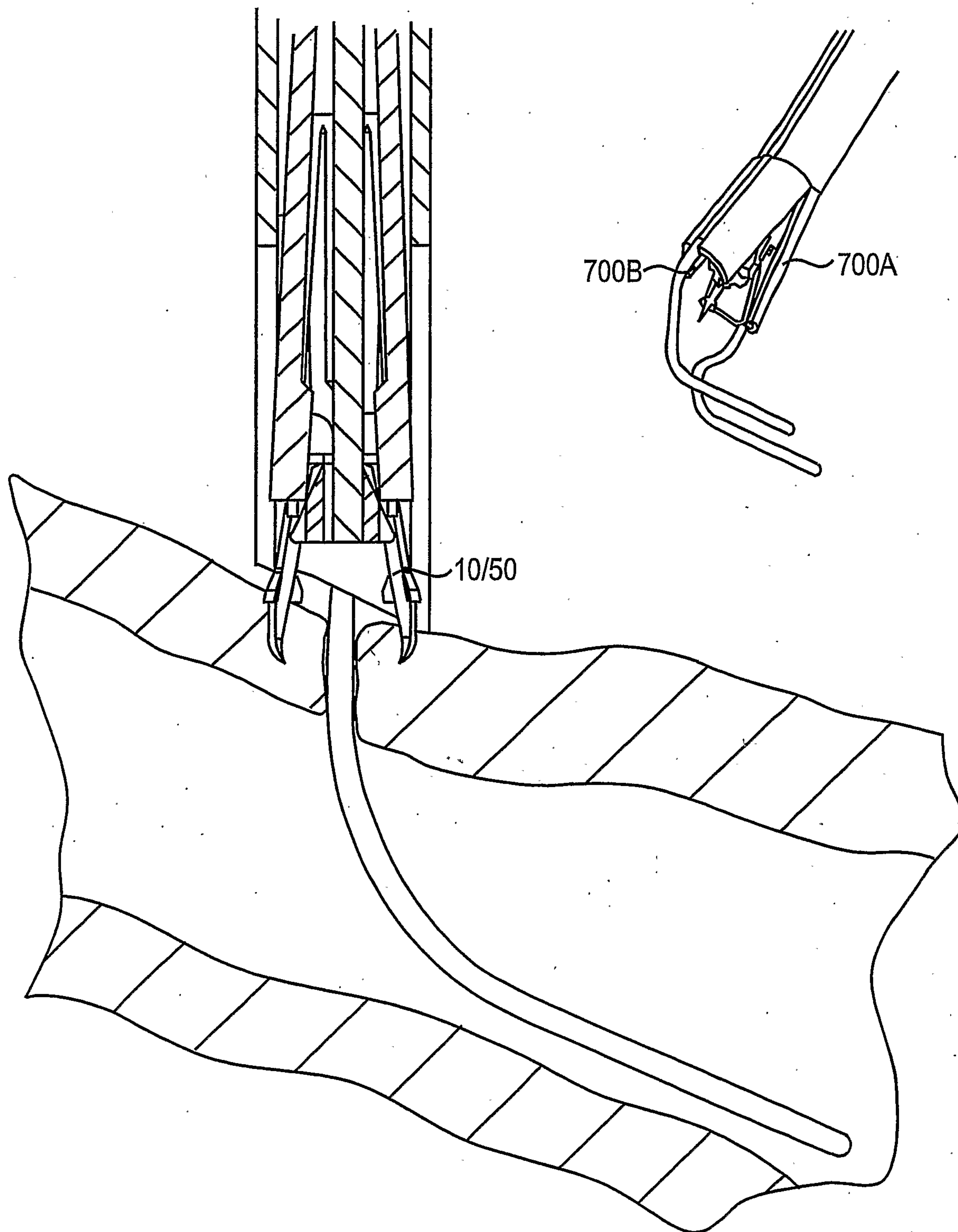
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FIG. 24

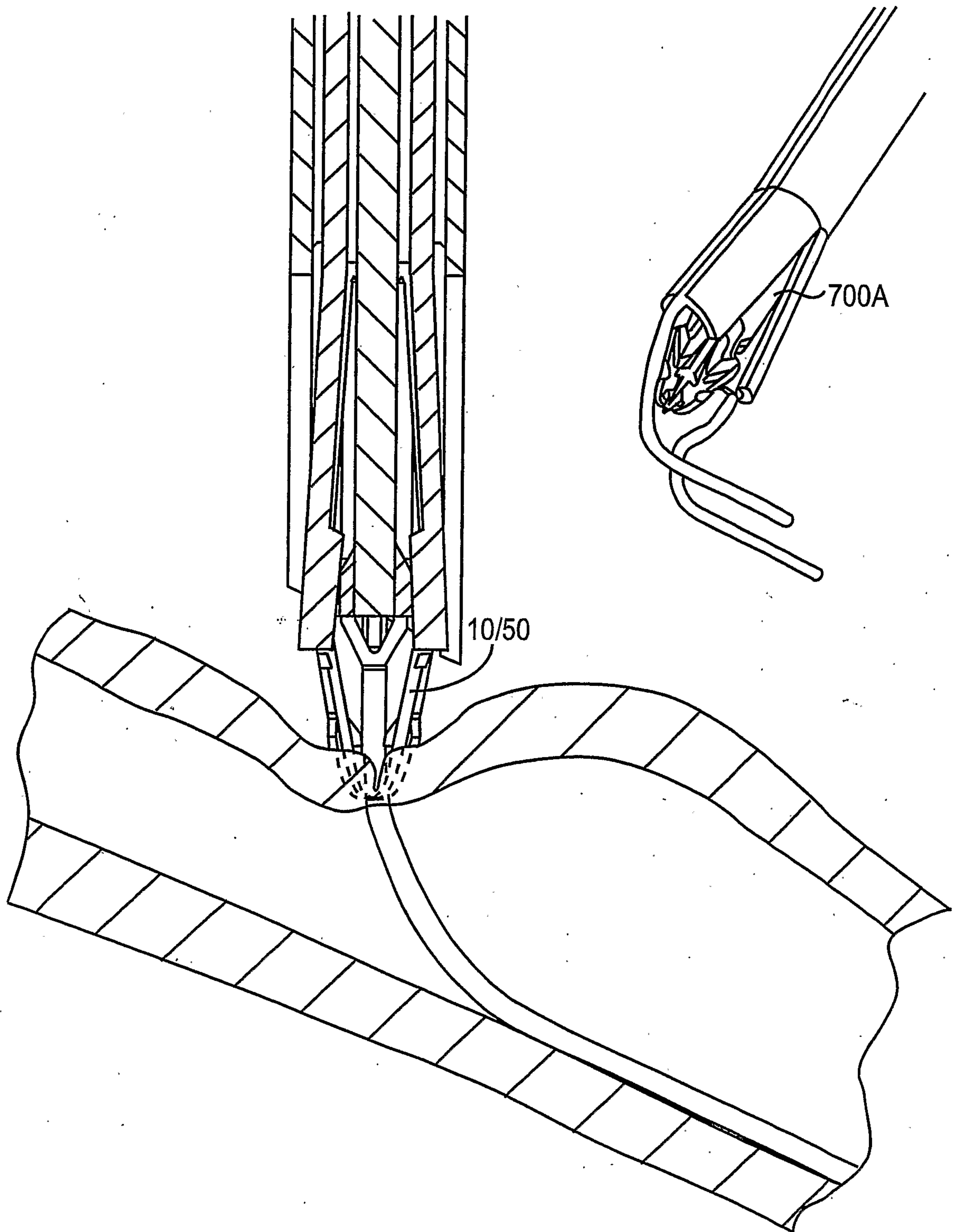
FIG. 24A



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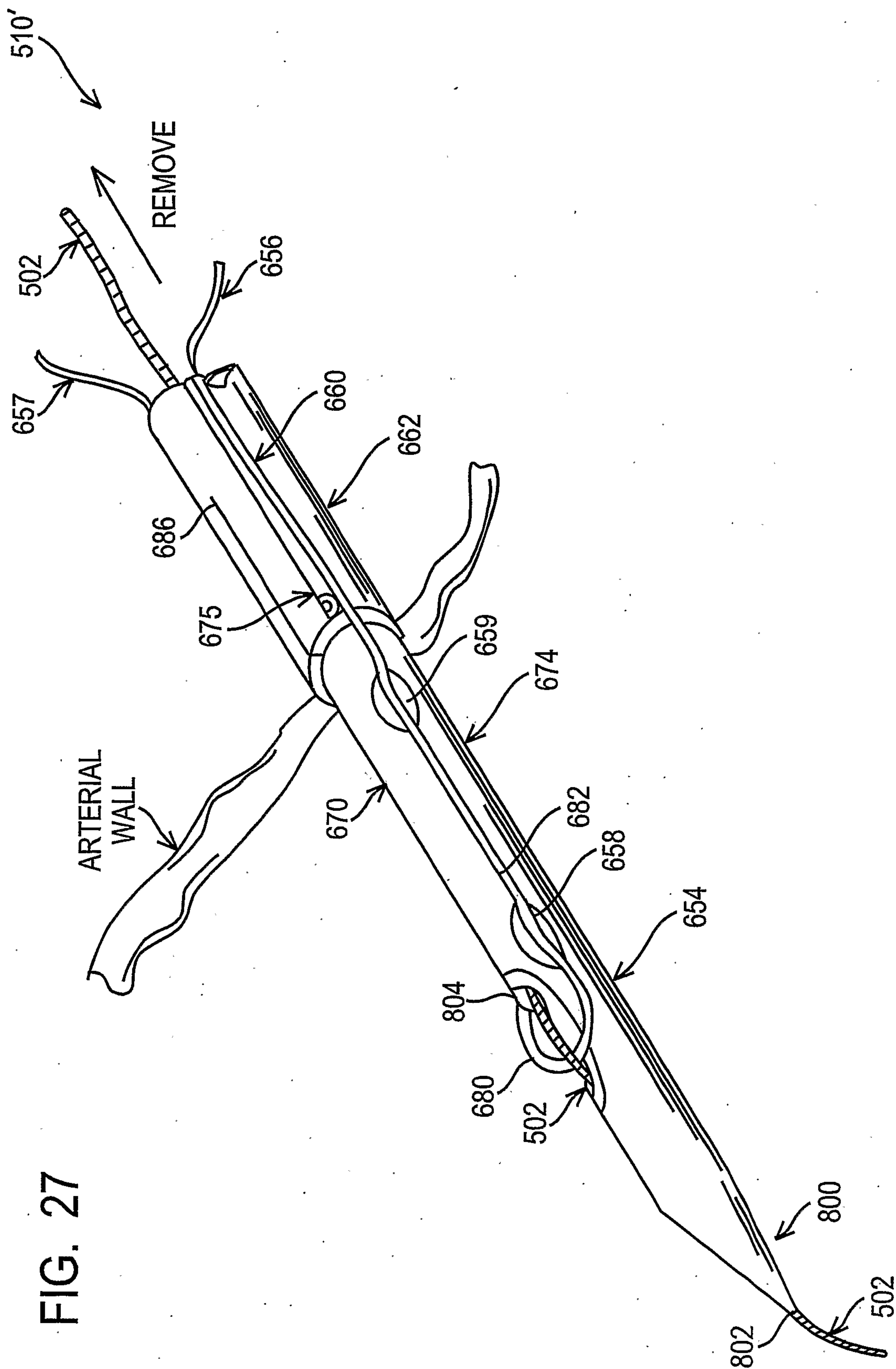
FIG. 25

FIG. 25A

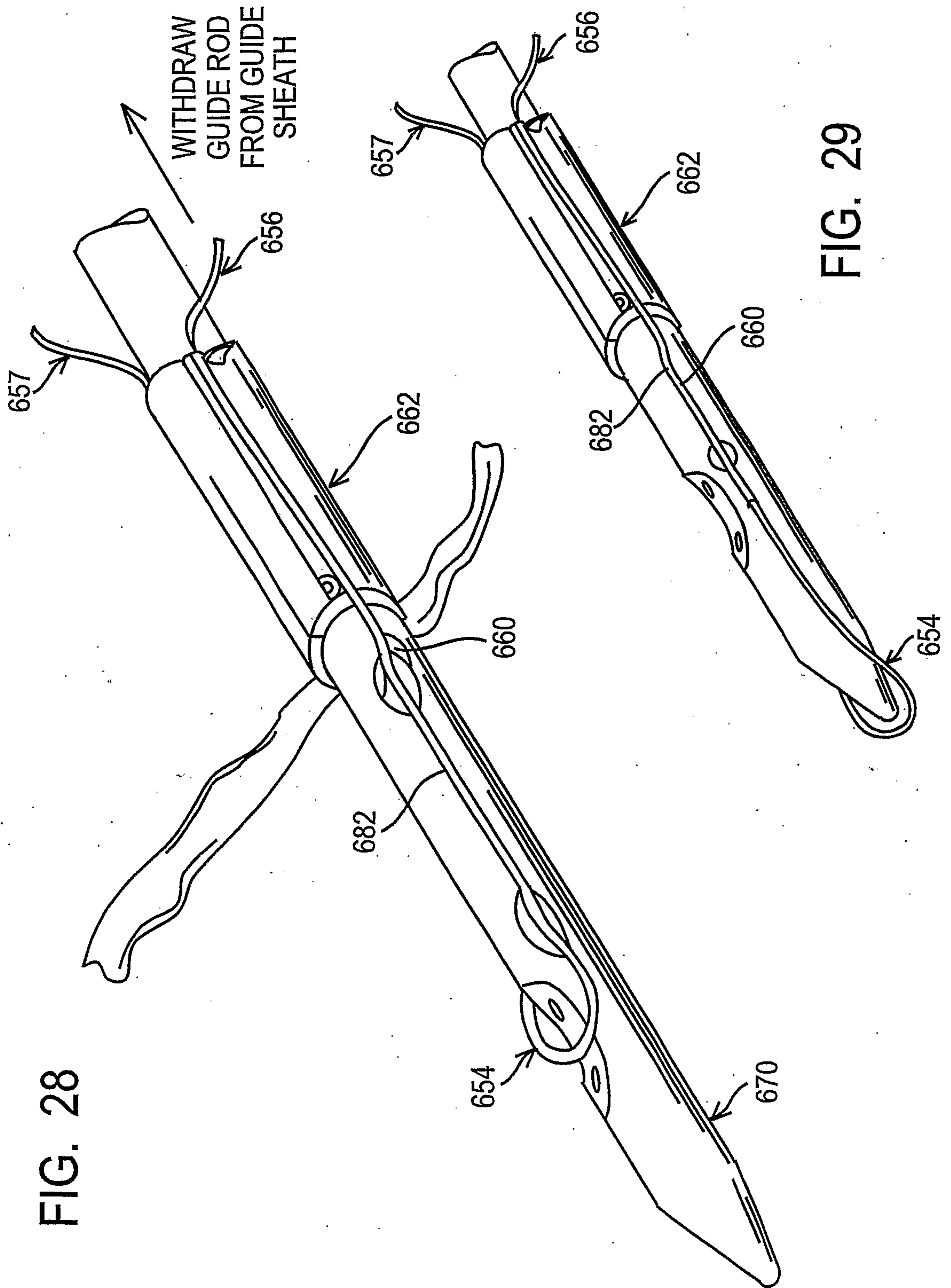


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FIG. 27



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FIG. 30

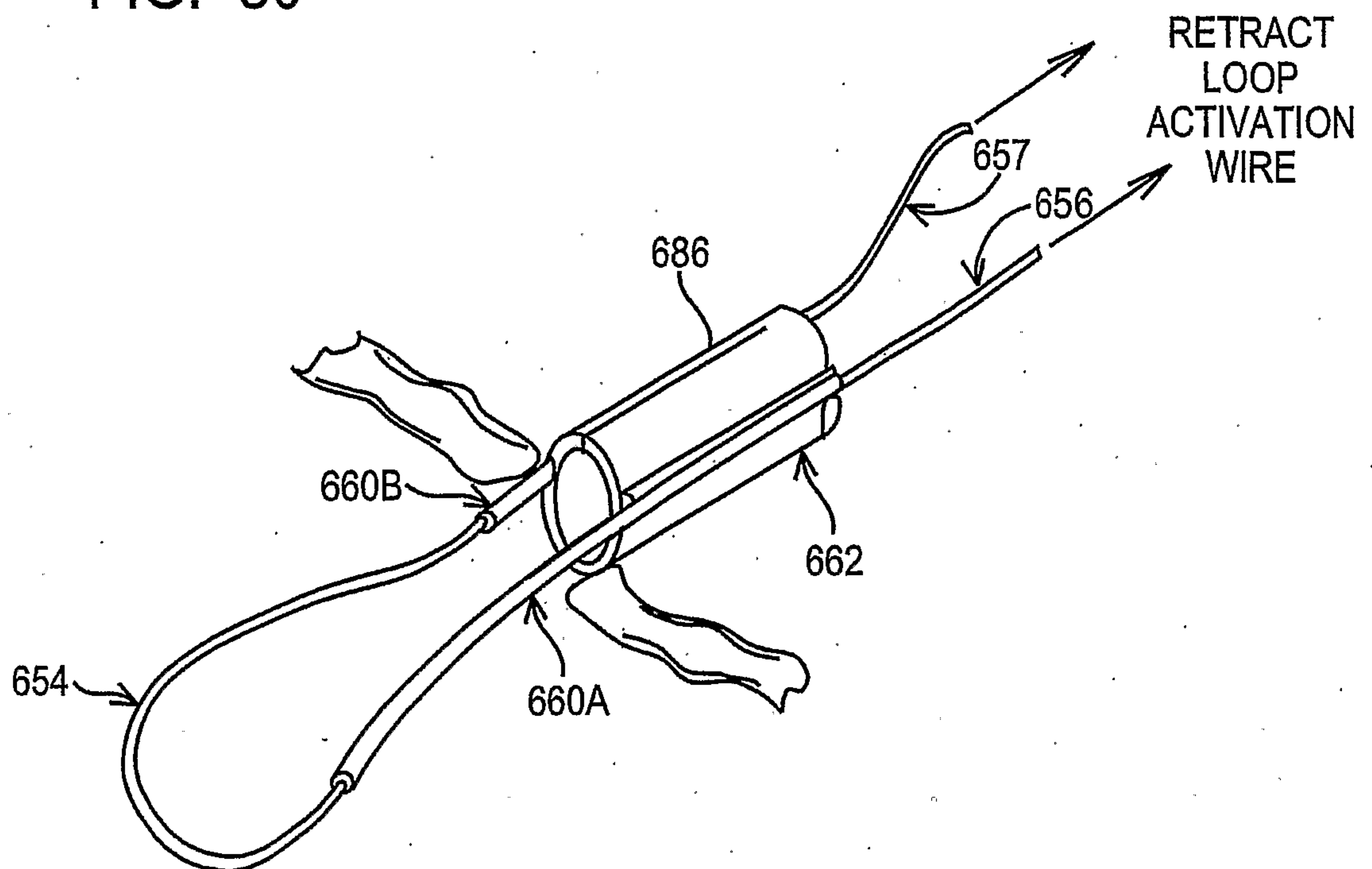
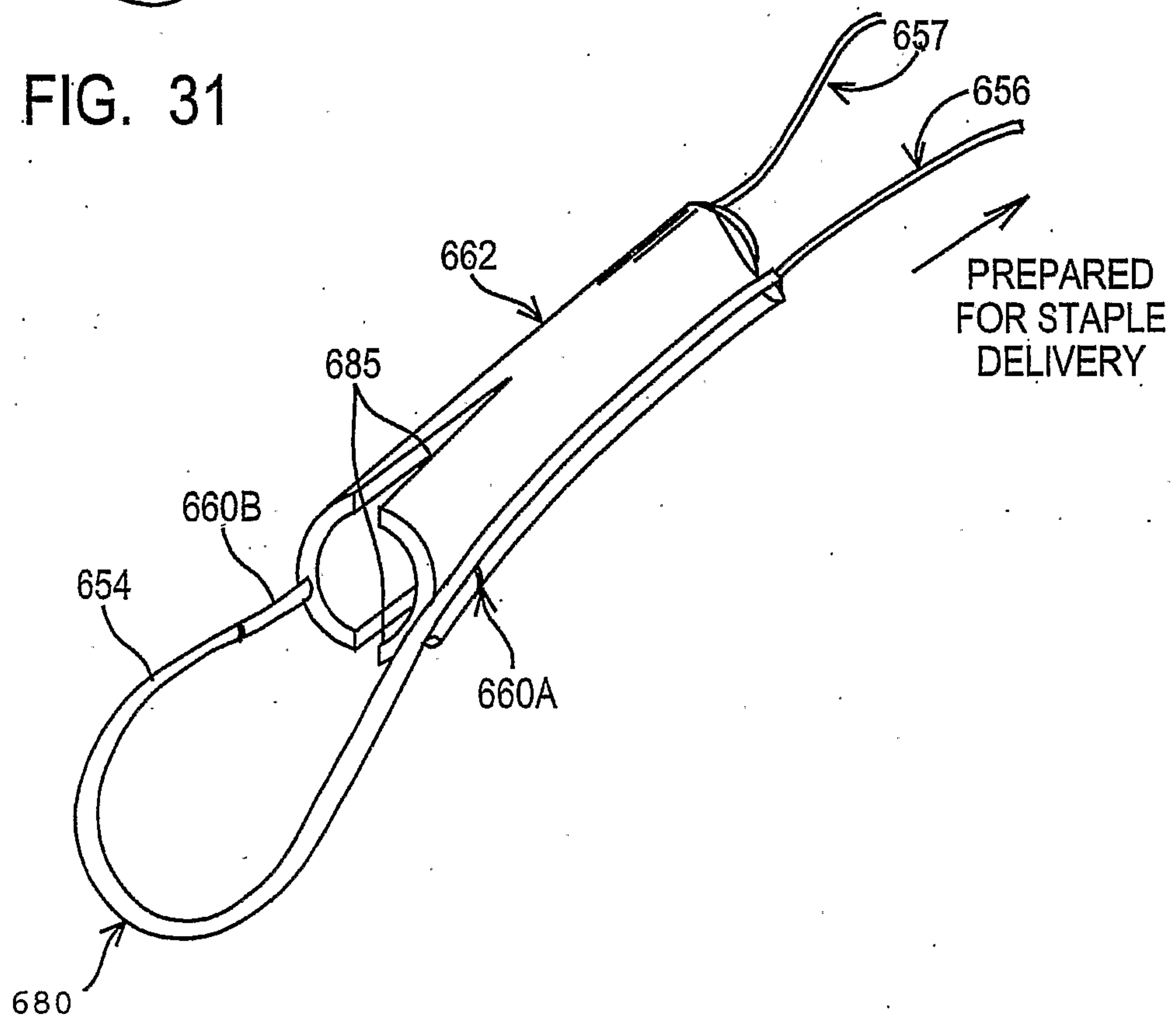
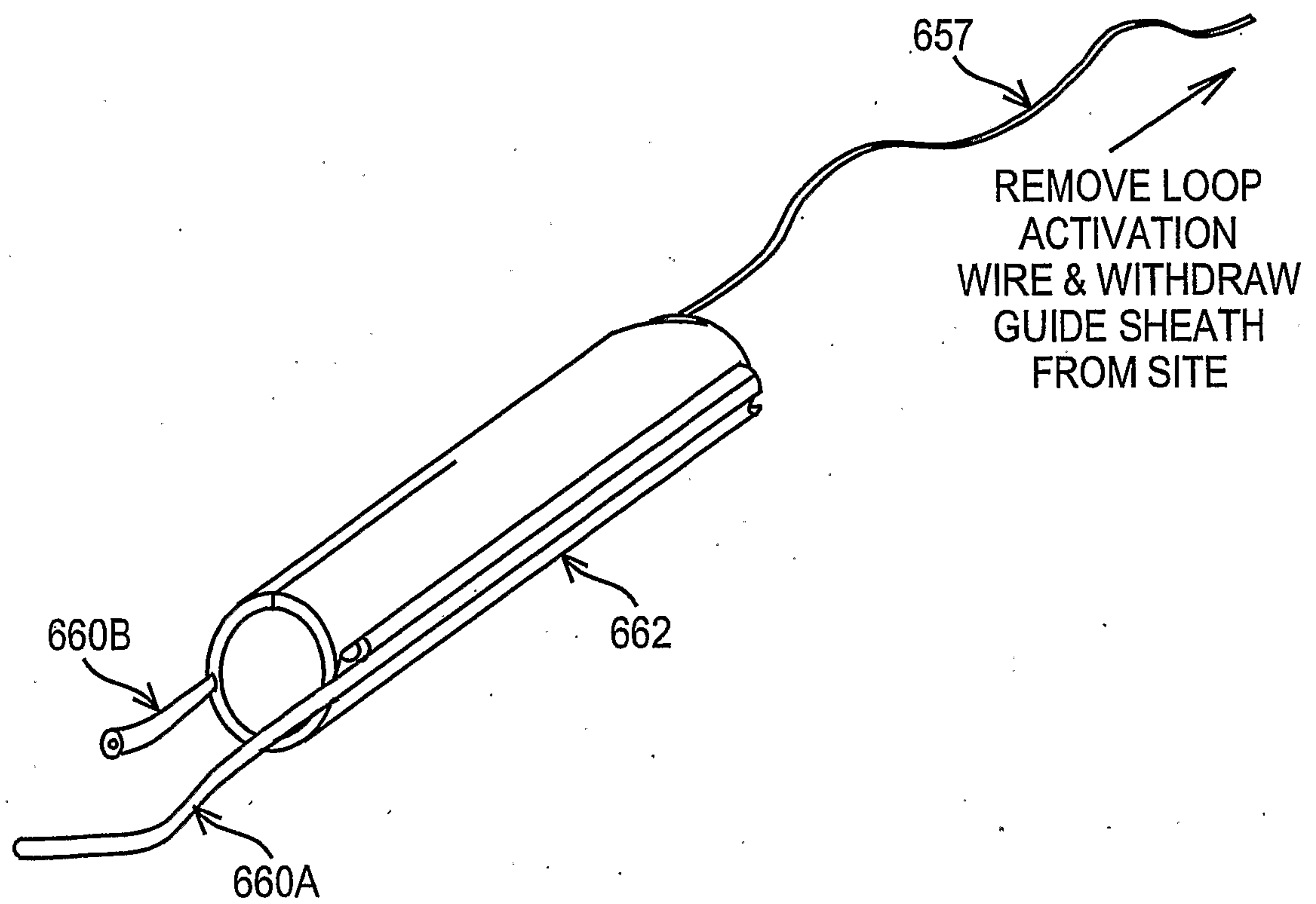


FIG. 31



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FIG. 32



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FIG. 33

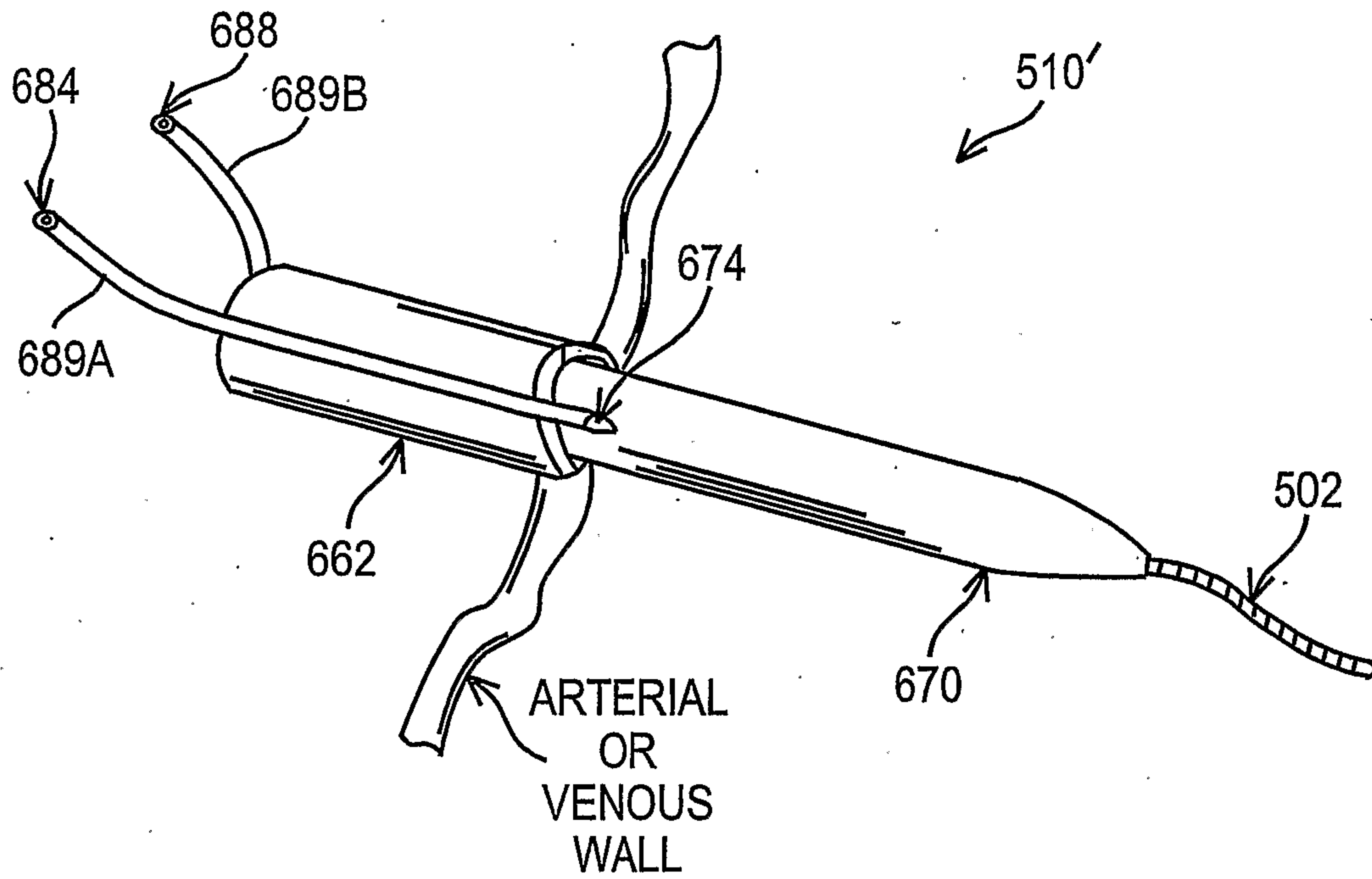
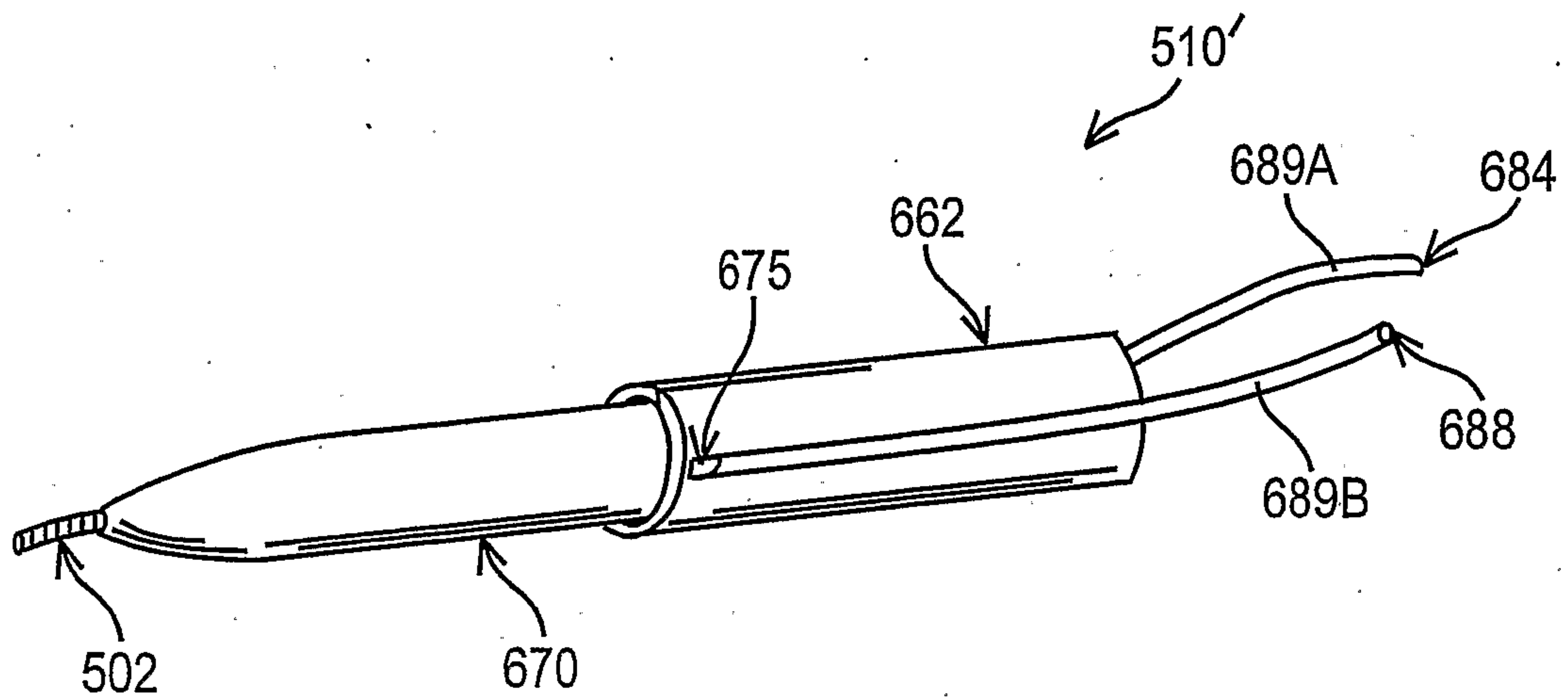


FIG. 34



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FIG. 35

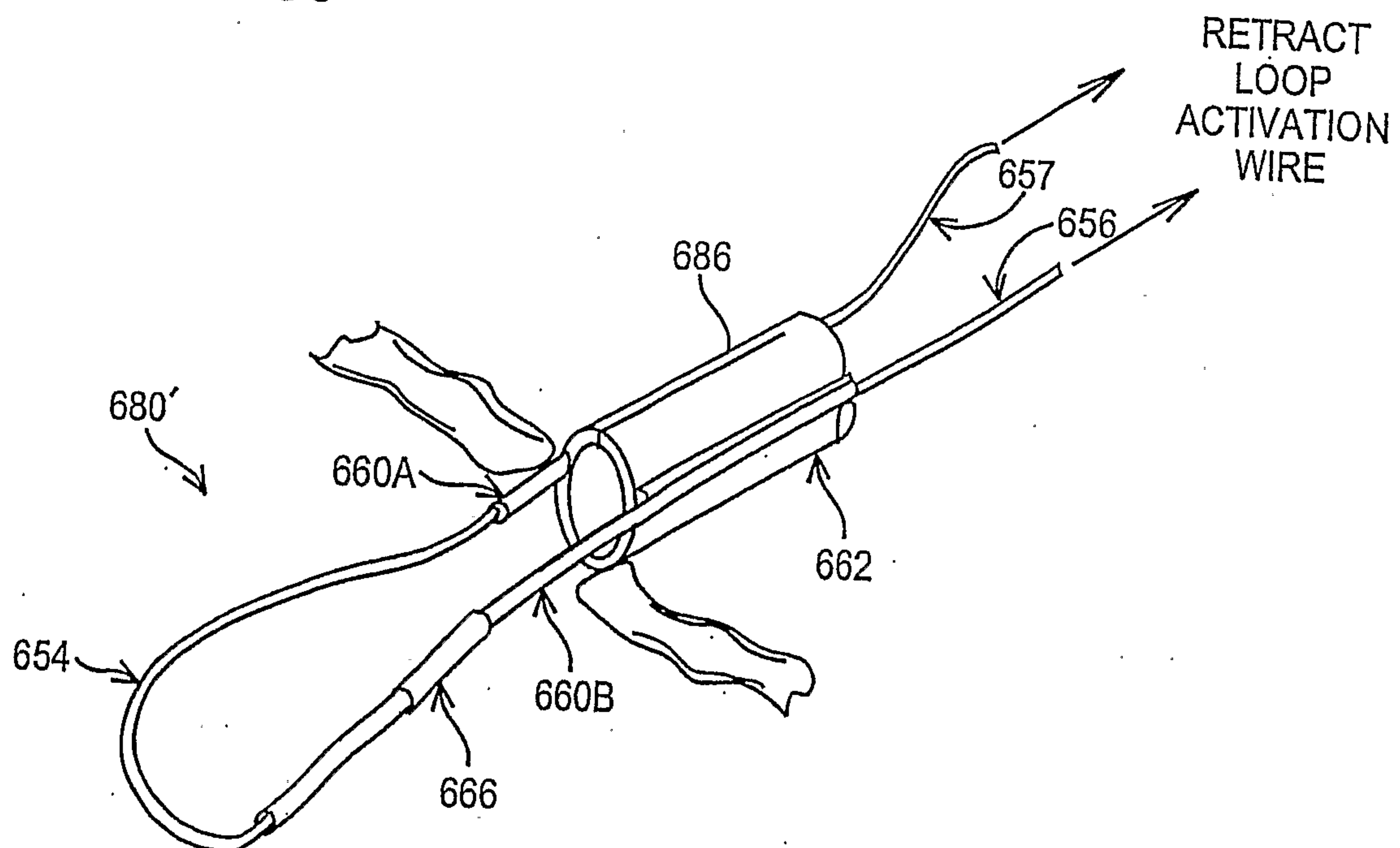
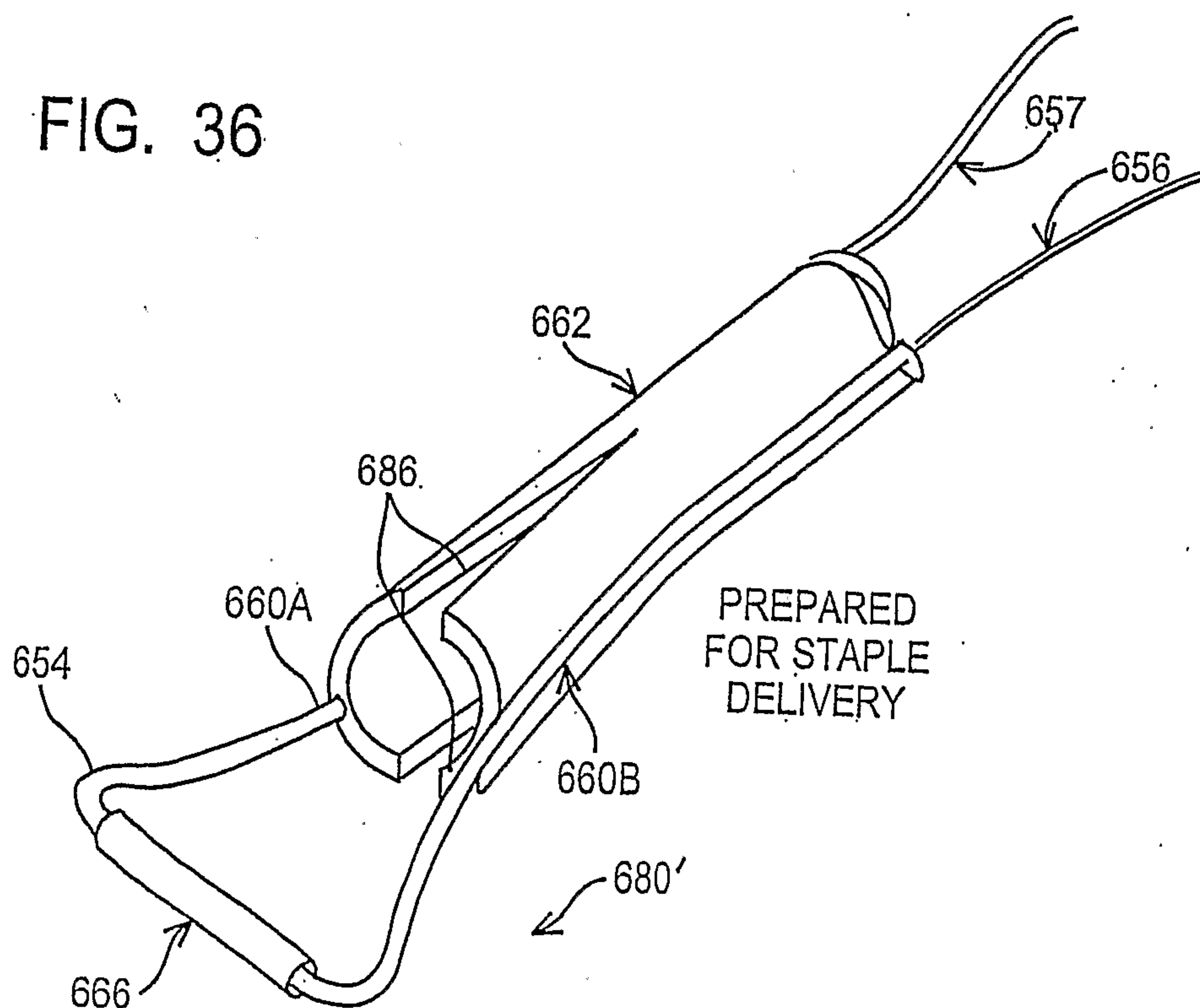
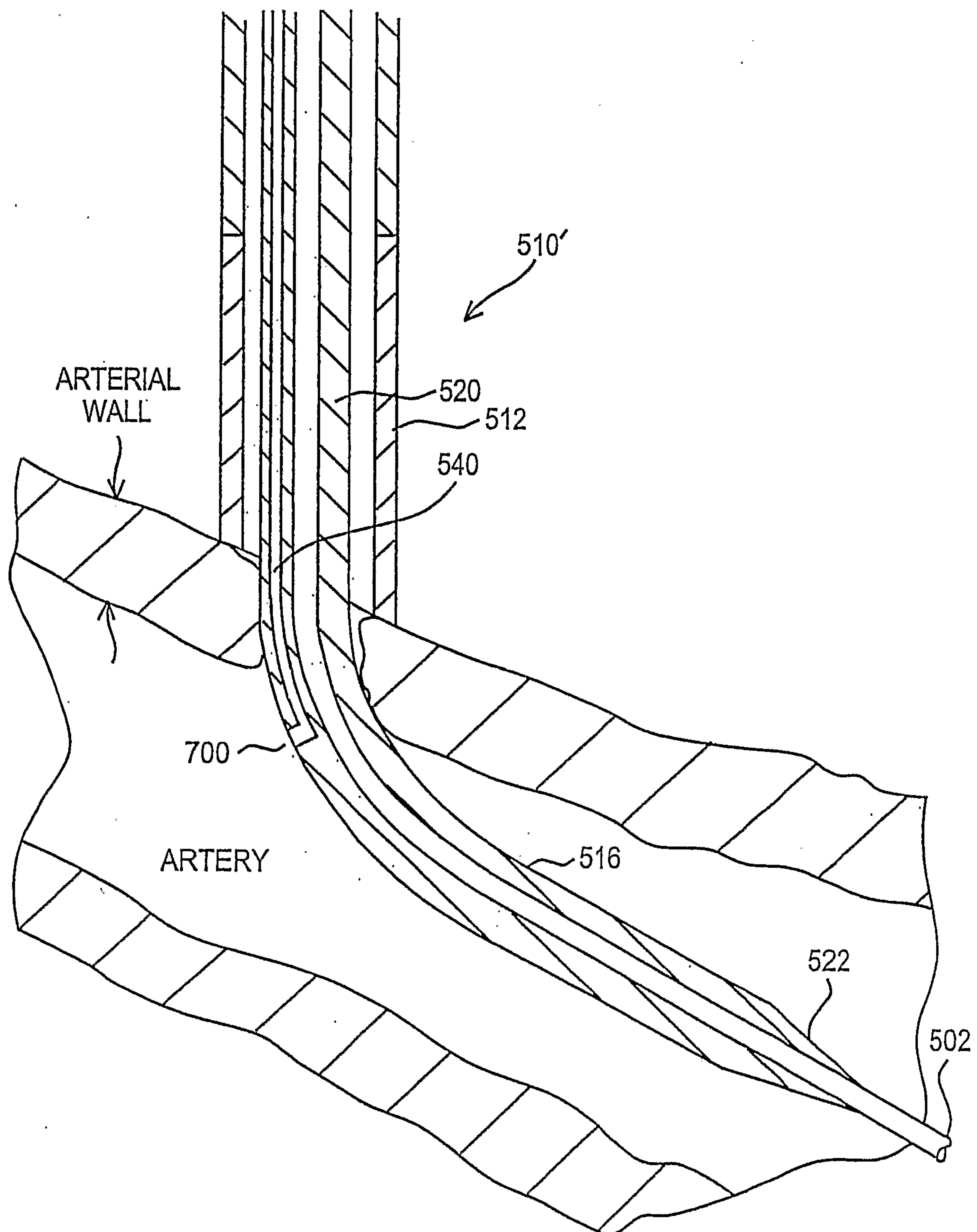


FIG. 36



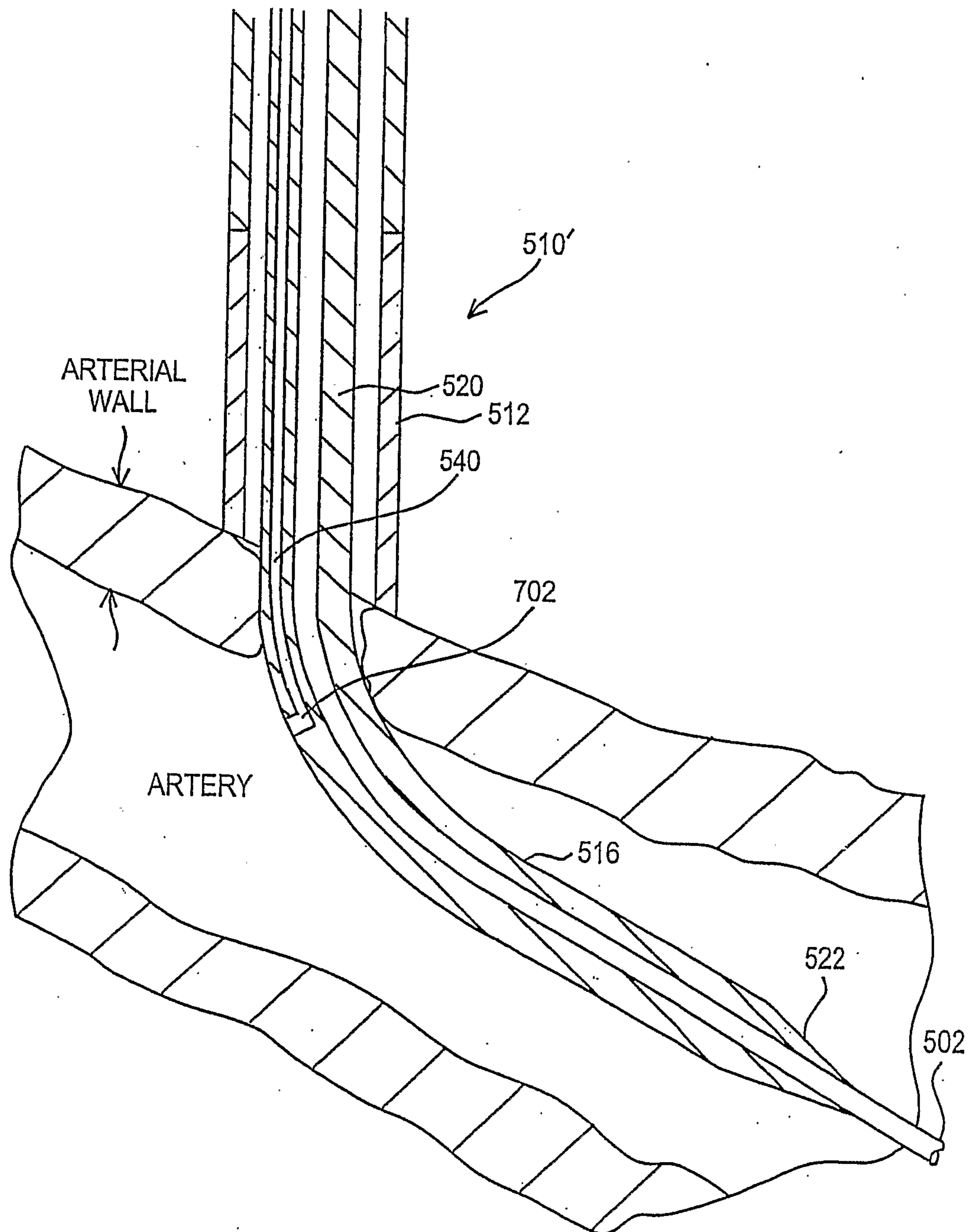
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FIG. 37



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FIG. 38



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FIG. 39

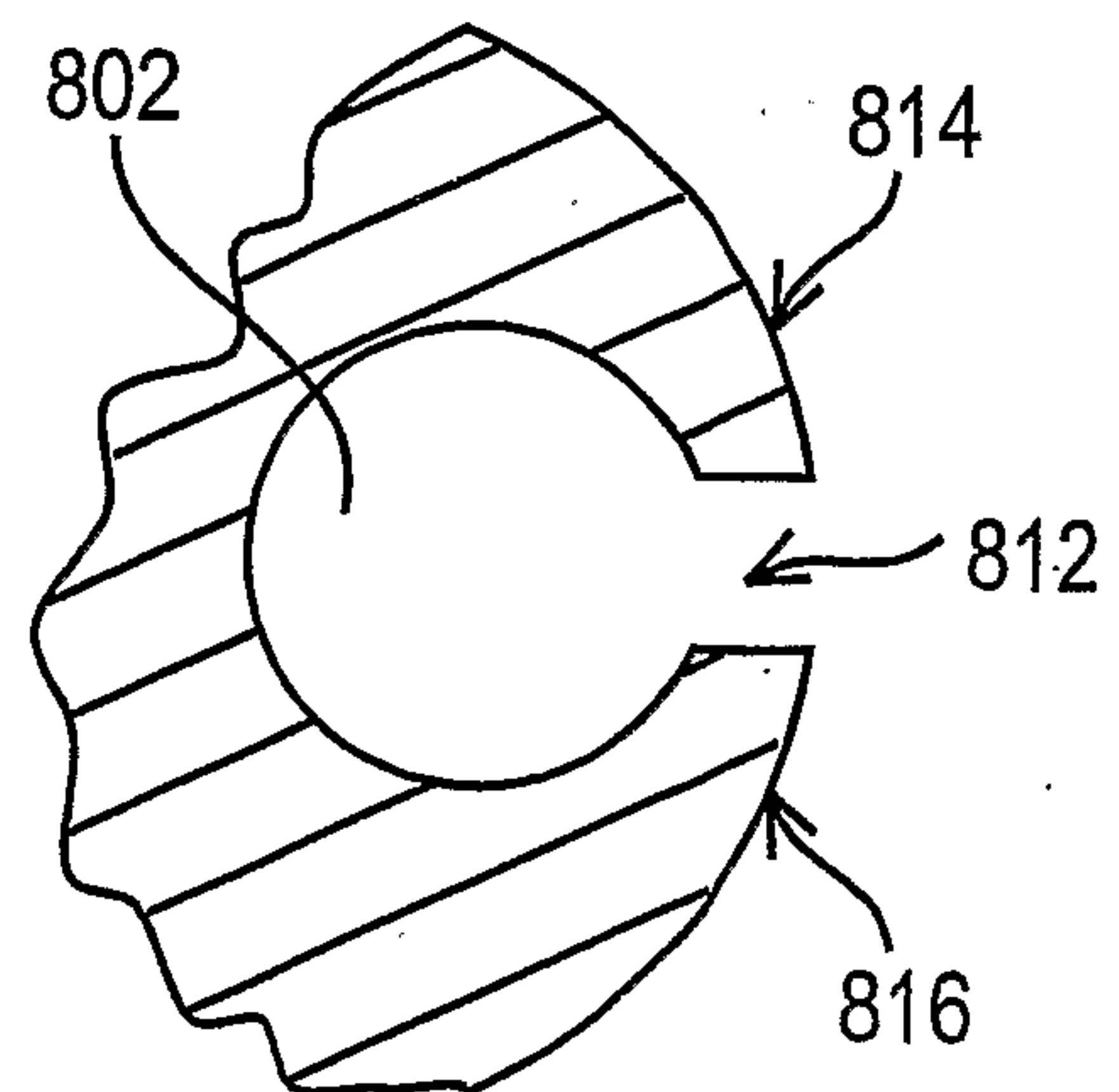
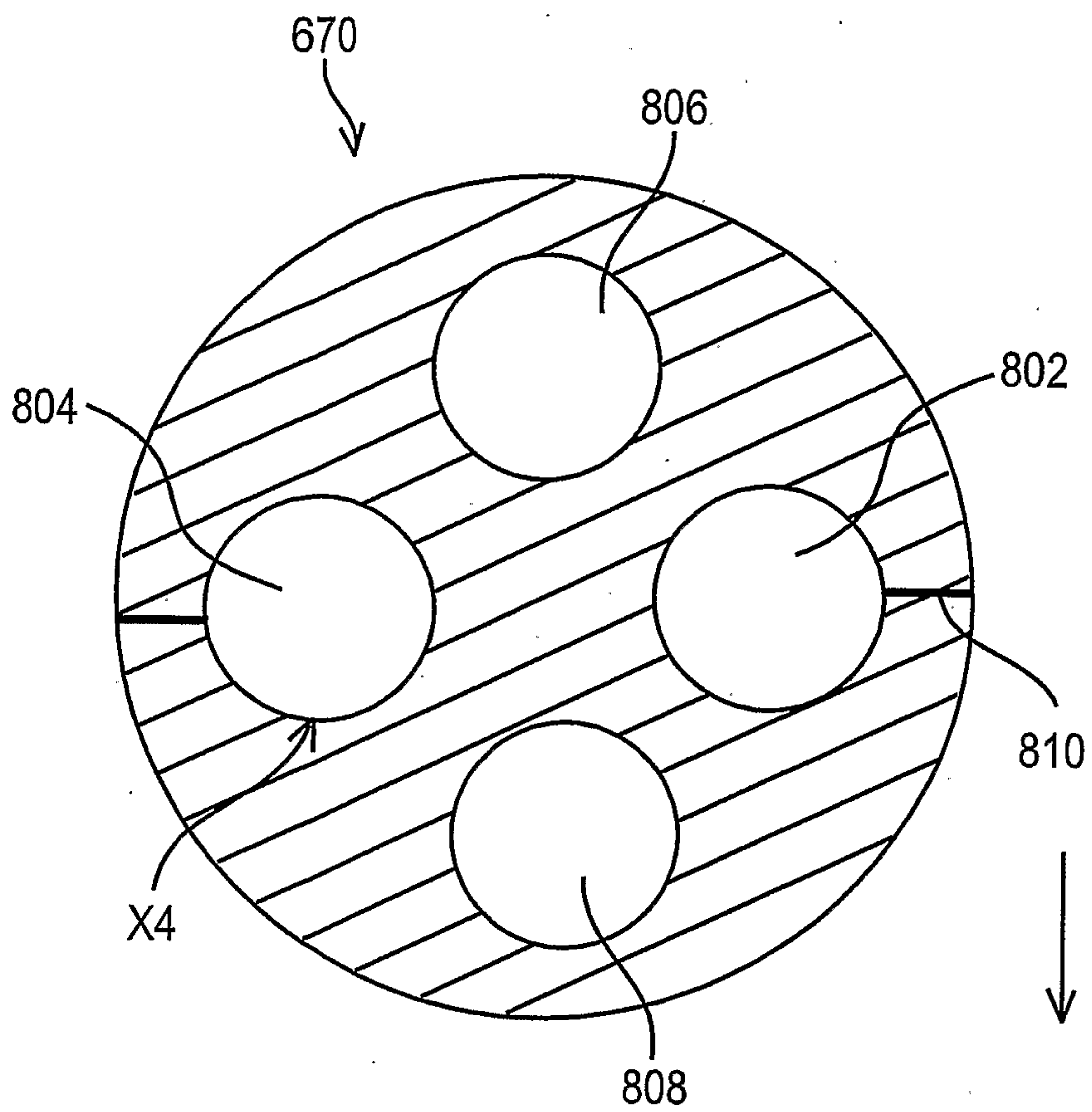
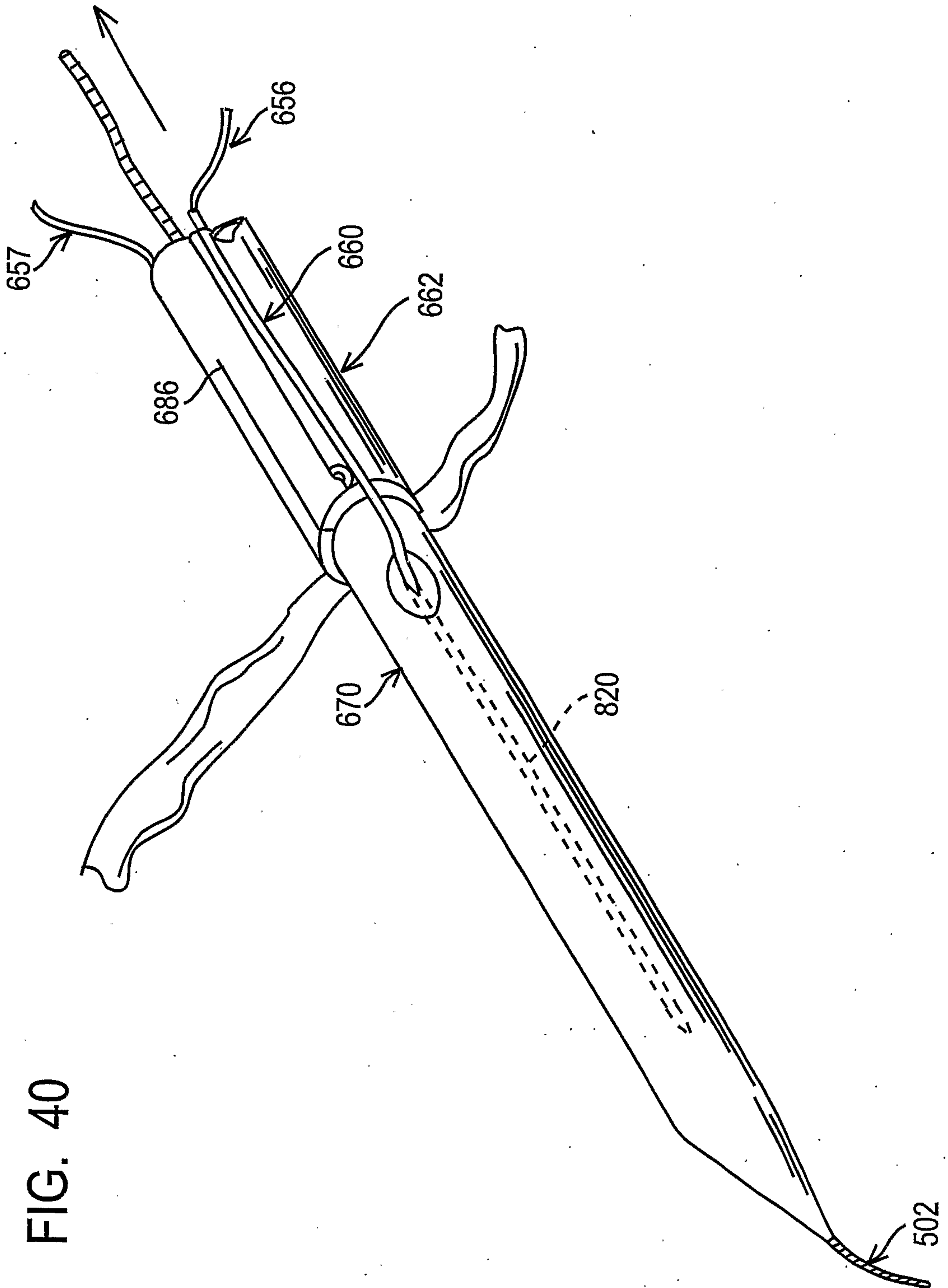


FIG. 39A

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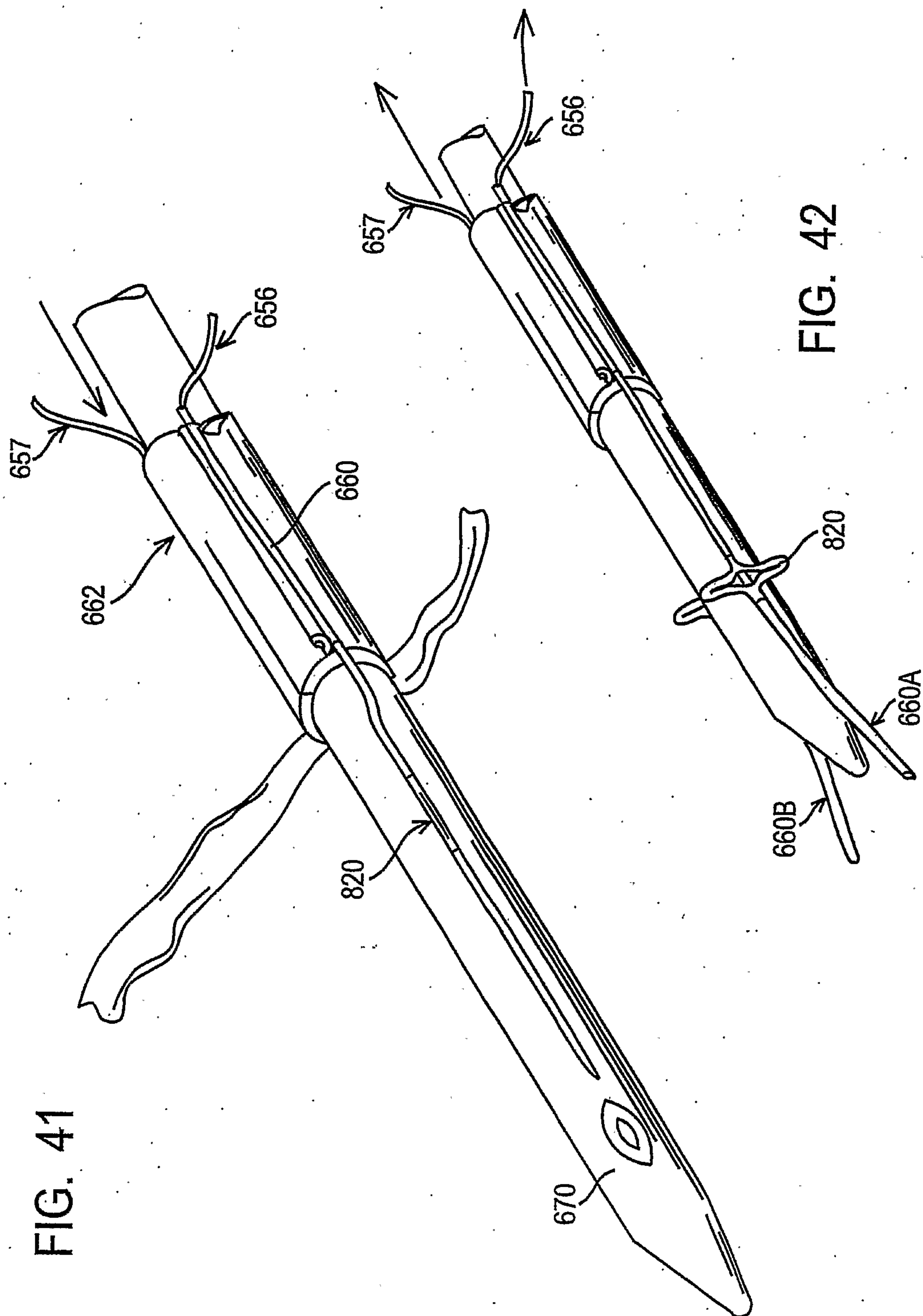


FIG. 41

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FIG. 43

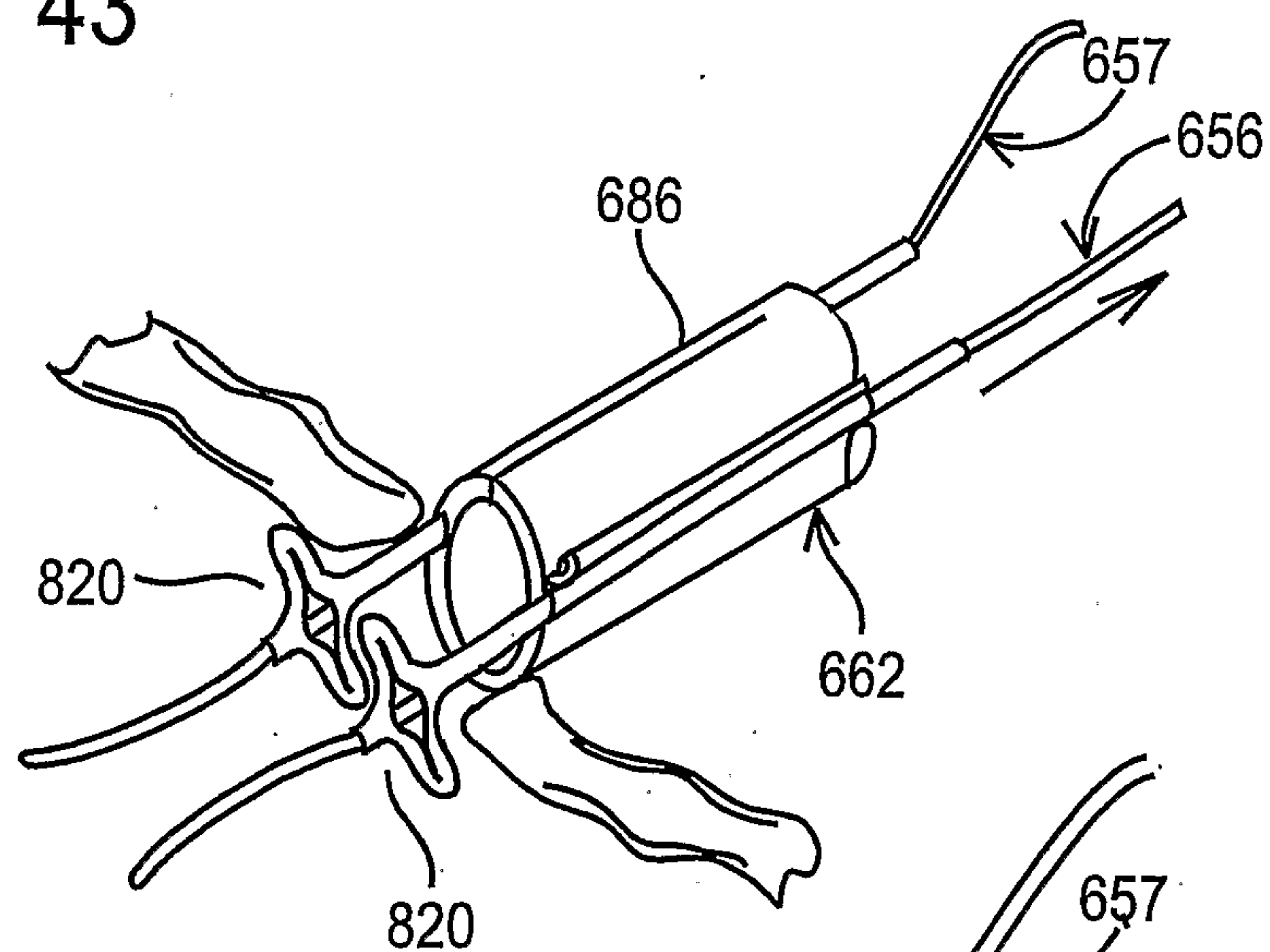


FIG. 44A

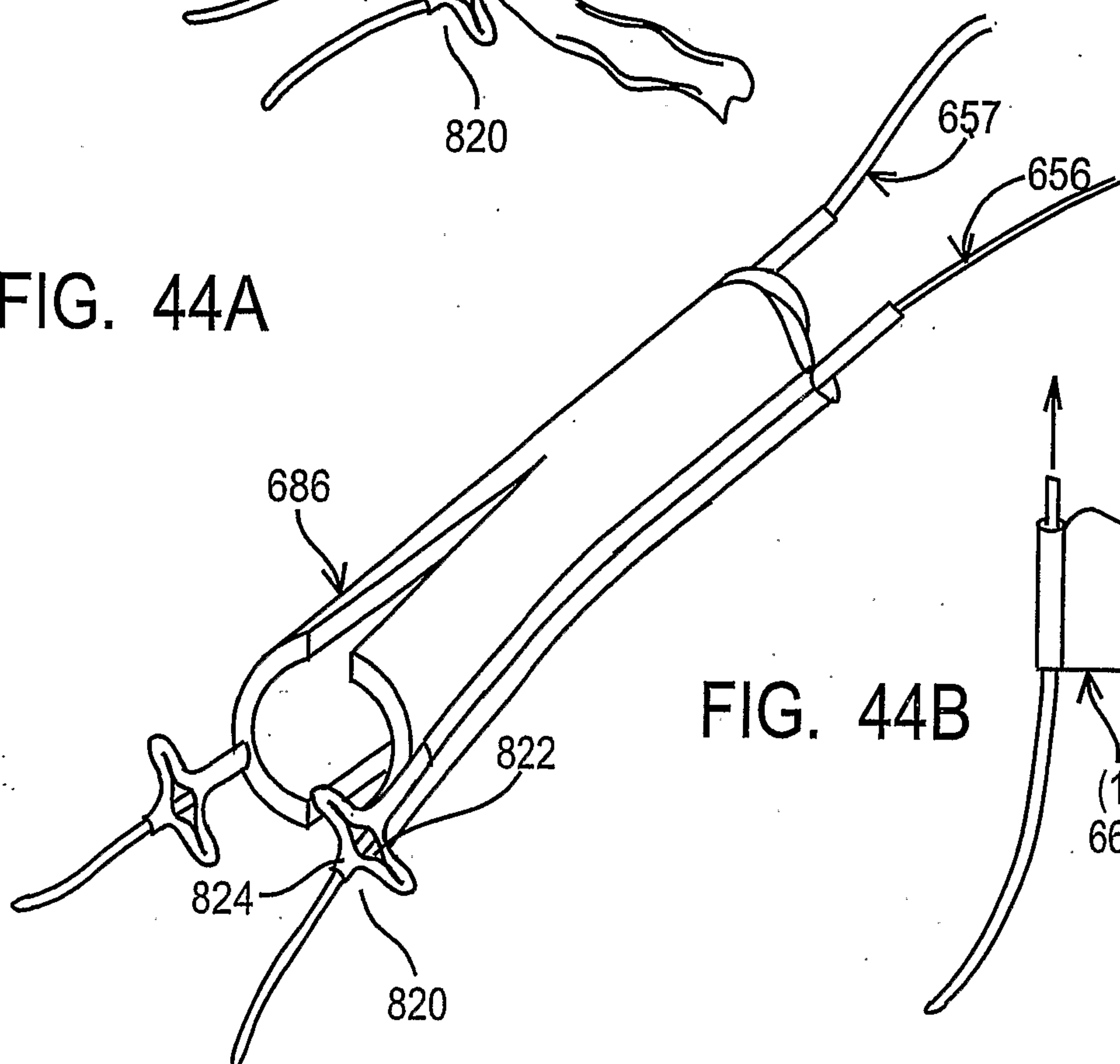


FIG. 44B

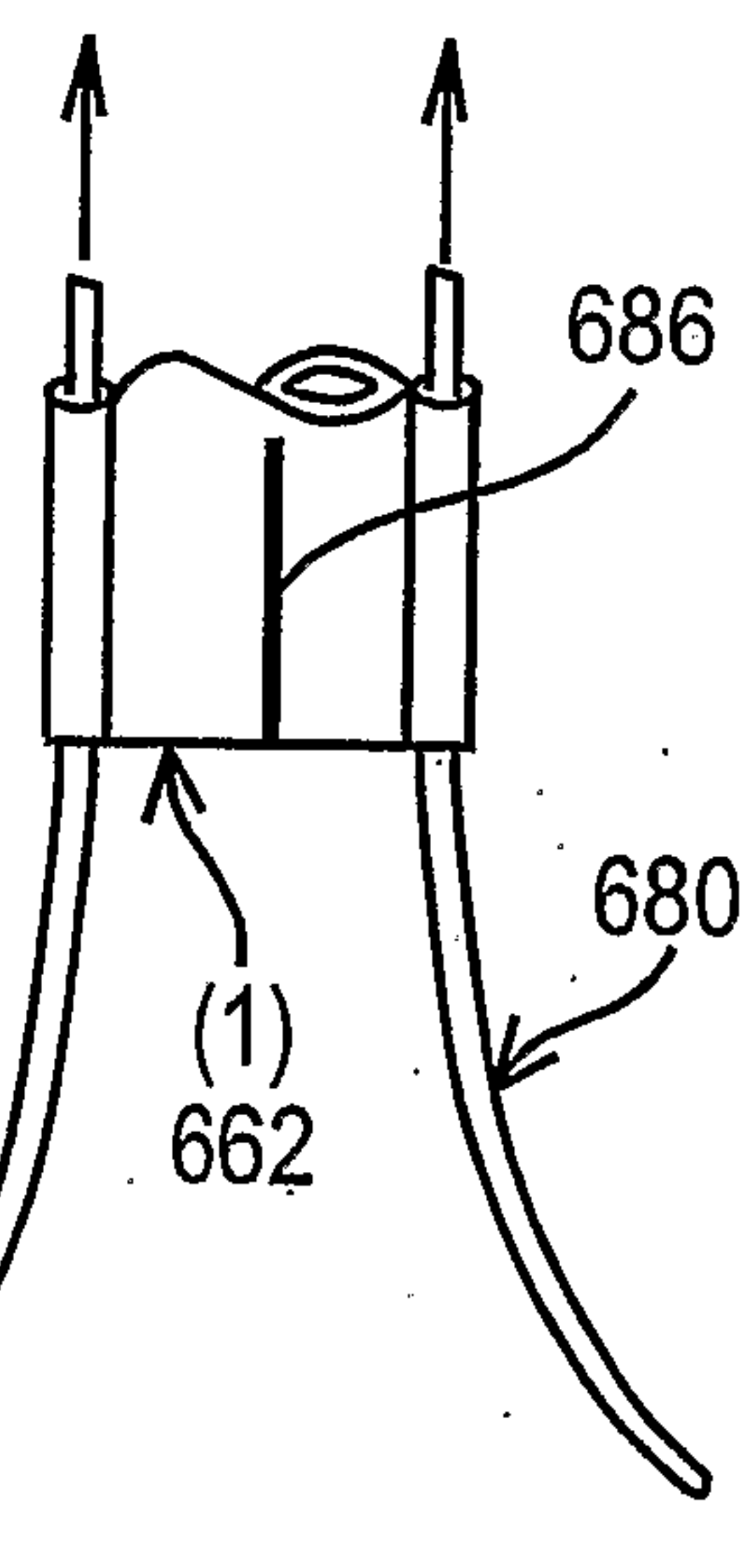
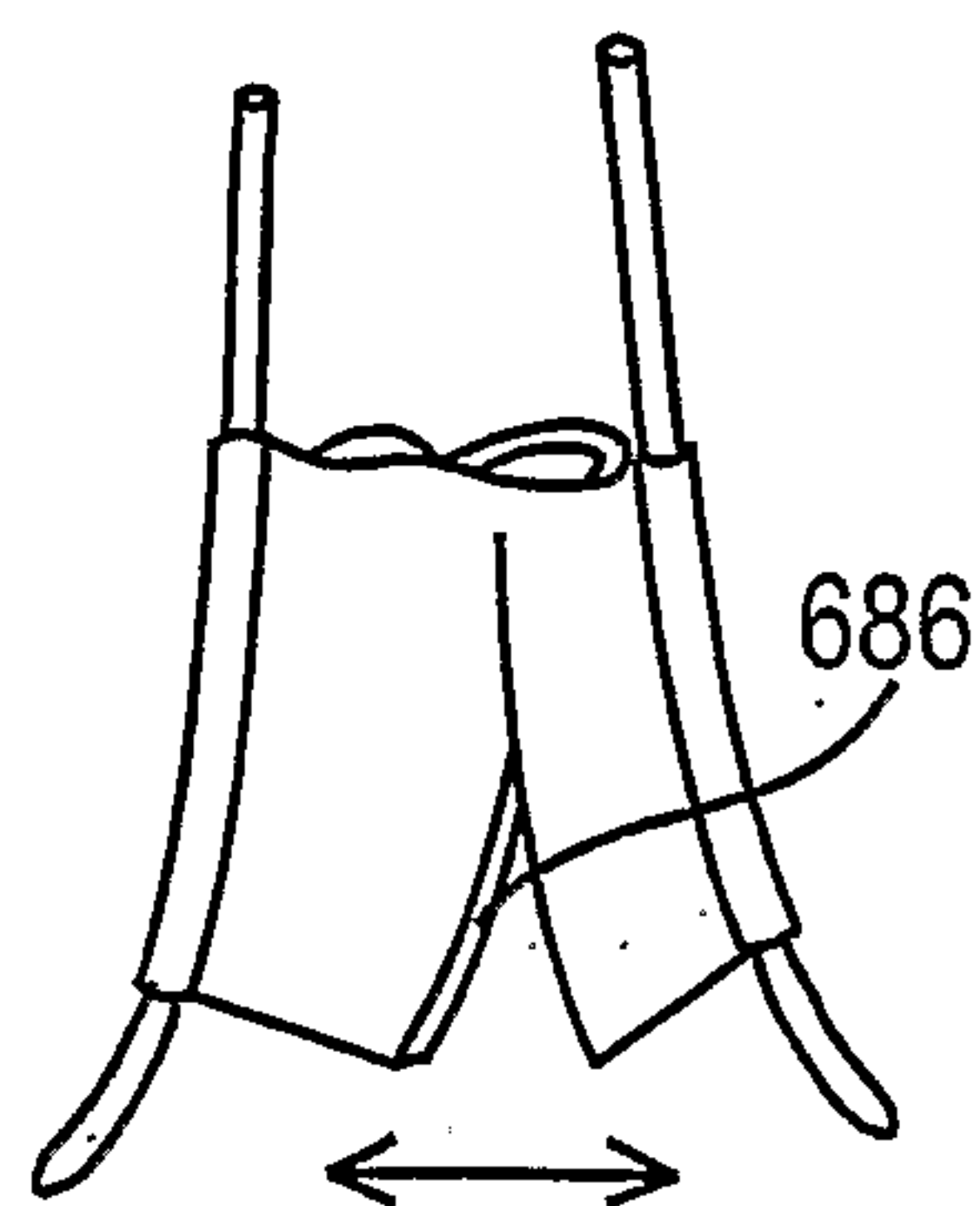
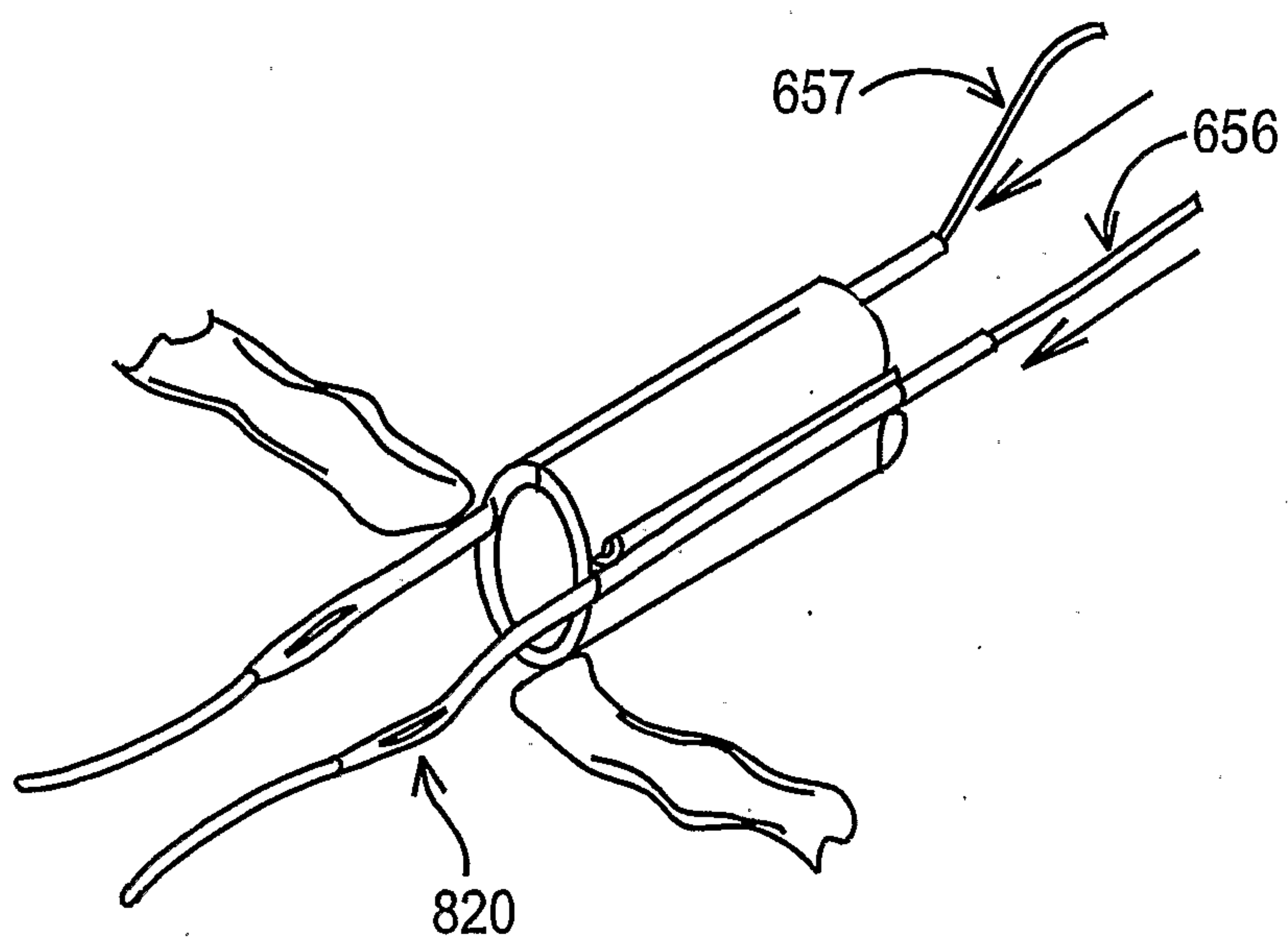


FIG. 44C

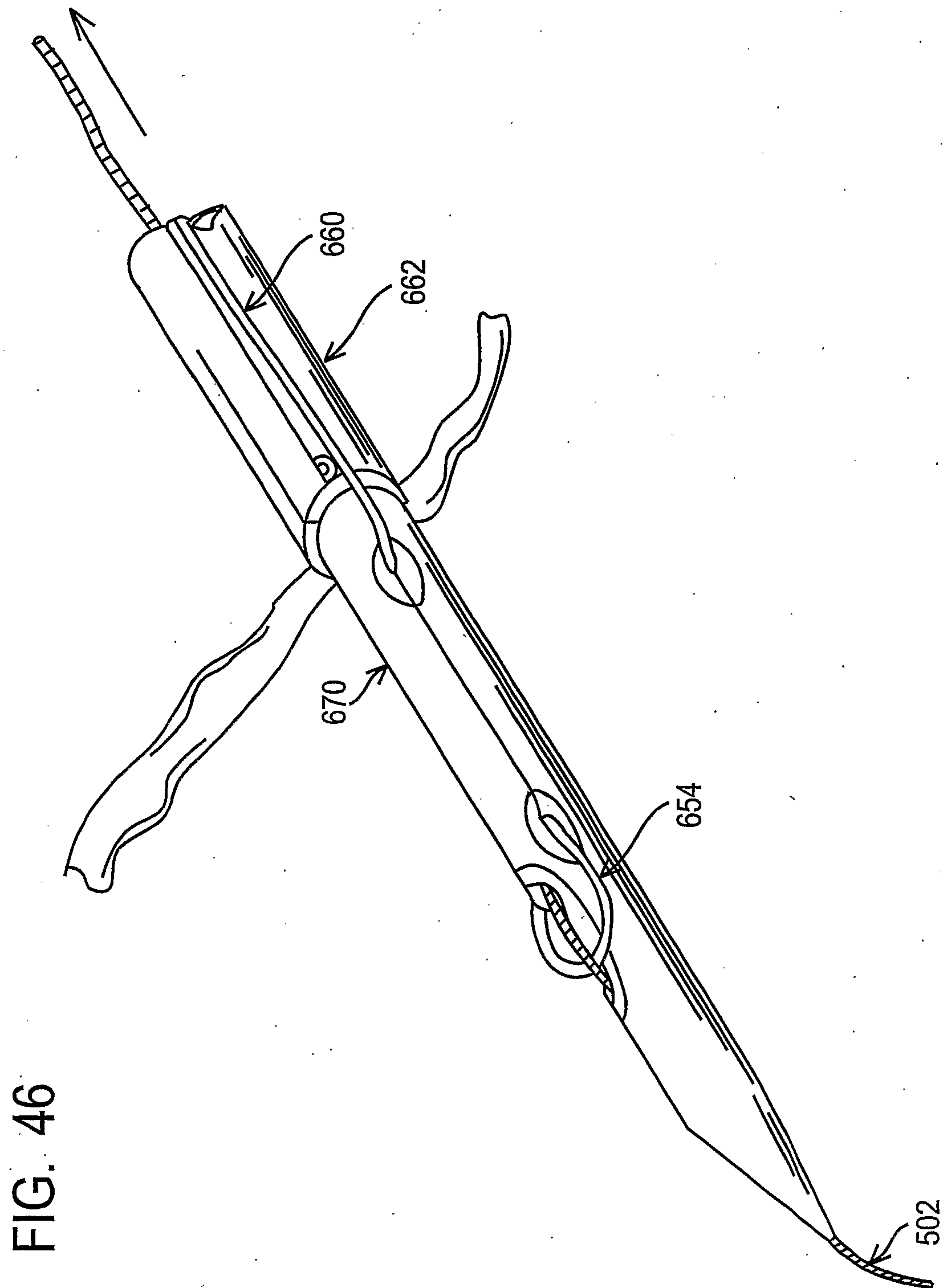


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FIG. 47

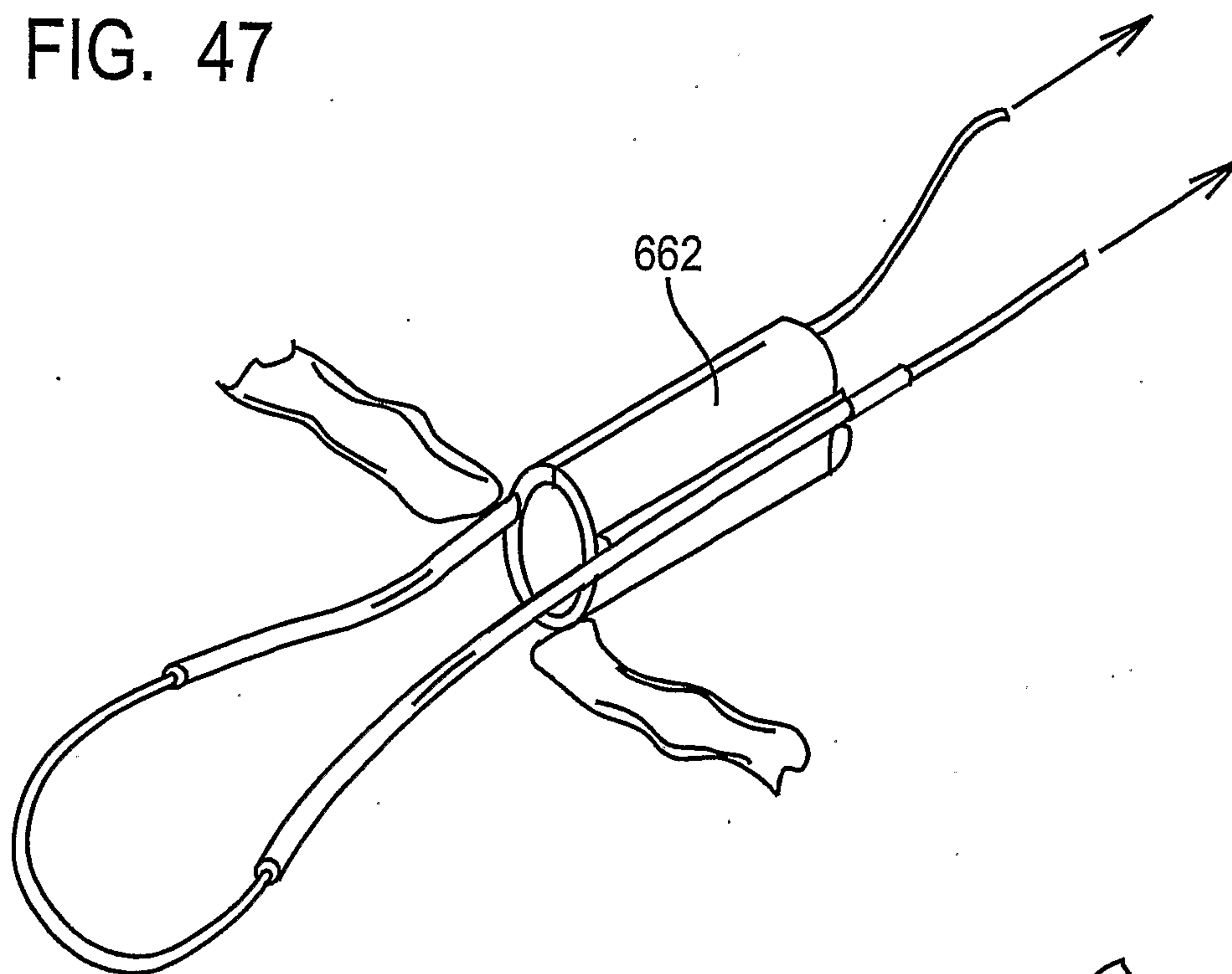
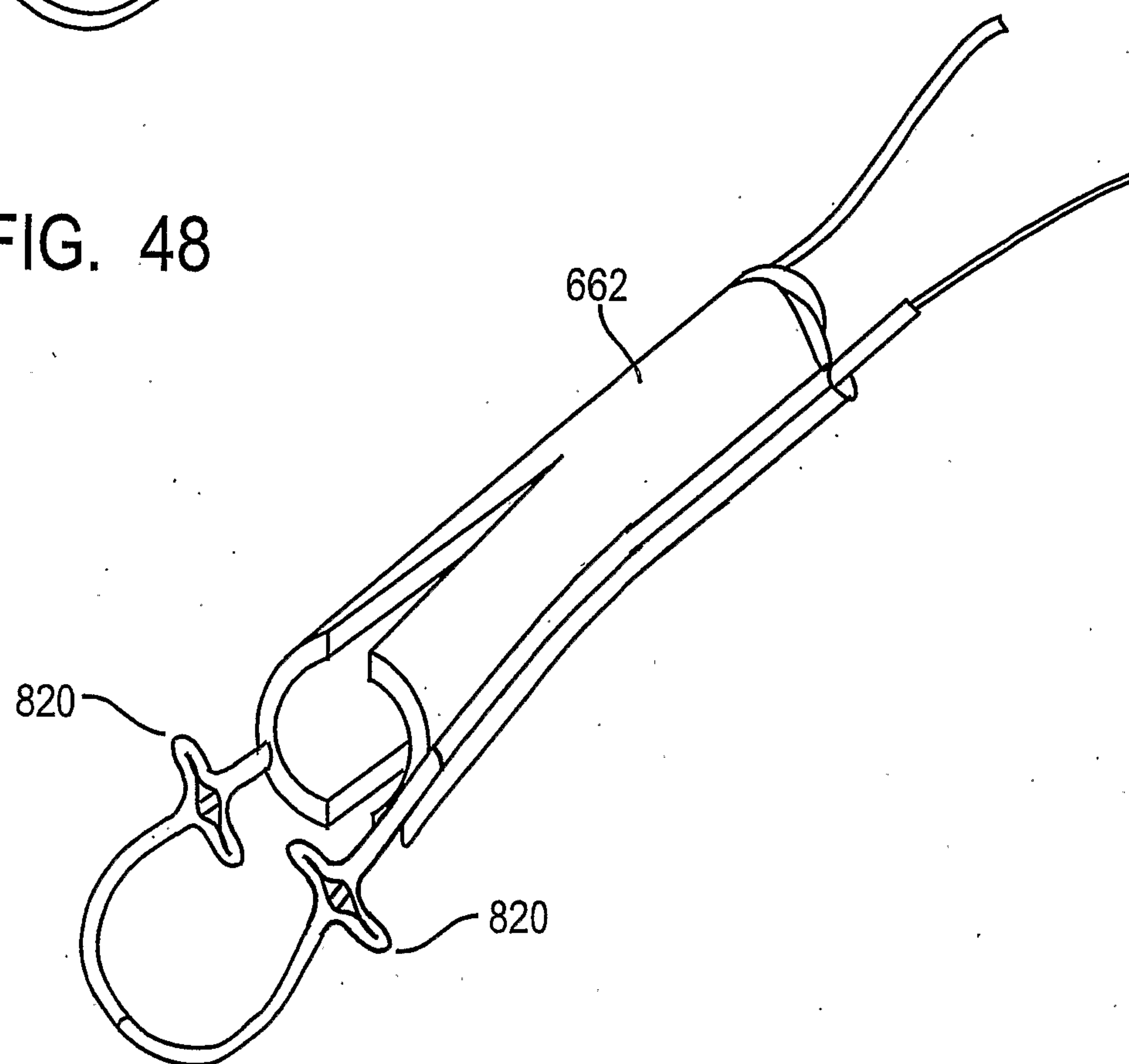


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FIG. 49A

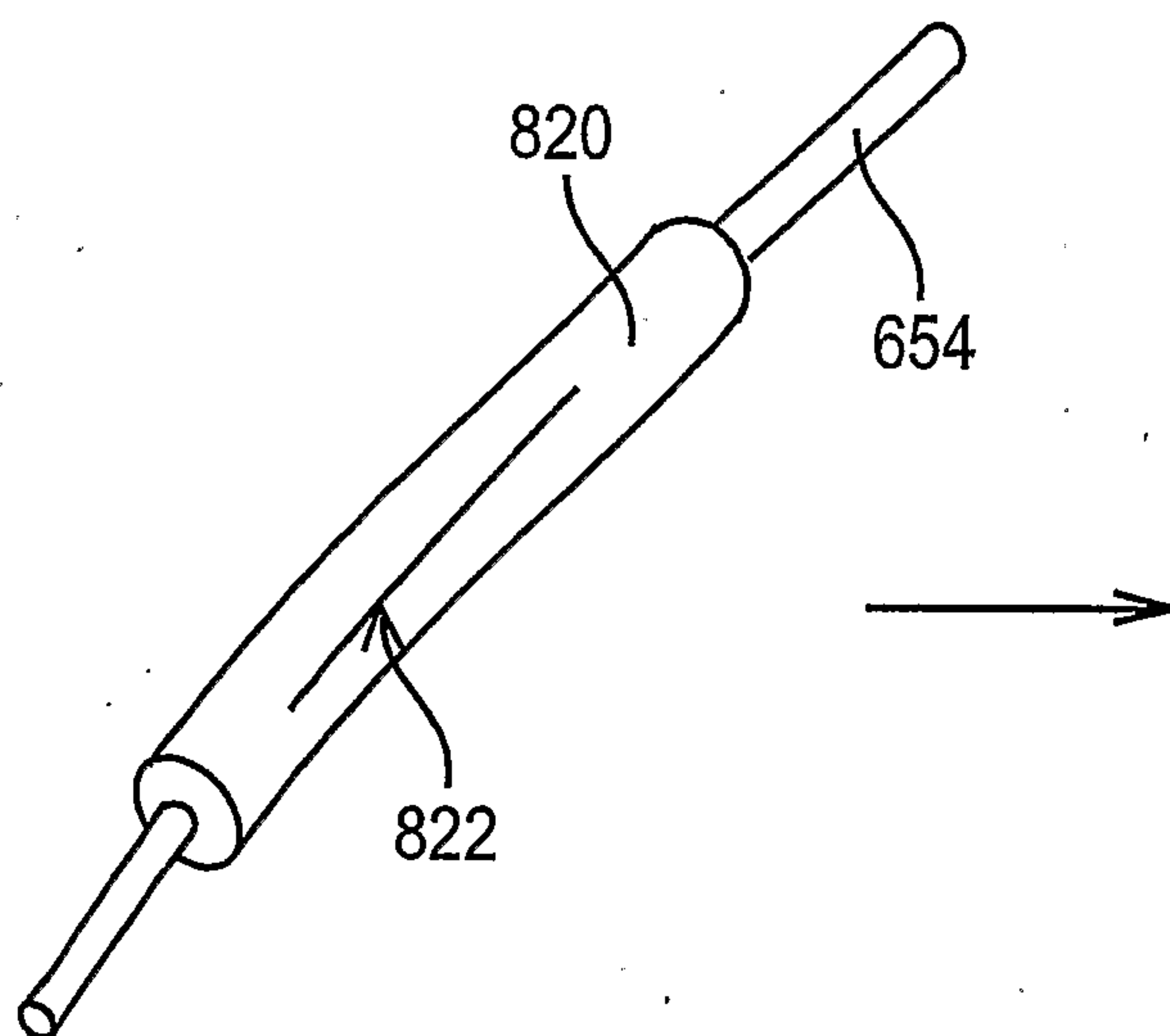


FIG. 49B

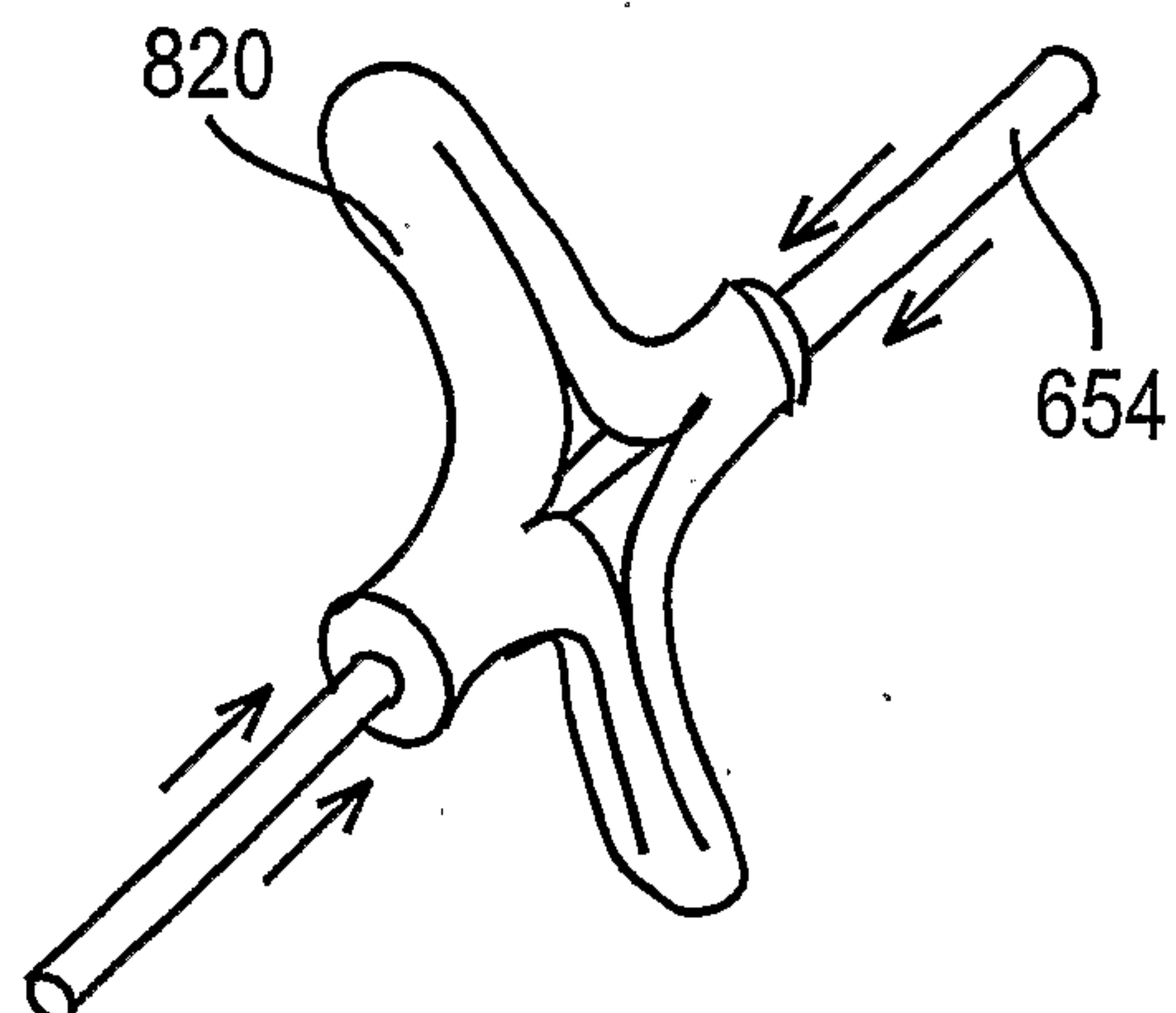


FIG. 50A

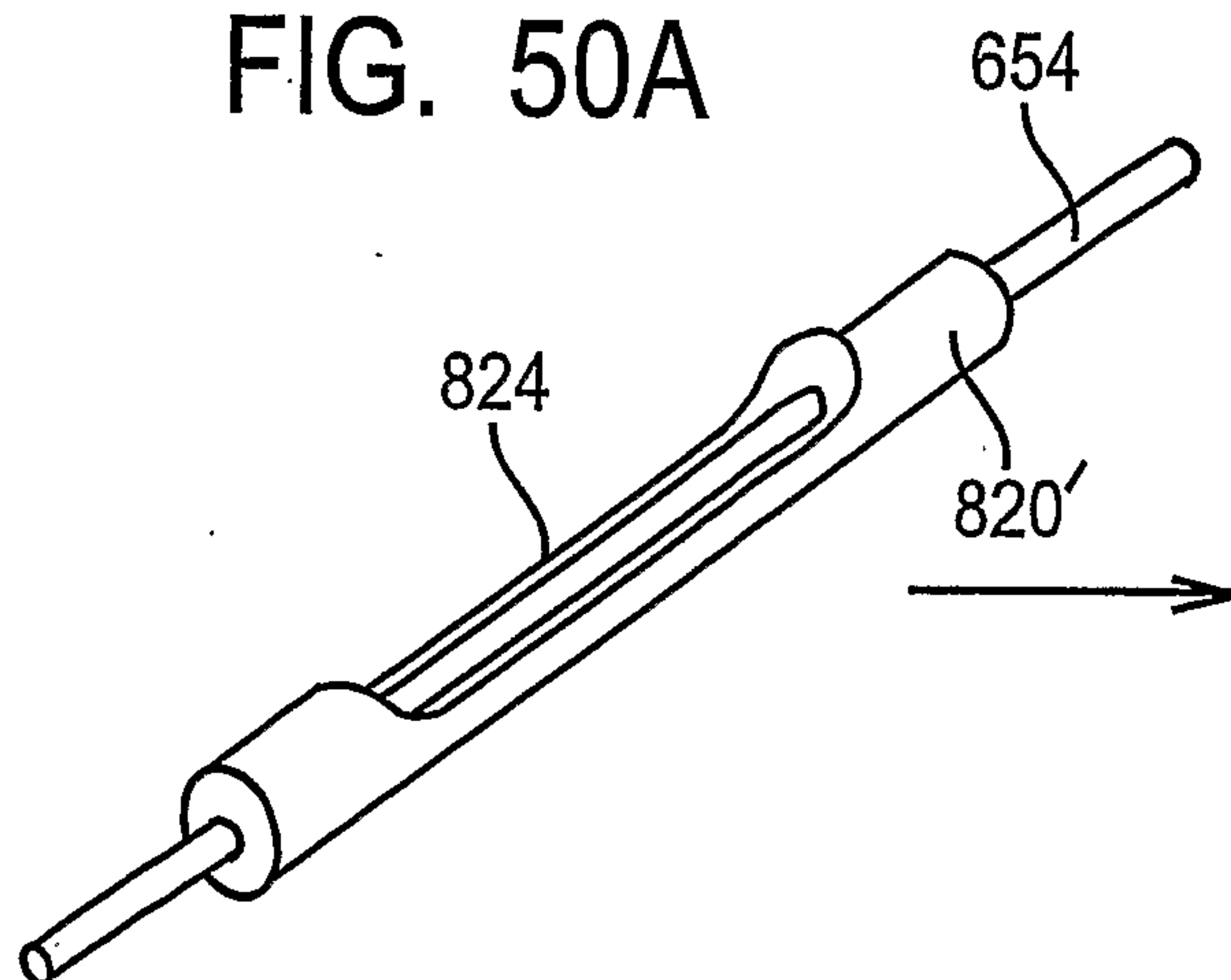


FIG. 50B

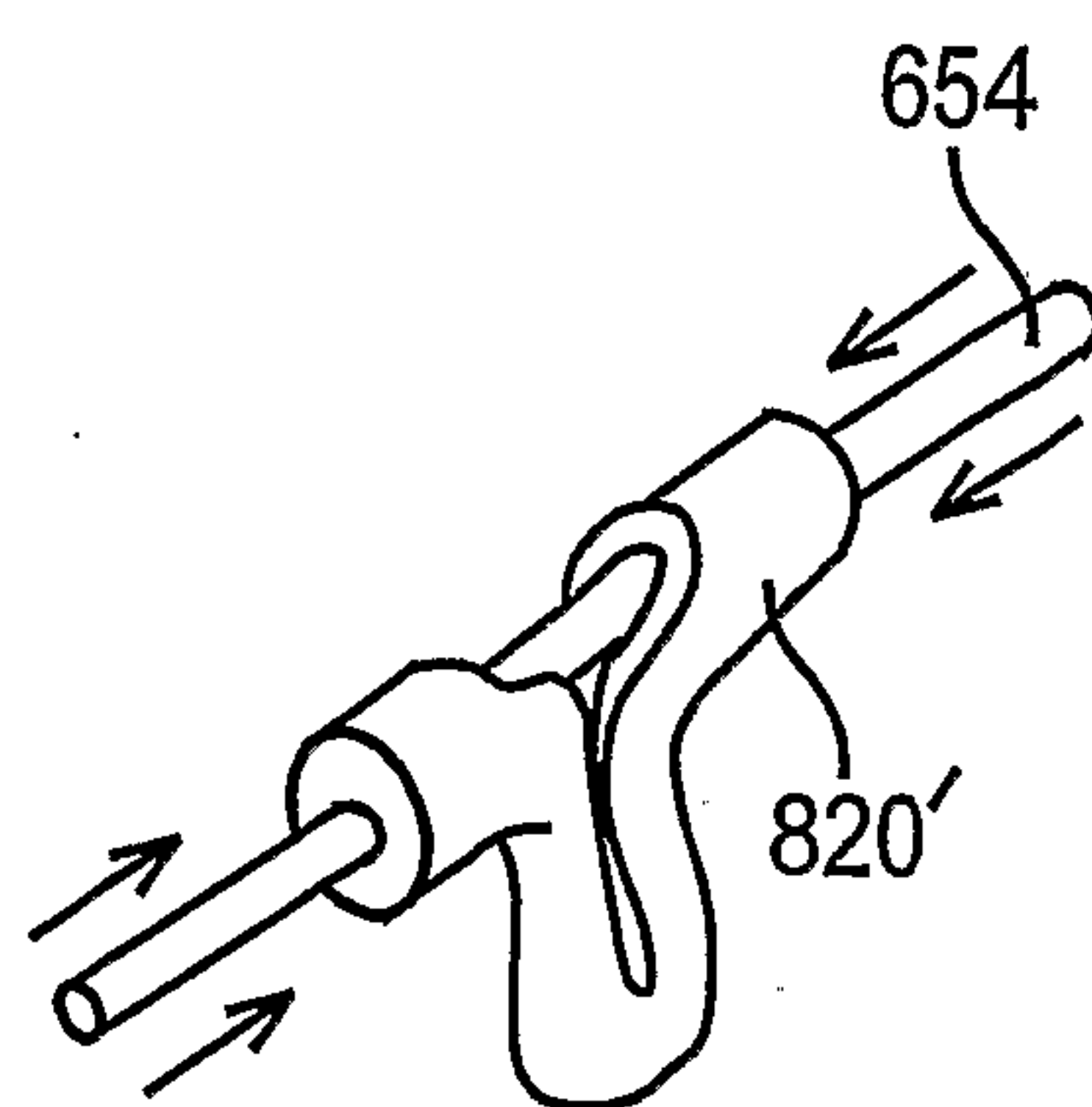


FIG. 51A

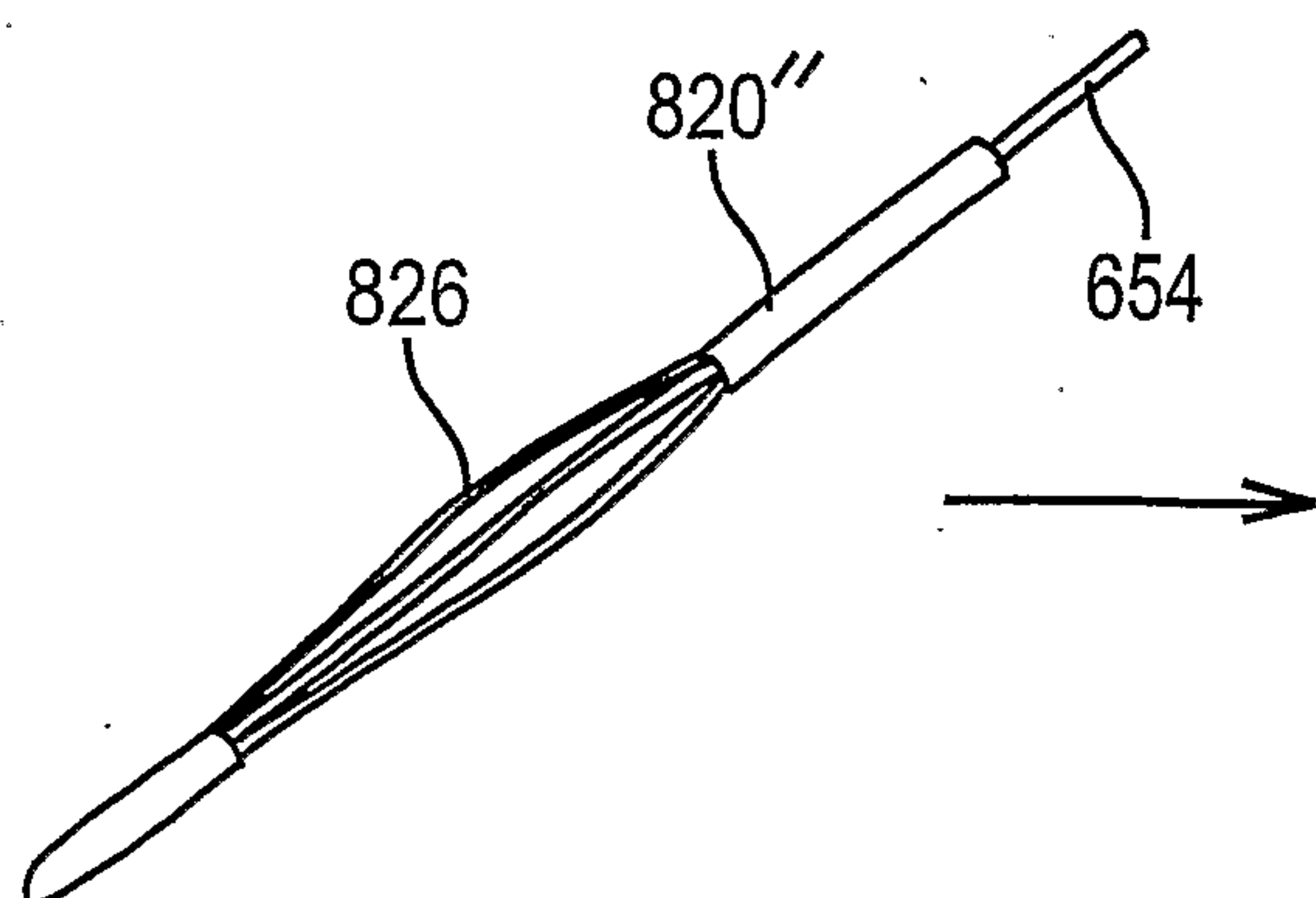


FIG. 51B

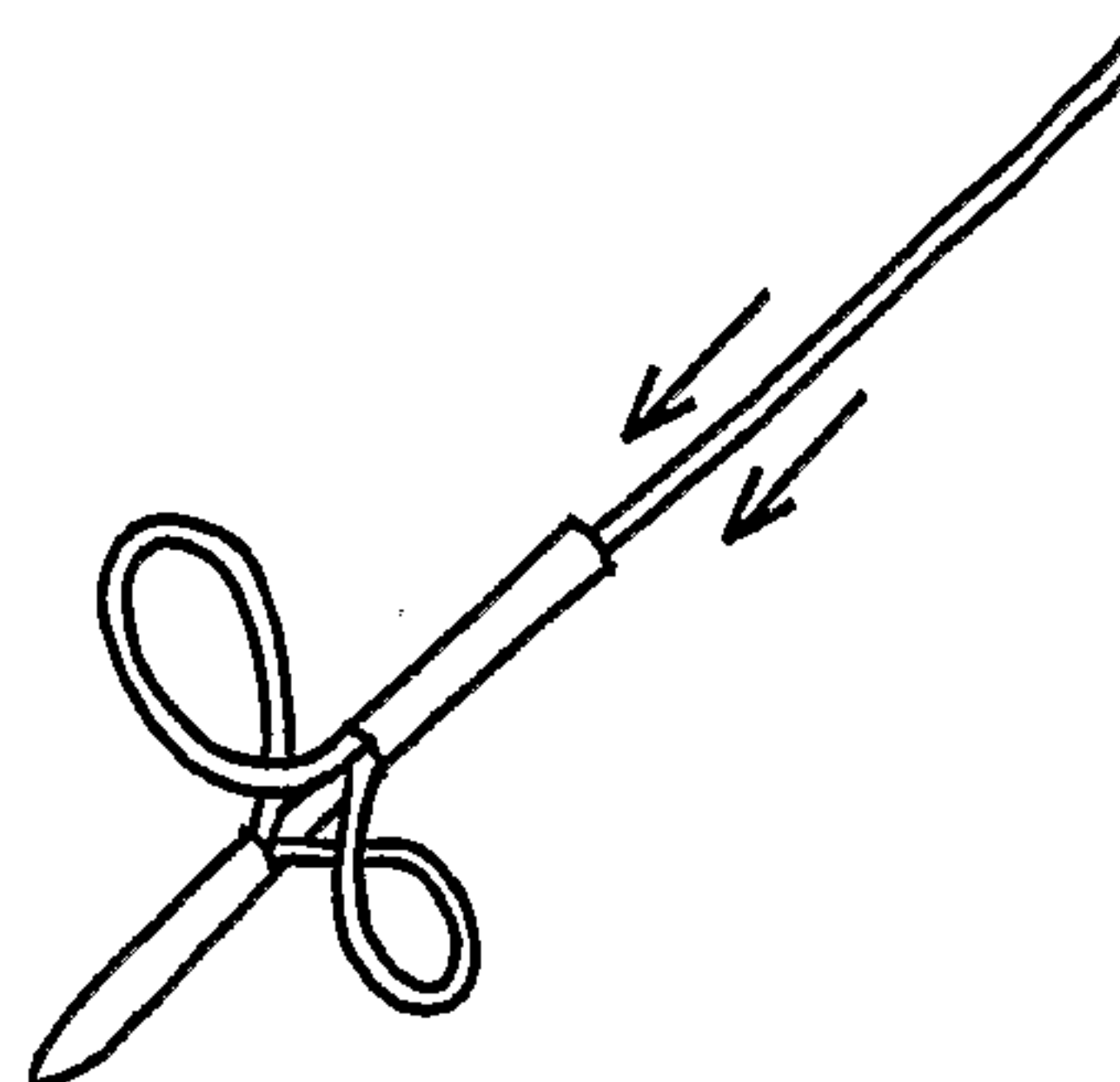
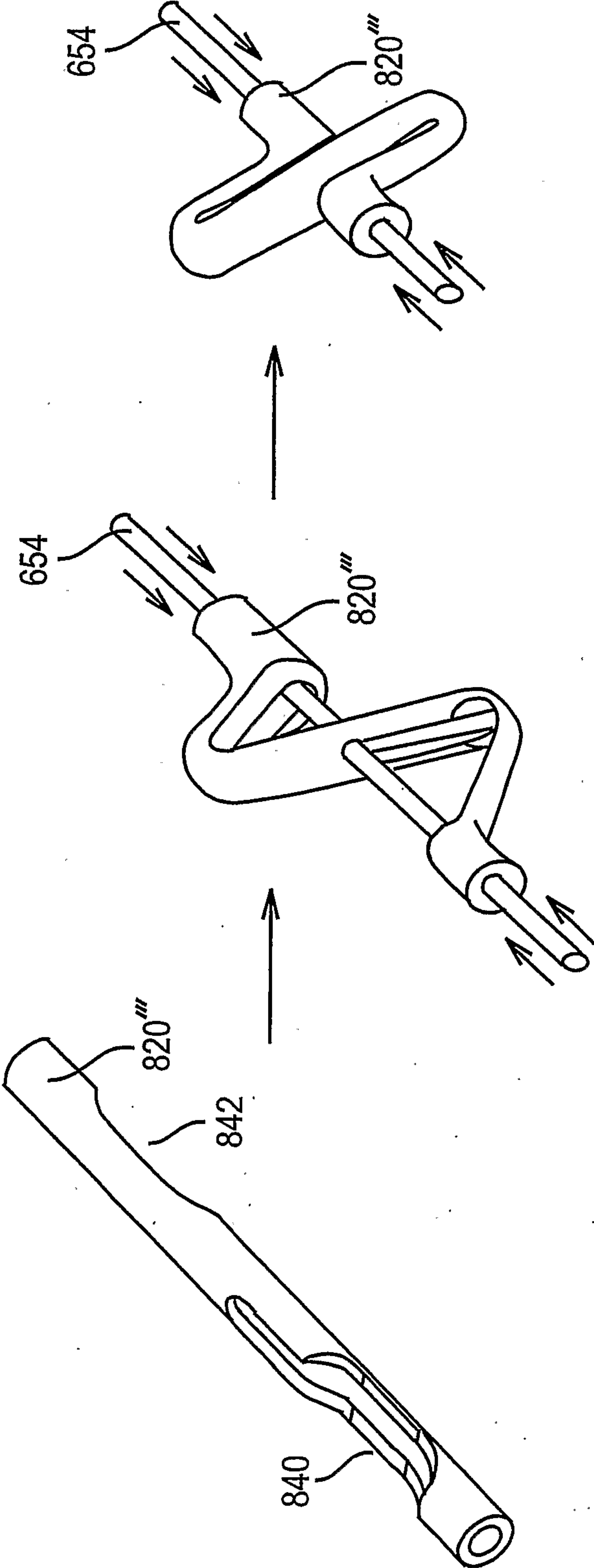


FIG. 52A FIG. 52B FIG. 52C



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FIG. 53A

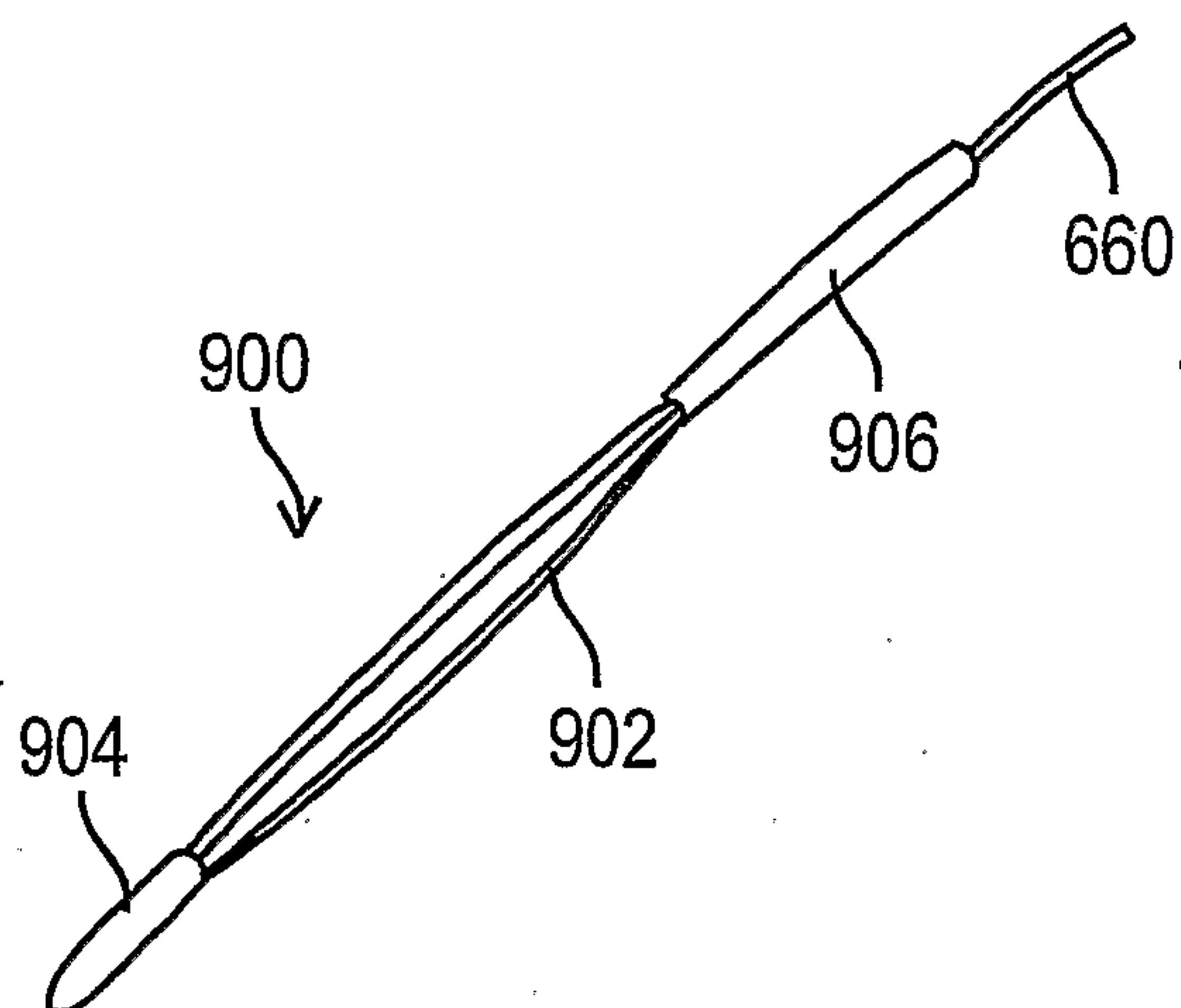


FIG. 53B

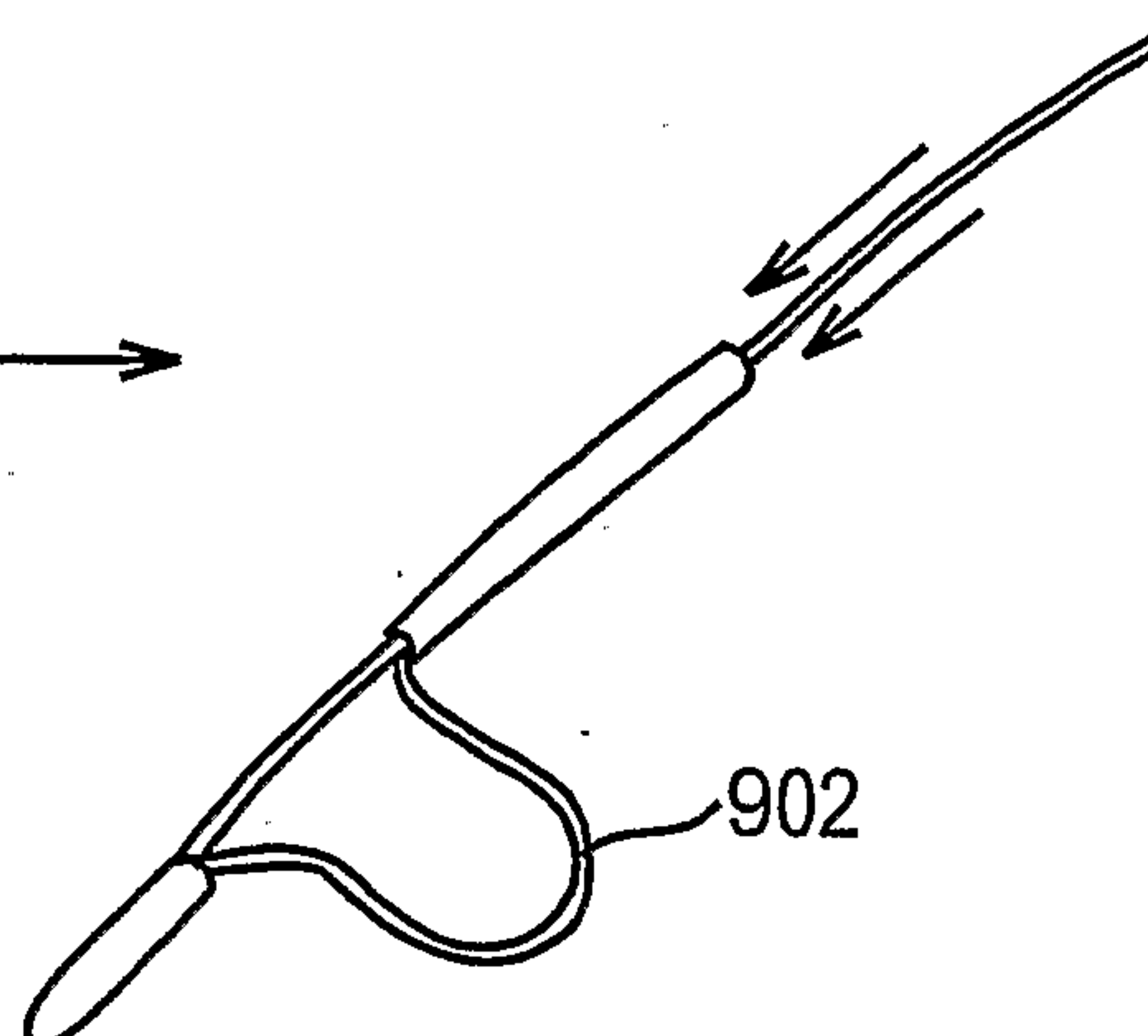


FIG. 54A

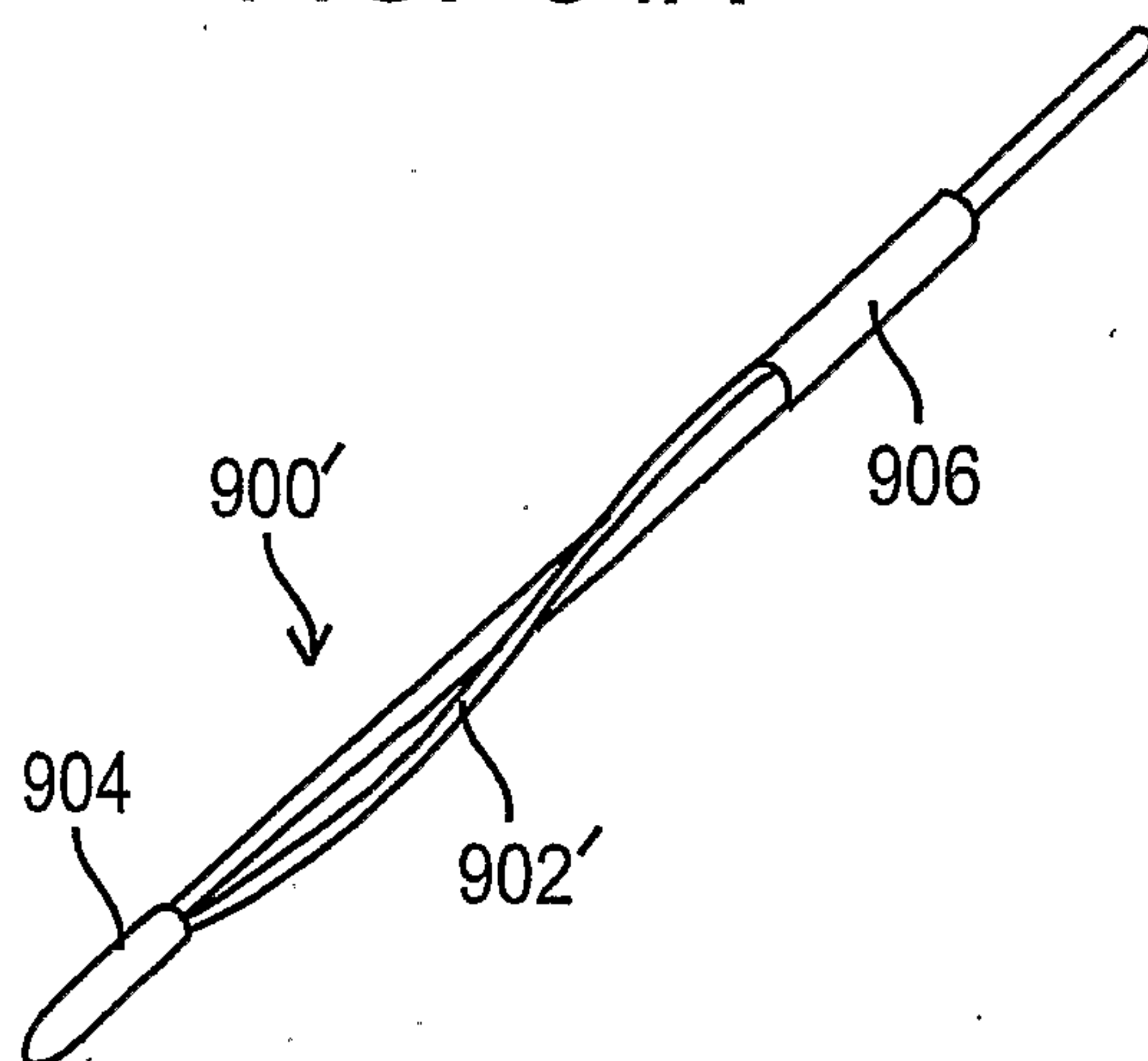


FIG. 54B

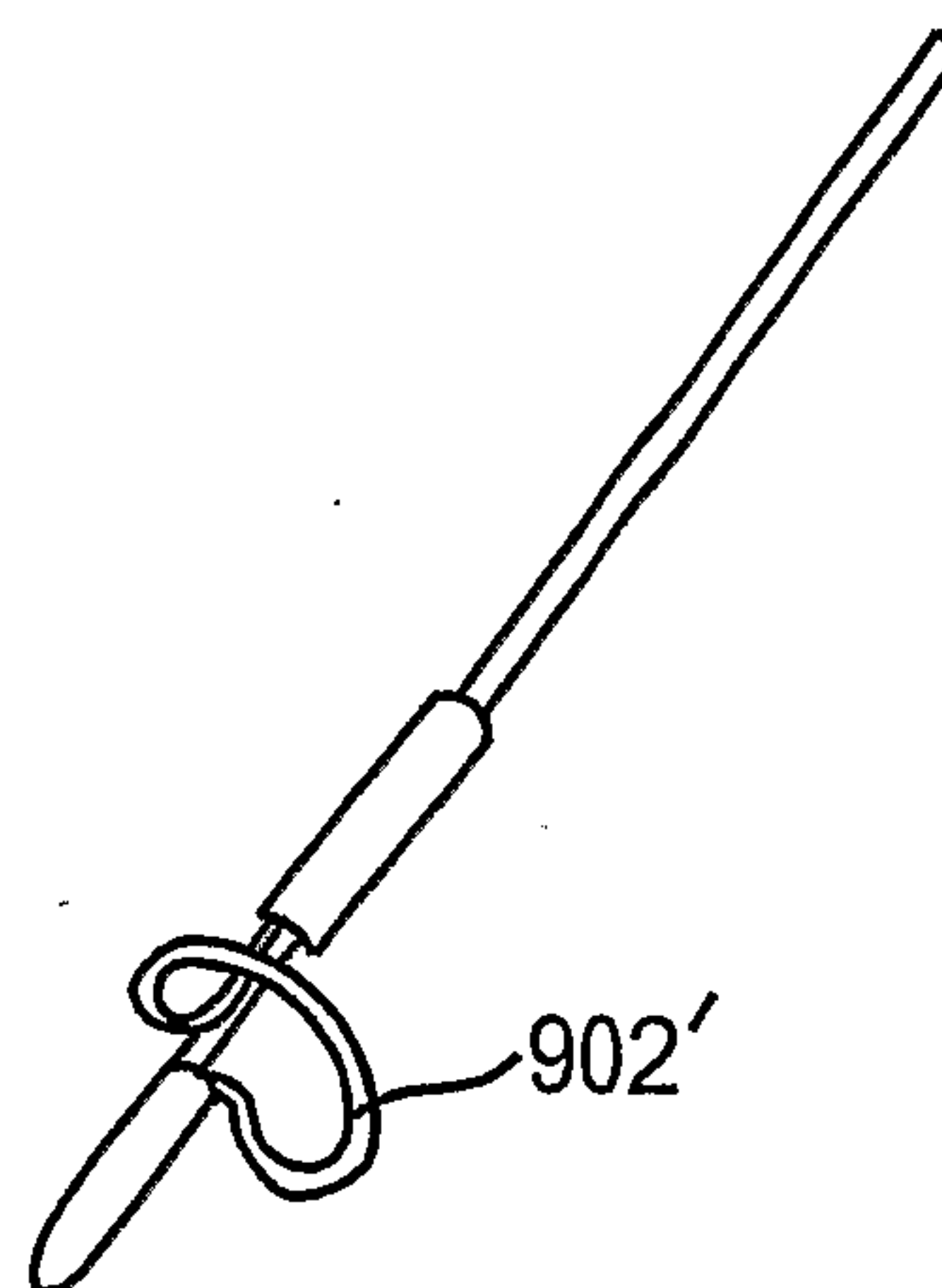


FIG. 55A

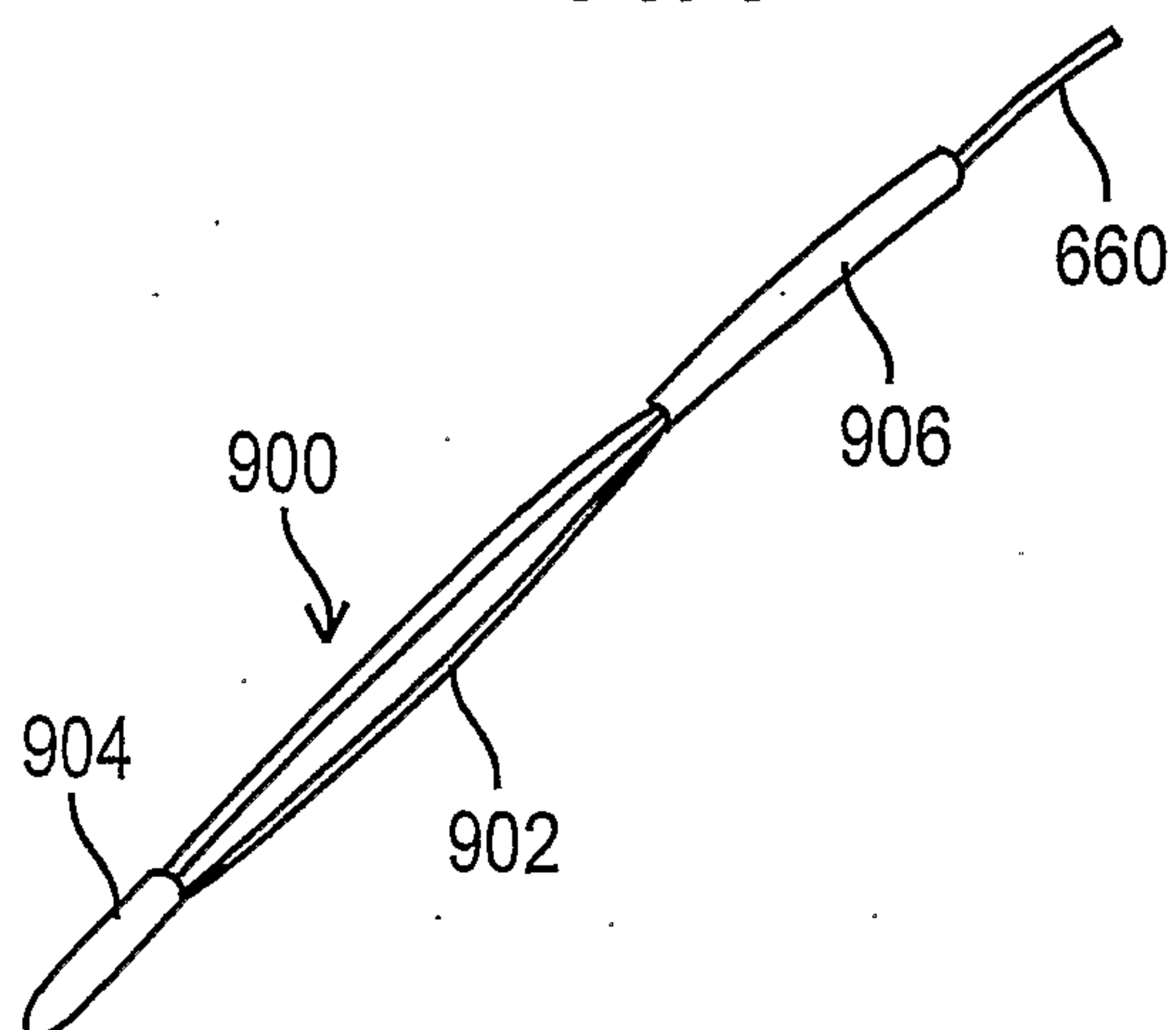
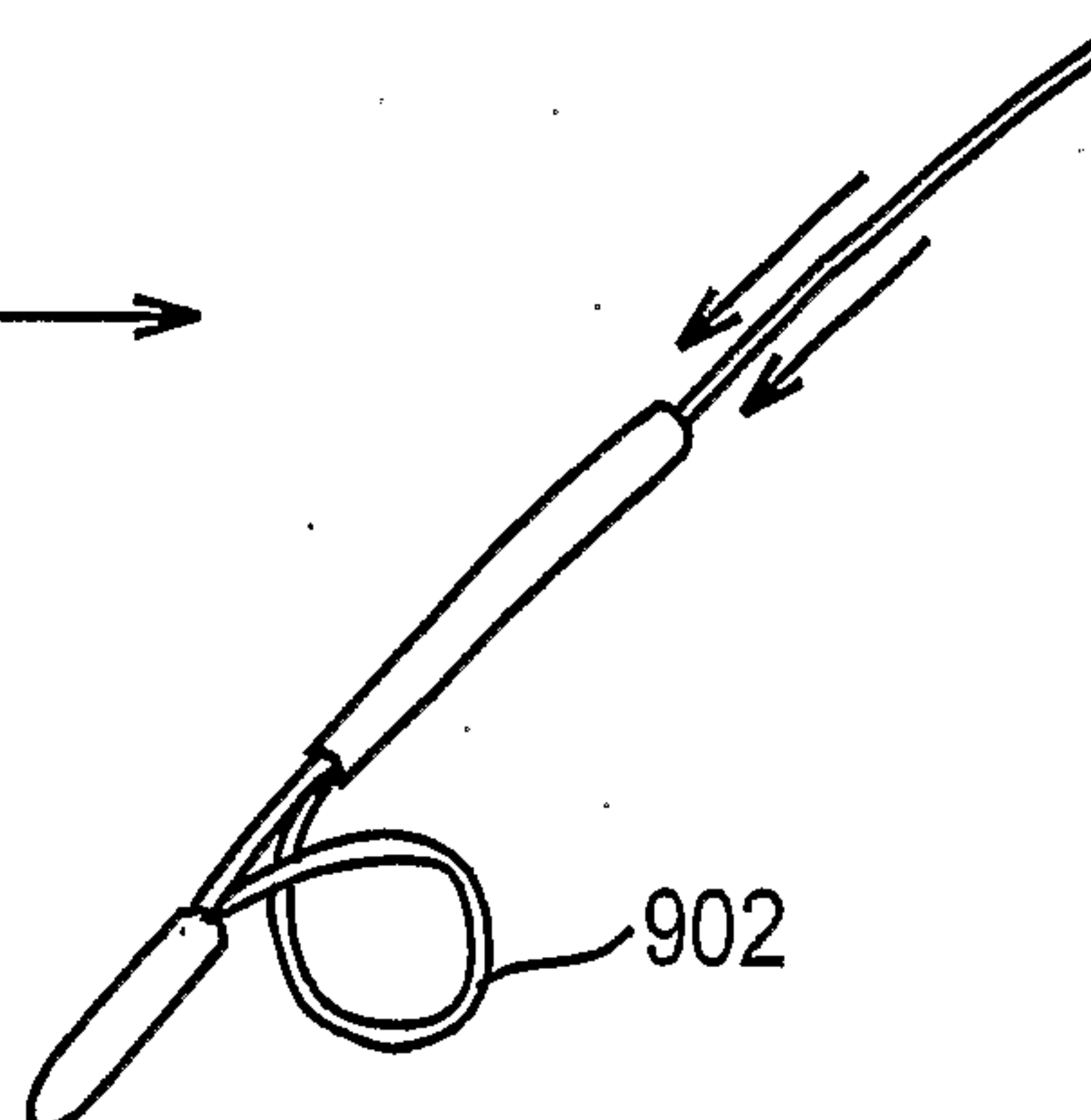


FIG. 55B



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FIG. 56A

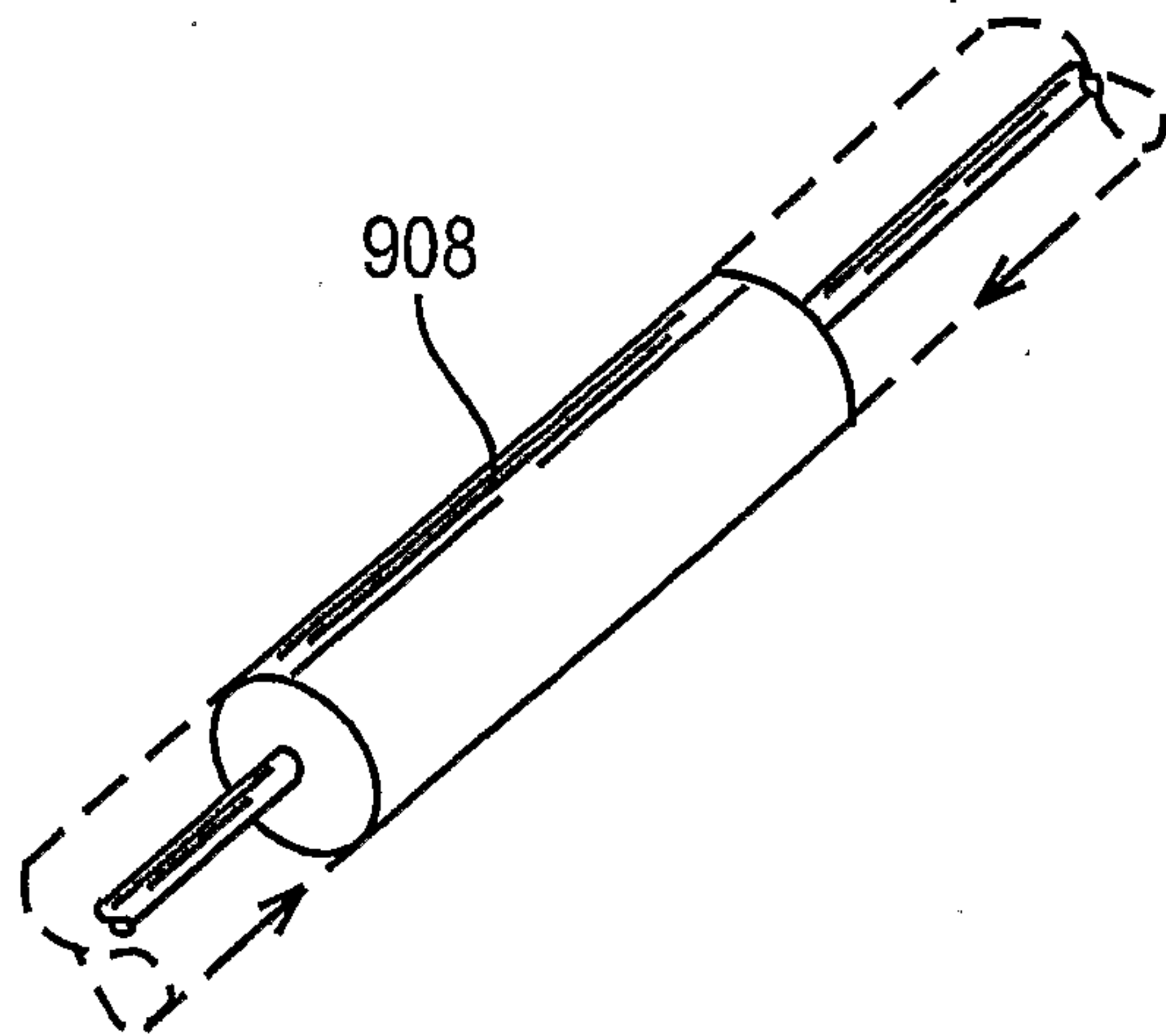


FIG. 56B

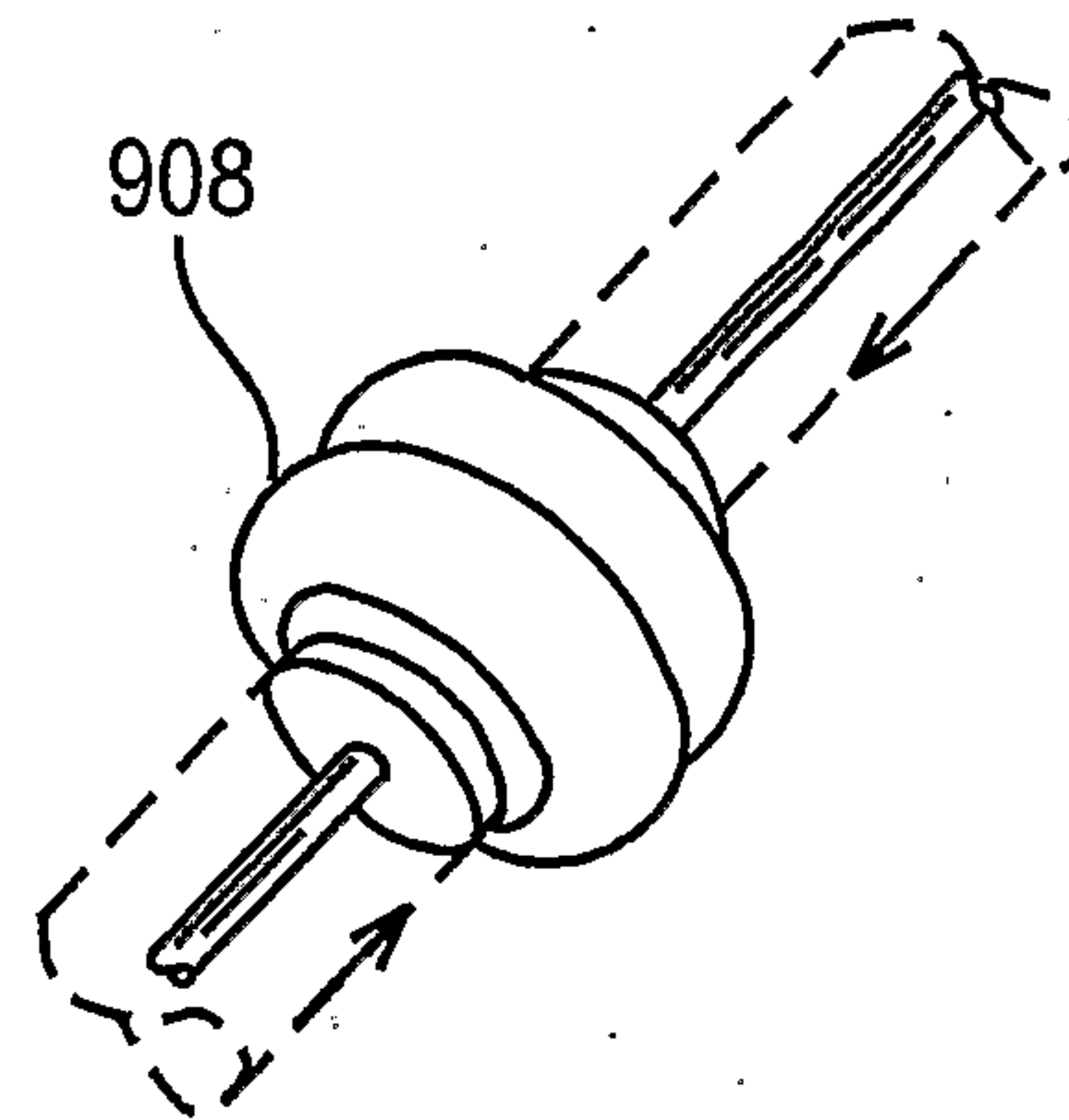


FIG. 57A

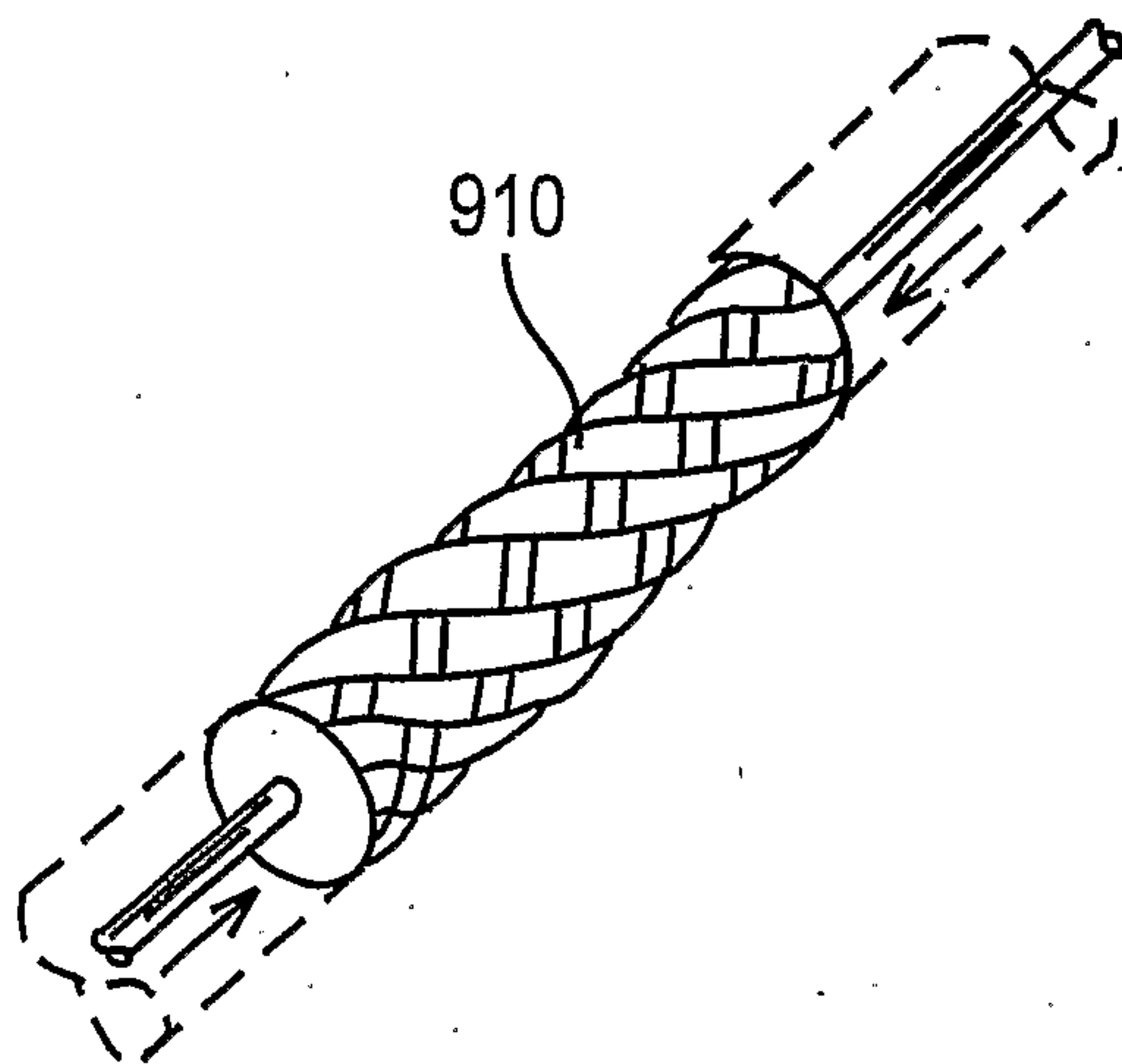
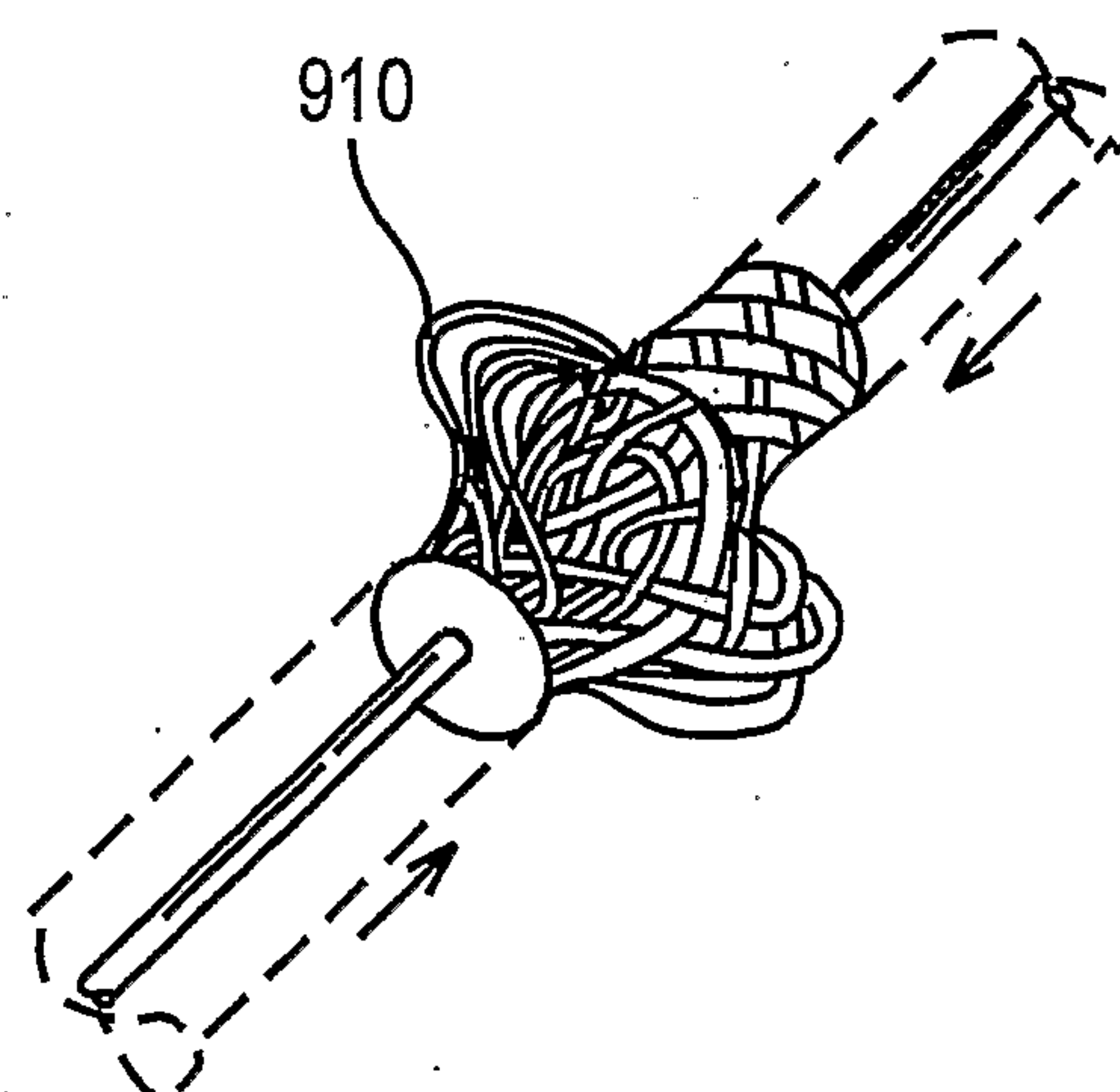


FIG. 57B



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FIG. 58

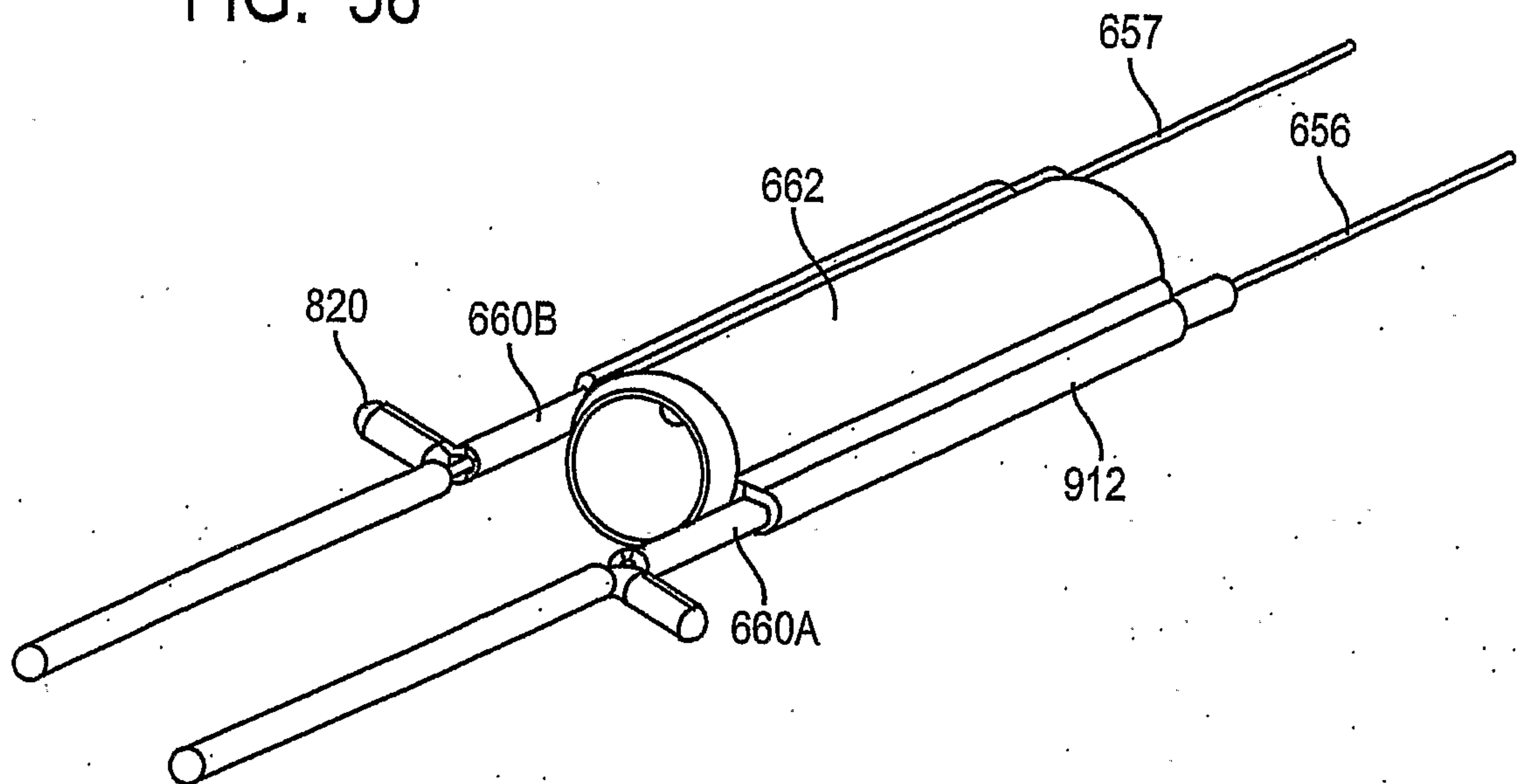
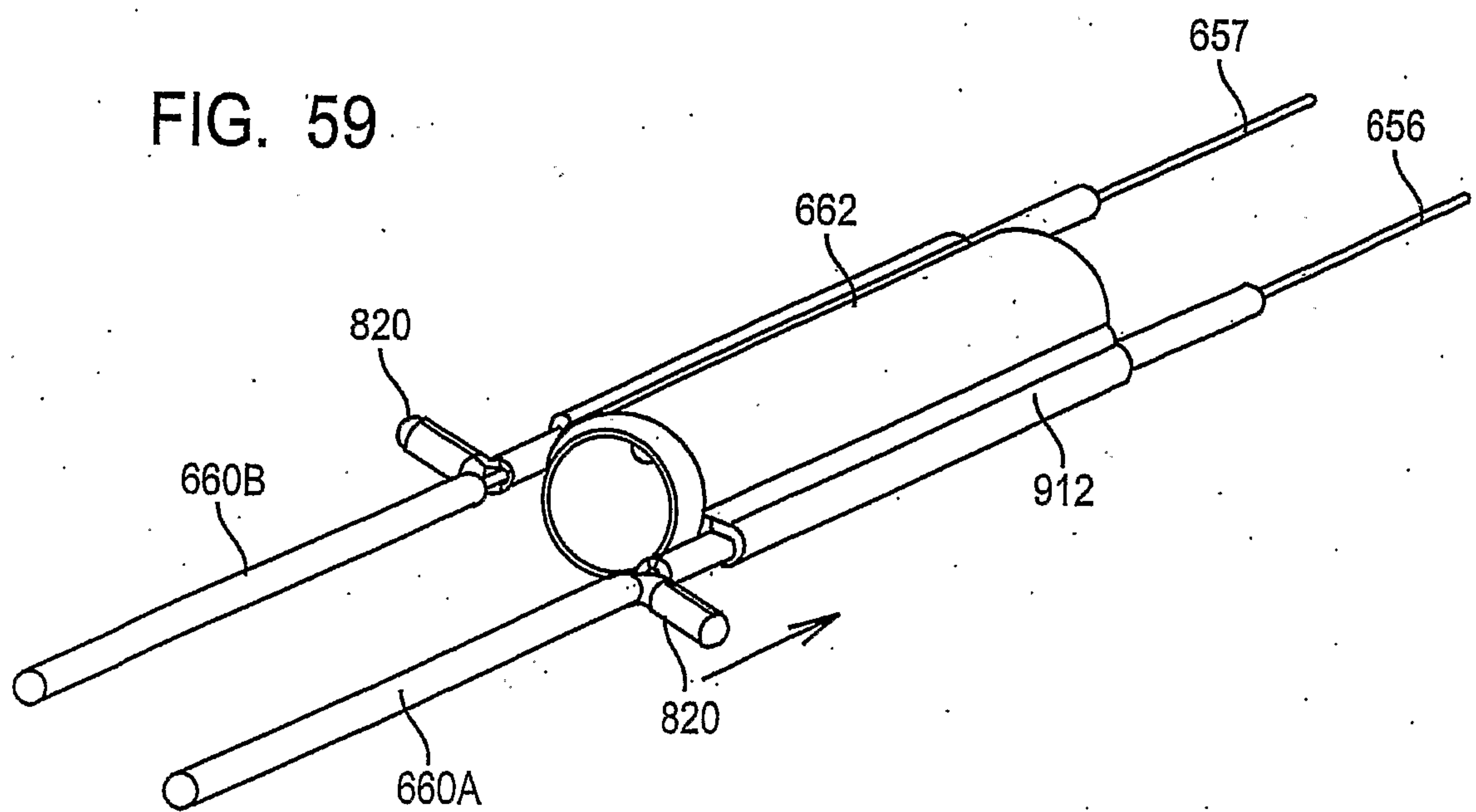
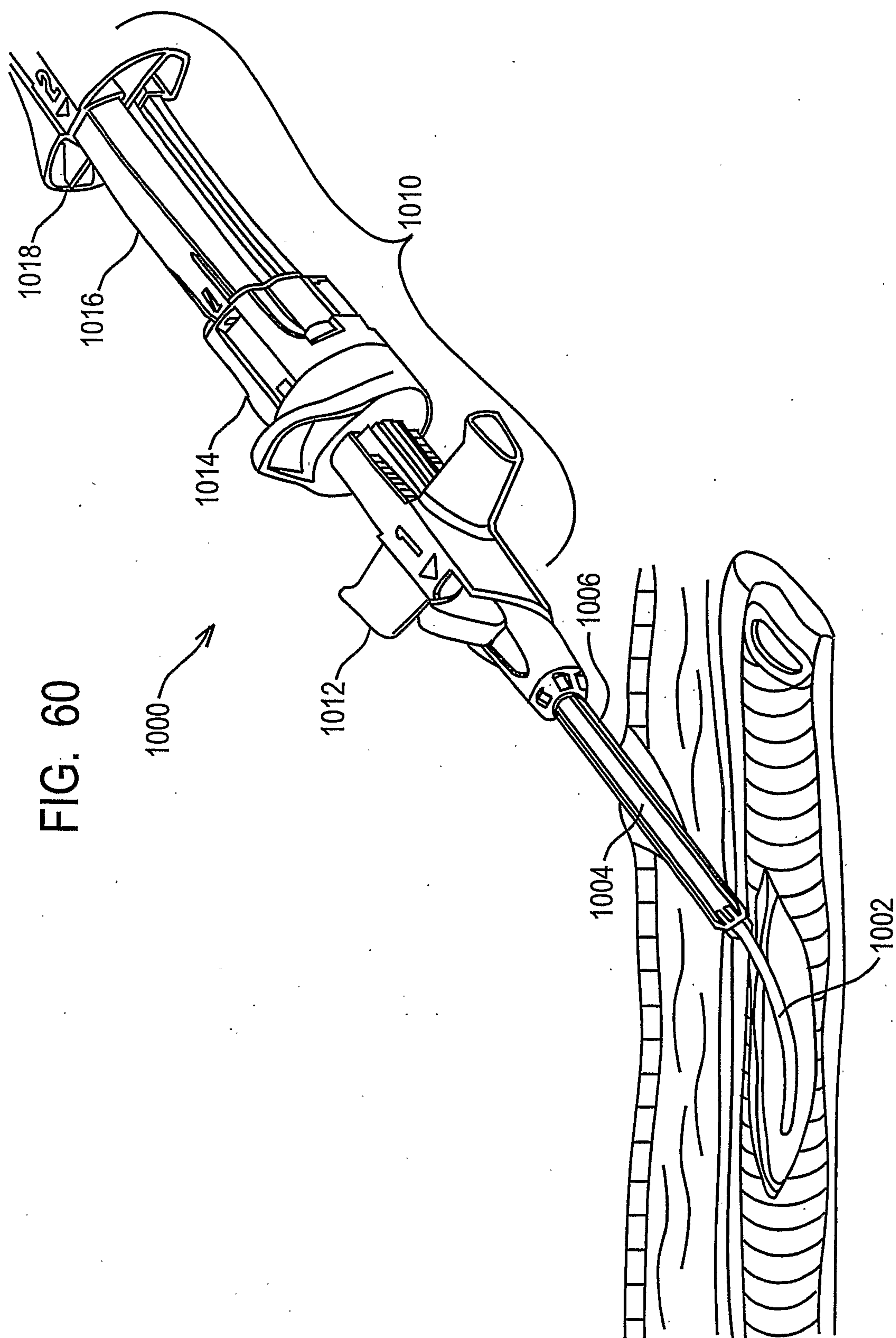


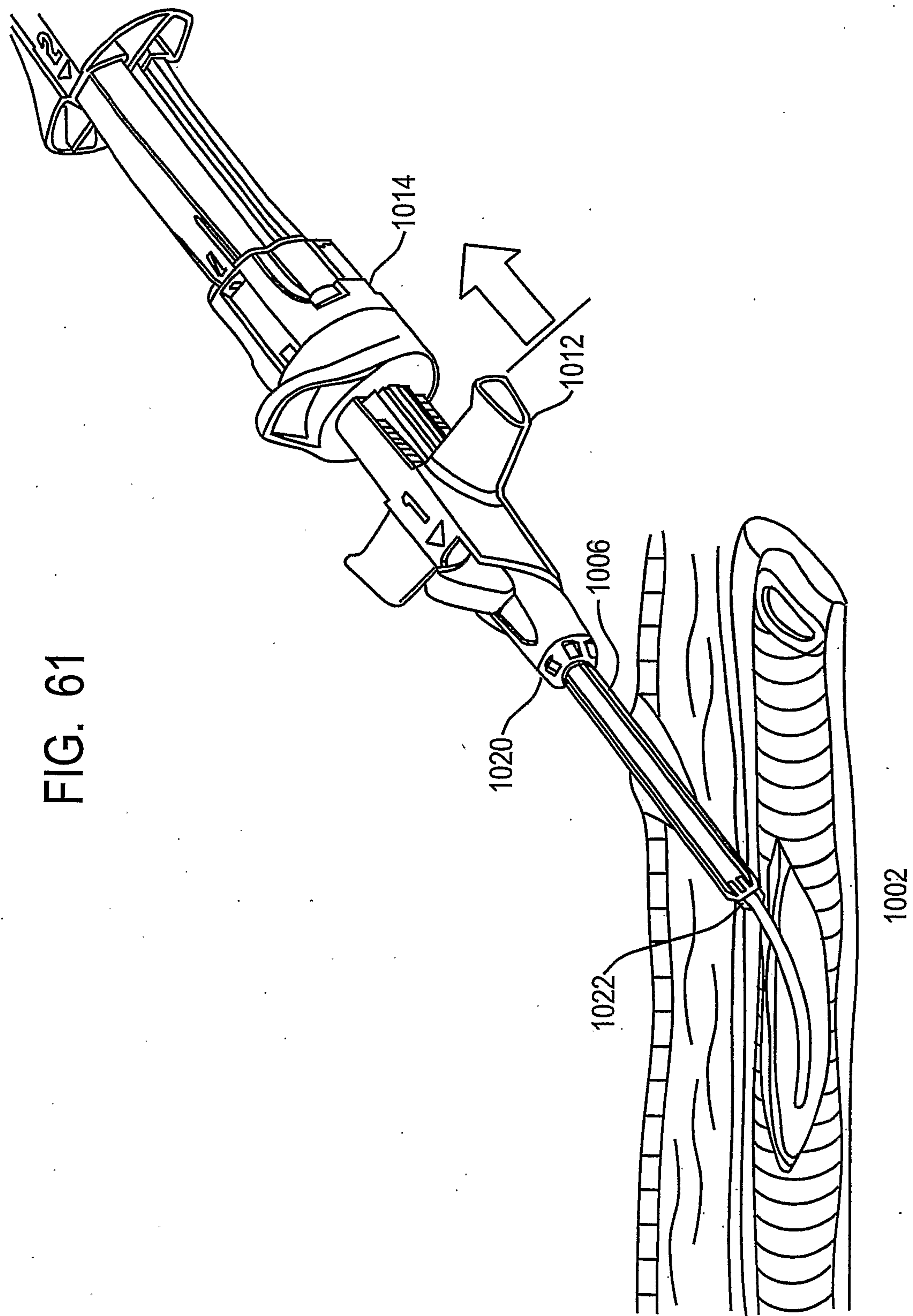
FIG. 59



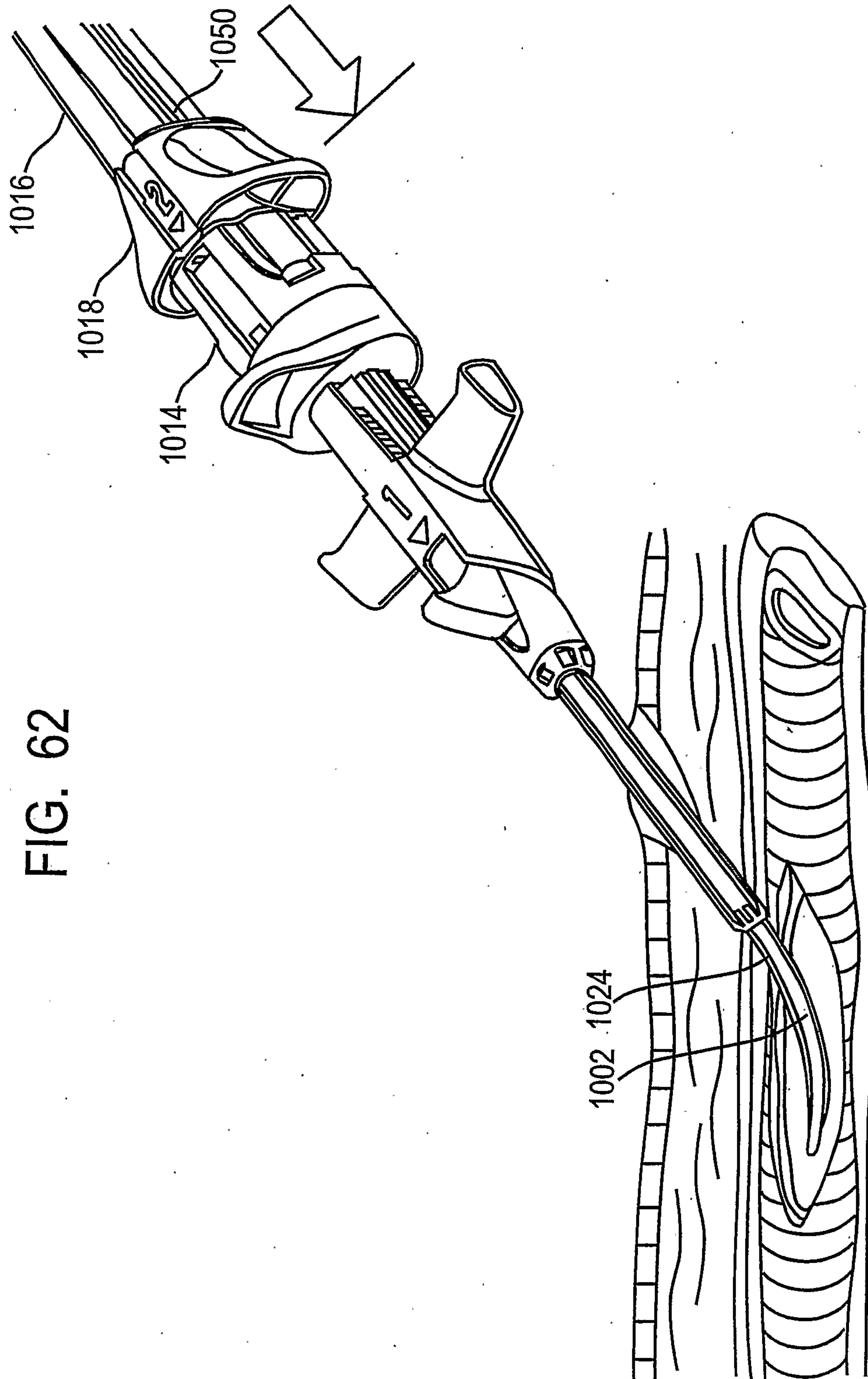
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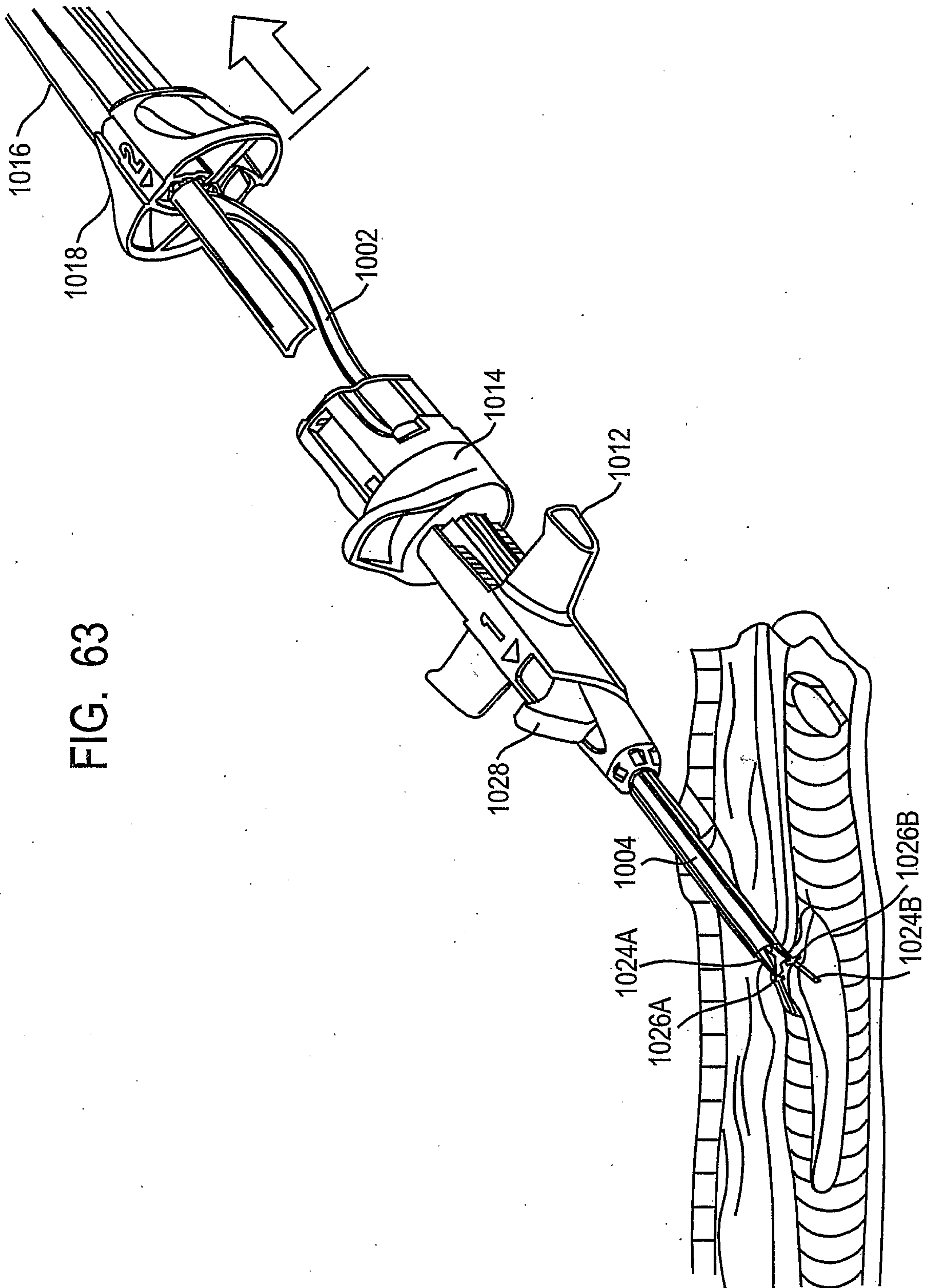


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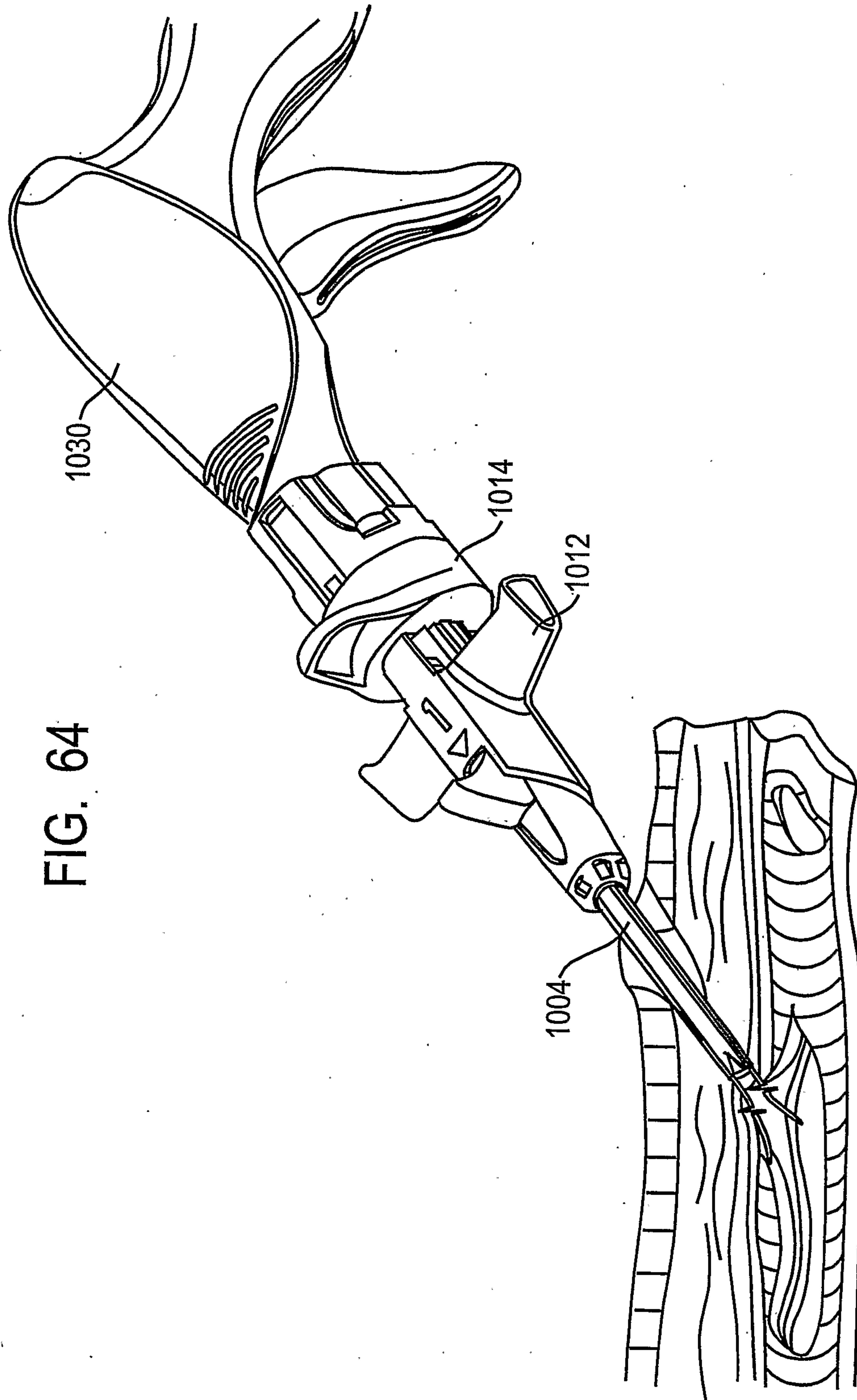


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FIG. 63



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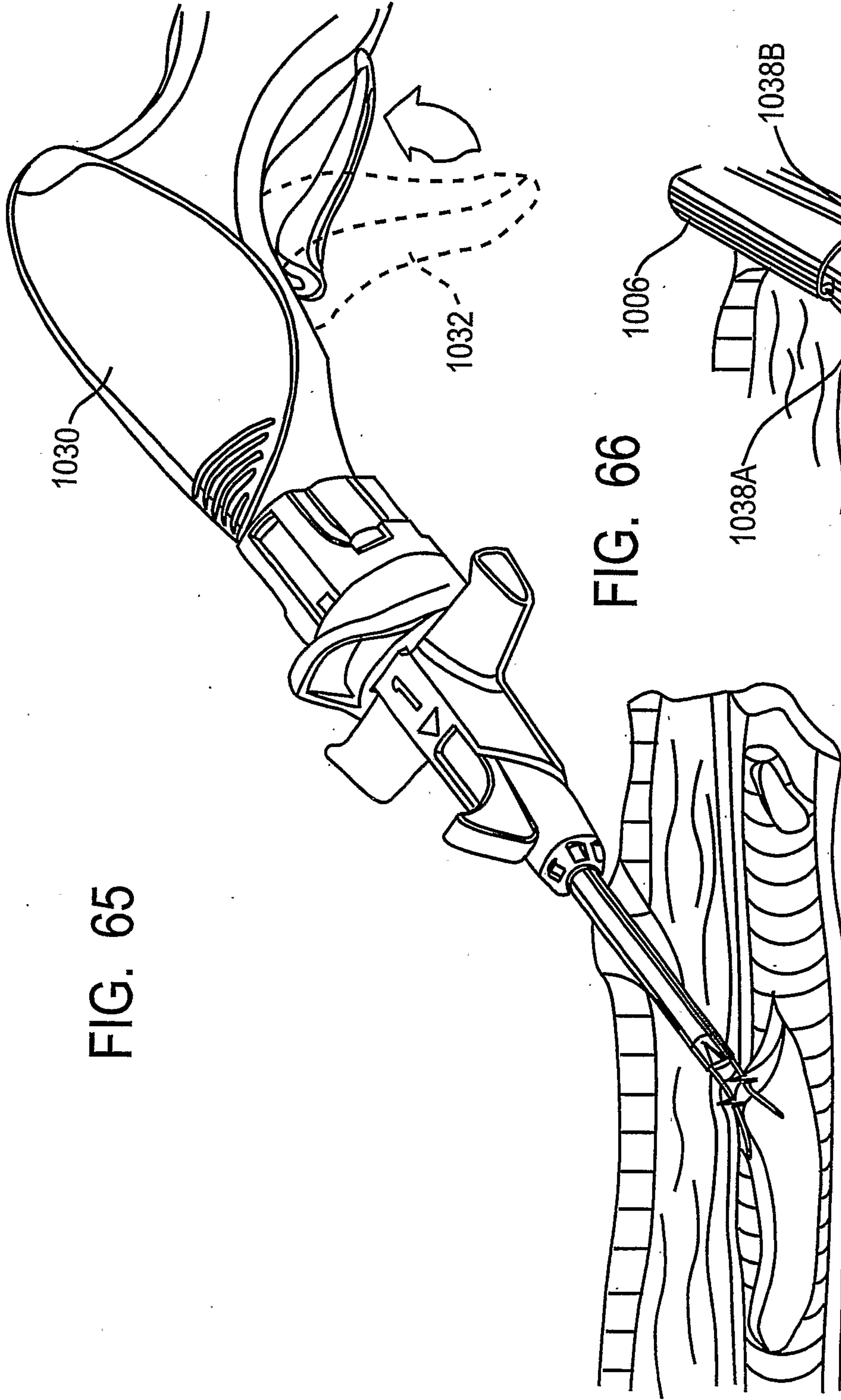


FIG. 66

