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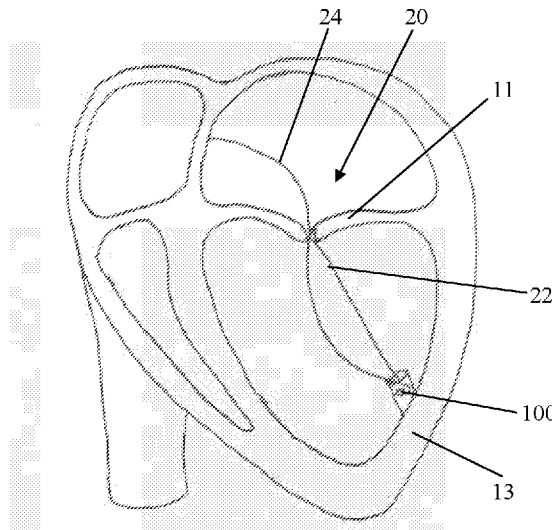


Fig. 12B

(57) Abstract: Various embodiments of anchors are configured to be inserted into a heart wall of a patient to anchor a suture as an artificial chordae under an appropriate tension for proper valve function. Such anchors are particularly suitable for use in intravascular, transcatheter procedures as described above given the inherent difficulties in providing sufficient force for insertion of an anchor into the heart wall with a flexible catheter and adjusting a length and tension of artificial chordae from exterior of the heart.



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**SYSTEMS AND METHODS FOR TRANSCATHETER  
HEART VALVE REPAIR**

**RELATED APPLICATION**

This application claims the benefit of U.S. Application No. 16/406,736 filed May 8, 2019, which claims the benefit of U.S. Provisional Application No. 62/669,096 filed May 9, 2018; and claims the benefit of U.S. Application No. 16/406,764 filed May 8, 2019, which claims the benefit of U.S. Provisional Application No. 62/669,115 filed May 9, 2018; and claims the benefit of U.S. Application No. 16/406,799 filed on May 8, 2019, which claims the benefit of U.S. Provisional Application No. 62/669,123 filed on May 9, 2018, each of which are hereby fully incorporated herein by reference.

**TECHNICAL FIELD**

The present invention relates to minimally invasive delivery of a suture. More particularly, the present invention relates to anchoring of a suture as an artificial chordae tendineae for a flailing or prolapsing leaflet in a beating heart.

**BACKGROUND**

The mitral and tricuspid valves inside the human heart include an orifice (annulus), two (for the mitral) or three (for the tricuspid) leaflets and a subvalvular apparatus. The subvalvular apparatus includes multiple chordae tendineae, which connect the mobile valve leaflets to muscular structures (papillary muscles) inside the ventricles. Rupture or elongation of the chordae tendineae results in partial or generalized leaflet prolapse, which causes mitral (or tricuspid) valve regurgitation. A commonly used technique to surgically

correct mitral valve regurgitation is the implantation of artificial chordae (usually 4-0 or 5-0 Gore-Tex sutures) between the prolapsing segment of the valve and the papillary muscle.

This technique for implantation of artificial chordae was traditionally done by an open heart operation generally carried out through a median sternotomy and requiring cardiopulmonary bypass with aortic cross-clamp and cardioplegic arrest of the heart. Using such open heart techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for manipulation of surgical instruments, removal of excised tissue, and/or introduction of an artificial chordae through the atriotomy for attachment within the heart. However, these invasive open heart procedures produce a high degree of trauma, a significant risk of complications, an extended hospital stay, and a painful recovery period for the patient. Moreover, while heart valve surgery produces beneficial results for many patients, numerous others who might benefit from such surgery are unable or unwilling to undergo the trauma and risks of such techniques.

Techniques for minimally invasive thoracoscopic repair of heart valves while the heart is still beating have also been developed. U.S. Patent No. 8,465,500 to Speziali, which is incorporated by reference herein, discloses a thoracoscopic heart valve repair method and apparatus. Instead of requiring open heart surgery on a stopped heart, the thoracoscopic heart valve repair methods and apparatus taught by Speziali utilize fiber optic technology in conjunction with transesophageal echocardiography (TEE) as a visualization technique during a minimally invasive surgical procedure that can be utilized on a beating heart. More recent versions of these techniques are disclosed in U.S. Patent Application Publication Nos. 8,758,393 and 9,192,374 to Zentgraf, which disclose an integrated device that can enter the

heart chamber, navigate to the leaflet, capture the leaflet, confirm proper capture, and deliver a suture as part of a mitral valve regurgitation (MR) repair. These minimally invasive repairs are generally performed through a small, between the ribs access point followed by a puncture into the ventricle through the apex of the heart. Although far less invasive and risky for the patient than an open heart procedure, these procedures still require significant recovery time and pain.

Some systems have therefore been proposed that utilize a catheter routed through the patient's vasculature to enter the heart and attach a suture to a heart valve leaflet as an artificial chordae. While generally less invasive than the approaches discussed above, transcatheter heart valve repair can provide additional challenges. For example, with all artificial chordae replacement procedures, in addition to inserting a suture through a leaflet, the suture must also be anchored at a second location, such as at a papillary muscle in the heart, with a suture length, tension and positioning of the suture that enables the valve to function naturally. If the suture is too short and/or has too much tension, the valve leaflets may not properly close. Conversely, if the suture is too long and/or does not have enough tension, the valve leaflets may still be subject to prolapse. Proper and secure anchoring of the suture away from the leaflet is therefore a critical aspect of any heart valve repair procedure for inserting an artificial chordae. In the case of transcatheter procedures, such anchoring can be difficult because it can be difficult for the flexible catheter required for routing through the patient's vasculature to apply sufficient force to stably insert traditional suture anchors into, e.g., the myocardium. In addition, adjusting length of a suture in a transcatheter procedure is difficult as it is not possible for the surgeon to physically control the suture and its length once the suture is in the heart.

## SUMMARY

Disclosed herein are various embodiments of anchors configured to be inserted into a heart wall of a patient to anchor a suture as an artificial chordae under an appropriate tension for proper valve function. Some of the disclosed anchor embodiments “toggle” from a first position for delivery of the anchor to the heart wall and a second position for insertion of the anchor into the heart wall. In some embodiments, it is the “toggle” to the second position that provides the necessary insertion force for inserting the anchor into the heart muscle sufficient to retain the anchor from accidental withdrawal from the heart wall during normal valve operation (e.g., when a valve leaflet pulls on the suture attached to the anchor during systole). Such anchors are particularly suitable for use in intravascular, transcatheter procedures as described above given the inherent difficulties in providing sufficient force for insertion of an anchor into the heart wall with a flexible catheter.

In one embodiment, a method of anchoring a suture in a patient’s heart as an artificial chordae includes intravascularly accessing a patient’s heart and inserting a suture into a heart valve leaflet of the patient’s heart. A portion of the suture can be attached to a low profile tissue anchor or “toggle anchor” including an anchor body and an anchor tip. The toggle anchor can be inserted into the patient’s heart intravascularly with an anchor delivery catheter with the toggle anchor in a delivery position having the anchor tip extending generally axially with respect to the anchor body such that the toggle anchor fits within the anchor delivery catheter and is configured to be positioned adjacent a heart wall of the patient’s heart. The toggle anchor can then be advanced out of the anchor delivery catheter and into the heart wall such that the toggle anchor transitions from the delivery position into an anchoring position with the anchor tip being oriented generally transverse to the anchor body as the toggle anchor is advanced into the heart wall in the anchoring position. In some embodiments, the

transition from the delivery position to the anchoring position provides a force sufficient to cause the anchor tip to penetrate into the heart wall. The anchor delivery catheter can then be removed from the heart leaving the toggle anchor in the heart with the suture extending between the leaflet and the toggle anchor as an artificial chordae.

In one embodiment, an anchor is configured to be implanted into a patient's heart wall to anchor a suture extending from a valve leaflet of the heart as an artificial chordae. The anchor can include an anchor shaft and an anchor tip extending from a distal end of the anchor shaft. The anchor tip can be configured for delivery to the heart wall in a delivery configuration generally axially aligned with the anchor shaft such that the anchor shaft and anchor tip can be contained within an anchor delivery catheter. The anchor tip can further be configured to toggle from the delivery configuration into an anchor configuration when advanced out of the anchor delivery catheter and into the heart wall with the anchor tip being generally transverse to the anchor shaft in the anchor configuration to retain the anchor within the heart wall.

Some of the disclosed anchor embodiments transition from a first position for delivery of the anchor to the heart wall to a second position for insertion of the anchor into the heart wall. In some embodiments, it is the transition to the second position that provides the necessary insertion force for inserting the anchor into the heart muscle sufficient to retain the anchor from accidental withdrawal from the heart wall during normal valve operation (e.g., when a valve leaflet pulls on the suture attached to the anchor during systole). Such anchors are particularly suitable for use in intravascular, transcatheter procedures as described above given the inherent difficulties in providing sufficient force for insertion of an anchor into the heart wall with a flexible catheter.

In one embodiment, a method of anchoring a suture in a patient's heart as an artificial

chordae includes intravascularly accessing a patient's heart and inserting a suture into a heart valve leaflet of the patient's heart. A portion of the suture can be attached to a radial arm tissue anchor or "spider anchor" including an anchor body and one or more anchor tines. The spider anchor can be inserted into the patient's heart intravascularly with an anchor delivery catheter with the spider anchor in a delivery position having the anchor tine(s) extending generally axially with respect to the anchor body such that the spider anchor fits within the anchor delivery catheter. The spider anchor can then be advanced out of the anchor delivery catheter and into the heart wall such that the spider anchor transitions from the delivery position into an anchoring position with the anchor tines flaring or curving outwardly relative to the anchor body as the spider anchor is advanced into the heart wall into the anchoring position. In some embodiments, the transition from the delivery position to the anchoring position provides a force sufficient to cause the anchor tines to penetrate into the heart wall. The anchor delivery catheter can then be removed from the heart leaving the spider anchor in the heart with the suture extending between the leaflet and the spider anchor as an artificial chordae.

In one embodiment, an anchor is configured to be implanted into a patient's heart wall to anchor a suture extending from a valve leaflet of the heart as an artificial chordae. The anchor can include an anchor shaft and one or more anchor tines extending from a distal end of the anchor shaft. Anchor tines can be configured for delivery to the heart wall in a delivery configuration generally axially aligned with the anchor shaft such that the anchor shaft and anchor tines can be contained within an anchor delivery catheter. Anchor tines can further be configured to flare or curve outwardly from the delivery configuration into an anchoring configuration when advanced out of the anchor delivery catheter and into the heart wall to retain the anchor within the heart wall. In one embodiment, anchor tines

automatically transition to the anchoring configuration upon exiting the anchor delivery catheter due to the anchor tines being pretreated to have a shape memory in the anchoring configuration.

Also disclosed herein are various embodiments of suture adjustment mechanisms for anchors configured to be inserted into a heart wall of a patient to anchor a suture as an artificial chordae under an appropriate tension for proper valve function. Suture adjustment mechanisms can be configured to retain suture ends extending from the leaflet to the anchor with sufficient force to prevent natural movement of the leaflet from adjusting a length of the suture between the anchor and the leaflet. Free ends of the suture can extend from the anchor external to the body as tensioning strands. A surgeon can supply sufficient force on the tensioning strands from external the body to adjust a length and tension of the suture between the anchor and the leaflet.

In one embodiment, a suture adjustment mechanism is embodied in an anchor configured to be implanted into a patient's heart wall to anchor a suture extending from a valve leaflet of the heart as an artificial chordae. The anchor can include an anchor body and a means for retaining a suture within the anchor body. The means for retaining a suture is configured to enable adjustment of a length of the suture extending between the anchor body and the valve leaflet by pulling tensioning strands of the suture extending from the anchor body out of the patient's heart while preventing forces applied on the length of the suture extending between the anchor body and the valve leaflet due to movement of the leaflet from adjusting the length of the suture extending between the anchor body and the valve leaflet.

The above summary is not intended to describe each illustrated embodiment or every implementation of the subject matter hereof. The figures and the detailed description that follow more particularly exemplify various embodiments.

## BRIEF DESCRIPTION OF THE DRAWINGS

Subject matter hereof may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying figures, in which:

FIGS. 1A-1K depict various steps in a method of anchoring a suture in a beating heart of a patient to function as an artificial chordae according to an embodiment.

FIG. 2 depicts a low profile tissue anchor for an artificial chordae according to an embodiment.

FIGS. 3A-3C depict a low profile tissue anchor for an artificial chordae according to an embodiment.

FIGS. 4A-4C depict a low profile tissue anchor for an artificial chordae according to an embodiment.

FIGS. 5A-5D depict a low profile tissue anchor for an artificial chordae according to an embodiment.

FIG. 6 depicts a radial arm tissue anchor for an artificial chordae according to an embodiment.

FIG. 7 depicts a radial arm tissue anchor for an artificial chordae according to an embodiment.

FIG. 8 depicts a radial arm tissue anchor for an artificial chordae according to an embodiment.

FIG. 9 depicts a radial arm tissue anchor for an artificial chordae according to an embodiment.

FIGS. 10A – 10B depict a radial arm tissue anchor for an artificial chordae according to an embodiment.

FIGS. 11A – 11D depict insertion of a radial arm tissue anchor for an artificial chordae into a body of a patient according to an embodiment.

FIGS. 12A-12B depict steps in a method of anchoring a suture in a beating heart of a patient to function as an artificial chordae according to an embodiment.

FIGS. 13A-13F depict a suture length and tension adjustment mechanism according to an embodiment.

FIGS. 14A-14C depict a suture length and tension adjustment mechanism according to an embodiment.

FIG. 15 depicts a suture length and tension adjustment mechanism according to an embodiment.

FIGS. 16A-16B depict a suture length and tension adjustment mechanism according to an embodiment.

While various embodiments are amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the claimed inventions to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the subject matter as defined by the claims.

#### DETAILED DESCRIPTION OF THE DRAWINGS

The present disclosure is generally directed to anchoring and/or adjusting a length and/or tension of sutures inserted as artificial chordae into one or more heart valve leaflets through an intravascular, transcatheter approach. A heart valve leaflet may be captured and a suture inserted through the leaflet in any manner known in the art. One such leaflet capture

catheter and procedure is disclosed in copending U.S. Patent Application No. 16/363,701, which is hereby incorporated by reference herein. Another transcatheter procedure for inserting an artificial chordae is disclosed in U.S. Patent Publication No. 2016/0143737, which is hereby incorporated by reference herein.

Referring to Figures 1A-1K, a procedure for anchoring a suture inserted as an artificial chordae in a transcatheter procedure on a beating heart of a patient following insertion of the suture into a leaflet is schematically depicted. In this embodiment, a loop of suture has been inserted through the leaflet and the two free ends of the suture then inserted through the loop to form a girth hitch knot around the edge of the leaflet. Further detail regarding attaching a suture to a leaflet in this manner can be found in U.S. Patent Publication No. 2017/0290582, which is hereby incorporated by reference herein.

Following insertion of the suture 20 into the leaflet 11, the deployment catheter used to insert the suture is withdrawn through the guide catheter 14 and the two free ends 22 of the suture 20 are also withdrawn external to the body. The suture ends 22 are then attached to an anchor contained in an anchor driving catheter 30. Alternatively, the anchor could be pre-attached to the suture prior to insertion of the suture into the leaflet. The anchor driving catheter 30 is inserted into the guide catheter 14, routed through the catheter into the body and advanced passed the leaflet 11 to the heart wall 13 below the valve at, for example, a papillary muscle as shown in Figures 1B-1D. The anchor driving catheter 30 is then used to insert the anchor 100 into the myocardium as shown in Figures 1D-1G and as described in more detail below.

After insertion of the anchor 100 into the heart tissue, the anchor driving catheter 30 is withdrawn to a position superior of the valve as shown in Figure 1H and the length and tension of the suture ends 22 extending from the leaflet 11 are tested and adjusted until it is

determined that normal valve function has been achieved. This determination can be made through use of ultrasonic imaging, for example. The tension is adjusted through a tensioning strand 24 of the suture depicted in Figure 1H. Once the proper length and tension has been determined using, for example, transesophageal echocardiography or other non-invasive methods, the anchor driving catheter 30 is advanced back down along the tensioning strand 24 and to sever the strand at the anchor 100. The entire catheter system, including the anchor driving catheter 30 and the guide catheter 14 is then withdrawn from the patient's body. Referring to Figure 1K, the suture 20 remains in the body extending between the leaflet 11 and the anchor 100 to function as an artificial chordae tendineae

Disclosed herein are various embodiments of anchors that can be employed in procedures such those described above to anchor a suture as an artificial chordae. Such anchors maintain positioning and length of the suture (i.e., tension) to ensure proper leaflet functionality during the cardiac cycle.

Referring now to Figure 2, one embodiment of a low profile tissue anchor or "toggle anchor" 100 for anchoring a suture as an artificial chordae is depicted. Toggle anchor 100 generally includes an anchor tip 102 and an anchor shaft 104. Anchor tip 102 can be configured to pivot with respect to anchor shaft 104. In one embodiment, anchor tip 102 can be connected to anchor shaft 104 with a pin 106. Pin 106 can be configured as a generally cylindrical rod extending through aligned apertures in the anchor shaft 104 and the anchor tip 102 to enable the anchor tip to pivot about pin 106 with respect to anchor shaft.

Figures 3A-3C depict various configurations that one embodiment of a low profile tissue anchor or toggle anchor 100 as depicted in Figure 2 can take on to enable the toggle anchor to be delivered through the guide catheter into the heart and anchored within the myocardium of the heart. Figure 3A depicts a delivery position or configuration of the toggle

anchor 100 for when the anchor 100 and anchor driving catheter 30 are guided through the guide catheter 14 and the anchor driving catheter 30 is advanced adjacent the myocardium. In this configuration, the anchor tip 102 is generally longitudinally aligned with the anchor shaft 30, which enables the anchor 100 to be contained within the anchor driving catheter 30 so that the anchor 100 can be routed through the guide catheter 14.

Adjacent the myocardium, the anchor tip 102 is advanced out of the anchor driving catheter 30 and as the anchor edge 108 is driven into the myocardium, the anchor tip 102 pivots with respect to the anchor shaft 104 about pin 106 as shown in Figure 3B. In one embodiment, the anchor tip 102 automatically pivots when advanced out of the anchor driving catheter 30 when it is no longer constrained into the delivery position by the anchor driver 30, which provides the necessary force to insert the anchor tip 102 into the heart wall. In another embodiment, the anchor tip 102 pivots due to a force of the beating heart wall on the anchor tip 102. As the anchor tip 102 is further driven into the heart muscle, the anchor tip 102 can continue to rotate to a final, anchoring position transverse to the anchor shaft 106 that inhibits inadvertent removal of the anchor tip 102. In the depicted embodiment, the anchor tip 102 is oriented at a generally 90 degree angle with respect to the anchor shaft 106 in the anchoring position. In various embodiments, the anchor tip 102 can be oriented at other angles, such as a 45 degree angle, 60 degree angle, or any angle between about 45 degrees and about 90 degrees. The anchor tip 102 and, in some embodiments, the anchor shaft 104 then remain in the body with one or more sutures extending between the anchor 100 and a leaflet as an artificial chordae. In one embodiment, anchor shaft 104 includes a tensioning mechanism through which a tension on the suture can be adjusted. Examples of such tensioning mechanisms can be found in U.S. Patent Application No. 16/406,764 filed May 9, 2018, entitled Suture Length Adjustment for Minimally Invasive Heart Valve Repair,

which is hereby incorporated by reference herein in its entirety.

Figures 4A-4C depict a low profile tissue anchor or toggle anchor 200 according to another embodiment. Toggle anchor 200 can include an anchor tip 202 and an anchor shaft 204. The suture 20 can extend through a suture lumen 206 in the anchor shaft 202, into a tip lumen 208 in the anchor tip 202 and attach to the anchor tip 202 at a suture attachment point 210 within tip lumen 208. As shown in Figure 4B, anchor shaft 204 can be selectively detachable from anchor tip 202. In practice, tension in the suture 20 holds the anchor tip 202 proximally against the anchor shaft 204 with a distal shaft connector 214 seated within the tip lumen 208 of the anchor tip 202 as the anchor 200 is advanced to the myocardium with the anchor driver 30 (not pictured in Figures 4A-4C). The anchor driver 30 drives the anchor edge 212 into the myocardium to insert the anchor tip 202 into the heart muscle. As the anchor tip 102 is driven into the heart wall, the anchor can automatically pivot from the generally longitudinally position shown in Figures 4A-4B to the more transverse position shown in Figure 4C to inhibit accidental removal of the anchor from the tissue. As the anchor tip 202 is inserted into the heart wall, the anchor shaft 204 disengages from the anchor tip 202 and can then be withdrawn from the body along the suture 20. The anchor tip 202 remains embedded in the heart wall with the suture 20 extending therefrom to a valve leaflet.

Figures 5A-5D depict a low profile tissue anchor or toggle anchor 300 according to a further embodiment. Toggle anchor 300 includes an anchor body 302 having one or more anchor tips extending distally therefrom. A suture (not pictured) can be attached to toggle anchor 300 within anchor body 300. In one embodiment, anchor tips can be configured as tines 304 that are unitarily formed with anchor body 302 in a monolithic construction. Four tines 304 extend radially around anchor body 302 in the depicted embodiment, but toggle anchors having greater or fewer tines can be utilized, including embodiments having only a

single tine. Tines 304 function similarly to anchor tips 102 above that pivot to anchor within the tissue such that the tines function as a hingeless toggle.

Still referring to Figures 5A-5D, each tine 304 can include an arm 306 that unitarily extends from a distal end of the anchor body 302 of toggle anchor 300. Tines 304 each further include a pointed tip 308 and a leg 310 extending from the tip 308 proximally back towards the anchor body 302. Tines 304 can each be biased outwardly towards an anchoring configuration. In one embodiment, this is accomplished by forming tines 304 or toggle anchor 300 from a shape memory material such as, for example, Nitinol. As depicted in Figure 5A, tines 304 can take on a longitudinal delivery configuration in which the tines 304 extend generally axially with respect to the anchor body 302 when constrained by the anchor driving catheter 30. As the toggle anchor 300 is advanced distally from the anchor driver 30 and into the heart muscle 13, the tines 304 automatically toggle into the anchoring configuration as shown in Figures 5B and 5C. This toggling motion creates the necessary force to drive the tines 304 into the heart muscle 13. In the depicted embodiment, the tines 304 are oriented at a generally 45 degree angle with respect to the anchor body 302. In various embodiments, the tines 304 can be oriented at various other angles, such as, for example, 60 degrees, 90 degrees or any angle between about 45 degrees and about 90 degrees. Once the tines 304 are generally fully inserted into the heart wall 13, the anchor driving catheter 30 can be withdrawn with the toggle anchor 100 firmly retained in the heart. In one embodiment, the legs 310 of tines 304 are offset from the tine arms 306 to increase the pullout force required for the anchor to be removed to more stably seat the anchor in the heart wall 13, as can be seen in, for example, Figure 5D. In some embodiments, anchor body 302 can include a tensioning mechanism for adjusting a tension on the suture, as described above.

Disclosed herein are various embodiments of anchors configured to be inserted into a

heart wall of a patient to anchor a suture as an artificial chordae under an appropriate tension for proper valve function. Some of the disclosed anchor embodiments “toggle” from a first position for delivery of the anchor to the heart wall and a second position for insertion of the anchor into the heart wall. In some embodiments, it is this “toggle” that provides the insertion force for inserting the anchor into the heart muscle sufficient to retain the anchor from accidental withdrawal from the heart wall during normal valve operation (e.g., when a valve leaflet pulls on the suture attached to the anchor during systole). Such anchors are particularly suitable for use in intravascular, transcatheter procedures as described above given the inherent difficulties in providing sufficient force for insertion of an anchor into the heart wall with a flexible catheter.

Referring now to Figure 6-8, one embodiment of a radial arm tissue anchor 400 or “spider anchor” for anchoring a suture as an artificial chordae is depicted. Spider anchor 400 generally includes a plurality of elongate anchor tines or radial arms 402 extending outwardly away from an anchor body or shaft 404. In one embodiment, spider anchor 400 can further include one or more suture bars 406 that aid in adjusting a tension and/or length of one or more sutures connected to spider anchor. Examples of such tensioning mechanisms can be found in U.S. Patent Application No. 16/406,764, entitled Suture Length Adjustment for Minimally Invasive Heart Valve Repair, previously incorporated by reference herein in its entirety.

According to embodiments, spider anchor 400 can include various numbers of tines 402. For example, Figure 6 depicts spider anchor 400 having four tines. Figure 7 depicts spider anchor 400 having six tines and Figure 8 depicts spider anchor 400 having eight tines. According to various embodiments, spider anchors as disclosed herein can include as few as three tines and as many as twelve or more tines.

Tines 402 can each include an elongate body 408 and a distal tip 410. Distal tip 410 is sharpened to aid in insertion of tines 402 into heart tissue. According to some embodiments, as depicted in Figures 6-8, elongate body 408 of anchor tines 402 may be generally smooth. According to alternative embodiments, as illustrated in FIG. 9, elongate body 408 of anchor tines 402 may be serrated. Such a serrated configuration further secures the anchor 400 into the body by increasing the force that would be required to pull the tines 402 out of the heart muscle.

According to some embodiments, spider anchor 400 may be made of a shape memory material such as, for example, Nitinol. In such embodiments tines 402 can be formed with anchor body 404 in a monolithic construction. In some embodiments, tines 402 and body 404 can be formed by laser cutting tines 402 from a Nitinol tube. In other embodiments, tines 402 can be formed from a laser cut tube and a separate body 404 can surround and/or be attached to the remaining tube portion from which the tines extend.

Figures 10A-10B depict a radial arm tissue anchor or spider anchor 500 according to another embodiment. Anchor 500 similarly includes an anchor body or shaft 504 with a plurality of anchor tines 502 extending therefrom. In this embodiment, anchor tines 502 are unitarily formed with anchor body 504 in a single monolithic construction, as discussed above. Figures 10A-10B further depict one embodiment of a heat treatment process for providing shape memory to anchor tines 502 that includes a two stage process. Figure 10A depicts the first stage of the process in which the tines 502 are partially curved with respect to anchor body 504. In one embodiment of this configuration, the outer diameter of the anchor, as determined by how far outwardly the anchor tines 502, is 13 millimeters. Figure 10B depicts a second stage of the process after the tines 502 have been heat set in the first stage that further curves the tines 502 with respect to body 504. In one embodiment of this

configuration, the outer diameter of the anchor is 8 millimeters. In such embodiments, tines are heat set to a curved geometry such that upon deployment from a delivery catheter, as discussed below, tines 502 lose restraint from the delivery catheter and regain their curved shape, securing them in the muscle.

Figures 11A-11D depict a radial arm tissue anchor or spider anchor 600 according to a further embodiment. Spider anchor 600 includes an anchor body or shaft 604 having one or more anchor tines 602 extending distally therefrom. A suture (not pictured) can be attached to spider anchor 600 within anchor body 604. Anchor tines 602 can be unitarily formed with anchor body 604 in a monolithic construction as described herein. Each tine 602 can include an elongate arm 608 that unitarily extends from a distal end of the anchor body 604 of spider anchor 600. Tines 602 each further include a pointed tip 610 at a distal end of each elongate arm 608. As discussed above, tines 602 can each be biased outwardly towards an anchoring configuration.

Still referring to Figures 11A-11D, these figures further depict a procedure for inserting one embodiment of a radial arm tissue anchor or spider anchor 600 into a heart wall. Figure 11A depicts a delivery position or configuration of the spider anchor 600 for when the anchor 600 and anchor driving catheter 30 are guided through the guide catheter 14 (not pictured) and the anchor driving catheter 30 is advanced adjacent the myocardium. In this configuration, the anchor tines 602 are generally axially or longitudinally aligned with the anchor shaft 604, which enables the anchor 600 to be contained within the anchor driving catheter 30 so that the anchor 600 can be routed through the guide catheter 14 (not pictured).

Adjacent the myocardium 13, the anchor tines 602 are advanced out of the anchor driving catheter 30 and as the anchor tips 610 are driven into the myocardium, the elongate arms 608 of the anchor tines 602 flare or curve outwardly with respect to the anchor shaft 604

as shown in Figure 11B. The anchor tines 602 automatically flare when advanced out of the anchor driving catheter 30 when no longer constrained in the delivery position by the anchor driver 30 due to their heat set, shape memory curved form, which provides the necessary force to insert the anchor tines 602 into the heart wall 13. As the anchor tines 602 are further advanced out of the guide catheter 30 and driven into the heart muscle, the anchor tines 602 can continue to curve or flare outwardly and upwardly into a final, anchoring position that inhibits inadvertent removal of the anchor tines 602. The anchor 600 then remains in the body with one or more sutures extending between the anchor 600 and a leaflet as an artificial chordae. In one embodiment, anchor shaft 604 includes a tensioning mechanism through which a tension on the suture can be adjusted, as previously referenced herein.

Disclosed herein are various embodiments of anchors configured to be inserted into a heart wall of a patient to anchor a suture as an artificial chordae under an appropriate tension for proper valve function. Some of the disclosed anchor embodiments transition from a first position for delivery of the anchor to the heart wall to a second position for insertion of the anchor into the heart wall. In some embodiments, it is this transition that provides the necessary insertion force for inserting the anchor into the heart muscle sufficient to retain the anchor from accidental withdrawal from the heart wall during normal valve operation (e.g., when a valve leaflet pulls on the suture attached to the anchor during systole). Such anchors are particularly suitable for use in intravascular, transcatheter procedures as described above given the inherent difficulties in providing sufficient force for insertion of an anchor into the heart wall with a flexible catheter.

Figures 12A-12B depict further details regarding adjustment of the length and tension of the suture 20 according to an embodiment. After initial insertion of the anchor 100 into the heart wall 13, the free ends 22 of the suture 20 extend between the anchor and the leaflet

11 and the tensioning strand 24 of the suture 20 extends out of the body where it is accessible to the surgeon, as described above. Figure 12A depicts one example of an initial configuration prior to suture adjustment. In the depicted configuration, a length of the suture ends 22 between the anchor 1000 and the leaflet 11 is too long such that there is not enough tension on the leaflet 11, which could cause the leaflet 11 to continue to prolapse. Figure 12B depicts a final configuration after suture adjustment. In this configuration, the length of the suture ends 22 between the anchor 100 and the leaflet 11 have been shortened to provide a tension that enables the leaflet 11 to coapt with the other leaflet during systole while preventing the leaflet 11 from prolapsing. Once proper suture length and tension has been achieved as shown in Figure 2B, the tensioning strand 24 can be severed as discussed above.

Disclosed herein are various embodiments of mechanisms that can be employed to adjust the length and/or tension of a suture as an artificial chordae in procedures such as those described above. Such mechanisms enable suture adjustment from outside the body in a transcatheter, intravascular procedure.

Figures 13A-13E depict a suture adjustment mechanism 700 of a suture anchor 1000 according to an embodiment. Suture adjustment mechanism 700 can be disposed adjacent a proximal portion of an anchor body 1004 of suture anchor 1000. For sake of clarity, only body portion 1004 of suture anchor 1000 is depicted. Although not shown in these figures for sake of clarity, suture anchor 1000 would further include a distal portion for embedding the anchor into heart tissue, such as, for example the anchors disclosed above.

Suture adjustment mechanism 700 includes an actuation tube 702 and a pair of pins or bars 704. Actuation tube 702 can surround a portion of anchor body 1004 of anchor 1000. Bars 704 can extend transversely across a long axis of anchor body 1004. Bars 704 can extend through and be supported within opposing apertures 1005 through anchor body 1004.

Bars 704 can further extend through and be supported within opposing apertures 705 in the actuation tube 702 adjacent the apertures 1005 in the anchor body 1004. In the depicted embodiment, bars 704 can seat within apertures 1005, 705, in a generally horizontal side-by-side and parallel configuration with each other. An actuation projection 706 on one or both sides of the actuation tube can extend from actuation tube 702 into the aperture 705 and can be selectively positioned between pins, as will be discussed below.

A suture 20 can extend into anchor body 1004 and be wrapped around pins/bars as shown in more detail in Figures 13B-13D. For sake of clarity, it is noted that only a single suture end is shown in these Figures. However, it should be noted that each suture inserted through a leaflet will have a pair of suture ends attached to the suture adjustment mechanism 700. As shown in these figures, each suture end 22 extending from the leaflet to the anchor 1000 wraps completely around both pins/bars. The suture 20 then extends between the bars 704 as tensioning strands 24 extending back out of the body to the surgeon, as described above.

The actuation projection 706 of actuation tube 702 can be biased to a proximal position as shown in Figure 13E and can be actuated downwardly as shown in Figure 13F to drive the bars 704 apart. In use, when anchor 1000 is attached to the anchor delivery catheter 30, the delivery catheter 30 can interface with the actuation tube 702 to actuate the projection 706 downwardly to force the bars 704 apart. This space between the bars 704 enables the anchor 1000 to slide along the tensioning strand 24 from a position outside the body where the anchor 1000 is attached to the suture 20 to within the heart adjacent the myocardium where the anchor 1000 is to be inserted. Following insertion of the anchor 1000, the anchor delivery catheter 30 is withdrawn as discussed above. Once the anchor delivery catheter 30 is detached from the actuation tube 702, the tube returns to the proximal position shown in

Figure 13E and the tensioning strand 24 of the suture 20 is held between the bars 704 with sufficient force such that the forces applied on the free ends 22 of the suture (wrapped around the bars 704) by the natural movement of the leaflet to which the suture is attached are not sufficient to move the suture. However, a surgeon operating the tensioning strands 24 of the suture 20 external to the body can supply sufficient force by pulling on the tensioning strands 24 to shorten the distance between the anchor 1000 and the leaflet (see Figures 12A-12B). The actuation tube can be utilized to release the suture tension applied to the valve leaflet in a situation where increasing the length of the suture between the anchor and the leaflet is desired by the surgeon following the assessment of the valve function. Once the tension and length of the suture 20 have been properly adjusted and the tensioning strand 24 is severed as discussed above, the suture length will be fixed.

Figures 14A-14C depict a suture adjustment mechanism 800 according to another embodiment. Suture adjustment mechanism 800 is similar to suture adjustment mechanism 700 in that the suture 20 wraps around a pair of bars or pins 804 contained in a proximal portion of an anchor body 1004 of suture anchor 1000. In contrast to the generally horizontally aligned bars 704 of suture adjustment mechanism 700, the bars 804 of suture adjustment mechanism 800 are oriented and aligned generally vertically with respect to each other. Bars 804 can extend through the anchor body 1004 similar to the embodiment described above.

The suture ends 22 extending between the leaflet and the anchor 1000 wrap around the bars 804 and the free ends or tensioning strands 24 extend between the bars 804, as shown in Figures 14B-14C. A leaf spring 802 can be positioned within anchor body 1004 to apply a force to bias the bars together, either by directly contacting the lower bar 804 or by contact a housing element that contains the pins. Tension on the suture and the length between the

anchor 1000 and the leaflet can be adjusted by pulling on the tensioning strands 24 outside the body with sufficient force to pull the suture 20 through the bars 804 and shorten the connection to the leaflet. In one embodiment, the force required by the surgeon to pull the suture through the mechanism is 0.1 pounds. Natural forces of the leaflet on the suture ends 22 are not sufficient to pull the suture through the bars 804, and because the suture ends 22 are wrapped around the pins 804 such forces increase the inward clamping force provided by bars 804 to the tensioning strands 24 positioned therebetween. Tension can be released by exerting force downward onto leaf spring to enable the pins to spread apart. Such a force can be applied by, for example, a catheter such as delivery catheter 30 as the anchor 1000 is advanced from external the body along the suture 20 to the myocardium where it is to be anchored.

As noted above, in the previous embodiments only a single suture end has been shown for sake of clarity. In practice, each suture will have a pair of ends 22 extending from the leaflet and a corresponding pair of tensioning strands 24. In one embodiment, each anchor 1000 and corresponding tensioning mechanism 700, 800 can accommodate a pair of sutures connected to the leaflet, which therefore includes two pairs (4) of suture ends 22 extending to the leaflet and two pairs (4) of tensioning strands 24 extending out of the body, as depicted schematically in Figure 15.

Figures 16A-16B depict a suture adjustment mechanism 900 defined in an anchor body 1004 of an anchor 1000 according to a further embodiment. Essentially, this embodiment replaces the pins or bars 704, 804 of the previous embodiments with apertures 904 formed through opposing sides of the anchor body 1004. In one embodiment, apertures 904 include a distal aperture 904a and a proximal aperture 904b. In the depicted embodiment, the distal apertures 904a are generally circular and the proximal apertures 904b

are elongate. Suture adjustment mechanism 900 can further include a suture wrapping sleeve 902. Suture wrapping sleeve 902 can be positioned around the elongate proximal apertures 904b.

Referring to Figure 16B, each suture end 22 of a suture 20 extending from the leaflet enters into anchor body 1004 through an open proximal end of anchor body 1004 and extends into a hollow interior of anchor body 1004. The suture ends 22 then extend out of the distal apertures 904a and are wrapped around the suture wrapping sleeve 902 at the elongate proximal apertures 904b. The suture 20 then extends back out of the body as a pair of tensioning strands 24 for adjusting a length of each respective suture end 22 relative to the leaflet. As with previous embodiments, a surgeon can provide sufficient force on the tensioning strands 24 to adjust the length and tension of the suture ends 22, but the natural forces of the leaflet are insufficient to adjust the wrapped suture ends 22.

Various embodiments of systems, devices, and methods have been described herein. These embodiments are given only by way of example and are not intended to limit the scope of the claimed inventions. It should be appreciated, moreover, that the various features of the embodiments that have been described may be combined in various ways to produce numerous additional embodiments. Moreover, while various materials, dimensions, shapes, configurations and locations, etc. have been described for use with disclosed embodiments, others besides those disclosed may be utilized without exceeding the scope of the claimed inventions.

Persons of ordinary skill in the relevant arts will recognize that the subject matter hereof may comprise fewer features than illustrated in any individual embodiment described above. The embodiments described herein are not meant to be an exhaustive presentation of the ways in which the various features of the subject matter hereof may be combined.

Accordingly, the embodiments are not mutually exclusive combinations of features; rather, the various embodiments can comprise a combination of different individual features selected from different individual embodiments, as understood by persons of ordinary skill in the art. Moreover, elements described with respect to one embodiment can be implemented in other embodiments even when not described in such embodiments unless otherwise noted.

Although a dependent claim may refer in the claims to a specific combination with one or more other claims, other embodiments can also include a combination of the dependent claim with the subject matter of each other dependent claim or a combination of one or more features with other dependent or independent claims. Such combinations are proposed herein unless it is stated that a specific combination is not intended.

## CLAIMS

1. A method of anchoring a suture in a heart of a patient as an artificial chordae, comprising:

intravascularly accessing the heart;

inserting a suture into a heart valve leaflet of the heart;

attaching a portion of the suture to a tissue anchor, the tissue anchor include an anchor body and an anchor tip;

advancing the tissue anchor into the heart with an anchor delivery catheter with the tissue anchor in a delivery position having the anchor tip extending generally coaxially with respect to the anchor body such that the tissue anchor fits within the anchor delivery catheter;

positioning the tissue anchor adjacent a heart wall of the heart;

advancing the tissue anchor out of the anchor delivery catheter and into the heart wall such that the tissue anchor transitions from the delivery position into an anchoring position as the tissue anchor is advanced into the heart wall, the anchor tip being oriented at a non-coaxial angle to the anchor body in the anchoring position, and wherein the transition from the delivery position and anchoring position provides a force sufficient to cause the anchor tip to penetrate into the heart wall; and

removing the anchor delivery catheter from heart leaving the tissue anchor in the heart with the suture extending between the leaflet and the tissue anchor as an artificial chordae.

2. The method of claim 1, wherein the tissue anchor transitions from the delivery position into an anchoring position automatically when the anchor tip is advanced out of the anchor delivery catheter.

3. The method of claim 2, wherein the tissue anchor comprises a shape memory material

that automatically transitions into the anchoring position when not constrained by the anchor delivery catheter.

4. The method of claim 1, wherein the tissue anchor transitions from the delivery position into an anchoring position as the tissue anchor is advanced into by the anchor tip contacting the heart wall.

5. The method of claim 1, wherein the tissue anchor transitions from the delivery position into an anchoring position by the anchor tip pivoting with respect to the anchor shaft.

6. The method of claim 5, wherein the anchor tip pivots with respect to the anchor shaft about a pin.

7. The method of claim 1, wherein the anchor tip is unitarily formed with the anchor shaft as a single monolithic construction.

8. The method of claim 1, wherein the tissue anchor comprises a plurality of anchor tips radially arranged around a distal end of the anchor shaft.

9. The method of claim 1, further comprising disconnecting the anchor shaft from the anchor tip and removing the anchor shaft from the body.

10. The method of claim 1, further comprising adjusting a tension of the suture.

11. The method of claim 1, wherein the anchor tip being oriented at a non-coaxial angle to the anchor body in the anchoring position orients the anchor tip at an angle of greater than 45 degrees relative to the anchor body.

12. The method of claim 1, wherein the anchor tip being oriented at a non-coaxial angle to the anchor body in the anchoring position orients the anchor tip at an angle of about 90 degrees relative to the anchor body.

13. An anchor configured to be implanted into a heart wall of a heart of a patient to anchor a suture extending from a valve leaflet of the heart as an artificial chordae, the anchor comprising:

an anchor shaft; and

an anchor tip extending from a distal end of the anchor shaft, wherein the anchor tip is configured for delivery to the heart wall in a delivery configuration generally coaxially aligned with the anchor shaft such that the anchor shaft and anchor tip can be contained within an anchor delivery catheter, and wherein the anchor tip is configured to toggle from the delivery configuration into an anchor configuration when advanced out of the anchor delivery catheter and into the heart wall, the anchor tip being oriented at a non-coaxial angle to the anchor shaft in the anchor configuration to retain the anchor within the heart wall.

14. The anchor of claim 13, wherein the anchor tip is configured to transition from the delivery configuration into the anchoring configuration automatically when the anchor tip is advanced out of the anchor delivery catheter.

15. The anchor of claim 14, wherein the anchor tip comprises a shape memory material that automatically transitions into the anchoring position when not constrained by the anchor delivery catheter.
16. The anchor of claim 13, wherein the anchor tip transitions from the delivery configuration into the anchoring configuration by the anchor tip contacting the heart wall.
17. The anchor of claim 13, wherein the anchor tip transitions from the delivery configuration into the anchoring configuration by the anchor tip pivoting with respect to the anchor shaft.
18. The anchor of claim 17, wherein the anchor tip pivots with respect to the anchor shaft about a pin.
19. The anchor of claim 13, wherein the anchor tip is unitarily formed with the anchor shaft as a single monolithic construction.
20. The anchor of claim 13, further comprising a plurality of anchor tips radially arranged around a distal end of the anchor shaft.
21. The anchor of claim 13, wherein the anchor shaft is configuration to be disconnected from the anchor tip following insertion of the anchor tip into the heart wall.
22. A method of anchoring a suture in a heart of a patient as an artificial chordae,

comprising:

intravascularly accessing the heart;

inserting a suture into a heart valve leaflet of the heart;

attaching a portion of the suture to an anchor, the anchor including an anchor body and a plurality of anchor tines extending distally from the anchor body, each anchor tine including an elongate body and a distal tip;

advancing the anchor into the heart with an anchor delivery catheter with the anchor in a delivery position having the anchor tines extending generally axially with respect to the anchor body such that the anchor fits within the anchor delivery catheter;

positioning the anchor adjacent a heart wall of the heart;

advancing the anchor out of the anchor delivery catheter and into the heart wall such that the anchor transitions from the delivery position into an anchoring position as the anchor is advanced into the heart wall, the anchor tines curving generally outwardly with respect to the anchor body in the anchoring position, and wherein the transition from the delivery position to the anchoring position provides a force sufficient to cause the anchor tines to penetrate into the heart wall; and

removing the anchor delivery catheter from the heart leaving the anchor in the heart with the suture extending between the leaflet and the anchor as an artificial chordae.

23. The method of claim 22, wherein the anchor transitions from the delivery position into the anchoring position automatically when the anchor tines are advanced out of the anchor delivery catheter.

24. The method of claim 23, wherein the anchor comprises a shape memory material that

automatically transitions into the anchoring position when not constrained by the anchor delivery catheter.

25. The method of claim 24, wherein the shape memory material is heat set into the anchoring position.

26. The method of claim 22, wherein the anchor transitions from the delivery position into the anchoring position by the anchor tines curving with respect to the anchor shaft.

27. The method of claim 26, wherein the anchor tines flare outwardly with respect to the anchor shaft.

28. The method of claim 22, wherein the anchor tines are unitarily formed with the anchor shaft as a single monolithic construction.

29. The method of claim 22, wherein the plurality of anchor tines are radially arranged around a distal end of the anchor shaft.

30. The method of claim 22, further comprising adjusting a tension of the suture.

31. The method of claim 22, wherein the elongate body of one or more of the plurality of anchor tines is serrated.

32. An anchor configured to be implanted into a heart wall of a heart of a patient to

anchor a suture extending from a valve leaflet of the heart as an artificial chordae, the anchor comprising:

an anchor shaft; and

a plurality of anchor tines extending from a distal end of the anchor shaft, each anchor tine including an elongate body and a distal tip, wherein the anchor tines are configured for delivery to the heart wall in a delivery configuration generally axially aligned with the anchor shaft such that the anchor shaft and anchor tines can be contained within an anchor delivery catheter, and wherein the anchor tines are configured to transition from the delivery configuration into an anchor configuration when advanced out of the anchor delivery catheter and into the heart wall, the anchor tines being curved generally outwardly with respect to the anchor shaft in the anchor configuration to retain the anchor within the heart wall.

33. The anchor of claim 32, wherein the anchor tines are configured to transition from the delivery configuration into the anchoring configuration automatically when the anchor tines are advanced out of the anchor delivery catheter.

34. The anchor of claim 33, wherein the anchor tines comprise a shape memory material that automatically transitions into the anchoring position when not constrained by the anchor delivery catheter.

35. The anchor of claim 34, wherein the shape memory material is heat set into the anchoring position.

36. The anchor of claim 32, wherein the anchor tines transition from the delivery

configuration into the anchoring configuration by the anchor tines flaring outwardly with respect to the anchor shaft.

37. The anchor of claim 32, wherein the elongate body of one or more of the plurality of anchor tines is serrated.

38. The anchor of claim 32, wherein the anchor tines are unitarily formed with the anchor shaft as a single monolithic construction.

39. The anchor of claim 32, wherein the plurality of anchor tines are radially arranged around a distal end of the anchor shaft.

40. An anchor configured to be implanted into a heart wall of a heart of a patient to anchor a suture extending from a valve leaflet of the heart as an artificial chordae, the anchor comprising:

an anchor body; and

means for retaining a suture within the anchor body, wherein the means for retaining the suture is configured to enable adjustment of a length of the suture extending between the anchor body and the valve leaflet by pulling tensioning strands of the suture extending from the anchor body out of the heart while preventing forces applied on the length of the suture extending between the anchor body and the valve leaflet due to movement of the leaflet from adjusting the length of the suture extending between the anchor body and the valve leaflet.

41. The anchor of claim 40, wherein the means for retaining a suture within the anchor

body is a pair of pins disposed within the anchor body.

42. The anchor of claim 41, wherein the pair of pins are oriented in a generally horizontal configuration with respect to each other.

43. The anchor of claim 41, wherein the pair of pins are oriented in a generally vertical configuration with respect to each other.

44. The anchor of claim 40, wherein the means for retaining a suture within the anchor body is a pair of apertures extending through opposing sides of the anchor body.

45. The anchor of claim 41, further comprising means for adjusting a clamping force by which the pins retain the suture.

46. The anchor of claim 45, wherein the means for adjusting comprises a leaf spring that biases the pins into a compressed configuration to retain the suture by a clamping force between the pins.

47. The anchor of claim 46, wherein the leaf spring is configured to be engaged to separate the pins to lessen the clamping force on the suture.

48. The anchor of claim 45, wherein the means for adjusting comprises a sleeve extending around the anchor body.

49. The anchor of claim 48, wherein the sleeve is configured to be actuated to separate the pins to lessen the clamping force on the suture.

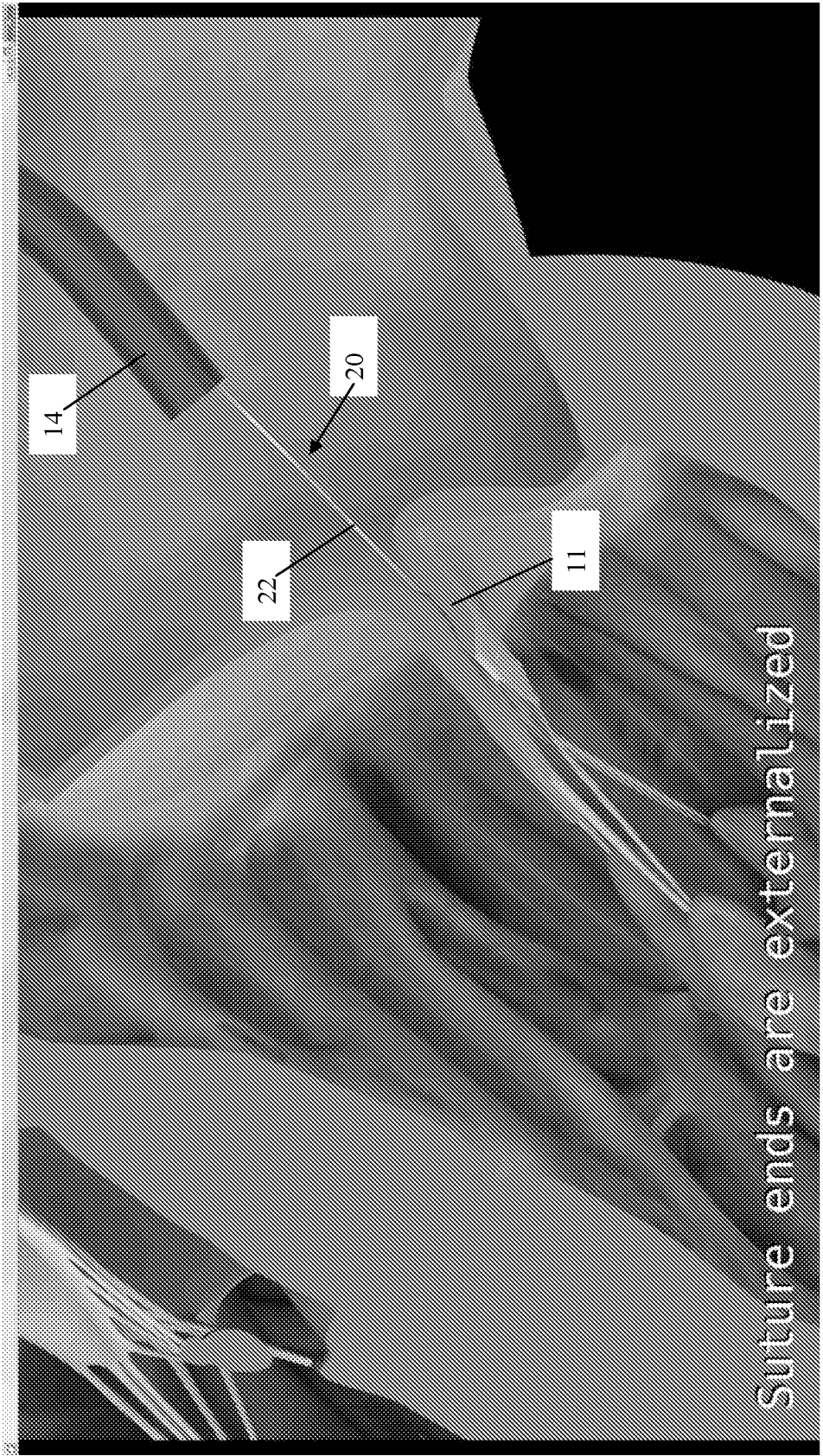


Fig. 1A

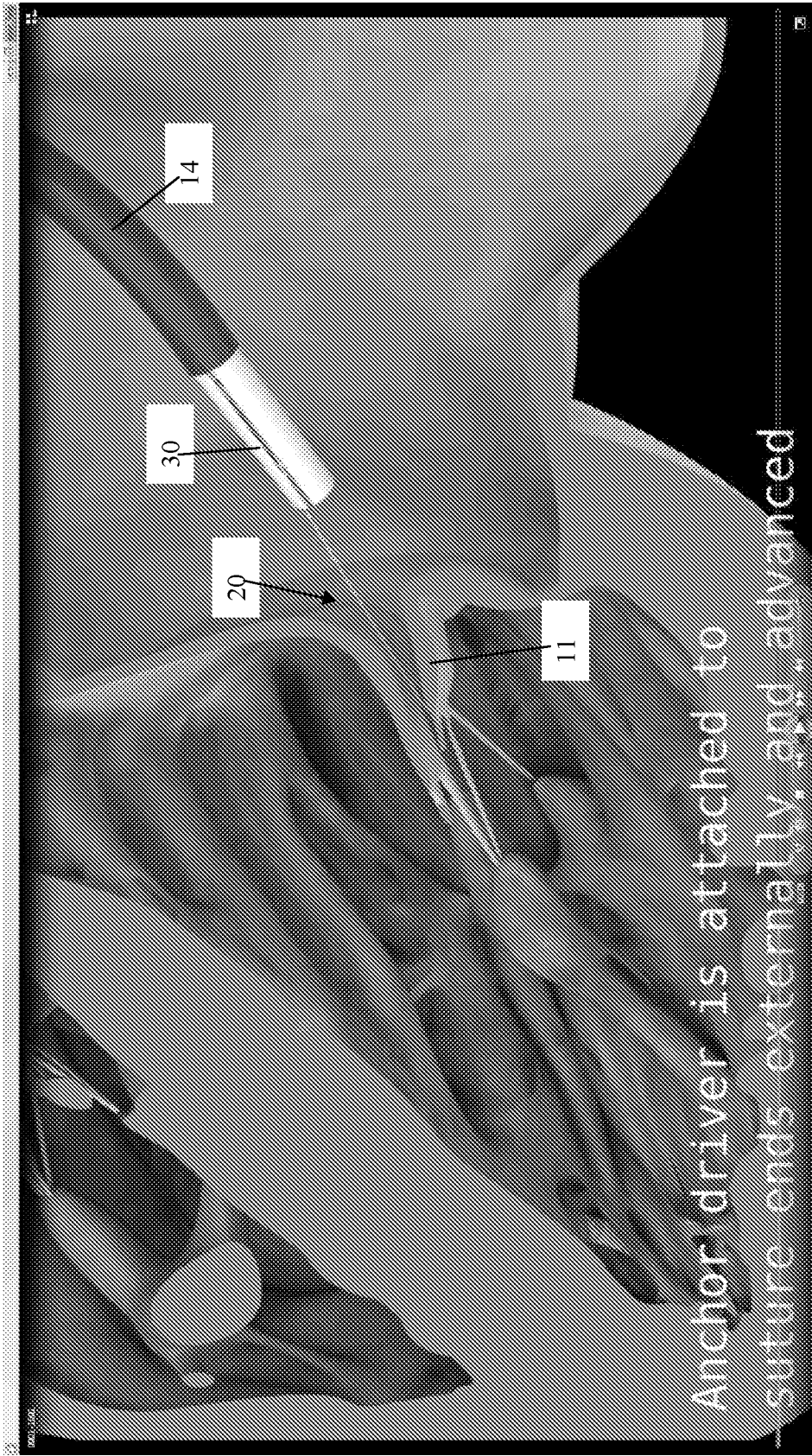


Fig. 1B

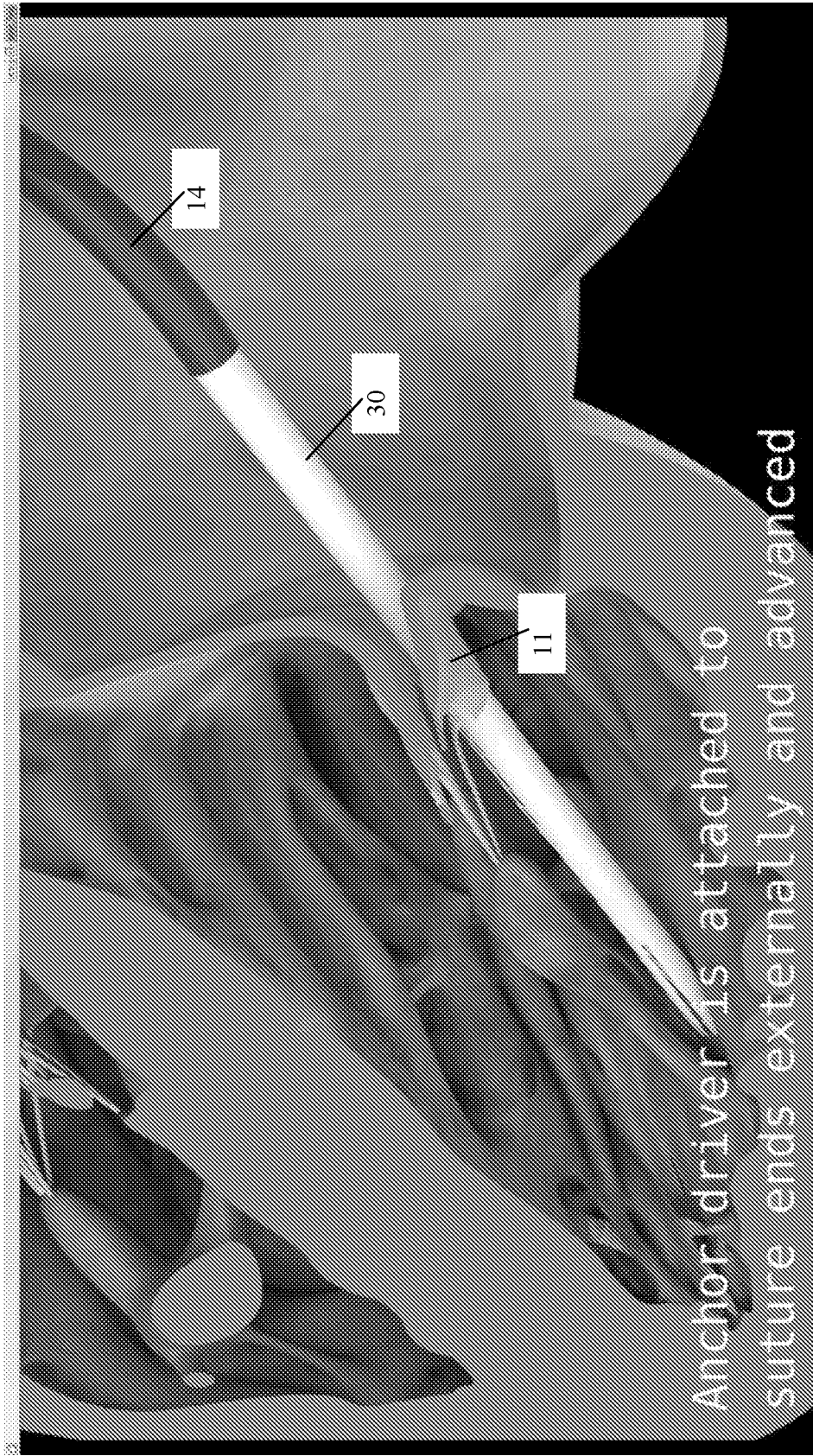


Fig. 1C

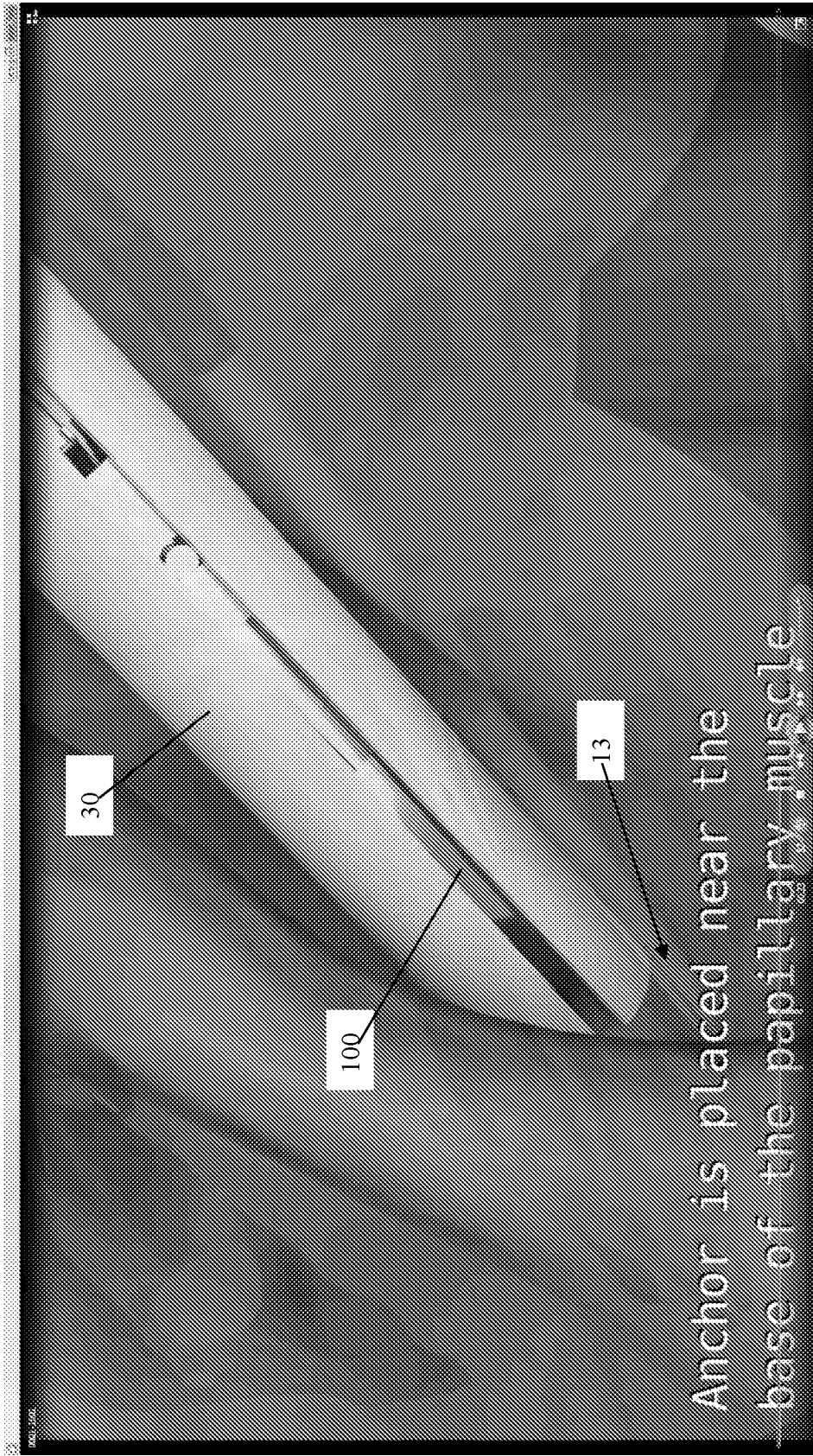


Fig. 1D

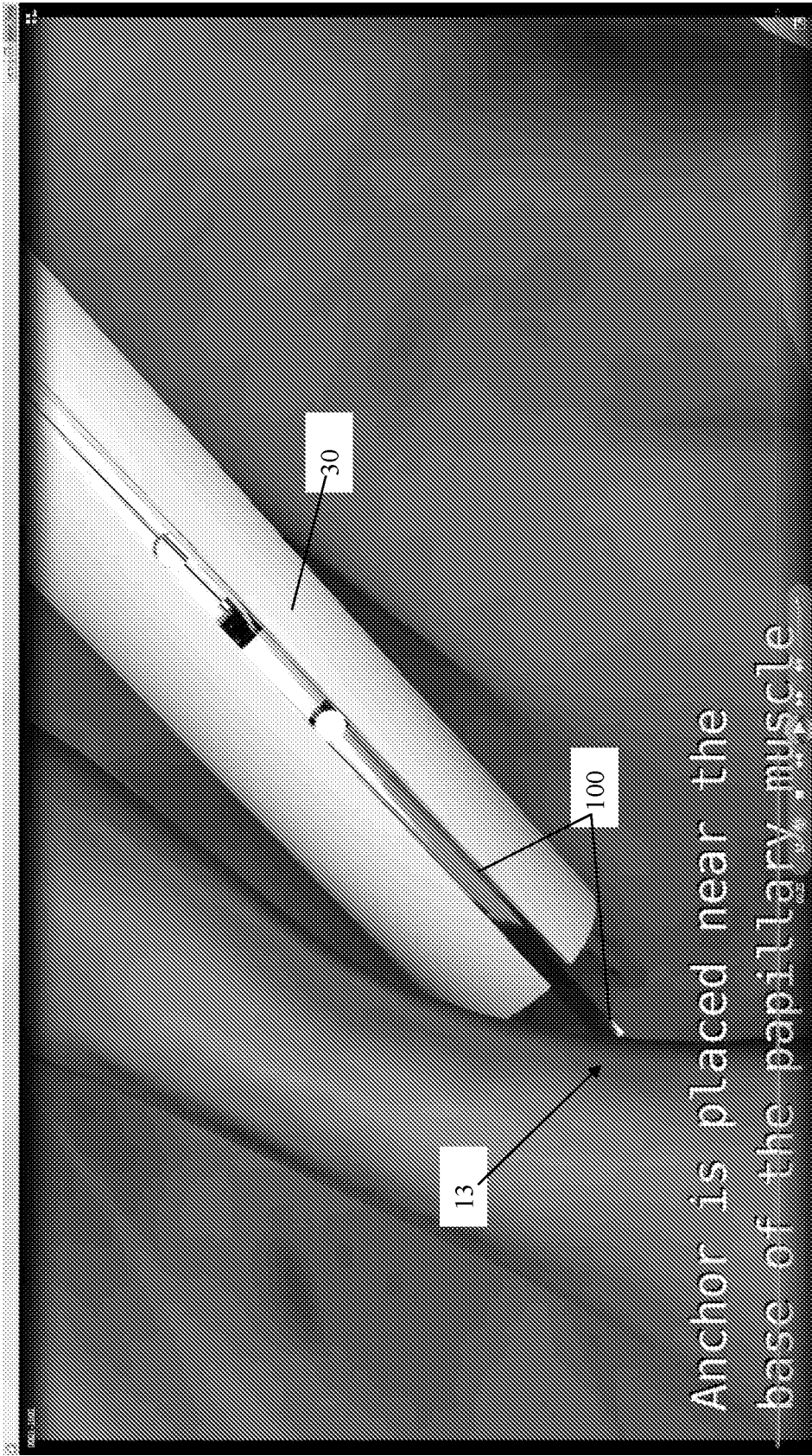


Fig. 1E

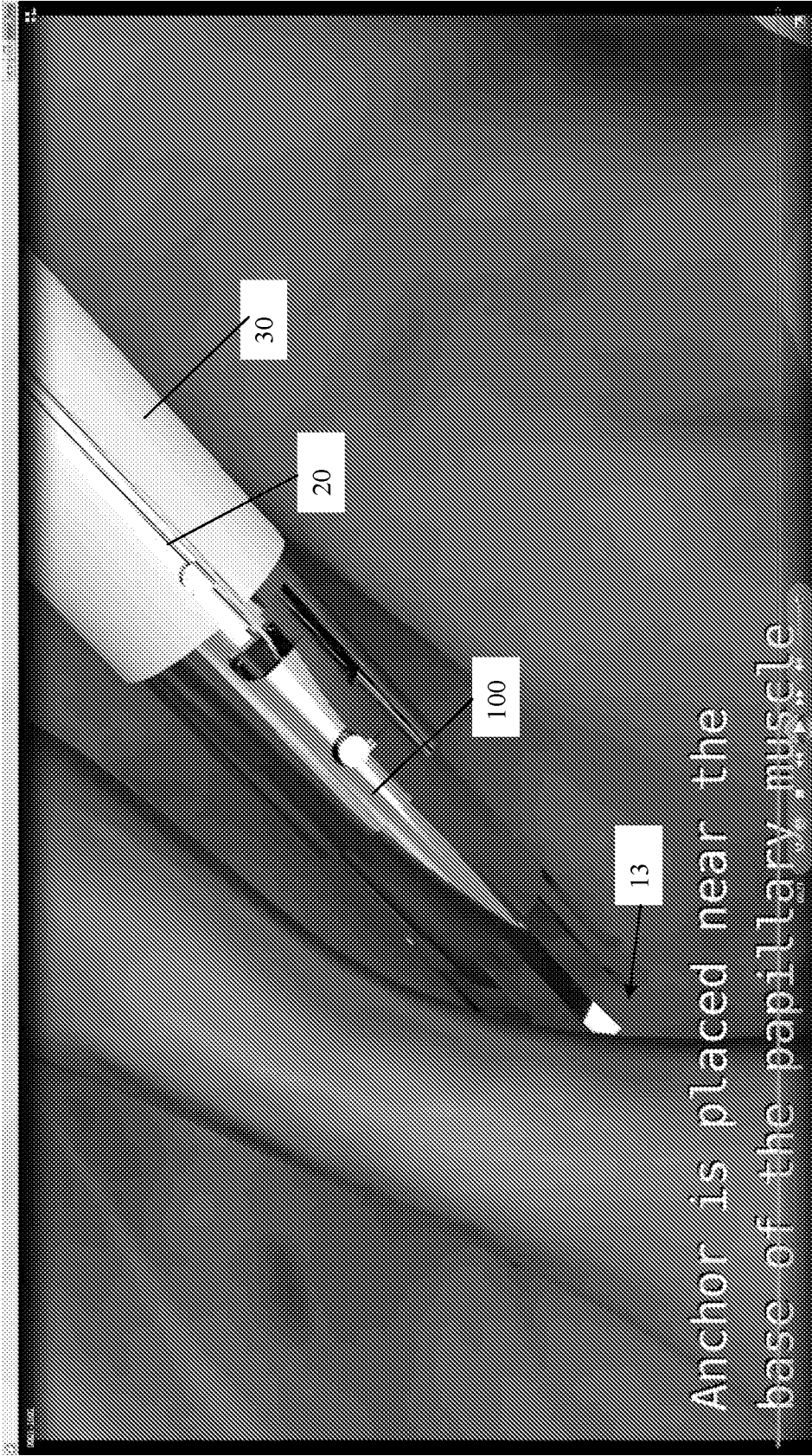


Fig. 1F



Fig. 1G

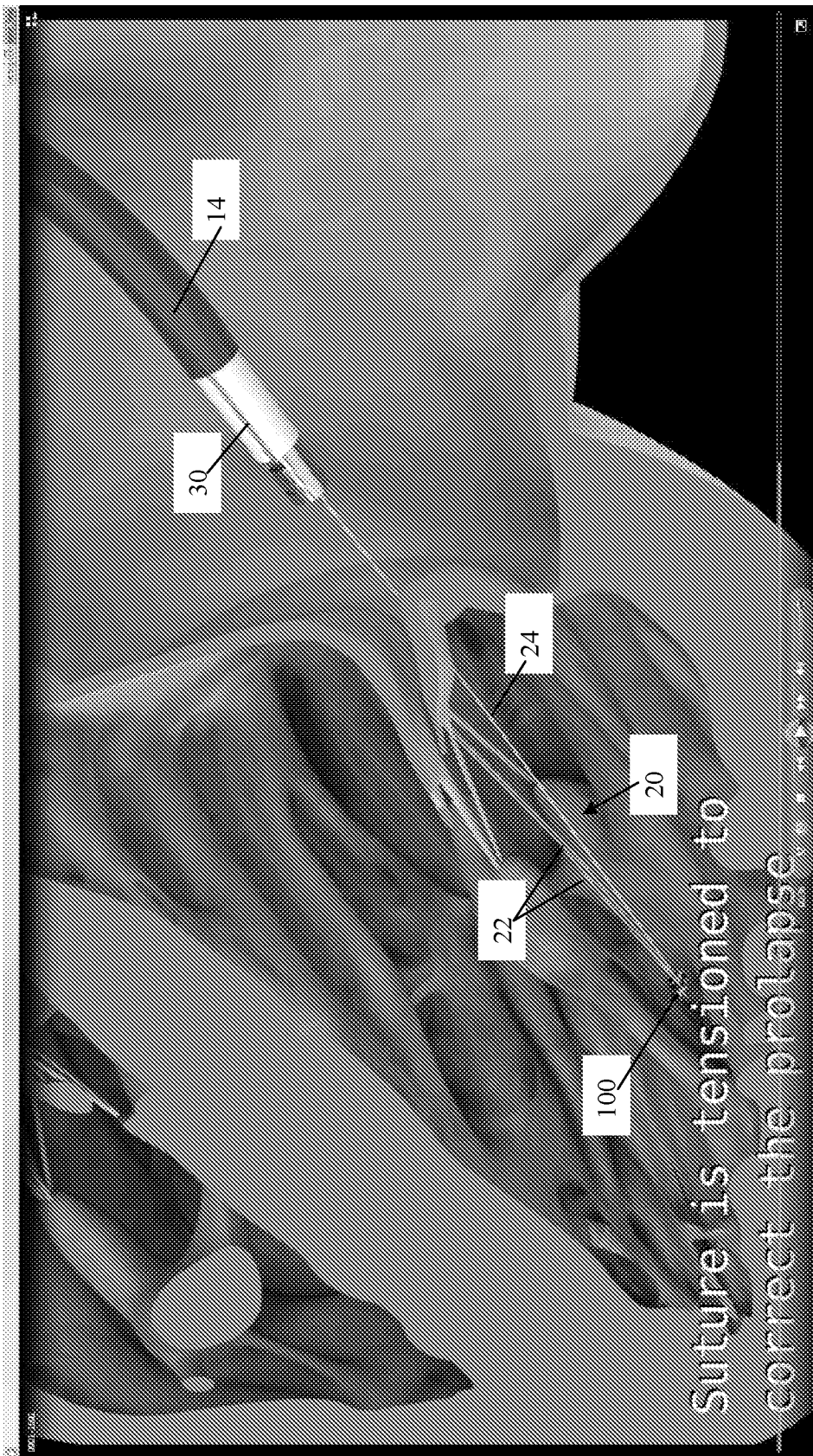


Fig. 1H

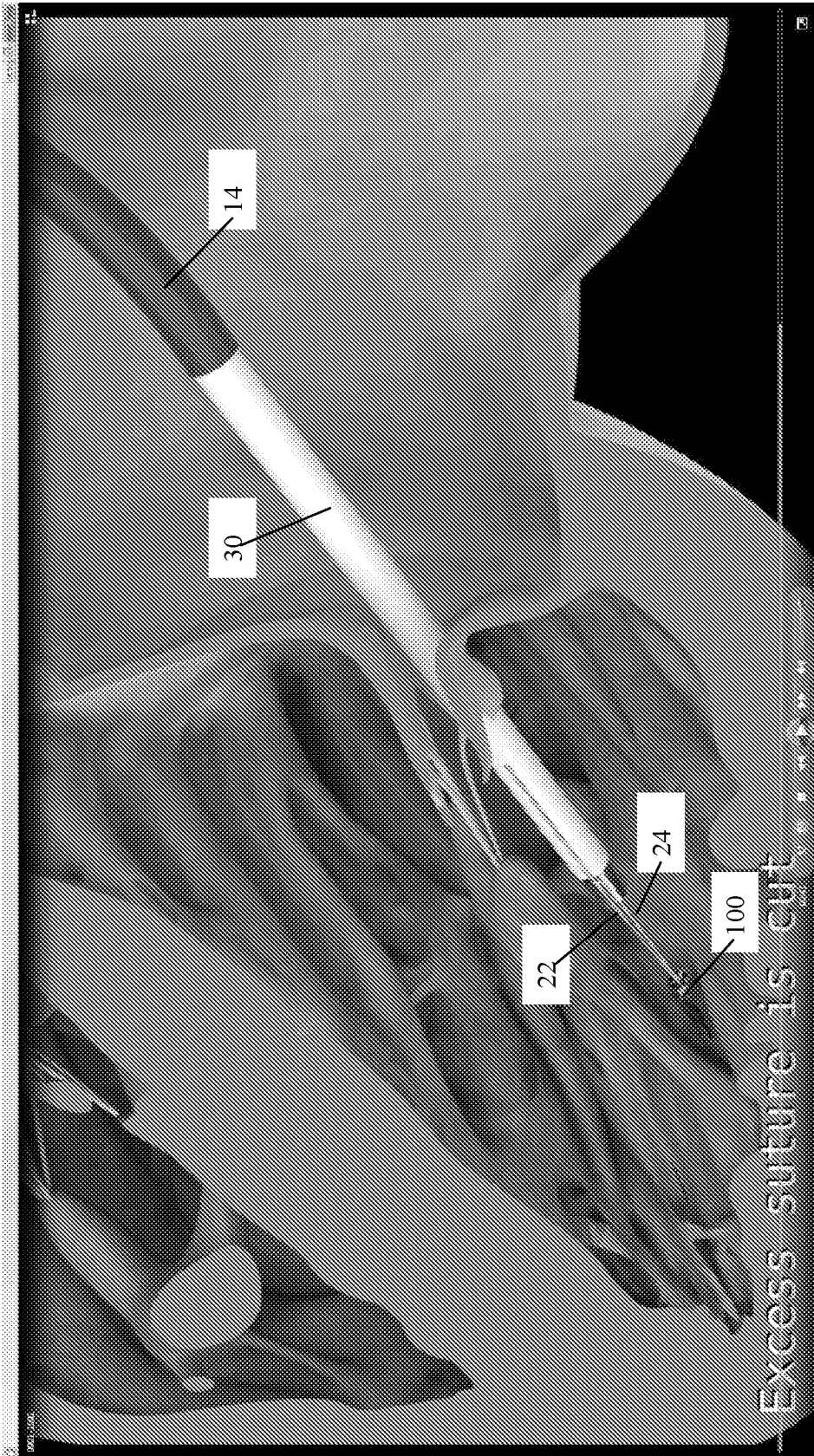


Fig. 1I

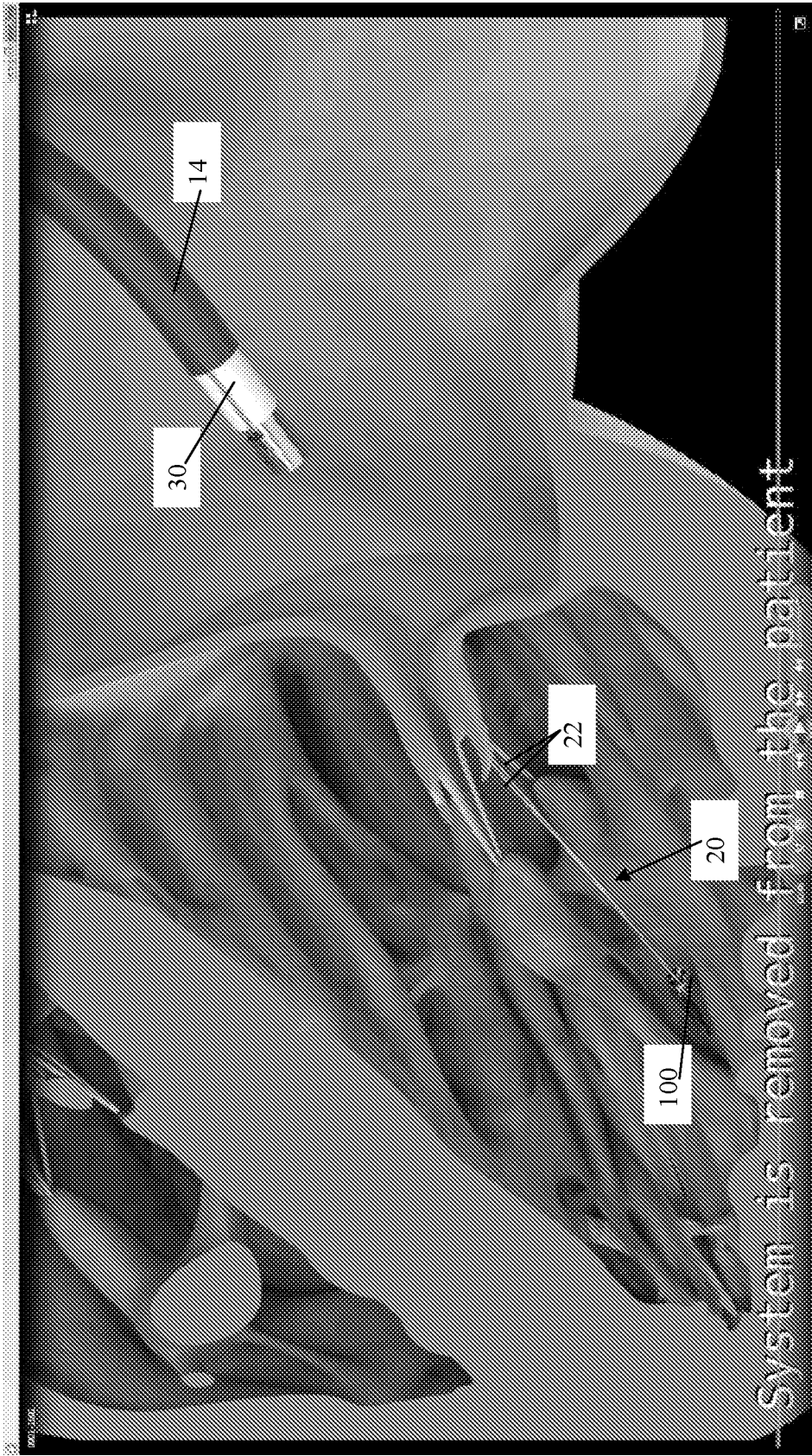


Fig. 1J



Fig. 1K

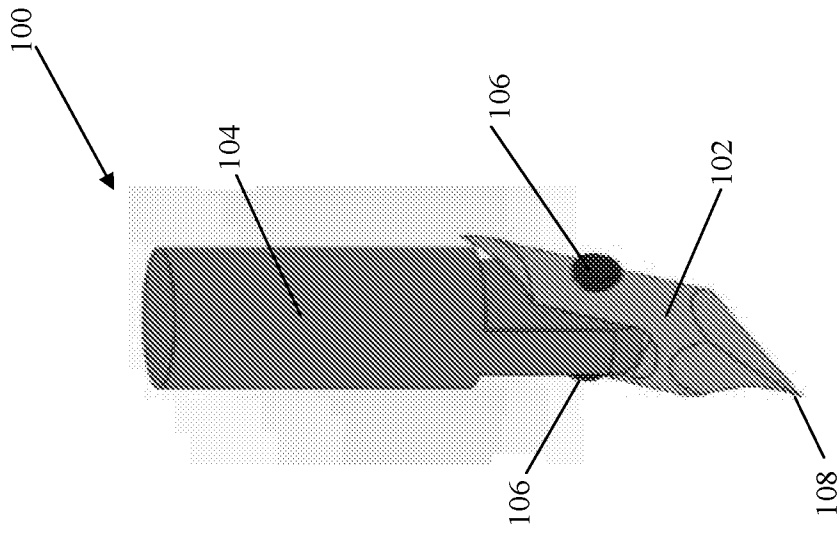


Fig. 2

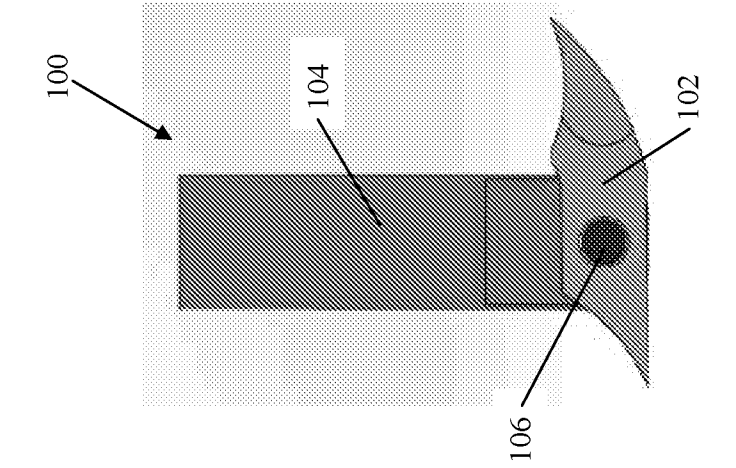


Fig. 3A

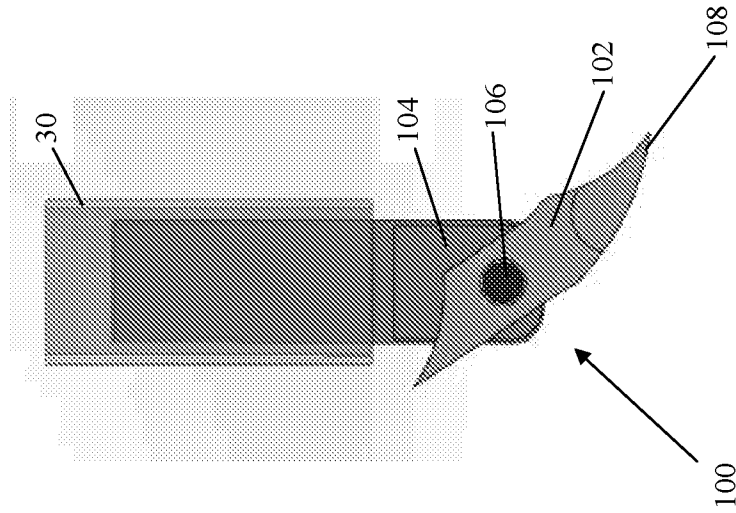


Fig. 3B

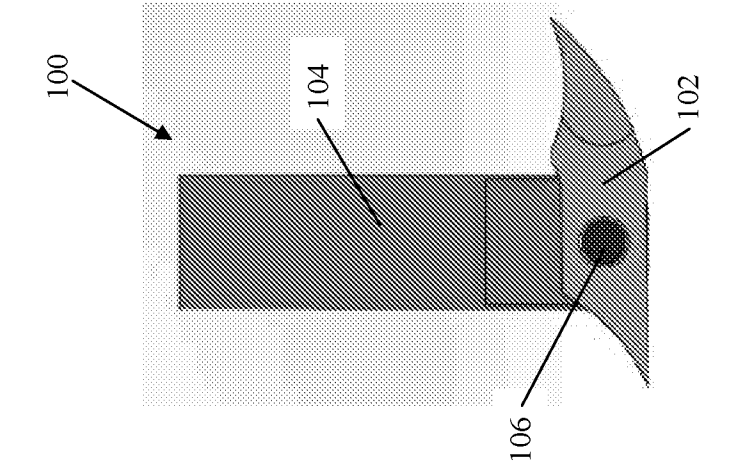


Fig. 3C

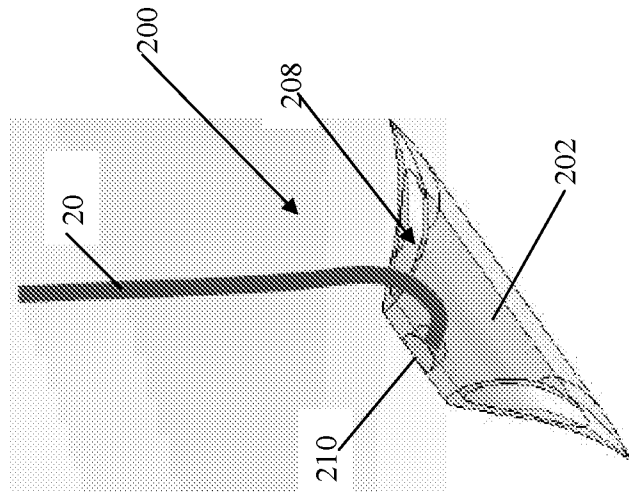


Fig. 4C

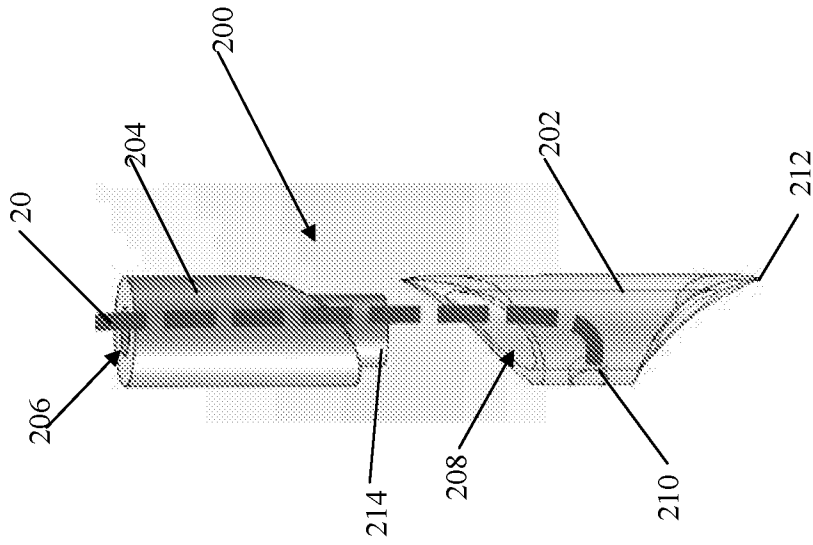


Fig. 4B

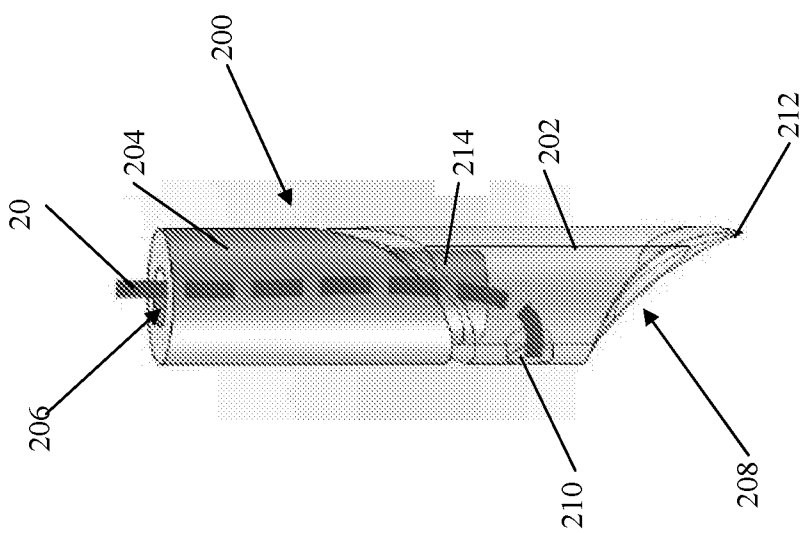


Fig. 4A

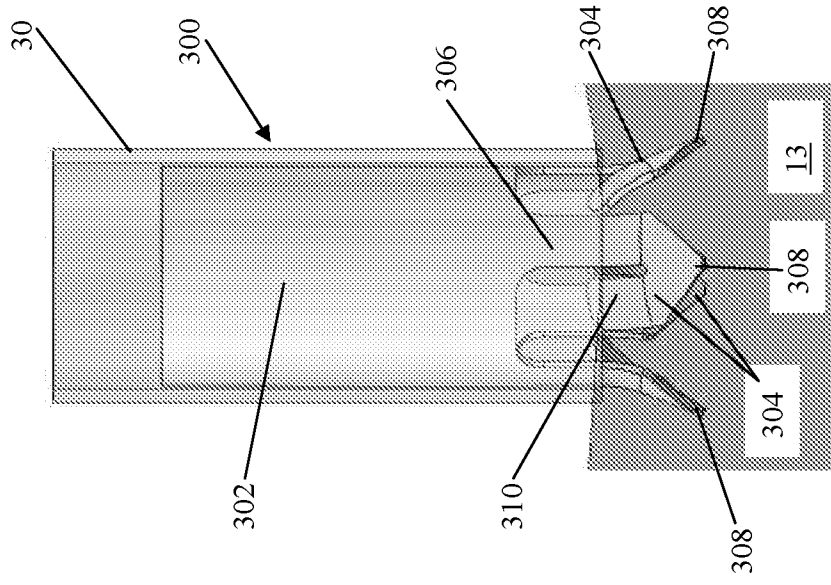


Fig. 5B

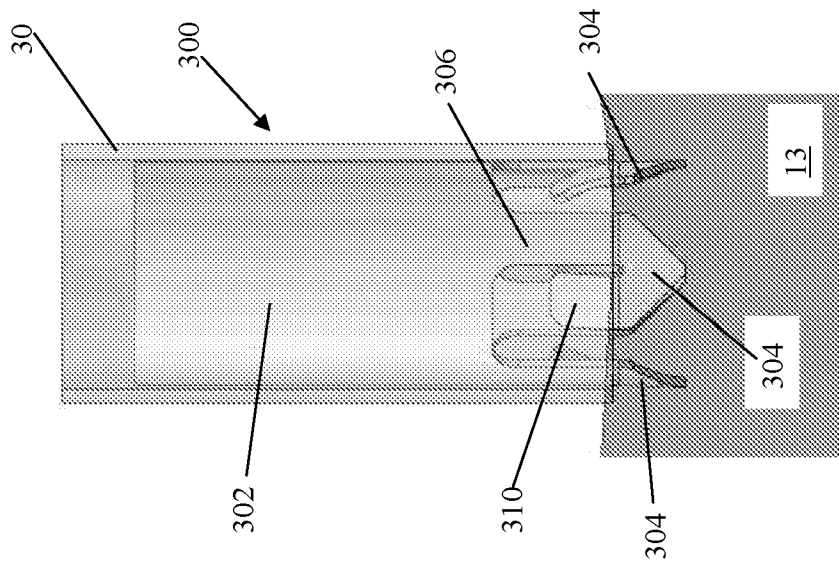


Fig. 5A

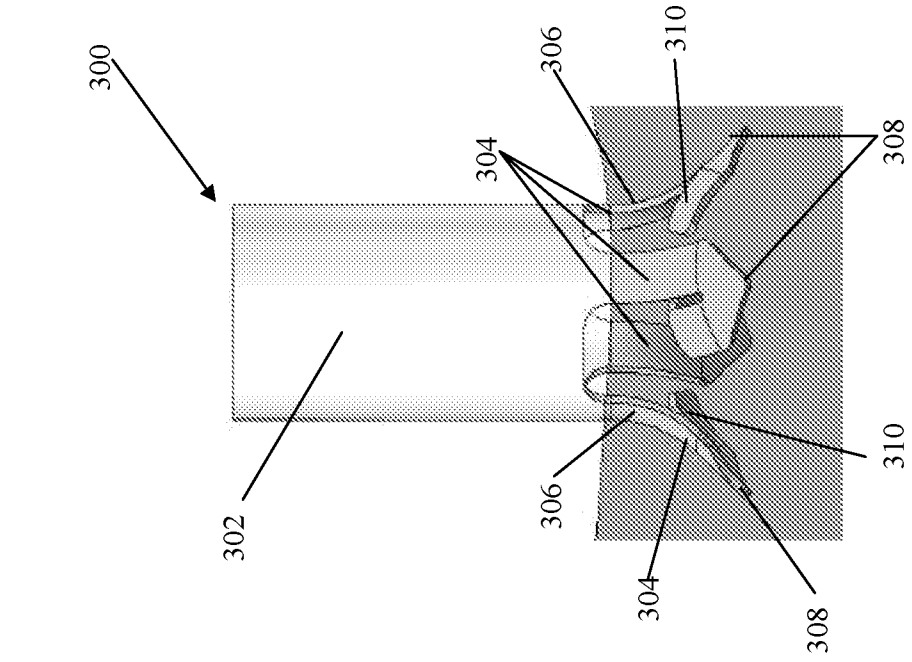


Fig. 5D

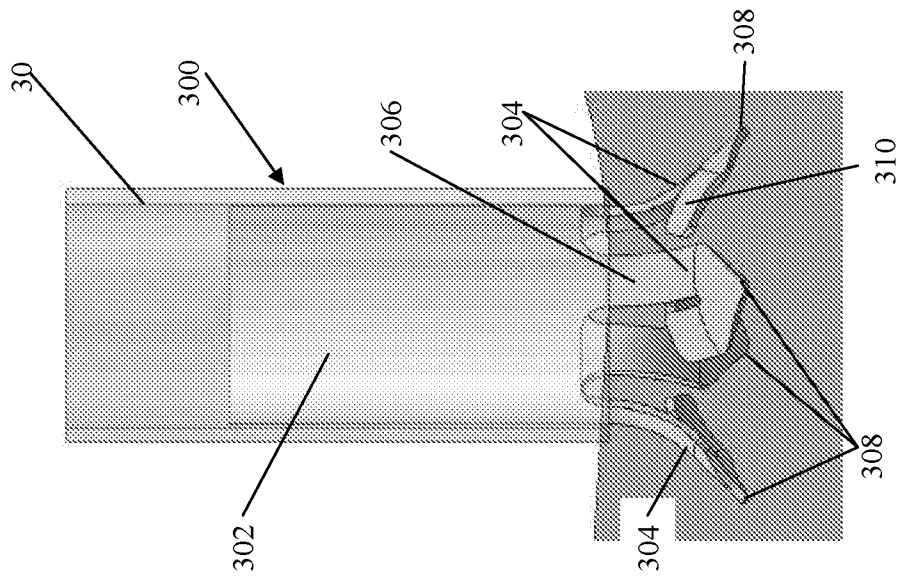


Fig. 5C

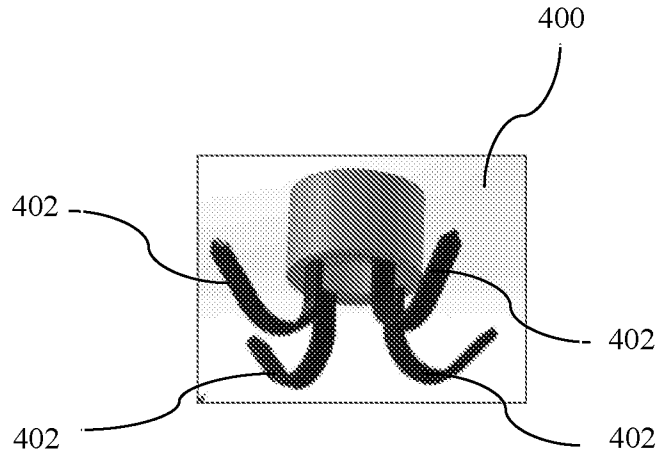


Fig. 6

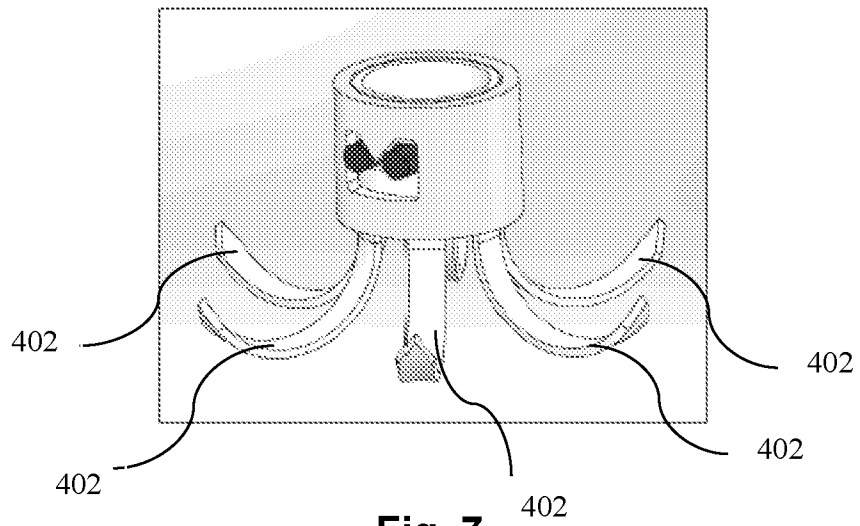


Fig. 7

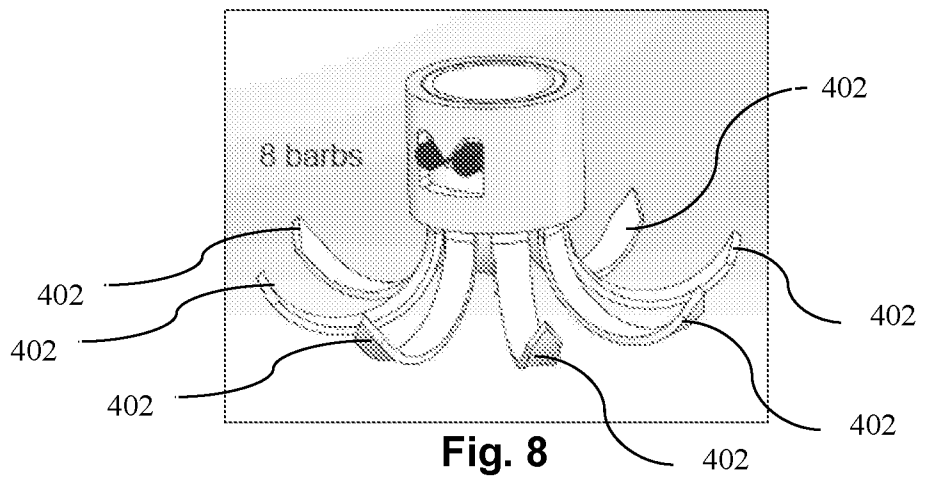
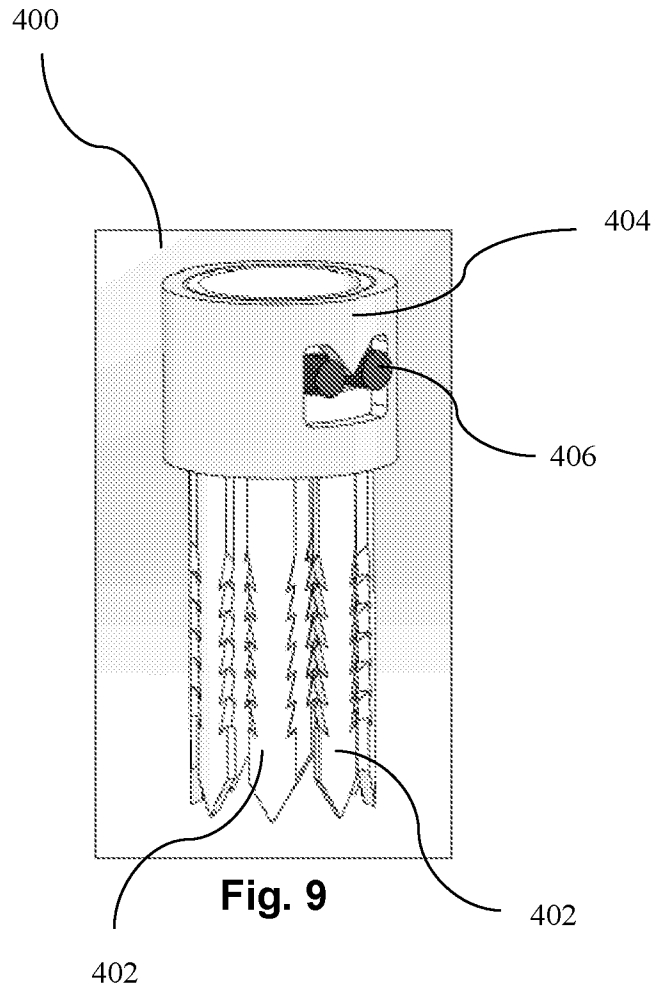
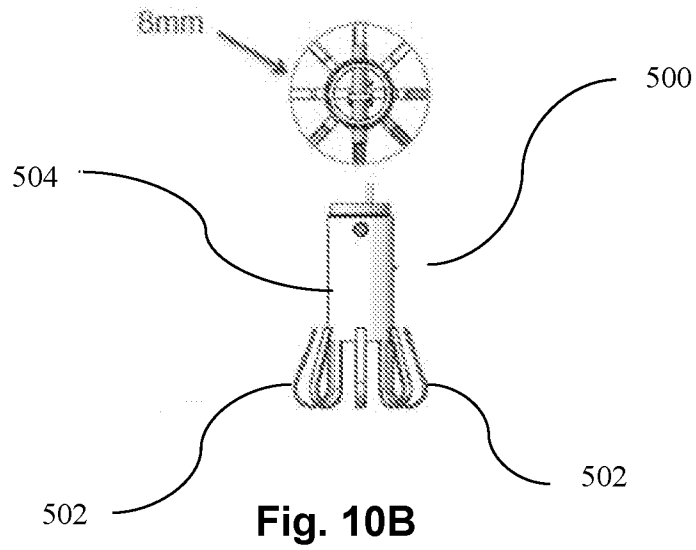
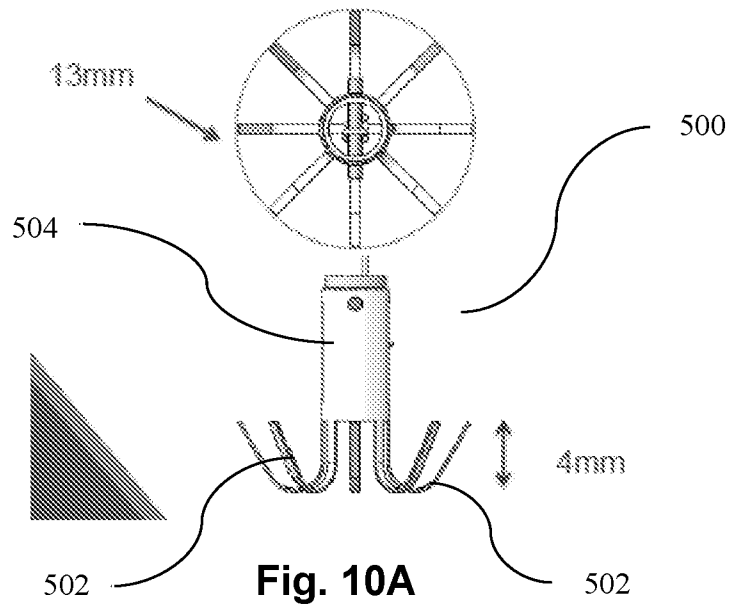


Fig. 8





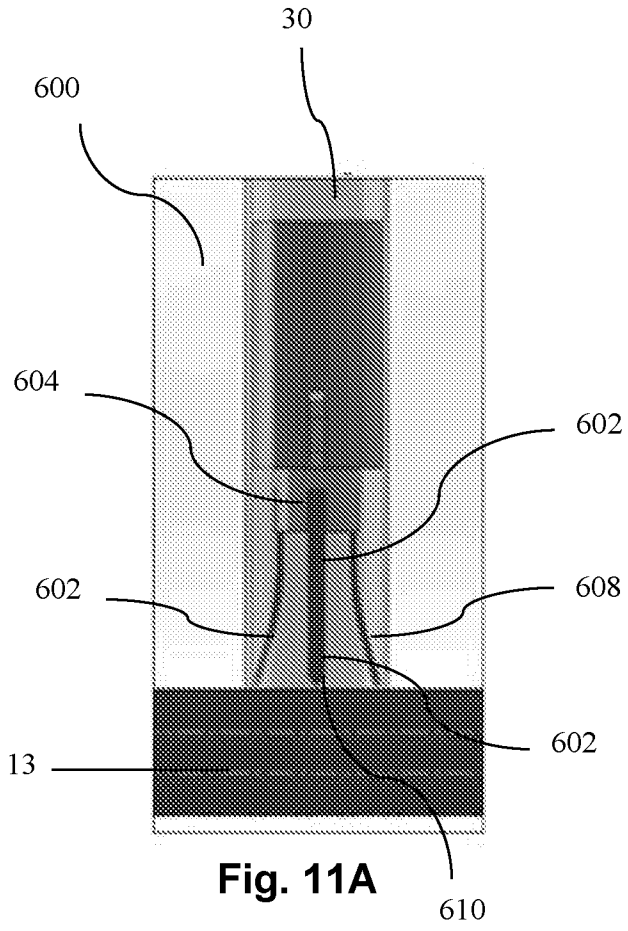


Fig. 11A

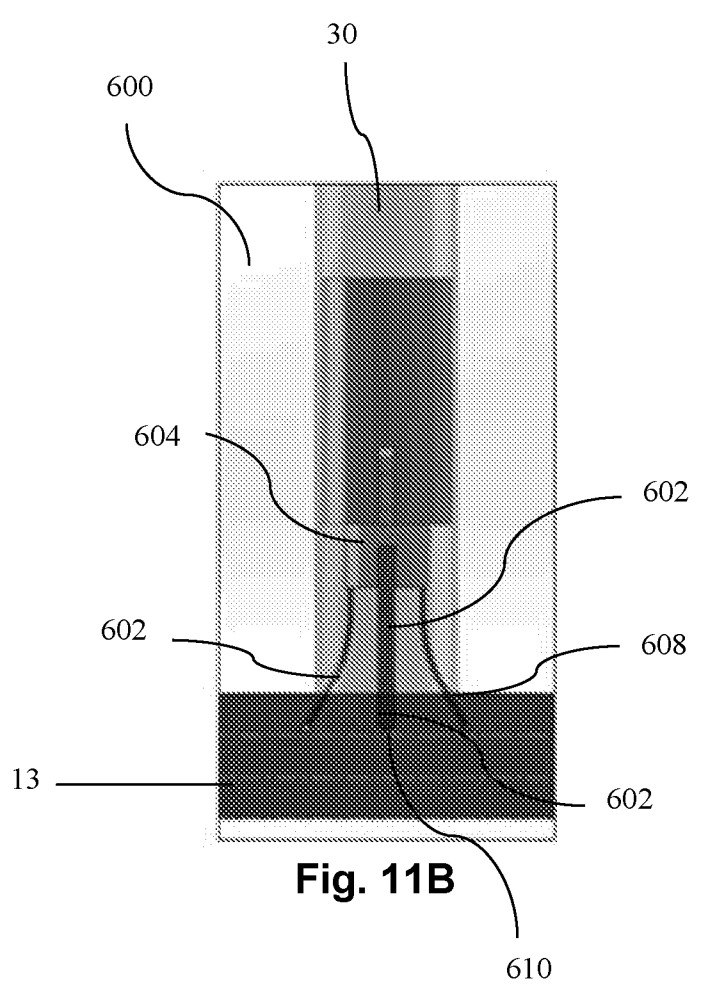


Fig. 11B

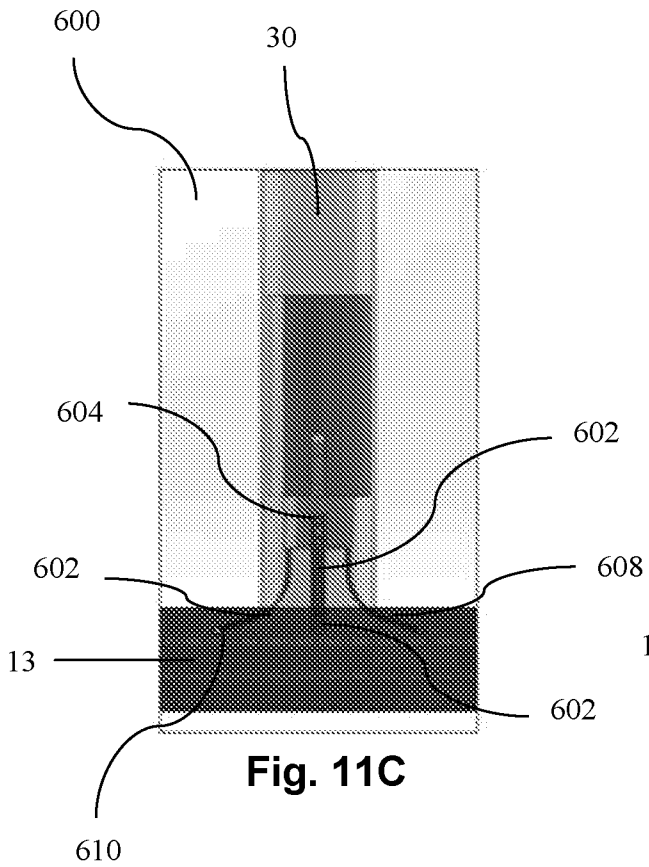


Fig. 11C

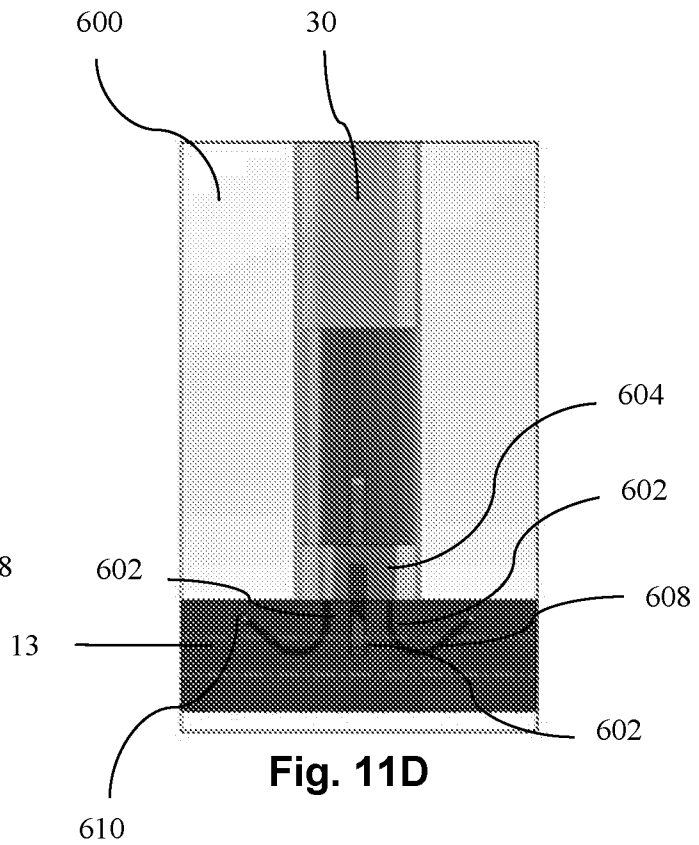


Fig. 11D

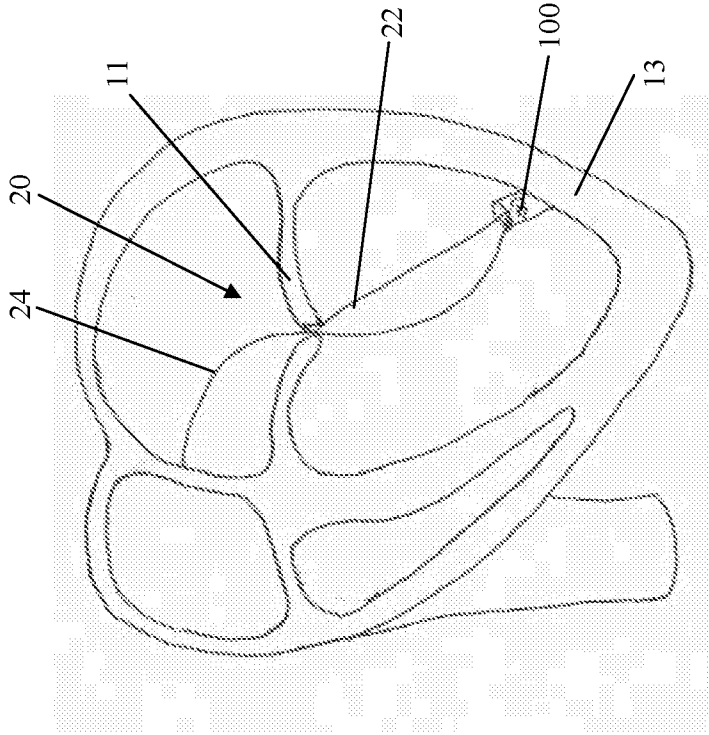


Fig. 12B

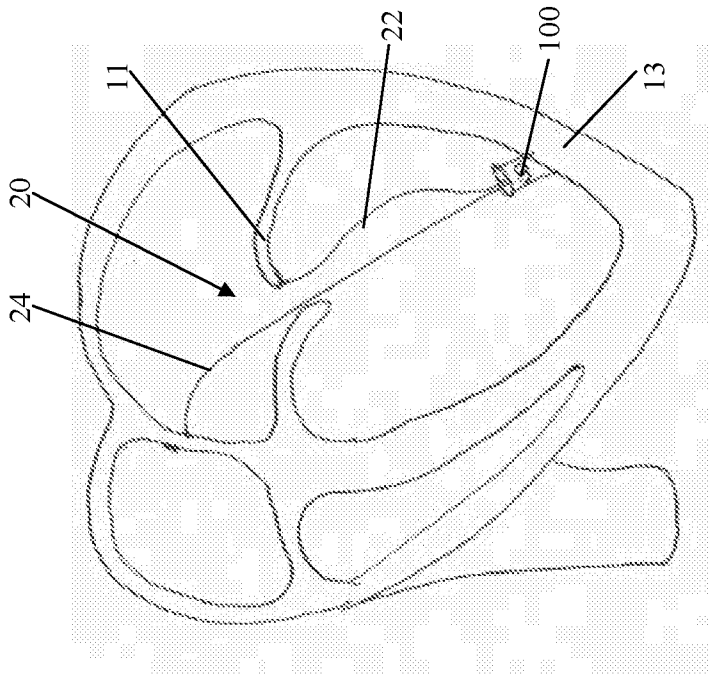


Fig. 12A

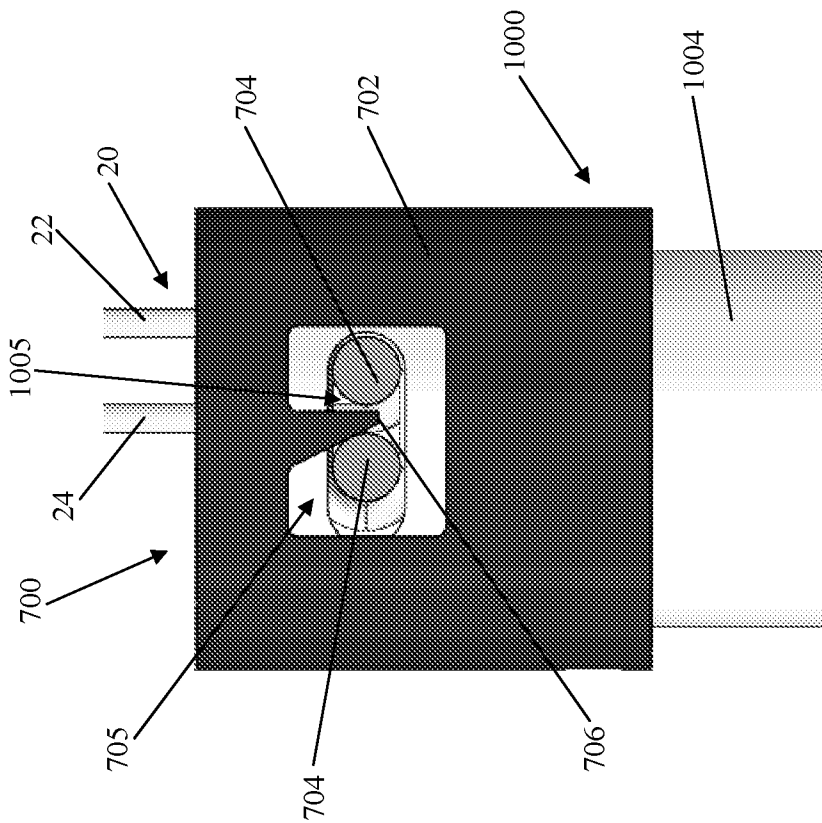


Fig. 13A

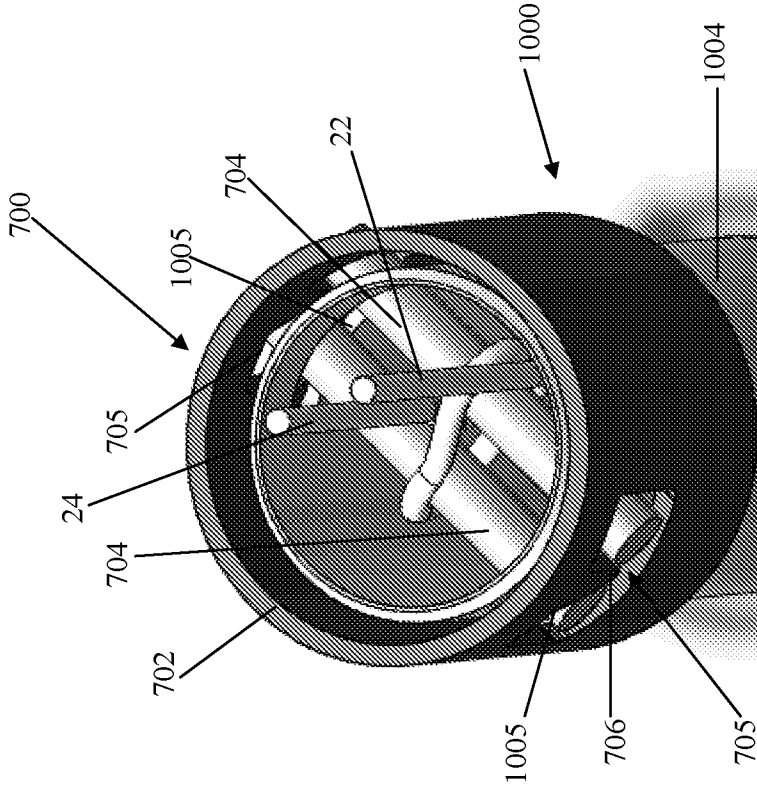


Fig. 13B

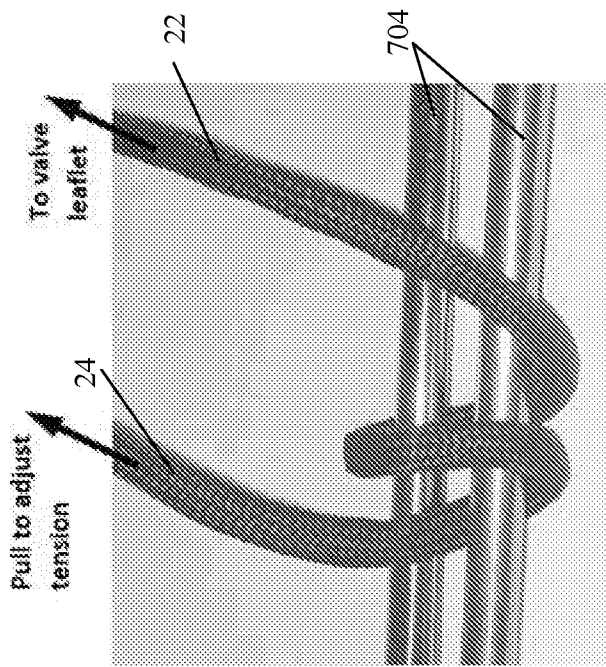


Fig. 13C

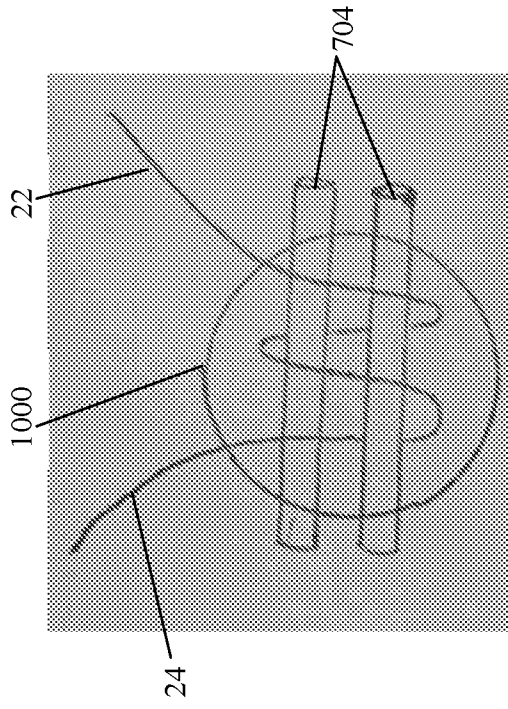


Fig. 13D

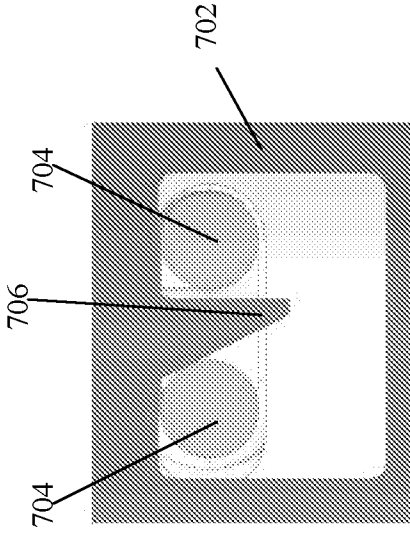


Fig. 13F

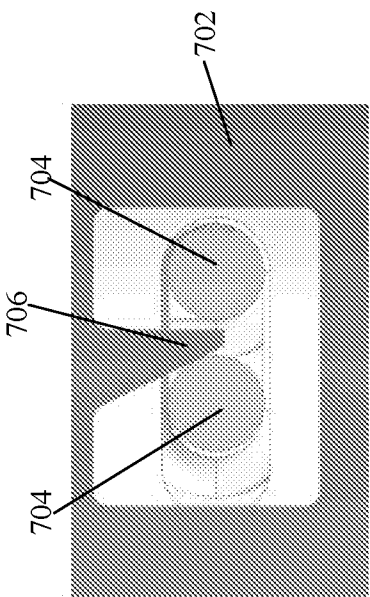


Fig. 13E



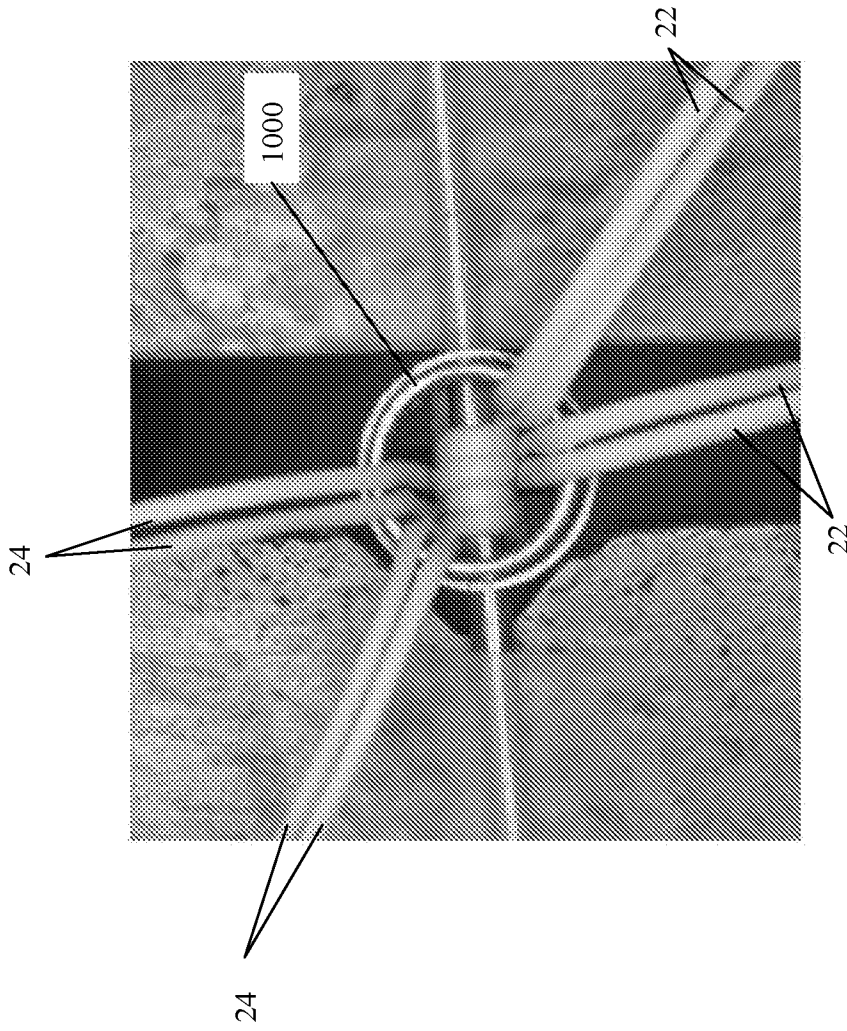


Fig. 15

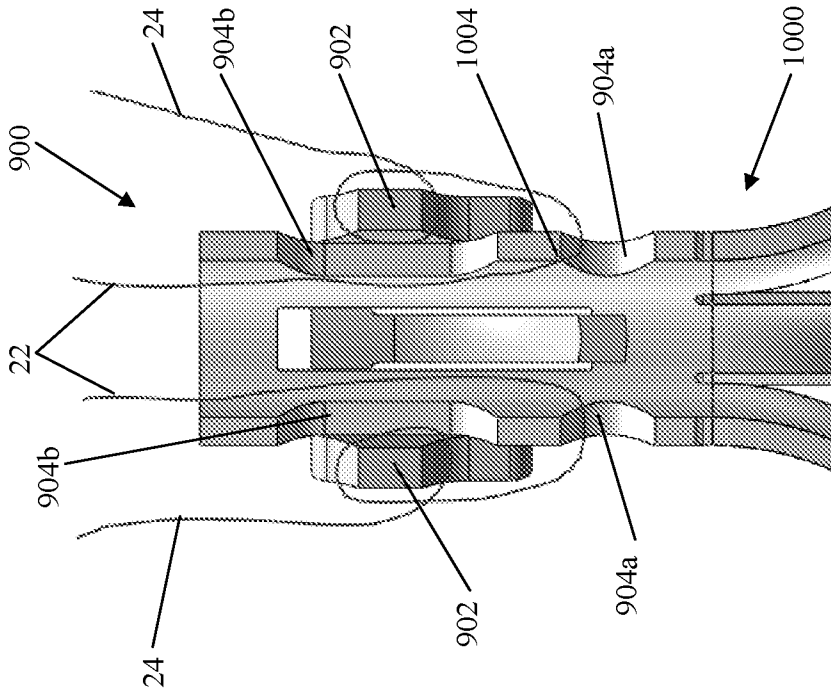


Fig. 16B

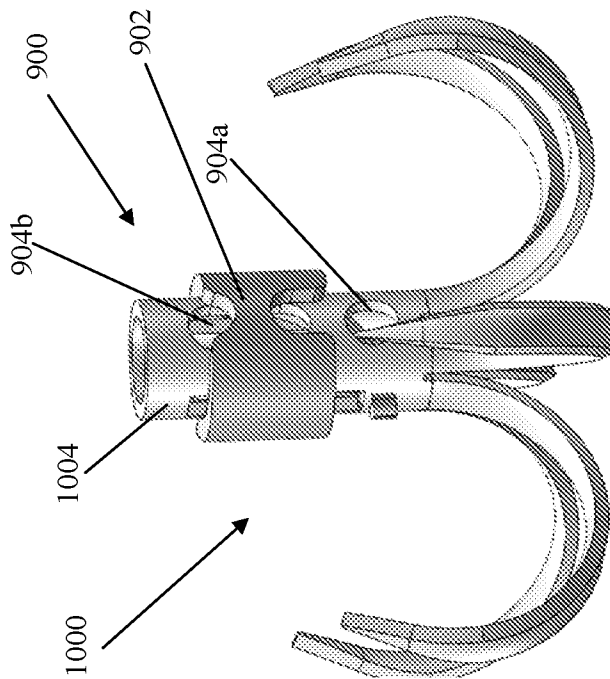


Fig. 16A

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 19/31451

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/24 (2019.01)

CPC - A61F 2/2457, A61F 2/2454, A61F 2/2466, A61B 17/0401

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History Document

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

See Search History Document

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2008/0195126 A1 (SOLEM) 14 August 2008 (14.08.2008) Entire document, especially Abstract, para[0054]-[0061], [0077]-[0078], [0089]-[0093], [0101]-[0103] and FIGS. 4A-5D, 12A-17C.	1-4, 7-11, 13-16, 19-30, 32-36, 38-39 ----- 5-6, 12, 31, 37
X -- Y	US 2014/0031926 A1 (KUDLIK et al.) 30 January 2014 (30.01.2014) Entire document, especially Abstract, para[0009], [0063] and FIGS. 6-7.	13, 17-18 ----- 5-6, 12
Y	US 2016/0106420 A1 (FOERSTER et al.) 21 April 2016 (21.01.2016) Entire document, especially Abstract, para[0020], [0022], [0026], [0030], [0036], [0040]-[0043] and FIGS. 1-3.	31, 37
A	US 9,877,833 B1 (PIPELINE MEDICAL TECHNOLOGIES, INC) 30 January 2018 (30.01.2018) Entire document.	1-39
A	US 2015/0313620 A1 (MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH) 06 November 2015 (06.11.2015) Entire document.	1-39
A	US 2007/0038293 A1 (ST. GOAR et al.) 15 February 2007 (15.02.2007) Entire document.	1-39

 Further documents are listed in the continuation of Box C. See patent family annex.

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

Date of the actual completion of the international search

03 July 2019

Date of mailing of the international search report

17 SEP 2019

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 571-273-8300

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300  
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 19/31451

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-39 directed towards suture anchors with a body and tip which transition from a generally linear delivery configuration, to a non-linear implantation configuration and methods in implanting said devices

Group II: Claims 40-49 directed towards means for enabling adjustment of a length of suture extending from an anchor

The inventions listed as Groups I-II do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding technical features for the following reasons:

----- see continuation sheet -----

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
1-39

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

----- Continuation of Box III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet) -----

#### Special Technical Features

Group I includes the special technical features the anchor tip/anchor tines is configured for delivery to the heart wall in a delivery configuration generally coaxially aligned with the anchor shaft such that the anchor shaft and anchor tip/tines can be contained within an anchor delivery catheter, and wherein the anchor tip/tines is configured to toggle from the delivery configuration into an anchor configuration when advanced out of the anchor delivery catheter and into the heart wall, the anchor tip/tines being oriented at a non-coaxial angle to the anchor shaft in the anchor configuration to retain the anchor within the heart wall, not required in any other group.

Group II includes the special technical features means for retaining a suture within the anchor body, wherein the means for retaining the suture is configured to enable adjustment of a length of the suture extending between the anchor body and the valve leaflet by pulling tensioning strands of the suture extending from the anchor body out of the heart while preventing forces applied on the length of the suture extending between the anchor body and the valve leaflet due to movement of the leaflet from adjusting the length of the suture extending between the anchor body and the valve leaflet, not required in any other group.

#### Common Technical Features

Groups I-II share the technical features of an anchor configured to be implanted into a heart wall of a heart of a patient to anchor a suture extending from a valve leaflet of the heart as an artificial chordae, the anchor comprising: an anchor body. However, these common technical features are anticipated by US 9,877,833 B1 to PIPELINE MEDICAL TECHNOLOGIES, INC (hereinafter: Pipeline). Pipeline describes an anchor configured to be implanted into a heart wall of a heart of a patient to anchor a suture extending from a valve leaflet of the heart as an artificial chordae, the anchor comprising: an anchor body (see FIGS. 4-13, Abstract, col 4, ln 33-44, col 8, ln 21-46).

Accordingly, Groups I-II lack unity under PCT Rule 13.