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STAPLER APPARATUS AND METHODS FOR USE

RELATED APPLICATION DATA

The present application claims benefit and is a continuation-in-part of co-pending application Serial No. 16/874,618, filed May 14, 2020, and claims benefit of co-pending U.S. provisional application Serial No. 62/947,903, filed December 13, 2019, the entire disclosures of which are expressly incorporated by reference herein.

FIELD OF THE INVENTION

The present invention relates generally to apparatus, systems, and methods for performing medical procedures, and, more particularly, to stapler apparatus for performing laparoscopic or other minimally invasive surgery, such as appendectomy, tubal ligation, cholecystectomy clipping, oophorectomy, hysterectomy, nephrectomy, splenectomy, lung biopsy, bariatric surgery, colon and intestine surgery, and vascular surgery, e.g., to remove an appendix of a subject, and to systems and methods for using such apparatus.

BACKGROUND

Appendicitis is seen in approximately 5-10% of the population in their life time. Since 1983, laparoscopic appendix surgery is the mainstay for treatment. In an example of conventional surgery to remove an appendix, the following steps may be performed. First, the appendix and its vessel may be initially identified e.g., lying within a fold of tissue called the mesoappendix. A window or surgical field may be created within the subject's body, and a stapler apparatus is then used, e.g., to initially staple and divide the structure closest to the operator, and then to staple and divide the remaining structure.

For example, FIG. 1 shows exemplary anatomy of an appendix, which may have one of a variety of orientations relative to the intestine, most commonly retrocecal (64%) or pelvic (32%), although less common positions may also be encountered, as shown. An appendicular artery and other blood vessels (not shown) deliver blood to the appendix, whose location relative to the intestine may also vary depending on the orientation of the appendix. The appendix and artery may be separated by fat and/or other tissue. Thus, during a procedure, upon accessing the abdominal cavity, the operator must identify the relative locations of the appendix and vessels before removing the appendix. For example, after identification, the operator may identify the intra-operative manifestation or

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positioning of the appendix and its vessel, i.e., to identify whether the appendix is closer to the operator and the vessel is positioned further away or vice-versa, and then sequentially staple and divide the closer structure, and then the more distant structure.

To perform laparoscopic or open surgery, a device may be introduced carrying a camera that is independent from the stapler, e.g., to enable visualization of the surgical space and anatomy from the side, e.g., when the stapler is introduced and used to remove the appendix. Existing laparoscopic staplers generally include a cartridge having multiple rows of staples equally distributed on either side of a knife.

One of the most common complications from such surgery is post-operative bleeding. The bleeding is generally sub-clinical in approximately 15%, and clinical in approximately 5% patients, i.e., requiring further intervention. The majority of bleeding occurs from the staple line on individual vessels or vessels within the wall of intestine. For example, "B" shaped clips may create a lumen between the tines that may allow blood or other fluid to escape. Other complication include leaking of intestinal fluid from the intestinal lumen.

Accordingly, apparatus and methods that facilitate laparoscopic surgery, e.g., to remove an appendix would be useful.

SUMMARY

The present invention is directed to apparatus, systems, and methods for performing medical procedures, and, more particularly, to stapler apparatus for performing surgery, such as laparoscopic or other minimally invasive surgery, such as appendectomy, tubal ligation, cholecystectomy clipping, hysterectomy, nephrectomy, splenectomy, oophorectomy, lung biopsy, bariatric surgery, colon and intestine surgery, and vascular surgery, e.g., to remove an appendix of a subject or to perform other intestinal procedures, vascular surgery, lung surgery, and the like, and to systems and methods for using such apparatus.

In accordance with an exemplary embodiment, an apparatus is provided for performing a medical procedure that includes a shaft including a proximal end and a distal end sized for introduction into a patient's body; first and second jaws on the distal end of the shaft that are movable relative to one another between open and closed positions, thereby directing first and contact surfaces of the first and second jaws away from and towards one another, respectively, the first jaw carrying one or more staples deployable

from the first contact surface; a Doppler radar or other sensor on one of the first and second contact surfaces; and a handle on the proximal end of the shaft comprising a first actuator for opening and closing the jaws, e.g., a trigger to close the second jaw adjacent the first jaw to capture tissue between the contact surfaces, a second actuator for deploying one or more staples from the first jaw into tissue between the first and second contact surfaces, e.g., after locking the jaws closed using the trigger or a separate locking mechanism, and a third actuator for activating the Doppler or other sensor to detect blood flow in the tissue.

In an exemplary embodiment, the first and second jaws may be carried on an end effector removably coupled to the distal end of the shaft. The first jaw may carry first and second sets of staples, e.g., each set arranged in rows adjacent one another, optionally arranged within a replaceable cartridge. A cutting element may be disposed on the distal end, e.g., movable between the first and second sets of staples, e.g., using a fourth actuator on the handle to advance the cutting element to sever the stapled tissue. In addition or alternatively, a thermal element or other hemostasis element may also be provided on one of the first and second jaws, e.g., opposite the Doppler sensor, and the handle may include a fifth actuator for activating the hemostasis element to deliver thermal energy to the stapled tissue. Optionally, the handle may include one or more additional actuators, e.g., one or more controls for positioning and/or activating a light and/or camera carried on the distal end of the shaft or the end effector.

In accordance with another embodiment, an end effector is provided for a stapler apparatus including a shaft including a proximal end including a handle and a distal end sized for introduction into a patient's body. The end effector may include one or more connectors for removably connecting the end effector to the distal end of the shaft and, optionally, a cartridge insertable into a recess of one of the jaws. The first and second jaws are movable relative to one another between open and closed positions, thereby directing contact surfaces of the first and second jaws away from and towards one another, respectively. For example, the first jaw may be fixed and the second jaw may be pivotally mounted to open and close relative to the first jaw, e.g., to capture tissue between the contact surfaces. One or more staples are carried by the first jaw, e.g., in a replaceable cartridge, such that actuation of a staple actuator on the handle deploys one or more staples from the first jaw into tissue between the contact surfaces and towards the second jaw to deform the one or more staples. Optionally, a Doppler radar sensor and/or hemostasis element may be provided on one of the contact surfaces to detect blood flow in the tissue.

In accordance with still another embodiment, a method is provided for performing a surgical procedure within a patient's body that includes introducing first and second jaws on a distal end of a shaft into a region within the patient's body; with the jaws in an open position, placing tissue within the region between contact surfaces of the first and second jaws; closing the jaws to engage the tissue; actuating a staple actuator to deploy one or more staples from the first jaw into the tissue towards the second jaw to deform the one or more staples and secure the tissue. For example, the second jaw may be closed to squeeze the tissue between the contact surfaces and, optionally, may be locked in the closed position. The staple(s) may be then be deployed from the first jaw using the staple actuator such that they are directed through the tissue and engage anvils or shaping surfaces on the second jaw to deform tines of the staple(s). A Doppler or other sensor on one of the contact surfaces may be activated to detect blood flow in the stapled tissue; and after confirming that blood flow has discontinued in the stapled tissue, a cutting element may be actuated to sever the stapled tissue from adjacent tissue at the region.

In accordance with yet another embodiment, a method is provided for performing an appendectomy within a patient's body that includes introducing first and second jaws on a distal end of a shaft into an abdominal cavity of the patient's body; placing an appendix and appendicular artery within the abdominal cavity between contact surfaces of the first and second jaws; actuating one or both of the first and second jaws to secure the appendix and artery between the contact surfaces; and deploying one or more staples from the first jaw through the appendix and artery to staple the appendix and artery. Thereafter, a Doppler sensor on one of the contact surfaces may be activated to detect blood flow in the stapled appendix and artery, and, if blood flow is detected, a thermal element may be activated to deliver thermal energy to stop blood flow, e.g., alternately to detect and cauterize the tissue. Once blood flow has stopped, a cutting element may be actuated to simultaneously sever the appendix and artery.

In accordance with another embodiment, an apparatus is provided for performing a medical procedure that includes a shaft including a proximal end, a distal end sized for introduction into a patient's body, and a longitudinal axis extending between the proximal and distal ends; first and second jaws on the distal end of the shaft that are movable relative to one another between open and closed positions, thereby directing first and contact surfaces of the first and second jaws away from and towards one another, respectively, the first jaw carrying first and second sets of staples positioned on opposite sides of a cutting

element, wherein at least some of the staples are a different size than other staples; and a handle on the proximal end of the shaft. For example, each set of staples may include one to five rows of staples aligned along the longitudinal axis, with two to fifty staples in each row. The staples in each set and/or each row may have different sizes depending on the anatomy encountered. For example, the apparatus may include a plurality of available cartridges, each including different arrangements of staples, that may be selected and inserted into a cavity of the first jaw. The handle includes a first actuator for driving the staples from the first jaw into tissue between the first and second contact surfaces and towards the second jaw to deform the staples; and a second actuator for advancing the cutting element from a retracted position to an advanced position aligned with the longitudinal axis to sever the stapled tissue.

In accordance with yet another embodiment, an end effector is provided for a stapler apparatus including a shaft comprising a proximal end including a handle, a distal end sized for introduction into a patient's body, and a longitudinal axis extending between the proximal and distal ends. The end effector may include one or more connectors for removably connecting the end effector to the distal end of the shaft; first and second jaws that are movable relative to one another between open and closed positions using a first actuator on the handle, thereby directing first and contact surfaces of the first and second jaws away from and towards one another, respectively; and a cartridge carried by the first jaw comprising first and second sets of staples arranged in rows on opposite sides of a cutting element such that actuation of a second actuator on the handle deploys the staples into tissue between the first and second contact surfaces and drives the staples against the second jaw to deform the one or more staples, wherein at least some of the staples are a different size than other staples.

In accordance with still another embodiment, a staple is provided for delivery into tissue that includes a substantially straight base element including first and second ends; a first tine extending from the first end substantially perpendicular to the base, the first tine having a first length and including one or more notches adjacent a tip of the first tine; and a second tine extending from the second end substantially perpendicular to the base to a second tip, the second tine having a second length longer than the first length and longer than the length of the straight base such that, when the second tine is bent adjacent the base, the second tip of the second tine is engaged in the one or more notches located on the first tine.

In accordance with another embodiment, a port is provided for introducing one or more instruments into a patient's body that includes an elongate tubular member comprising a proximal end, a distal end sized for introduction into a patient's body, and a lumen extending between the proximal and distal ends, thereby defining a longitudinal axis there
5 between; a display; and one or more deployment arms on the tubular member adjacent the distal end carrying an imaging device, each deployment arm comprising a first end pivotably coupled to the tubular member and a second free end that is movable from a retracted position wherein the second end is aligned with a wall of the tubular member and a deployed position wherein the second end moves outwardly relative to the longitudinal axis
10 for presenting images on the display.

In accordance with still another embodiment, a port is provided for introducing one or more instruments into a patient's body that includes an elongate tubular member comprising a proximal end, a distal end sized for introduction into a patient's body, and a primary lumen extending between the proximal and distal ends for receiving an instrument
15 therethrough, and a plurality of secondary lumens positioned around the primary lumen and extending between the proximal and distal ends; and a video module. The video module may include a hub; a display; and a plurality of elongate imaging elements mounted to the hub and sized for introduction simultaneously into respective secondary lumens of the tubular member such that distal tips of the imaging elements are positioned adjacent the
20 distal end of the tubular member for acquiring images beyond the distal end.

Other aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate exemplary embodiments of the invention, in which:

FIG. 1 is a detail showing exemplary anatomy of an appendix, which may have a variety of orientations relative to the intestine.

FIG. 2A is a side view of an exemplary embodiment of a stapler apparatus including
30 a reusable portion including a shaft extending from a handle and a disposable end effector coupled to the shaft.

FIGS. 2B and 2C are side and perspective views, respectively, of the apparatus of FIG. 2A with a display on the reusable portion.

FIG. 2D is a perspective view of an alternative embodiment of a stapler apparatus including a robotic control system coupled to the proximal end of the apparatus.

FIG. 2E is a perspective view of a robotic adapter/extender device that may be used to connect a stapler apparatus to a robotic control system, such as that shown in FIG. 2D.

5 FIGS. 3A and 3B are perspective and side views, respectively, of an exemplary embodiment of an end effector that may be coupled to the shaft of the apparatus of FIG. 2A, the end effector including a first jaw carrying a plurality of staples within a cartridge and a second jaw pivotable relative to the first jaw between an open position (FIG. 3A) and a closed position (FIG. 3B).

10 FIG. 3C is a cross-sectional view of the end effector of FIGS. 3A and 3B with the jaws spaced apart.

FIG. 3D is a perspective view of an alternative embodiment of an end effector without a blade or cutting element.

FIG. 4A is a top view of the first (bottom) jaw of the end effector shown in FIGS. 3A and 3B with a cartridge carrying staples received in a cavity of the jaw.

FIGS. 4B and 4C are top views of alternative embodiments of first jaws and cartridges that may be provided that include different size staples and receptacles.

FIGS. 5A-5C are cross-sectional views showing alternative embodiments of jaws and cartridges including a Doppler sensor and/or thermal element at different locations on the jaws.

FIGS. 6A and 6B are perspective views of an exemplary embodiment of an access port including a deployable imaging system carried on deployment arms in retracted and deployed configurations, respectively.

FIG. 6C is a perspective view of the access port of FIGS. 6A and 6B with a portion of the tubular shaft removed to show details of the deployment arms of the imaging system.

FIGS. 6D and 6E are top views of the access port of FIGS. 6A and 6B, respectively, with a portion of the tubular shaft removed to show details of the deployment arms of the imaging system.

FIGS. 7A and 7B are perspective views of an exemplary embodiment of a staple or clip that may be delivered using the stapler apparatus herein.

FIG. 7C is a side view of the staple of FIGS. 7A and 7B.

FIG. 7D is a side view of the staple of FIGS. 7A and 7B, showing a first tine of the staple being deformed and engaged with a second tine of the staple.

FIGS. 8A-8E are side views of alternative embodiments of staples or clips that may be delivered using the stapler apparatus herein.

FIGS. 9A and 9B are perspective and side views, respectively, of another exemplary embodiment of an access port including a disposable tubular member and a reusable video
5 module that may be coupled to the tubular member.

FIG. 9C is a perspective view of the access port of FIGS. 9A and 9B with imaging elements of the video module activated.

FIG. 10 is a perspective view of the tubular member of FIGS. 9A-9C.

FIG. 11 is a perspective view of a video module that includes elongate imaging
10 sleeves receivable in corresponding lumens of the tubular member.

FIGS. 12A and 12B are details of the distal end of the tubular member of FIG. 10 before and after inserting the imaging sleeves of the video module into secondary lumens of the tubular member.

FIG. 13A is a perspective view of the access port of FIGS. 9A-9C with a stapler
15 apparatus inserted through a primary lumen of the tubular member.

FIG. 13B is a detail of a distal end of the access port of FIG. 13A showing an end effector of the stapler apparatus.

FIG. 14 is a perspective view of another embodiment of a stapler apparatus including an integral video module including a display and a plurality of imaging sleeves
20 extending from a handle of the apparatus and insertable into an end effector (not shown).

FIGS. 15A-15D are details showing a wedge actuation mechanism for deploying a staple from a cartridge received in a jaw of an end effector.

FIG. 16 is a flowchart showing an exemplary method for using the apparatus herein to perform an appendectomy.

FIG. 17 is a flowchart showing an exemplary method for using an access port and stapler to perform a surgical procedure.

FIGS. 18A-18C are perspective views of alternative embodiments of stapler apparatus including an integral imaging sleeve carrying a display.

FIG. 18D is a perspective view of the imaging sleeve and display of the apparatus of
30 FIG. 18A.

FIG. 18E is a perspective view of the imaging sleeve of the apparatus of FIG. 18A.

FIG. 18F is a longitudinal cross-section of the imaging sleeve of FIG. 18D.

FIGS. 18G and 18H are cross-sectional details of an imaging assembly that may be provided on the distal end of the imaging sleeve of FIGS. 18D-18E.

FIGS. 19A and 19B are perspective and side views, respectively, of an end effector of a stapler apparatus including a grasper.

5 FIG. 20 is a detail of a subject's anatomy showing a method for performing a tubal ligation procedure using the grasper and stapler apparatus shown in FIGS. 19A and 19B.

FIG. 21A is a side view of another example of a stapler apparatus including a grasper mounted on a shaft of the stapler apparatus.

10 FIGS. 21B and 21C are top views of the stapler apparatus of FIG. 21A, showing the grasper in retracted and deployed orientations, respectively.

FIGS. 22A and 22B are perspective views of a stapler apparatus including a pair of graspers.

15 FIG. 22C is a cross-sectional view of a distal region of a stapler apparatus including examples of auxiliary lumens that may be provided in a shaft of the apparatus, e.g., for slidably receiving one or more auxiliary instruments, such as the grasper in FIGS. 22A and 22B.

FIG. 23 is a schematic showing examples of combinations of actuators and end effectors that may be provided for performing laparoscopic surgical procedures.

FIG. 24 is a side view of another example of a clip.

20 FIG. 25 is a side view of an exemplary end effector carrying the clip of FIG. 24.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

Before the exemplary embodiments are described, it is to be understood that the invention is not limited to particular embodiments described, as such may, of course, vary.

25 It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

30 Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included or excluded in the

range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included.

5 Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, some potential and exemplary methods and materials are now described.

10 It must be noted that as used herein and in the appended claims, the singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to “a compound” includes a plurality of such compounds and reference to “the polymer” includes reference to one or more polymers and equivalents thereof known to those skilled in the art, and so forth.

15 Turning to the drawings, FIG. 2A shows an exemplary embodiment of a stapler apparatus 8 that may be used during a medical procedure, e.g., during laparoscopic surgery to remove a patient’s appendix (not shown). Generally, the apparatus 8 includes a reusable shaft/handle portion or handpiece 10 including a shaft 20 and a handle 30, and a disposable, single-use portion or end effector 40, e.g., configured to receive a single-use cartridge (not
20 shown), which may be removably coupled to the shaft 20 before or during a procedure, as described further below. Alternatively, at least some of the components of the end effector 40 may be permanently incorporated into the reusable portion 10, e.g., such that the entire apparatus 8 may be single-use or may be cleaned between procedures and reused.

As shown, the shaft 20 is an elongate member, e.g., a substantially rigid tubular
25 body, including a proximal end 22 and a distal end 24, defining a longitudinal axis 26 extending there between. The shaft 20 may include one or more lumens or passages (not shown) extending between the proximal and distal ends 22, 24, e.g., for receiving actuator elements, wires, and/or other components, as described elsewhere herein. At least the distal end 24 of the shaft 20 is sized for introduction into a patient’s body, e.g., having a diameter
30 sufficiently small enough to be received through a port or cannula to allow introduction into a laparoscopic surgical space within a patient’s body.

Optionally, at least a portion of the shaft 20 may be malleable, e.g., such that at least a distal region of the shaft 20 may be deformed into a desired shape outside the patient’s

body, which the shaft 20 may maintain during introduction. Alternatively, at least a distal region of the shaft 20 and/or the end effector 40 may be flexible, e.g., for introduction into body passages, such as blood vessels, GI passages, and the like, such that the distal region follows the passages during introduction. Optionally, in this alternative, the shaft 20 may include one or more steering wires or other elements therein (not shown) that may be actuated to change the shape of the shaft 20, e.g., to facilitate introduction into a desired location and/or manipulation within the patient's body.

The handle 30 may include a handgrip 32, e.g., shaped and/or otherwise configured to facilitate holding and/or manipulating the apparatus 8 during use. In addition, the handle 30 may include one or more actuators, e.g., for operating mechanical and/or electrical components on the stapler assembly 40. For example, a trigger or other jaw actuator 34 may be provided, e.g., adjacent the handgrip 32, that may be pulled or otherwise actuated to jaws 46, 47 and a separate actuator (not shown) may be provided to subsequently deploy one or more staples (not shown) from the stapler assembly 40. For example, the trigger 34 may be pulled to close the second jaw 48 immediately adjacent the first jaw 46 to engage tissue between contact surfaces 46a, 48a, e.g., as described further elsewhere herein. Optionally, the trigger 34 may include a ratchet mechanism to allow the second jaw 48 to move towards the first jaw 46 while preventing opening, e.g., to squeeze tissue between the jaws 46, 48, e.g., until a release mechanism is actuated. Alternatively, a separate locking mechanism may be provided on the handle 30, which may be selectively activated to lock and release the second jaw 48, as described elsewhere herein. In addition or alternatively, several other actuators may be included on the handle 30 or shaft 20 to achieve independent actuation of various functions/parts of the end effector, such as a staple actuator that be advanced to deploy one or more staples and/or retracted, a cutting actuator for blade actuation (forward and backward), a Doppler sensor trigger, an electrical cautery power switch, and/or an actuator for controlling end effector orientation.

Optionally, as shown in FIGS. 2B and 2C, a display or other output device 38 may be provided on the handle 30, e.g., to facilitate observing or otherwise monitoring the procedure. For example, a camera, light, and/or other imaging device (not shown) may be provided on the stapler assembly 40 and/or the distal end 24 of the shaft 20 that may be used to acquire images of a surgical space into which the stapler assembly 40 is introduced, as described further elsewhere herein. In one embodiment, a display 38 may be removably mounted on the handle 30, which may include one or more connectors or cables (not

shown) that may be coupled to corresponding connectors on the handle 30, which are, in turn, coupled to one or more wires extending to the imaging device on the stapler assembly 40. Alternatively, the display 38 may be permanently mounted to the handle 30 and one or more wires or other elements may communicate with the imaging device. In another
5 alternative, a display (not shown) may be provided that is separate from the apparatus 8, and the apparatus 8 may include a communications interface, e.g., a wireless transmitter, that may transmit signals from the imaging device wirelessly, e.g., using Bluetooth or other communications protocols, to allow images to be presented on the display.

For example, a CMOS, CCD, or other imaging element (not shown) may be
10 provided on the distal end 24 of the shaft 20 (or alternatively on the end effector 40) that is oriented to acquire images of the region beyond the stapler assembly 40 and/or between jaws 46, 48 of the end effector 40. One or more wires and/or optical fiber may transmit signals to the display 38, which may include a processor to process the signals and present the images on a screen of the display 38. In addition or alternatively, one or more LEDs or
15 other light sources may be provided on the distal end 24 of the shaft 20 (or alternatively on the end effector 40), e.g., adjacent the imaging element to provide illumination for the images. For example, one or more lights may be arranged circumferentially on the distal end 24 of the shaft 20, such as a circular Xenon LED lamp (not shown), e.g., operating at 200-2500 W, that may provide dispersed illumination (due to internal reflections in the
20 lamp) without generating thermal energy that may damage nearby tissue. Alternatively, one or more LEDs or other light sources (not shown) may be provided in the handle 30, and light may be transmitted using light conductive material such as optical fiber or transparent plastic to provide illumination to the distal end 24. The handle 30 and/or display 38 may include one or more controls (not shown), e.g., to turn the illumination source(s) and/or
25 imaging element(s) off and on, as desired. Optionally, the imaging element(s) and/or illumination source(s) may be movable relative to the end effector 40, e.g., rotated about the longitudinal axis 26 and, if so, one or more actuators (not shown) may be provided on the handle 30 to rotate or otherwise adjust their position during a procedure. In a further alternative, the apparatus 8 may include an integral imaging sleeve carrying a display,
30 similar to other embodiments herein. Optionally, multiple CMOS chips or other imaging elements may be provided on the distal end 24 and/or on an integral imaging sleeve (not shown) that are spaced apart from one another such that multiple images may be acquired from different angles. A processor may receive the signals from the multiple imaging

elements simultaneously and process them to provide a single combined image including a three-dimensional construction of the field of view.

Returning to FIG. 2A, generally, the end effector 40 on the distal end 24 of the shaft 20 includes first and second jaws 46, 48 carrying one or more staples (not shown) and, optionally, one or more additional components for use during a procedure. For example, as shown in FIGS. 3A-3C, the end effector 40 may include a removable cartridge 50 receivable within a recess, track, or other cavity 46c within the first jaw 46. The end effector 40 may also include a tubular housing 42 from which the first jaw 46 extends that includes a proximal end 44 that may be connected to the distal end 24 of the shaft 20, e.g., using one or more detents, latches, sockets, threads and/or other connectors (not shown) on the proximal end 44 of the housing 40 and/or the distal end 24 of the shaft 20. When the end effector 40 is mechanically connected to the shaft 20 by the connector(s), additional connectors may automatically engage, e.g., to mechanically couple actuatable components on the end effector 40 with actuator elements in the shaft 20 and/or electrically couple electrical components on the end effector 40 with corresponding wires in the shaft 20 (not shown), as will be appreciated by those skilled in the art. For example, a wedge mechanism (not shown, see, e.g., FIGS. 15A-15D) may be provided within the housing 42 adjacent the first jaw 46 that may be coupled to an actuator shaft (also not shown) within the shaft 20 such that actuation of a staple actuator on the handle 30 may be activated to advance and retract the actuator shaft and wedge to deliver the staples, as described elsewhere herein.

As shown, the first jaw 46 may be integrally formed with or otherwise fixed relative to the housing 42, e.g., such that the first jaw 46 remains aligned with the axis 26 of the shaft 20 during use. The second jaw 48 may be movably mounted to the housing 42, e.g., by one or more hinges or other features (not shown) such that the second jaw 48 may be pivotable between an open position, e.g., as shown in FIG. 3A, and a closed position, e.g., as shown in FIG. 3B. In the open position, contact surfaces 46a, 48a of the jaws 46, 48 may be spaced apart from one another, e.g., to allow a tissue structure to be positioned between the jaws 46, 48, e.g., on the first contact surface 46a, while in the closed position, the contact surfaces 46b, 48b may be immediately adjacent one another, e.g., substantially parallel to one another, as shown in FIG. 3B. For example, in the closed position, the contact surfaces 46a, 48a may have sufficient clearance between them to squeeze, secure, and/or otherwise engage tissue positioned between the jaws 46, 48.

The jaws 46, 48 may be biased to one of the open and closed positions or may be actuatable between the open and closed positions. For example, the jaws 46, 48 may be provided initially in a closed position, e.g., to facilitate introduction into a patient's body, whereupon a lock or other mechanism may be released, whereupon the second jaw 48 may automatically move to the open position, and the actuator 34 on the handle 30 may become active to deploy staples and/or close the second jaw 48, as described further elsewhere herein. Alternatively, the trigger 34 on the handle 30 may be pulled or released to close and open the second jaw 48 without deploying staples to facilitate introduction and/or manipulation of the cartridge 40, e.g., until a switch or other control is actuated to activate deployment of the staples. A locking mechanism, e.g., a ratchet or other lock (not shown), may be provided to prevent the second jaw 48 from opening until released.

With particular reference to FIG. 3A, the first jaw 46 may receive a disposable cartridge 50 which may be received in cavity 46c of the first the jaw 46 such that an exposed surface 50a of the cartridge 50 defines the first contact surface 46a. The cartridge 50 may carry a plurality of staples (not shown), e.g., in arranged in a plurality of rows aligned with the axis 26 of the shaft 20. For example, in the embodiment shown, the contact surface 50a of the cartridge 50 includes recesses or receptacles 52 arranged in three rows 52a, 52b, 52c from which staples may be deployed simultaneously and/or in rapid succession.

Optionally, the cartridge 50 or first jaw 46 may include a thermal element 56 on the first surface 46a adjacent the rows of staples. For example, the cartridge 50 may include sets of staples disposed on opposite sides of the thermal element 56, e.g., with the sets aligned with the axis 26 of the shaft 20. Alternatively, as shown in FIGS. 5A-5C, the thermal element may be omitted from the jaws/cartridge, if desired. If the staples are carried by a cartridge 50 that is removable from the first jaw 46, the thermal element 56 may be mounted on an exposed surface of the cartridge 50, e.g., if the cartridge 50 provide the first contact surface 46a. Alternatively, the thermal element 56 may be permanently mounted on the first jaw 46 and the cartridge 50 may define the portions of the first contact surface 46a on either side of the thermal element 56 (not shown).

In the example shown in FIGS. 3A and 4A, a first row or set of staple receptacles 52a may be located on the right side of the thermal element 56 (from the perspective of a user holding the handle 30 of the apparatus 8), and second and third rows or sets of staple receptacles 52b, 52c may be located on the left side of the thermal element 56. For

example, in this configuration, the first set of staples may be delivered into the appendix being removed, while the second set of staples may be delivered into the intestine and remain within the patient's body after the appendix is removed. Alternatively, the arrangement of the receptacles 52 may be reversed if desired, e.g., with the first set on the left and the second set on the right for approaches where the appendix is on the left (from the perspective of the operator of the apparatus 8) and the intact intestine is on the right. As shown, the second set of receptacles 52b, 52c may include two rows of staples that are staggered relative to one another along the axis 26, e.g., to enhance stapling a tissue structure captured in the jaws 46, 48, as described elsewhere herein.

In the embodiment shown in FIGS. 3A and 4A, the receptacles 52 have similar dimensions, e.g., having the same length aligned with the axis 26, and the staples deployable from the receptacles 52 may have the same dimensions. Alternatively, the dimensions of the receptacles and, consequently, the staples, may be varied along each row and/or in different rows, as described further elsewhere herein.

For example, FIG. 4B shows an alternative embodiment of a first jaw 146 (generally similar to jaw 46) except that the rows of staple receptacles 152 include a first or proximal set of receptacles 153a and a second or distal set of receptacles 153b that have different sizes. For example, as shown, the first two receptacles in each row 152 (in the proximal set 153a) are larger than the remaining five receptacles (in the distal set 153b). In this alternative, when the staples are deployed, the larger, proximal staples will be deployed first followed by the smaller, distal staples, e.g., as the staple actuator (e.g., a piston and/or sledge, not shown) advances and the pushes the staples against the second jaw 48 (also not shown) to deform the deployed staples.

Alternatively, as shown in FIG. 4C, different size staples may be provided in one or more of the rows on the first jaw 246. For example, as shown, the first row may include receptacles 252a that are larger than the second and third rows of receptacles 252b, 252c. Consequently, larger staples may be deployed from the first row of receptacles 252a than the others. For example, it may be desirable to use larger staples to staple an appendix while smaller staples may be used to staple the blood vessel delivering blood to the appendix. Many smaller staples may enhance cutting off blood flow to the vessel, which may reduce risk of subsequent bleeding when the appendix is severed and removed. Thus, cartridges may be provided with multiple rows on either the left or right side of the cutting element 60 and with larger staples on the other side such that an appropriate cartridge may

be selected and connected to the handpiece 30 based on the actual anatomy encountered. Optionally, one or more additional rows or sets of staples may be provided adjacent the first, second, and/or third rows. For example, multiple sets of staples (e.g., 1-5) may be delivered into the appendix being removed and/or into the intestine.

5 Returning to FIG. 3A, the contact surface 48a of the second jaw 48 may include corresponding recesses 54, e.g., arranged in rows opposite the receptacles 52, e.g., such that the recesses 54 are disposed directly above respective receptacles 52 in the closed position, e.g., to deform and/or otherwise close staples deployed from the receptacles 52, as described further elsewhere herein. For example, the recesses 54 may include ramped surfaces,
10 anvils, and/or other features to deform one or both of the tines of the staples as they are deployed, as described further elsewhere herein.

 Optionally, the second jaw 48 may include a Doppler radar or other sensor 58, e.g., located on the second contact surface 48a generally opposite the thermal element 56. For example, the Doppler sensor 58 may be an elongate crystal element mounted on the second
15 contact surface 56 and aligned along the axis 26 (when the second jaw 48 is closed). The Doppler sensor 58 may be configured to transmit radar signals and receive reflections from the tissue captured between the jaws 46, 48 to identify whether blood is flowing within the tissue, e.g., using systems and methods known in the art.

 As can be seen in FIG. 3C, the thermal element 56 and Doppler sensor 58 may be
20 located opposite one another on the first and second jaws 46, 48, respectively, between the rows of staple receptacles 52 and recesses 54. This configuration may facilitate identifying blood flow within tissue captured between the jaws 46, 48 and then delivering thermal energy to cauterize, ablate, or necrose the tissue, e.g., to stop subsequent blood flow, as described elsewhere herein.

25 In an exemplary embodiment, the thermal element may include one or more electrodes, e.g., a single elongate electrode 56, e.g., extending axially along the first contact surface 46a, which may be coupled to a source of electrical energy, e.g., a generator (not shown), in the handle 30 and/or connected to the handle 30, as described further elsewhere herein. For example, as shown in FIG. 3C, the electrode 56 may include a thermal insulator
30 block 56a, e.g., formed from ceramic and/or other material that is not electrically conductive, and an electrode element 56b supported by the block 56a, e.g., to prevent conduction from the electrode 56 to other components of the end effector 40 and/or delivering energy to tissue that is not directly contacted by the electrode element 56b. In the

embodiment shown, a single electrode 56 may be provided for delivering radiofrequency energy in a mono-polar configuration to cauterize the contacted tissue, e.g., similar to Bovie® devices, as described elsewhere herein. Alternatively, multiple electrodes may be provided that are spaced apart from one another on the first contact surface 46a, which may be used to deliver RF energy in a bi-polar configuration. In a further alternative, other elements may be provided for delivering other forms of energy, e.g., laser, energy to cauterize contacted tissue.

Alternatively, the location of the thermal element 56 and Doppler sensor 58 may be reversed, if desired, e.g., with the thermal element on the second contact surface and the Doppler sensor on the first contact surface (not shown). In a further alternative, the thermal sensor may be omitted entirely and only a Doppler sensor 58 may be provided on one of the jaws, e.g., on the second jaw 48, as shown in FIG. 5A. Thus, in this alternative, the first jaw 46' does not include a thermal element.

In yet another alternative, the Doppler sensor may be provided at other locations on the second contact surface on any of these embodiments. For example, as shown in FIG. 5B, a Doppler sensor 58 may be provided along one side of the second jaw 48, i.e., adjacent the third row of recesses 54c opposite the third row of staple receptacles 52c.

In the embodiments shown in FIGS. 3C, 5A, and 5B, the Doppler sensor is oriented substantially perpendicular to the second contact surface. In this configuration, the centerline of the radar signals transmitted will also be perpendicular to the second contact surface. Alternatively, it may be desirable to orient the Doppler sensor at a non-perpendicular angle relative to the contact surface. For example, as shown in FIG. 5C, another example is shown in which a Doppler sensor 58''' is mounted on the second jaw 48''' such that the sensor defines an angle relative to the second contact surface 58a'''.

Thus, in this alternative, the centerline of transmitted radar signals may directed diagonally from the second contact surface 58a'''. Such a configuration may be useful, e.g., to direct the radar signals towards a tissue structure of particular interest, e.g., towards the blood vessel of the appendix, e.g., defining an angle relative to the direction of blood flow rather than perpendicular to the direction of blood flow.

Returning to FIGS. 3A-3C, the end effector 40 may also include a blade or other cutting element 60 slidably disposed relative to the jaws 46, 48. For example, the first and second jaws 46, 48 may include respective slots or grooves 62, 64 aligned with the axis 26 that receive the blade 60, e.g., when the blade is advanced from a retracted position (not

shown), e.g., received within the housing 42 immediately adjacent the contact surfaces 46a, 48a, to an advanced position, i.e., where a sharpened edge 60a of the blade 60 is advanced distally along the slots 62, 64 towards distal tips 46b, 48b of the jaws 46, 48 (the blade 60 is shown partially advanced in FIG. 3A). As can be seen in FIG. 3B, the blade 60 may extend
5 between the contact surfaces 46a, 48a of the jaws 46, 48, such that the edge 60a cuts through or otherwise severs tissue (not shown) positioned between the jaws 46, 48 in the closed position, as described further elsewhere herein. Alternatively, as shown in FIG. 3D, the blade may be omitted and an end effector 140 may be provided that includes jaws 146, 148 carried by a housing 142 without a cutting element. In this alternative, the jaws 146,
10 148 may include any arrangement of receptacles 152 for staples (not shown) and recesses, similar to other embodiments herein. Although not shown, the end effector 140 may include a Doppler sensor and/or thermal element or one or both of these components may also be omitted.

Optionally, the cartridge 40 may include one or more additional components for use
15 during a procedure. For example, an illumination source and/or imaging element may be mounted on the housing 42, e.g., to facilitate imaging and/or monitoring use of the apparatus 8 during a procedure. In an exemplary embodiment, a CMOS, CCD, or other imaging element and/or one or more LEDs or other light sources (not shown) may be provided on the end effector 40, e.g., adjacent the proximal end of the first jaw 46 where the
20 second jaw 48 pivots, that may be oriented distally to acquire images of the region beyond the stapler assembly 40. For example, the field of view of the imaging element may include the first contact surface 46a of the first jaw 46 such that an operator may use the images to position and/or orient a desired tissue structure on the contact surface 46a before actuating the second jaw 48 to close.

25 The apparatus 8 may be used to deliver staples into tissue during a medical procedure, e.g., during a laparoscopic surgical procedure, such as an appendectomy. It will be appreciated, however, that the apparatus 8 (and the other embodiments herein) may be used for a variety of minimally invasive surgical procedures, such as tubal ligation, cholecystectomy clipping, hysterectomy, nephrectomy, splenectomy, oophorectomy, lung
30 biopsy, bariatric surgery, colon and intestine surgery, and vascular surgery. Initially, a surgical space may be created, e.g., by introducing a trocar and/or cannula device (not shown) through the patient's skin and intervening tissue to a target region, e.g., the patient's

abdominal cavity, and insufflating or otherwise opening the space to access a desired tissue structure, such as an appendix indicated for removal.

An end effector 40 and cartridge 50 may be selected and connected to the distal end 24 of the shaft 20 before introduction into the patient's body. For example, based on the anatomy encountered, the operator may select a cartridge 50 including a particular arrangement of staples, e.g., including uniform-size staples or different size staples, such as those described elsewhere herein, insert the cartridge 50 into the cavity 46c of the first jaw 46, e.g., before or after connecting the end effector 40 the shaft 20. Once the apparatus 8 is ready, the distal end 24 of the shaft 20 carrying the end effector 40 may be introduced into the surgical space, e.g., through a cannula or other port (not shown), until the jaws 46, 48 are located the surgical space. For example, the surgical space may be initially accessed using a needle, trocar, and/or dilator device, e.g., punctured through the patient's skin and intervening tissue into the abdominal cavity to approach the appendix, and a cannula may be positioned through the puncture. Gas may be delivered through the cannula or other device to insufflate and create a surgical cavity or space.

The distal end 24 of the shaft 40, carrying the selected end effector 40 and/or cartridge 50, may then be introduced through the cannula into the surgical space. For example, the jaws 46, 48 may be initially locked in the closed position to facilitate introduction through the cannula and then may be released once located within the surgical space, whereupon the second jaw 48 may open. Alternatively, the second jaw 48 may be biased to open but may be manually or otherwise closed to allow insertion through the cannula.

With the jaws 46, 48 in the open position within the surgical space, tissue within the region, e.g., the patient's appendix, may be placed on the contact surface 46a of the first jaw 46 and/or otherwise positioned between the jaws 46, 48. For example, both the appendix and the appendicular artery may be positioned between the jaws 46, 48, e.g., with one distal to the other depending on the orientation of the appendix.

Once the tissue is positioned as desired, the trigger actuator 34 may be manipulated to close the second jaw 48 and lock the tissue in place between the contact surfaces 46a, 48a. For example, the trigger 34 may include a ratchet mechanism that allows the second jaw 48 to close while preventing it from reopening, or a separate locking mechanism (not shown) may activated once the second jaw 48 is closed to engage the tissue. A separate staple actuator (not shown) may then be used to deploy one or more staples from the first

jaw 46 into and through the tissue and towards the second jaw 48 to deform the staples(s) and engage the tissue.

For example, as the stapler actuator is pushed, an actuation shaft (not shown) within the shaft 20 may advance a wedge or other staple actuation element (not shown) within the cartridge 50 or end effector 40 to begin deploying staples from the receptacles 52 out of the first contact surface 50a/46a of the first jaw 46 upwardly towards the second jaw 48, thereby causing one or more tines of the staples to contact the corresponding recesses 54 in the second contact surface 48a and deform to staple the tissue. FIGS. 15A-15D show an exemplary embodiment of a wedge actuator 66 slidable within a passage 53 within a cartridge 50 that includes an angled or ramped distal surface 66a that may push corresponding ramped surfaces 68a of pistons (one piston 68 shown) within respective receptacles 52 upwardly to push the corresponding staples 90 towards the second jaw 48 (not shown in FIGS. 15A-15D), where tines of the staples 90 are deformed within the corresponding recesses 54, as described elsewhere herein. For example, the wedge 66 may be coupled to a stapler actuator shaft (not shown) that may be advanced and retracted within the passage 53, e.g., to advance the wedge 66, thereby slidably engaging the ramped surface 66a of the wedge 66 with ramped surfaces 68a of the pistons 68 and directing the pistons 68 upwardly in the respective receptacles 52, as shown in FIGS. 15B-15D. The wedge 66 may then be retracted back to the position shown in FIG. 15A. It will be appreciated that other stapler mechanisms may be used instead, such as those disclosed in U.S. Patent Nos. 4,608,981, 4,633,874, 5,104, 025, 5, 307,976, 5,709, 680, and European Patent No. 1,157,666, the entire disclosures of which are expressly incorporated by reference herein.

The deployment of the staples may be sequential within each set, e.g., simultaneously delivering first staples from each of the sets 52a-52c at the proximal end of the first jaw 46 and, as the trigger 34 continues to be pulled, additional staples are deployed until the desired length of stapling, whereupon actuation may be discontinued, which may leave one or more staples closest to the distal tip 46a of the first jaw 46 undeployed. In this manner, the operator may control how many staples are deployed based on the extent to which the staple actuator is pulled. Alternatively, the actuator 34 may be binary, i.e., wherein, when the trigger 34 is initially pulled, all of the staples in the first jaw are deployed in rapid succession.

If the apparatus 8 includes a Doppler sensor 58, e.g., on the second jaw 48, the Doppler sensor 58 may be activated, e.g., using a radar actuator (not shown) on the handle

30, to detect blood flow in the stapled tissue. For example, signals from the sensor 58 may be transmitted, e.g., via one or more wires (not shown) in the shaft 20 to a processor in the handle 30, which may analyze the signals to confirm whether blood flow has discontinued in the stapled tissue. The apparatus 8 may include an output device, e.g., an indicator light, speaker, and the like (not shown), e.g., on the handle 30 that may provide a positive indication that blood flow has stopped. The operator may then manipulate another actuator, e.g., a slider, dial, and the like (not shown) on the handle 30 to advance the blade 60 to sever the stapled tissue from adjacent tissue.

If the output device indicates that blood is still flowing in the stapled tissue, additional actions may be taken to cauterize the tissue and/or stop blood flow. For example, if the apparatus 8 includes the thermal element 56, the operator may activate the thermal element to deliver thermal energy to the stapled tissue. For example, a button or switch (not shown) on the handle 30 may be activated to deliver RF energy from a power source coupled to the handle 30 via one or more wires (not shown) in the shaft 20 to the electrode(s) 56a on the first jaw 46 to cauterize the stapled tissue. Energy may be delivered until the output device/Doppler sensor 58 provides a confirmation that blood flow has stopped, whereupon the blade 60 may be advanced to sever the tissue, e.g., to simultaneously sever the appendix and the appendicular artery.

Optionally, before severing the tissue, the second jaw 48 may be released and opened and the jaws 46, 48 repositioned relative to the stapled tissue and then closed and locked at one or more subsequent positions, e.g., to use the Doppler sensor 58 to confirm blood flow has stopped and/or deliver further thermal energy to cauterize the tissue. Once desired, the blade 60 may be used to sever the tissue.

The apparatus 8 may then be removed from the surgical space and the procedure completed using conventional methods. For example, the blade 60 may be retracted, and the Doppler sensor 58 and/or hemostasis element 56 may be deactivated (if not already). The end effector 40 may be removed from the patient's body with the second jaw 48 remaining locked to remove the excised tissue.

Optionally, the procedure may be illuminated and/or monitored using an illumination source and/or imaging element on the end effector 40 and/or shaft 20, as described elsewhere herein. In addition or alternatively, other light sources and/or imaging devices may be provided to monitor the procedure. For example, a separate endoscope may

be introduced into the surgical space, e.g., via a different cannula or port (not shown) than the cannula used to introduce the apparatus 8.

Turning to FIG. 2D, an alternative embodiment of a stapler apparatus 8' is shown that includes a shaft 20' carrying an end effector 40, which may generally be similar to any of the embodiments described elsewhere herein. Unlike the apparatus 8 shown in FIG. 2A, the apparatus 8' includes a robotic control system 10' coupled to the proximal end 22' of the shaft 20'. The control system 10' may include one or more electrical and/or mechanical actuators, e.g., for advancing and/or retracting the distal end 24' of the shaft 20' and/or for rotating the shaft 20' around longitudinal axis 26'. In addition, the control system 10' may include one or more actuators (not shown) for controlling components on the end effector 40, for opening and closing the jaw 48, for advancing and/or retracting the blade (not shown), for activating the Doppler sensor and/or thermal element (also not shown), and the like. FIG. 2E shows an example of a robotic adapter/extender 11' that may be used to couple a shaft an apparatus, such as the apparatus 8' of FIG. 2D, to a control system 10'.

This alternative may allow a procedure to be performed remotely, e.g., by a surgeon or other operator outside the surgical space at the same location as the patient, or from a remote location. For example, the operator may manipulate a control panel (not shown) immediately outside the surgical space that may control the actuators of the control system 10' via wired or wireless communications. Alternatively, the operator may be at a remote location and the control system may be operated by commands transmitted via a network, e.g., including wired or wireless communications networks, such as telephony networks and/or the Internet. Images from an imaging device on the end effector 40 and/or the distal end 24' of the shaft 20 and/or a port or other device into which the stapler 8' is introduced may be communicated via the same network to one or more displays (not shown) that may be viewed by the operator to perform a procedure, similar to those described elsewhere herein.

In another alternative, a cannula or access port may be provided that includes one or more illumination and/or imaging elements, and the apparatus 8 or 8' (or any other embodiments herein) may be introduced using the access port. For example, turning to FIGS. 6A-6E, an exemplary embodiment of an access port 70 is shown that generally includes an elongate tubular body 72 including a proximal end 74, a distal end 76 sized for introduction into a patient's body, and one or more lumens or passages 78 extending at least partially between the proximal and distal ends 74, 76. For example, the tubular body 72

may include a primary lumen 78a sized to receive one or more instruments therethrough that extends from an outlet in the proximal end 74 to an outlet in the distal end 76, such as any of the stapler apparatus described elsewhere herein. In addition, the tubular body 72 may include one or more secondary lumens (not shown), e.g., extending at least partially from the proximal end 74 towards the distal 76, e.g., for receiving actuator elements, wires, and/or other components, as described elsewhere herein. The tubular body 72 may be substantially rigid or alternatively at least a portion of the tubular body 72, e.g., a distal portion, may be malleable or flexible (not shown).

A handle or hub 80 may be provided on the proximal end 74, e.g., to facilitate manipulation of the access port 70 during use. The hub 80 may include one or more valves or seals (not shown), which may seal the primary lumen 78a yet facilitate inserting an instrument into the primary lumen 78a, e.g., providing a substantially fluid-tight seal around the instrument. In this manner, the seal(s) may prevent insufflation gas or other fluid to escape through the primary lumen 78a, e.g., when the access port is introduced into a patient's body, as described elsewhere herein.

In addition, a display or other output device 82 may be provided on the hub 80, e.g., to facilitate observing or otherwise monitoring the procedure using one or more imaging devices on the access port 80. For example, a distal portion of the tubular body 72 may include a pair of deployable arms 84 including first ends 84a pivotally coupled to the tubular body 72 and second or free ends 84b that may carry one or more cameras, light sources, and/or other imaging device, as described further below.

In one embodiment, the display 82 may be removably mountable on the hub 80, which may include one or more connectors or cables (not shown) that may be coupled to corresponding connectors on the hub 80, which are, in turn, coupled to one or more wires extending to the imaging device(s) on the arms 84. Thus, in this alternative, the display 82 may be reusable and the tubular body 72 may be disposable/single-use. Alternatively, the display 82 may be permanently mounted to the hub 80 and one or more wires or other elements may communicate with the imaging device(s). Thus, in this alternative, the entire access port 80 may be cleaned and reused or may be single-use. In a further alternative, the access port 80 may include a communications interface that may transmit signals from the imaging device wirelessly, e.g., using Bluetooth or other communications protocols, to allow images to be presented on a remote display.

In an exemplary embodiment, a CMOS, CCD, or other imaging element (not shown) may be provided on the free end 84b of one of the arms 84 and one or more LEDs or other light sources may be provided on the free end 84b of the other arm 84. Alternatively, separate light sources and imaging elements may be provided on both arms, e.g., to provide multiple images simultaneously on the display 82. In a further alternative, only one arm may be provided, if desired, including one or more light sources and/or imaging elements on its free end.

In any of these embodiments, one or more wires may transmit signals from the imaging element(s) to the display 82, which may include a processor to process the signals and present the images on a screen of the display 82. The imaging element(s) may include a field of view oriented distally beyond the distal end 76 of the tubular body 72, e.g., to illuminate and/or image an instrument deployed within a region beyond the distal end 76.

The arms 84 are movable between a retracted configuration, e.g., as shown in FIGS. 6A and 6D, which may facilitate introduction into a patient's body, and a deployed configuration, e.g., as shown in FIGS. 6B, 6C, and 6E, where the imaging device may be used to acquire images during a procedure. In one embodiment, the arms 84 may be biased to the retracted configuration, but may be directed to the deployed configuration when an instrument is inserted into the primary lumen 78a, as described further below. Alternatively, the arms 84 may be actuated (or moved) by a user selectively between the retracted and deployed configurations, if desired.

For example, with particular reference to FIGS. 6D and 6E, the first ends 84a of the arms 84 may include ramps or other features 84c that extend partially into the primary lumen 78a. Consequently, when an instrument is inserted into the lumen 78a, the instrument may contact the ramps 84c, thereby deflecting the arms 84 outwardly to the deployed configuration. As can be seen in FIG. 6E, in the deployed configuration, the ramps 84c may be substantially flush with the wall of the tubular body 72 such that the ramps 84c do not interfere with manipulation of the instrument. When the instrument is removed, the arms 84 may return automatically back towards the retracted configuration. Alternatively, the arms 84 may remain deployed until actuated or until the access port 70 is removed, e.g., whereupon the arms may be collapsed inwardly as they contact tissue along the exit path. In another alternative, a circumferential light source, such as a circular Xenon LED lamp (not shown) may be provided on the distal end of the access port instead of the arms.

Turning to FIGS. 7A-7D, an exemplary embodiment of a staple or clip 90 is shown that may be delivered using any of the stapler apparatus herein. Generally, the staple 90 includes a base 92, e.g., a substantially straight segment, from which first and second tines 94, 96 extend, e.g., substantially perpendicular to the base 92. The tines 94, 96 may be substantially straight terminating in respective tips 95, 97. Thus, for example, the base 92 and tines 94, 96 may define a substantially rectangular “U” shape, e.g., with rounded transitions between the base 92 and the tines 94, 96. As shown, the first tine 94 has a length that is substantially shorter than the second tine 96. In addition, the second tine 96 has a length from the base 92 to its tip 97 that is longer than the length of the base 92. Consequently, the second tine 96 may be bent or otherwise deformed towards the first tine 94, e.g., as shown in FIG. 7D.

In the example shown, the staple 90 has a cross section that is substantially uniform along the length of the staple 90, e.g., along a length of the first tine 94, along the base 92, and along the second tine 96. For example, the staple may have a substantially rectangular (with or without sharp corners), oblong, or other generally flattened cross-section, e.g., having a width “w” that is thicker than a thickness “t,” as indicted in FIGS. 7A-7D.

In addition, the first tine 94 includes a notch 98 adjacent its tip 95 configured to receive the tip 97 of the second tine 96 when it is deformed. For example, as shown, the tip 97 of the second tine 97 may be beveled such that the tip 97 tapers towards the first tine 94, which may enhance the tip 97 being locked into the notch 98. Alternatively, as shown in FIG. 8A, the tip 97a of the second tine 96a may be beveled in the opposite direction, i.e., away from the first tine 92a. In addition, or alternatively, the staple may include different ridges for different thickness compression.

Optionally, as shown in FIG. 8C, the first tine 94c may include a plurality of notches 98c spaced apart from one another along the length of the first tine 94c. Thus, in this embodiment, the tip 97c of the second tine 96c may be ratcheted sequentially into the notches 98c, e.g., simply locked into the top notch 98c or down into one of the notches further down on the first tine 94c. Although three notches 98c are shown in FIG. 8C, it will be appreciated that any desired number of notches (two or more) may be provided on the first tine 94c. Alternatively, the first tine may be provided without any notches (not shown), and the stapler actuator may be configured to bend or otherwise deform the tip of the first tine over the second tine (after the second tine has been bent).

In another option, shown in FIG. 8B, a radius of the transition between the base 92b and the second tine 96e may be increased, e.g., compared to the staple 90 shown in FIG. 7C, which may reduce the force to bend the second tine 96e during use. In yet another option, shown in FIG. 8D, the tip 95d of the first tine 94d may include a bevel that is oriented
5 towards the second tine 96d (as opposed to being oriented away from the second tine 96, as in the staple 90 shown in FIG. 7C). In still another option, shown in FIG. 8E, a staple 90e may be provided that includes a bump 93e in the base 92e, which may be configured to enhance the pinching/closure of the tissues entrapped within the staples. It will be appreciated that any of these options may be included in one or more of the staples included
10 in any of the stapler apparatus described elsewhere herein.

With additional reference to FIGS. 3A-3C, a plurality of staples, such as staple 90 shown in FIGS. 7A-7D (or any of the alternatives) may be provided in each of the receptacles 52 in the first jaw 46. With the receptacles 52 aligned along the axis 26 of the shaft 20, the base 92 of each staple 90 may be seated at the bottom of the respective
15 receptacle with the first tine 94 closer to the distal tip 46b of the first jaw 46 and the second tine 96 closer to the proximal housing 42 (or reverse). Consequently, as the staples are deployed upwardly from the receptacles 52, both tines 94, 96 may be driven through the tissue adjacent the contact surface 46a of the first jaw 46, and the second tines 96 may then be received in the respective recesses 54 in the second jaw 48 as the staples are pushed
20 upward toward the second jaw 48. This action may facilitate bending the second tines 96 distally towards the first tines 94. Thus, the second tines 96 may be bent or otherwise deformed above the tissue towards the tips 93 of the first tines 94 until the tips 97 of the second tines 96 are received in the respective notches 98, thereby locking the staples 90 and compressing the captured tissue.

Turning to FIGS. 9-12, another exemplary embodiment of an access port 170 is shown that includes an elongate tubular body 172 and a video module 180 that may be coupled to the tubular body 172, e.g., to allow introduction of one or more instruments through the port 170 into a surgical space within a patient's body while acquiring images within the surgical space, generally similar to other embodiments herein. As shown in FIG.
30 10, the tubular body 172 includes a proximal end 174, a distal end 176 sized for introduction into a patient's body, and one or more lumens or passages 178 extending between the proximal and distal ends 174, 176. For example, the tubular body 172 may include a primary lumen 178a sized to receive one or more instruments therethrough, such

as the stapler apparatus 8 shown in FIGS. 13A and 13B and/or described elsewhere herein. In addition, the tubular body 172 includes one or more secondary lumens 178b, e.g., positioned within a sidewall of the tubular body 172 around the primary lumen 178a. For example, as best seen in FIGS. 12A and 12B, three secondary lumens 178b may be positioned together on one side of the primary lumen 178a and a fourth secondary lumen 178b may be provided on an opposite side of the primary lumen 178a to acquire two sets of images simultaneously, as described further elsewhere herein. Outlets 179b of the secondary lumens 178b at the distal end 176 may be open or may include a transparent cover, membrane, and the like (not shown) to prevent bodily fluids or other materials from entering the secondary lumens 178b from the distal end 176. The tubular body 172 may be substantially rigid or alternatively at least a portion of the tubular body 172, e.g., a distal portion, may be malleable or flexible (not shown).

The video module 180 generally includes an annular hub 182 from which a plurality of elongate sleeves, tubes, or other imaging elements 184 extend, e.g., provided in an arrangement corresponding to the secondary lumens 178b in the tubular body 172. The imaging sleeves 184 may be sized to be inserted into the secondary lumens 178b simultaneously from the proximal end 174 of the tubular body 172 such that distal tips 184b thereof are disposed adjacent the distal end 176 of the tubular body 172, e.g., extending slightly from the outlets 184b for acquiring images beyond the distal end 176.

Optionally, the proximal end 174 of the tubular body 172 and the hub 182 may include cooperating connectors (not shown) to removably couple the hub 182 to the tubular body 172, e.g., such that the access port 170 may be manipulated as a unitary device.

In addition, one or both of the proximal end 174 of the tubular body 172 and the hub 182 may include one or more valves or seals (not shown), e.g., to seal the primary lumen 178a yet facilitate inserting an instrument into the primary lumen 178a, e.g., providing a substantially fluid-tight seal around the instrument. In this manner, the seal(s) may prevent insufflation gas or other fluid to escape through the primary lumen 178a, e.g., when the access port 170 is introduced into a patient's body, as described elsewhere herein.

In addition, a display or other output device 186 may be provided on the hub 182, e.g., to facilitate observing or otherwise monitoring the procedure using one or more imaging devices on the access port 170. In one embodiment, the display 186 may be removably mountable on the hub 182, which may include one or more connectors or cables (not shown) that may be coupled to corresponding connectors on the hub 182.

Alternatively, the display 186 may be permanently mounted to the hub 182. In a further alternative, a display may be provided separate from the access port 170 and images may be transmitted wirelessly or via wired connection from the access port 170, similar to other embodiments herein.

Each sleeve 184 may include an elongate tubular body, e.g., formed from stainless steel or other metal, plastic, and/or composite material including a lumen for carrying one or more imaging components. The sleeves 184 may be substantially rigid or, alternatively, may be sufficiently flexible to follow the shape of the lumens 178b, e.g., if the tubular body 172 is malleable or flexible and directed to a nonlinear shape.

In an exemplary embodiment, at least one of the imaging sleeves 184 may carry a CMOS, CCD, or other camera (not shown) on its distal tip 184b to acquire the images. Alternatively, a lens may be provided on the distal tip 184b and a fiberoptic cable or other optical conductor (also not shown) may extend through the imaging sleeve 184 to the proximal end 184a, where the conductor may be coupled to a camera to acquire the images.

Similarly, at least one of the imaging sleeves 184 may carry an illumination source, e.g., an LED or other light source, on its distal tip 184b for transmitting light beyond the distal end 176 of the tubular body 172. Alternatively, the LED or other light source may be provided within the hub 180, and an optical conductor may extend from the proximal end 184a of the imaging sleeve 184 to its display tip 184b. In the example shown, the video module 180 includes a pair of sleeves 184 on opposite sides of the primary lumen 178a carrying cameras on distal tips 184(1), and a pair of sleeves 184 on opposite sides of one of the camera sleeves carrying an LED or other illumination source on the distal tips 184(2) (or may carry lenses coupled to cameras or LEDs), e.g., providing a field of view as shown in FIG. 9C. In this configuration, images may be acquired substantially simultaneously from opposite distal tips 184b(1) to provide binocular imaging on either side of the end effector 40 (as shown in FIG. 13B), with the distal tips 184b(2) providing off-axis illumination to minimize shadows or otherwise enhance illumination within a surgical space.

During use, the imaging elements 184 may be inserted into inlets 175b from the proximal end 174 of the tubular body 172 into the corresponding secondary lumens 178b until the distal tips 184b are positioned adjacent the distal end 176 of the tubular body 172, e.g., extending a desired distance from the outlets 179b to allow acquisition of images. Optionally, when the imaging elements 184 are fully inserted, connectors on the hub 182 and/or proximal end 174 may engage to secure the video module 180 relative to the tubular

body 172. The assembled access port 170 may then be introduced into a patient's body to allow introduction of one or more instruments to be introduced to perform a surgical procedure while acquiring images of the procedure, similar to other embodiments herein. For example, as shown in FIGS. 13A and 13B, an end effector 40 of a stapler apparatus 8
5 may be inserted through the primary lumen 178a to staple and/or remove tissue, as described elsewhere herein.

Upon completing the procedure, any instruments may be removed from the primary lumen 178a, and the port 170 may be removed from the patient's body using conventional methods. The video module 180 may be removed from the tubular body 172 and then
10 cleaned, sterilized, and/or otherwise prepared for use again in a subsequent procedure. The tubular body 172 may be single-use, and may be discarded after the procedure. Alternatively, the tubular body 172 may also be cleaned, sterilized, and/or otherwise prepared for reuse.

Turning to FIG. 14, another exemplary embodiment of a stapler apparatus 208 is
15 shown that includes a video module 280 integrated into a reusable shaft/handle portion 210. Generally, the handle portion 210 includes a shaft 220 extending from a handle 230 including actuation components (not shown), e.g., such that a disposable end effector (not shown) may be coupled to a distal end 224 of the shaft 220, similar to other embodiments herein.

Unlike the previous embodiments, a plurality of elongate imaging sleeves 284 also
20 extend from the handle portion 210, e.g., from a hub 282 from which the shaft 220 also extends. As shown, the imaging sleeves 284 may be positioned radially around the shaft 220 and may have a length longer than the shaft 220 such that distal tips 284b of the imaging sleeves 284 extend distally beyond the distal end 224 of the shaft 220. The video
25 module 280 may also include a display 286 mounted on the hub 282 (or elsewhere on the handle portion 210 and/or remote from the apparatus 280, as desired) coupled to one or more cameras and/or illumination sources (not shown) that may be used to acquire images beyond the distal tips 184b.

An end effector (not shown) may be coupled to the distal end 224 of the shaft 220
30 generally similar to other embodiments, e.g., to staple, cauterize, and/or remove tissue. In addition, the housing of the end effector may include a plurality of secondary lumens (also not shown) that may receive the imaging sleeves 284 such that the distal tips 284b are

disposed adjacent jaws of the end effector, e.g., similar to the configuration shown in FIG. 13B.

During use, a desired end effector may be received over the imaging sleeves 284 and coupled to the distal end 224 of the shaft. Optionally, a cartridge (not shown) may be loaded into one of the jaws of the end effector and then the end effector may be introduced into a patient's body to perform a surgical or other medical procedure, similar to other embodiments herein. IN this manner, the video module 280 may be used to acquire images during the procedure. Upon completing the procedure, the apparatus 208 may be removed, the end effector may be removed and, optionally discarded, and the handle portion 210 may be cleaned and/or otherwise prepared for use in another procedure, also similar to other embodiments herein.

Turning to FIG. 18A, still another exemplary embodiment of a stapler apparatus 308 is shown that includes an imaging apparatus 380 integrated into a reusable shaft/handle portion 310. As described further below, the entire apparatus 308 (including the imaging apparatus 380, shaft/handle portion 310 and end effector 40) may be introduced into a patient's body together, and the imaging apparatus 380 may provide a substantially stationary field of view while allowing at least some manipulation of the end effector 40.

Generally, the handle portion 310 includes a shaft 320 extending from a handle 330 including one or more actuators 534, e.g., for actuating components on an end effector 40 coupled to a distal end of the shaft 320, similar to other embodiments herein. For example, a disposable end effector 40 may be connected to the distal end of the shaft 320 before a procedure, although, alternatively, a permanent end effector may be provided on the shaft 320 instead (not shown). The end effector 40 may include jaws 46, 48 and, optionally, one or more other components, e.g., a blade or other cutting element, a grasper, a Doppler sensor, and/or a thermal element (shown), and the like, similar to other embodiments herein.

With additional reference to FIGS. 18D-18F, the imaging apparatus 380 includes a sleeve 370 including a hub 382 on its proximal end 372, e.g., adjacent the handle 330, an imager 384 on its distal end 374, e.g., proximal to the end effector 40, and a display 386 mounted to the hub 382. As shown in FIG. 18F, the sleeve 370 includes a lumen 376 extending between the proximal and distal ends 372, 374 that communicates with a port or opening 382a in the hub 382. Optionally, the sleeve 370 may include one or more secondary lumens, e.g., for receiving one or more wires, fiberoptic cables, and the like (not

shown) extending between the imager 384 and the display 386 and/or a processor in the handle portion 330.

The hub 382 may be coupled to a mount 388 that is, in turn, coupled to the display 386 to stabilize the display 386 relative to the sleeve 370. For example, as best seen in FIG. 18F, the mount 388 may include an elongate body 388a including sockets 388b on opposite ends thereof that may receive balls or other rotatable elements 388c, i.e., that may rotate or otherwise slide within the respective sockets 388b. Each rotatable element 388c includes a threaded nipple or other fastener 388d that extends from the respective socket 388b, which may be engaged with the hub 382 and display 386. For example, as shown in FIG. 18F, the hub 382 may include a threaded aperture or other fastener 382b that receives or otherwise engages with one fastener 388d of the mount 388, and the housing 386a of the display 386 may also include a threaded aperture or other fastener 386b that receives or otherwise engages with the other fastener 388d.

The mount 388 may be adjustable about one or more axes to adjust the location of the display 386 relative to the hub 382 and sleeve 370. For example, as shown in FIG. 18A, the mount 388 may be adjusted about both joints to position the display 386 in a distal position towards the end effector 40. It will be appreciated that the mount 388 may be adjustable to position the display 386 in a variety of positions, e.g., proximally over the handle 330 (not shown), offset laterally and the like given the flexibility of the ball and socket joints. The ball and socket joints may have sufficient resistance to movement such that the display 386 may be directed to a desired position by adjusting the mount 388, and then the joints may hold the display 386 in that position. Alternatively, the joints may include one or more set screws or other locking mechanisms (not shown) that may be released to allow adjustment and then may be fixed when the display 386 is positioned at a desired location.

It will be appreciated that other mounts may be provided between the hub 382 and display to provided desired degrees of adjustment. For example, in an alternative embodiment the apparatus may include a simple hinged joint (not shown) that allows the display to be adjusted to change an angle of the display relative to the hub and sleeve without moving the entire display longitudinally (or in other directions). For example, the hub may include a flange or other hinge member fixed to the hub that may be received in recess or other corresponding hinge member fixed in or to the housing of the display. Thus,

the display may be pivoted about the hinged joint to increase or decrease an angle of the display relative to the longitudinal axis as desired during use.

Returning to FIG. 18A and with additional reference to FIGS. 18G and 18H, the imager 384 may include an imager housing 384a fixed to the distal end 374 of the sleeve 370, e.g., by one or more of an interference fit, bonding with adhesive, fusing, cooperating connectors, and the like (not shown), and an imaging element 384b oriented to allow imaging beyond the distal end 374, e.g., to allow observation of the end effector 40 and/or a surgical space beyond the distal end 374. In exemplary embodiments, the imaging element 384b may include a CCD, CMOS, or other camera, and one or more light sources (not shown) that may be used to acquire images during a procedure, similar to other embodiments herein.

Optionally, in the exemplary embodiment shown in FIGS. 18G and 18H, the imaging element 384b may be mounted on an arm 384c that may be pivotally mounted to the housing 384a at pivot joint 384d, e.g., such that the imaging element 384b may be moved between an inner or low profile orientation (FIG. 18G) and an outer or active orientation (FIG. 18H). For example, a tab or other element 384e may be provided at the pivot 384d that extends into the lumen 376 of the sleeve 370 in the low profile orientation. As described elsewhere herein, during use, the apparatus 308 may be introduced into a patient's body in the low profile orientation and, when a stapler apparatus or other device (not shown) is introduced into the lumen 376, the tab 384e may be directed radially outwardly from the longitudinal axis 326 to direct the arm 384c outwardly, as shown in FIG. 18H. Alternatively, the handle 330 may include an actuator (not shown) that may be coupled to the arm 384c such that an operator may selectively direct the imaging element 384b radially outwardly or inwardly as desired during use.

In another alternative, the apparatus 308 may include an imaging element fixed relative to the distal end 374 of the sleeve 370. For example, one or more cameras and/or light sources (not shown) may be mounted within or to the wall of the sleeve 370 adjacent the distal end 374 to acquire images beyond the distal end 374, e.g., similar to the access ports and other devices described elsewhere herein.

In still another alternative, shown in FIG. 18B and 18C, an imaging apparatus 380' may be provided that includes a sleeve 370' including a hub 382' on its proximal end 372', e.g., adjacent the handle 330 or supporting display 386, and an imager 384' on its distal end 374, generally similar to the previous embodiments. In this alternative, the imager 384'

includes a rotatable housing 384a' carrying an imaging element 384b' on an arm 384c'. The housing 483a' may be rotatable relative to the distal end 374' of the sleeve 370' to any desired angle around the axis 326. For example, the imager 384' may include one or more motors or other actuators (not shown) that may be coupled to a control on the handle 330, which may be manipulated to rotate the housing 384a' to position the arm 384c' and, consequently, the imaging element 384b' at a desired location around the end effector 40. For example, as shown in FIG. 18C, the imaging element 384b' may be located on a right side of the end effector 40 (e.g., defining a zero degree angle or base location), while in FIG. 18D, the housing 384b' has been rotated to position the imaging element 384b' on a left side of the end effector 40 (e.g., defining a one hundred eight degree angle (180°) around the axis 326).

Optionally, the housing 384a' may also be movable axially relative to the distal end 374' of the sleeve 370,' e.g., to allow a focal length of the imaging element 384b' to be adjusted. Alternatively, the processor receiving signals from the imaging element 384b' for presentation on the display 386 may modify the images to allow for zooming or retracting the field of view of the imaging element 384b,' e.g., using software.

In addition, optionally, the apparatus 308' may include one or more features to substantially maintain a desired orientation of images presented on the display 386 that are acquired by the imaging element 384b'. For example, in one embodiment, the imaging element 384b' may be mounted on a rotating base (not shown) that rotates in an opposite direction to the housing 384a' of the imager 484,' e.g. offset by the same angle of rotation of the arm 384c' to keep the imaging element 384b' oriented "up" relative to the end effector 40. This may cause the images on the display to move in a circular motion corresponding to the arm 384c' moving but remain "top-up." Alternatively, a processor receiving signals from the imaging element 384b' for presentation on the display 386 may modify the images to maintain a stable field of view, i.e., to compensate for the circular motion of the imaging element 384b'.

In another embodiment, the imaging element 384b' may be fixed relative to the arm 384c' and the processor receiving signals from the imaging element 384b' for presentation on the display 386 may modify the images to maintain a stable field of view, i.e., maintaining a "top-up" view even if the imaging element 384b' is not oriented "up." Thus, as the imaging element 484b' rotates as the arm 384c' moves, the processor may rotate the images to maintain the top-up view.

Returning to FIG. 18A, the sleeve 370, hub 382, and imager 384 may be permanently integrated into the apparatus 308, i.e., with the sleeve 370 and hub 382 permanently mounted on the shaft 320 adjacent the handle 330. In one embodiment, the sleeve 370 and hub 382 may be fixed to the shaft 320 such that the sleeve 370 and hub 382 move integrally with the shaft 320, e.g., during introduction and/or manipulation of the shaft 320 using the handle 330. Alternatively, the sleeve 370 and hub 382 may be partially decoupled from movement of the shaft 320. For example, the sleeve 370 and hub 382 may be axially fixed relative to the shaft 320 but rotatably decoupled, i.e., such that the shaft 320 and, consequently, the end effector 40, may be rotatable relative to the sleeve 370 and therefore relative to the imager 384. Thus, the end effector 40 may be rotated within the field of view presented on the display 386 during a procedure, e.g., before or while actuating components on the end effector 40.

Alternatively, the shaft 320 (and consequently the end effector 40) may also be movable axially relative to the sleeve 370 and hub 382. For example, the sleeve 370 may be shorter than the shaft 320 such that the shaft 320 may be movable between a first or distal position, e.g., where the hub 382 contacts a portion of the handle 330 and the imager 384 is spaced a maximum distance from the end effector 40, and a second or proximal position, e.g., where the end effector 40 is immediately adjacent the imager 384. Optionally, the shaft 320 may include one or more stops, e.g., on the distal end 324 adjacent the end effector 40 to limit the range of longitudinal motion.

In another embodiment, shown in FIG. 18F, the hub 382 may include a plurality of slots or guides 382c spaced apart axially from one another with each slot 382c extending at least partially around the circumference of the lumen 376. The proximal end 322 of the shaft 320 may include an aperture or receptacle 323 that may be aligned axially and/or rotationally with one of the slots 382c, whereupon a set screw, pin, or other coupler 383 may be directed through the slot 382c into the receptacle 323. Consequently, the shaft 320 may then be fixed axially relative to the sleeve 370 while being rotatable with the angle of rotation limited by the circumferential length of the slot 382c. If desired, the coupler 383 may be removed from the receptacle 323 and the shaft 320 directed axially to one of the other slots 382c, whereupon the coupler 383 may be reengaged with the receptacle 323. Thus, the axial distance between the imager 384 and the end effector 40 may be changed to move the field of view closer or further from the end effector 40 during use and the guide

used to set the axial distance while allowing continued rotation of the shaft 320 and end effector 40.

During use, the apparatus 308 (or any of the variations just described) may be used similar to other embodiments herein to perform one or more procedures within a patient's body, e.g., an appendectomy surgery. Initially, a port (not shown) may be implanted, e.g.,
5 through the patient's skin into a surgical space, to allow introduction of the apparatus 308 and/or other devices during the procedure. As is known in the art, the port may include one or more valves or seals (also not shown) that may prevent fluids from leaking through the port when the end effector 40, shaft 320, and sleeve 370 are introduced through the port,
10 e.g., to allow insufflation of the surgical space.

When the imager 384 is positioned at a desired location within the surgical space, if desired, the display 386 may be positioned to facilitate viewing the end effector 40 and surgical space by the operator holding the handle 330. Optionally, the display 386 or the imaging sleeve 370 may include one or more features to help stabilize the apparatus 308
15 and/or the field of view of the imaging element 384b. For example, a pair of retractable legs (not shown) may be provided on the bottom of or elsewhere on the display 386 or on the sleeve 370, which may be deployed to stabilize the apparatus 308 relative to the patient's body. Optionally, the legs may be adjustable, e.g., a length and/or angle may be adjusted to position the legs against a desired location on the patient's torso after
20 introducing the apparatus 308. Alternatively, a stationary or movable frame (now shown) may be provided at the surgical site, which may be coupled to the display 386 and/or imaging sleeve 370 to stabilize the apparatus 308 during use.

If the shaft 320 is movable relative to the sleeve 370, the operator may manipulate the handle 330 to move the end effector, e.g., rotating and/or axially depending on the
25 connection between the shaft 320 and the sleeve 370/hub 38. The operator may then open and close the jaw 48, e.g., to grasp tissue between the jaws 46, 48, whereupon one or more staples may be delivered, e.g., in conjunction with using the Doppler sensor and/or thermal element, whereupon the blade may be advanced to sever the tissue, as described elsewhere herein.

30 Turning to FIGS. 19A and 19B, another exemplary embodiment of an end effector 340 is shown that may be used in conjunction with any of the stapler apparatus described elsewhere herein. Generally, similar to other embodiments, the end effector 340 includes a housing 342 that may be connected to a distal end 24 of a shaft 20 (which may be any of the

embodiments herein) or may be integrally provided on a shaft of a stapler apparatus (not shown). The end effector 340 includes first and second jaws 346, 348 carrying one or more staples (not shown) and, optionally, one or more additional components for use during a procedure, e.g., a blade 60 (shown in FIG. 19A, a Doppler sensor and/or a thermal element (not shown), similar to other embodiments herein. When the end effector 340 is mechanically connected to the shaft 20 by one or more connectors (not shown), additional connectors may automatically engage, e.g., to mechanically couple actuatable components on the end effector 340 with actuator elements in the shaft 20 and/or electrically couple electrical components on the end effector 340 with corresponding wires in the shaft 20 (not shown), as will be appreciated by those skilled in the art.

Similar to other embodiments herein, the first jaw 346 may be integrally formed with or otherwise fixed relative to the housing 342, e.g., such that the first jaw 346 remains aligned with the longitudinal axis 26 of the shaft 20 during use. The second jaw 348 may be movably mounted to the housing 342, e.g., by one or more hinges or other features (not shown) such that the second jaw 348 may be pivotable between open and closed positions, also similar to other embodiments herein. As shown in FIG. 19A, the first jaw 346 may receive a disposable cartridge 350, e.g., received in a cavity of the first the jaw 346, that carries a plurality of staples (not shown), e.g., in arranged in a plurality of rows aligned with the axis 26 of the shaft 20. For example, in the embodiment shown, the contact surface 350a of the cartridge 350 includes recesses or receptacles 352 arranged in three rows although it will be appreciated that the receptacles and/or staples may include any of the embodiments described elsewhere herein.

Unlike previous embodiments, the end effector 340 includes a grasper 360 that may be movable relative to the jaws 346, 348. For example, as shown, the grasper 360 includes an elongate tubular body 362 including a proximal end coupled to an actuator within the shaft 20 (not shown) and a distal end 364 disposed adjacent the first jaw 346. Fingers or other grasper elements 368 may extend distally from the distal end 364, e.g., from a lumen 366 extending between the ends of the tubular body 362. As shown, each grasper element 368 may include a hooked tip 368a although it will be appreciated that other tips may be provided to facilitate grasping tissue or other structures between the grasper elements 368.

The tubular body 362 of the grasper 360 may be aligned with the longitudinal axis 26 of the shaft 20 and, optionally, may be movable axially relative to the first jaw 346, e.g., between a proximal position, where the grasper elements 368 are disposed between the jaws

346, 348 or immediately beyond the distal tip 346a of the first jaw 346, and a distal position, where the grasper elements 368 are disposed distally away from the distal tip 346a. For example, the grasper elements 368 may be retractable entirely into the lumen 366 such that the entire grasper 360 may be retracted into the jaws 346, 348 and/or the jaws 346, 348 may include a recess (not shown) sized to receive the grasper elements 368 when the grasper 360 is retracted entirely into the jaws 346, 348.

The grasper elements 368 may be actuatable, e.g., using an actuator on a handle coupled to the shaft 20 (not shown), similar to other embodiments herein, e.g., such that the grasper elements 368 may be opened to position them around a tissue structure and then at least partially closed to secure the structure between them. For example, the grasper elements 368 may be biased to an open position and may be coupled to a rod or wire (not shown) extending into the lumen 366 of the tubular body 362 such that the grasper elements 368 may be at least partially retracted into the lumen 366, thereby directing the grasper elements 368 towards one another. Thus, the rod or wire may be directed axially relative to the tubular body 362 to deploy and open the grasper elements 368 and then retract and close them, as desired. Alternatively, other actuator elements (not shown) may be coupled to the grasper elements 368 to open and close them.

During use, the end effector 340 may be connected to the shaft 20 of a stapler apparatus (including a handle/reusable portion and, optionally, an imaging device similar to other embodiments herein) and used to perform a procedure within a patient's body, e.g., a tubal ligation procedure as shown in FIG. 20. For example, with the jaws 346, 348 closed and the grasper 360 retracted (e.g., entirely between the jaws 346, 348 or immediately distal to the jaws 346, 348), the end effector 340 may be introduced into a surgical space immediately adjacent a target structure (not shown), e.g., to position the jaws 346, 348 adjacent to one of the patient's fallopian tubes 4. The jaw 348 may be opened and the grasper 360 advanced until the grasper elements 368 are positioned around the fallopian tube 4, as shown. The grasper elements 368 may then be actuated to close and/or otherwise secure the fallopian tube 4, whereupon the grasper 360 may be retracted or the end effector 360 advanced to position the fallopian tube 4 between the jaws 346, 348. Similar to other embodiments herein, the second jaw 348 may be closed to clamp the tissue and one or more staples may be directed through the fallopian tube 4. The blade 60 may then be advanced to sever the fallopian tube 4. The second jaw 348 and/or grasper elements 368 may then

release the severed and stapled ends of the fallopian tube 4, and the apparatus may be removed.

Turning to FIGS. 21A-21C, another example of end effector 440 is shown that includes a grasper 460 positioned adjacent jaws 446, 448 of the end effector 440. Similar to
5 other embodiments herein, the end effector 440 includes a housing 442 that may be connected to a shaft 20 of a handle portion 30 (which may be any of the embodiments herein) and a pair of jaws 446, 448 for grasping tissue and/or delivering staples (not shown). Optionally, the end effector 440 may include one or more other components, e.g., one or more of a blade or other cutting element, a Doppler sensor, a thermal element, and the like
10 (not shown).

In this embodiment, the grasper 460 is connected to the housing 442 adjacent to the jaws 346, 348, e.g., at hinge or connection point 462 proximal to the jaws 446, 448. The grasper 460 includes one or more linkages 466 (two shown, although fewer or more linkages may be provided) that are coupled to grasper elements 468. The linkages 466 may
15 be coupled to an actuator (not shown) within the housing 442 and shaft 20 such that the grasper elements 468 may be manipulated, e.g., moved laterally relative to the housing 442 and/or to open and close the grasper elements 468. For example, the grasper 460 may be provided initially immediately adjacent the housing 442 and jaws 446, 448, e.g., aligned substantially axially with the shaft 20 in a retracted position, e.g., as shown in FIG. 21B, to
20 facilitate introduction into a surgical space. Once the end effector 440 is positioned within the surgical space, the grasper 460 may be actuated to move the grasper elements 468 away from the housing 442, as shown in FIG. 21C, e.g. to allow the grasper elements 468 to surround and hold a tissue structure (not shown), e.g., similar to the previous embodiment.

The grasper 460 may then be manipulated to pull the tissue structure between the
25 jaws 446, 448, whereupon the jaw 448 may be closed and staples delivered into the tissue structure. For example, the linkages 466 may be configured to align the grasper elements 468 axially relative to the shaft while moving laterally to grasp a tissue structure. When the grasper 460 is directed back towards the retracted position, the tissue structure may be pulled between the jaws 446, 448. Optionally, if the end effector 440 includes a blade or
30 other cutting element, after delivering the staples, the tissue structure may be severed and then the jaws 446, 448 and grasper elements 468 open to release the severed tissue structure.

Turning to FIGS. 22A and 22B, another alternative embodiment of a stapler apparatus is provided that includes an end effector 340 mounted on a distal end 524 of an

elongate shaft 520. Similar to the previous embodiments, the end effector 340 includes first and second jaws 346, 348 carrying one or more staples (not shown) and, optionally, one or more additional components for use during a procedure, e.g., a blade 60, a Doppler sensor, a thermal element, and the like. In addition, the end effector 340 includes a grasper 360 that may be movable relative to the jaws 346, 348 also similar to the previous embodiment. As shown, the grasper 360 may be movable axially, e.g., from a retracted position within the shaft 520 (FIG. 22B) to an advanced or deployed position (FIG. 22A). As shown, the grasper 360 includes an elongate tubular body 362 a pair of fingers or other grasper elements 368 that extend distally from a distal end 364 of a tubular body 362. The grasper elements 368 may be actuatable, e.g., using an actuator on a handle coupled to the shaft 520 (not shown), similar to other embodiments herein.

In addition, a second grasper 560 is provided that also includes a pair of fingers or grasper elements 568 extending from a distal end 564 of a tubular body 562. The grasper 560 may be movable relative to the end effector 340, e.g., slidable axially within a lumen 528 within a wall of the shaft 520, e.g., as shown in FIG. 22C. In one embodiment, the grasper 560 may be retractable into the lumen 528 to withdraw the grasper elements 568 into the shaft 520. Optionally, the grasper 560 may be removably entirely from the shaft 520, e.g., out of a port in a handle coupled to the shaft 520, e.g., such that the grasper 560 may be selectively introduced and/or removed via the lumen 528. In addition or alternatively, other auxiliary instruments (not shown) may be introduced and/or removed via the lumen 528.

During use, the end effector 340 may be connected to the shaft 520 (of a stapler apparatus including a handle/reusable portion and, optionally, an imaging device similar to other embodiments herein) and used to perform a procedure within a patient's body. The graspers 360, 560 may be advanced and/or otherwise manipulated to use the grasper elements 368, 568 to hold and/or manipulate tissue structures as desired, e.g., to position the tissue structure between the jaws 346, 348. Similar to other embodiments herein, the second jaw 348 may then be closed to clamp the tissue and one or more staples may be directed through the tissue structure and/or the blade 60 may then be advanced to sever tissue. The second jaw 348 and/or grasper elements 368, 568 may then release the severed and stapled ends of the tissue, and the apparatus may be removed.

Turning to FIG. 22C, an exemplary detail is shown of a shaft 520' that may be provided to deploy and/or retract the graspers 368, 568. As shown, the shaft 520' includes a

central lumen 527,' which may slidably receive the first grasper 368 shown in FIGS. 22A and 22B. It will be appreciated that other auxiliary instruments (not shown) may also be introduced via the central lumen 527,' e.g., between the jaws 346, 348 of the end effector 340. For example, a laser or other coagulation device (not shown) may be introduced via
5 the lumen 527' between the jaws 346, 348 and/or distally beyond the end effector 340, if desired, e.g., to cauterize, ablate, or otherwise treat tissue.

In addition, as shown in FIG. 22C, one or more auxiliary lumens 528' (two shown offset one hundred eight degrees from one another) may be provided within a wall of the shaft 520' for receiving the second grasper 568 and/or other instruments. In one
10 embodiment, the auxiliary lumen 528a' may include a ramped outlet 529a' to guide the instrument laterally outward from the shaft 520', or the auxiliary lumen 528b' may include an elbow outlet 529b' as desired depending on the instrument(s) to be introduced via the auxiliary lumen(s) 528.'

Turning to FIG. 23, a summary of actuator and end effectors is shown that may be
15 combined to provide various apparatus for performing a procedure, e.g., laparoscopically, as described elsewhere herein. For example, the actuator may include either a reusable handle/shaft portion 10, i.e., including a handle 30 coupled to a shaft 20, or a robotic control system 10,' as described elsewhere herein. Depending on the procedure, a desired end effector may be selected and coupled to the shaft 20, 20' and then introduced into a patient's
20 body. For example, housing 42 of end effector 40 may be connected to the shaft 20, 20' to staple a tissue structure captured between jaws 46, 48. Optionally, the end effector 40 may include one or more components similar to other embodiments herein, e.g., a blade or other cutting element, a grasper, a Doppler sensor, and/or a thermal element depending on the needs of the particular procedure.

Alternatively, other end effectors 240 may be connected to the shaft 20, 20', e.g.,
25 exchanged with or for the end effector 40. For example, end effector 240a may include a pair grasper elements 248a with hooked tips, while end effector 240b may include a pair of alligator jaws 248b, either of which may be actuated to open and close to grasp and/or otherwise manipulate tissue. End effector 240c includes a loop 248c that may be expanded
30 and/or contracted to grasp a tissue structure within the loop 248c.

Turning to FIG. 24, another example of a clip or fastener 190 is shown that includes a curved base 192 from which opposing arms 194 extend, e.g., to define a generally "U" or "V" shape. The clip 190 may be formed from stainless steel or other biocompatible

material, similar to other fasteners herein, that may be malleable or deformable. For example, as shown in FIG. 25, the clip 190 may be held between jaws 46, 48 of an end effector 40, which may be any of the embodiments herein, e.g., such that the arms 194 extend along opposite contact surfaces of the jaws 46, 48. The jaws 46, 48 may include
5 recesses or other features to hold and/or stabilize the base 192 of the clip 190.

During use, the end effector 40 may be introduced into a surgical space, similar to other embodiments herein, and a tissue structure positioned between the arms 194 and jaws 46, 48. For example, the second jaw 48 may be actuated to close, i.e., pivot towards the first jaw 46, similar to other embodiments herein, thereby directing the arms 194 of the clip
10 190 towards one another, e.g., to clamp the arms 194 around the tissue structure. This action may plastically deform at least the base 192 of the clip 190 such that subsequent opening of the second jaw 48 leaves the clip 190 secured around the tissue structure. The end effector 40 may be removed leaving the clip 190 and/or additional action may be taken. For example, if the end effector 40 includes a blade or other cutting element, the blade may
15 be actuated to sever the tissue structure and/or if the end effector 40 includes a thermal element, the thermal element may be activated to cauterize the tissue.

Alternatively, it will be appreciated that other staples or clips may be delivered using any of the stapler apparatus herein, such as those described in the provisional application incorporated by reference herein.

It will be appreciated that elements or components shown with any embodiment herein are exemplary for the specific embodiment and may be used on or in combination with other embodiments disclosed herein. In addition, although the apparatus herein have been described for particular use during an appendectomy procedure. It will be appreciated that the apparatus and methods herein may be used in a variety of surgical procedures, e.g.,
20 including open, minimally invasive, laparoscopic, and other procedures, where it is desired to staple and remove target tissues, e.g., within a patient's intestine, lungs, vasculature, and other locations.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in
30 detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the appended claims.

We claim:

1. An apparatus for performing a medical procedure, comprising:
a shaft comprising a proximal end, a distal end sized for introduction into a patient's
body, and a longitudinal axis extending between the proximal and distal ends;
5 first and second jaws on the distal end of the shaft that are movable relative to one
another between open and closed positions, thereby directing first and contact surfaces of
the first and second jaws away from and towards one another, respectively, the first jaw
carrying one or more staples deployable from the first contact surface;
a Doppler sensor on one of the first or second contact surfaces;
10 a thermal element disposed on one of the first jaw or second jaw for delivering
thermal energy; and
a handle on the proximal end of the shaft comprising a first actuator for selectively
moving the jaws between the open and closed positions, a second actuator for deploying one
or more staples from the first jaw into tissue between the first and second contact surfaces
15 and toward the second jaw to deform the one or more staples, and a third actuator for
activating the Doppler sensor to detect blood flow in the tissue.

2. The apparatus of claim 1, wherein the first and second jaws are carried on an
end effector removably coupled to the distal end of the shaft.

3. The apparatus of claim 2, further comprising a cartridge removably received
in the first jaw, the cartridge carrying the one or more staples.

4. The apparatus of claim 1, wherein the first jaw is fixed relative to the shaft
25 and the second jaw is pivotable relative to the first jaw between the open position to allow
tissue to be positioned on the first contact surface, and the closed position to secure the
tissue between the first and second contact surfaces.

5. The apparatus of claim 3, wherein the first actuator comprises a trigger for
30 directing the second jaw from the open position to the closed position to secure the tissue
between the first and second contact surfaces and the second actuator comprises a wedge
mechanism for driving the one or more staples from the first jaw through the tissue and
towards the second jaw to staple the tissue.

6. The apparatus of claim 5, wherein the first actuator further comprises a locking mechanism for locking the second jaw in the closed position.

5 7. The apparatus of claim 1, further comprising a processor coupled to the Doppler sensor for receiving signals from the Doppler sensor to identify blood flow in tissue contacting the Doppler sensor, and an output device coupled to the processor for providing an output indicating whether blood is flowing in the tissue.

10 8. The apparatus of claim 1, further comprising a cutting element disposed on the distal end, the handle comprising a fourth actuator for advancing the cutting element between the first and second jaws to sever the stapled tissue.

15 9. The apparatus of claim 1, wherein the first jaw carries a cartridge including first and second sets of staples positioned on opposite sides of the cutting element.

20 10. The apparatus of claim 9, wherein the first and second sets of staples are positioned in rows aligned with the longitudinal axis, and wherein the cutting element is advanceable from a retracted position to an advanced position aligned with the longitudinal axis.

25 11. The apparatus of claim 1, wherein the thermal element is disposed on one of the first jaw or second jaw generally opposite the Doppler sensor for delivering thermal energy to the stapled tissue.

30 12. The apparatus of claim 1, wherein the thermal element comprises an electrode carried on the first jaw, and wherein a source of electrical energy is coupled to the thermal element, the handle comprising an actuator for activating the source of energy to deliver the electrical energy to the electrode to deliver thermal energy to the stapled tissue.

13. The apparatus of claim 1, further comprising one or both of a camera and a light source on the distal end to facilitate imaging a region within the patient's body into which the first and second jaws are introduced.

14. An end effector for a stapler apparatus including a shaft comprising a proximal end including a handle, a distal end sized for introduction into a patient's body, and a longitudinal axis extending between the proximal and distal ends, the end effector comprising:

one or more connectors for removably connecting the end effector to the distal end of the shaft;

first and second jaws that are movable relative to one another between open and closed positions using a first actuator on the handle, thereby directing first and contact surfaces of the first and second jaws away from and towards one another, respectively, to engage tissue between the first and second contact surfaces;

one or more staples carried by the first jaw such that actuation of a second actuator on the handle deploys one or more staples from the first jaw into tissue between the first and second contact surface towards the second jaw to deform the one or more staples; and

a Doppler sensor on one of the first and second contact surfaces to detect blood flow in the tissue.

15. The end effector of claim 14, further comprising a cartridge removably received in the first jaw, the cartridge carrying the one or more staples.

16. The end effector of claim 14, wherein the first jaw is fixed relative to the shaft when the cartridge is connected to the distal end of the shaft and the second jaw is pivotable relative to the first jaw using the first actuator between the open position to allow tissue to be positioned on the first contact surface, and the closed position to engage the tissue, the end effector further comprising a wedge mechanism advanceable by the second actuator to drive the one or more staples from the first jaw through the tissue.

17. The end effector of claim 14, wherein the one or more staples comprise first and second sets of staples positioned in one or more rows aligned with the longitudinal axis of the shaft, the end effector further comprising a cutting element advanceable from a retracted position to an advanced position aligned with the longitudinal axis to sever the stapled tissue.

18. The end effector of claim 17, wherein each of the first and second sets of staples includes between one and five rows aligned with the longitudinal axis.

19. The end effector of claim 17, wherein the first and second sets of staples are
5 positioned in rows on opposite sides of the cutting element.

20. The end effector of claim 17, wherein the first set of staples comprise a plurality of first staples arranged in one or more rows aligned with the longitudinal axis and the second set of staples comprise a plurality of second staples arranged in one or more
10 rows aligned with the longitudinal axis, and wherein at least some of the second staples are a different size than the first staples.

21. The end effector of claim 17, wherein the first set of staples comprise a plurality of first staples aligned in a row, at least some of the first staples having a different
15 size than other first staples.

22. The end effector of claim 14, further comprising a thermal element disposed on one of the first and second jaws for delivering thermal energy to the stapled tissue.

20 23. The end effector of claim 22, wherein the thermal element comprises an electrode carried on one of the first and second jaws, and wherein a source of electrical energy is coupled to the thermal element when the end effector is connected to the distal end of the shaft for delivering electrical energy to the electrode to deliver thermal energy to the stapled tissue.

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24. The end effector of claim 14, further comprising one or both of a camera and a light source to facilitate imaging a region within the patient's body into which the first and second jaws are introduced.

30 25. An apparatus for performing a medical procedure, comprising:
a shaft comprising a proximal end, a distal end sized for introduction into a patient's body, and a longitudinal axis extending between the proximal and distal ends;

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first and second jaws on the distal end of the shaft that are movable relative to one another between open and closed positions, thereby directing first and contact surfaces of the first and second jaws away from and towards one another, respectively;

first and second sets of staples carried by the first jaw and positioned on opposite
5 sides of a cutting element, wherein at least some of the staples are a different size than other staples; and

a handle on the proximal end of the shaft comprising:

a first actuator for directing one or both of the first and second jaws to the closed position to secure tissue between the first and second contact surfaces, and

10 a second actuator for deploying the staples from the first jaw through the secured tissue towards the second jaw to deform the staples; and

a third actuator for advancing the cutting element from a retracted position to an advanced position aligned with the longitudinal axis to sever the stapled tissue.

15 26. The apparatus of claim 25, wherein the first and second set of staples are carried in a cartridge removably received in a cavity of the first jaw.

27. The apparatus of claim 25, wherein the first and second jaws are on an end effector removable from the distal end of the shaft/

20

28. An apparatus for performing a medical procedure, comprising:

a shaft comprising a proximal end, a distal end sized for introduction into a patient's body, and a longitudinal axis extending between the proximal and distal ends;

25 first and second jaws on the distal end of the shaft that are movable relative to one another between open and closed positions, thereby directing first and contact surfaces of the first and second jaws away from and towards one another, respectively;

a cartridge carried by the first jaw carrying first and second sets of staples positioned on opposite sides of a cutting element, wherein at least some of the staples are a different size than other staples; and

30 a handle on the proximal end of the shaft comprising:

a first actuator for directing one or both of the first and second jaws to the closed position to secure tissue between the first and second contact surfaces, and

a second actuator for deploying the staples from the first jaw through the secured tissue towards the second jaw to deform the staples; and

a third actuator for advancing the cutting element from a retracted position to an advanced position aligned with the longitudinal axis to sever the stapled tissue.

5

29. The apparatus of claim 28, wherein the first and second jaws are carried on an end effector removable from the distal end of the shaft/

30. The apparatus of claim 28, wherein the cartridge is removable from the first
10 jaw.

31. The apparatus of claim 28, wherein the cartridge at least partially defines the first contact surface.

15 32. The apparatus of claim 28, wherein the first and second sets of staples are arranged in rows aligned with the longitudinal axis.

33. The apparatus of claim 32, wherein each of the first and second sets of staples includes one or more rows of staples aligned with the longitudinal axis.

20

34. The apparatus of claim 32, wherein all of the staples in the first set are a different size than all of the staples in the second set.

35. The apparatus of claim 32, wherein the first set or the second set of staples
25 comprises a first subset of staples and a second subset of staples, and wherein the second subset of staples are a different size than the first subset of staples.

36. The apparatus of claim 28, further comprising a Doppler sensor on one of the first and second contact surfaces, and a fourth actuator for activating the Doppler sensor to
30 detect blood flow in the tissue.

37. The apparatus of claim 28, further comprising a thermal element disposed on one of the first and second jaws for delivering thermal energy to the stapled tissue.

38. The apparatus of claim 28, wherein the first jaw is fixed relative to the shaft and the second jaw is pivotable relative to the first jaw between the open position to allow tissue to be positioned on the contact surface, and the closed position to secure the tissue
5 between the first and second contact surfaces.

39. The apparatus of claim 38, wherein the first actuator comprises a trigger for directing the second jaw from the open position to the closed position to secure the tissue between the first and second contact surfaces and the second actuator is actuatable
10 independent of the trigger for driving the one or more staples from the first jaw through the tissue and towards the second jaw to staple the tissue.

40. The apparatus of claim 39, wherein the first actuator further comprises a locking mechanism for locking the second jaw in the closed position.

41. An end effector for a stapler apparatus including a shaft comprising a proximal end including a handle, a distal end sized for introduction into a patient's body, and a longitudinal axis extending between the proximal and distal ends, the end effector comprising:
15

20 one or more connectors for removably connecting the end effector to the distal end of the shaft;

first and second jaws that are movable relative to one another between open and closed positions using a first actuator on the handle, thereby directing first and contact surfaces of the first and second jaws away from and towards one another, respectively; and

25 a cartridge carried by the first jaw comprising first and second sets of staples arranged in rows on opposite sides of a cutting element such that actuation of a second actuator on the handle deploys the staples into tissue between the first and second contact surfaces and drives the staples against the second jaw to deform the one or more staples, wherein at least some of the staples are a different size than other staples.

30 42. The end effector of claim 41, wherein the cartridge is removable from the first jaw.

43. The end effector of claim 41, wherein the cartridge at least partially defines the first contact surface.

44. The end effector of claim 41, wherein each staple includes first and second
5 tines extending from opposite ends of a base, and wherein at least some of the staples include a base having a length different than other staples such that the tines are spaced from one another by different distances.

45. The end effector of claim 41, wherein each staple includes first and second
10 tines extending from opposite ends of a base, and wherein at least some of the staples have tine lengths that are different than other staples.

46. The end effector of claim 41, wherein the first tines include one or more notches and wherein the second tines have lengths sufficiently long such tips of the second
15 tines are engaged in the one or more notches when the staples are deformed.

47. The end effector of claim 41, wherein each staple includes first and second tines extending from opposite ends of a base, and wherein at least some of the staples have second tines having a length different than other staples.

48. The end effector of claim 41, wherein each of the first and second sets of staples includes one or more rows of staples aligned with the longitudinal axis.

49. The end effector of claim 41, wherein all of the staples in the first set are a
25 different size than all of the staples in the second set.

50. The end effector of claim 41, wherein the first set of staples comprise a first subset of staples and a second subset of staples, and wherein the second subset of staples are a different size than the first subset of staples.

51. The end effector of claim 41, further comprising a Doppler sensor on one of the first and second contact surfaces to detect blood flow in the tissue.

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52. The end effector of claim 41, further comprising a thermal element disposed on one of the first and second jaws for delivering thermal energy to the stapled tissue.

53. The end effector of claim 52, wherein the thermal element comprises an electrode carried on the first jaw, and wherein a source of electrical energy is coupled to the thermal element when the cartridge is connected to the distal end of the shaft for delivering electrical energy to the electrode to deliver thermal energy to the stapled tissue.

54. The end effector of claim 41, further comprising one or both of a camera and a light source to facilitate imaging a region within the patient's body into which the first and second jaws are introduced.

55. A staple for delivery into tissue, comprising:
a substantially straight base element including first and second ends;
a first tine extending from the first end substantially perpendicular to the base, the first tine having a first length and including one or more notches adjacent a tip of the first tine; and
a second tine extending from the second end substantially perpendicular to the base to a second tip, the second tine having a second length longer than the first length and longer than the length of the straight base such that, when the second tine is bent adjacent the base, the second tip of the second tine is engaged in the one or more notches located on the first tine.

56. The staple of claim 55, wherein the base includes a third length between the first and second tines, and wherein the second length is longer than the third length such that the second tip is receivable in the one or more notches.

57. The staple of claim 55, wherein the one or more notches are located on an inside surface of the first tine and the one or more notches include a blunt upper edge such that, when the second tip of the second tine is received in the notch, the second tip cannot move upwardly out of the notch.

58. The staple of claim 57, wherein the first tine has a single notch.

59. The staple of claim 57, wherein the first tine includes a plurality of notches spaced apart from one another along the first length, each of the notches including a blunt upper edge and a tapered lower edge to provide a ratchet allowing the second end to travel
5 downwardly into the notches sequentially but prevent the second tip from moving upwardly out of the notches.

60. The staple of claim 55, wherein the base, first tine, and second tine have a substantially uniform cross-section.

61. The staple of claim 60, wherein the cross-section is one of rectangular, oblong, or flattened circular.

62. The staple of claim 60, wherein the base, first tine, and second tine lie within
15 a plane, and wherein the cross-section of the staple defines a major dimension perpendicular to the plane and a minor dimension within the plane, the major dimension larger than the minor dimension.

63. The staple of claim 55, wherein the base defines an axis extending between
20 the first and second ends, and wherein the base includes a non-linear shape between the first and second ends that extends transversely relative to the axis.

64. The staple of claim 63, wherein the non-linear element comprises a bump that extends laterally from the axis.

65. The staple of claim 55, further comprising filleted transitions at the first and second ends transitioning from the base to the first and second tines.

66. The staple of claim 65, wherein the filleted transition from the base to the
30 second tine has a larger radius of curvature than the filleted transition from the base to the first tine.

67. A port for introducing one or more instruments into a patient's body, comprising:

an elongate tubular member comprising a proximal end, a distal end sized for introduction into a patient's body, and a lumen extending between the proximal and distal ends, thereby defining a longitudinal axis there between;

a display; and

one or more deployment arms on the tubular member adjacent the distal end carrying an imaging device, each deployment arm comprising a first end pivotably coupled to the tubular member and a second free end that is movable from a retracted position wherein the second end is aligned with a wall of the tubular member and a deployed position wherein the second end moves outwardly relative to the longitudinal axis for presenting images on the display.

68. The port of claim 67, wherein the one or more deployment arms comprise first and second arms, the first arm carrying an illumination source on the second end thereof, and the second arm carrying an imaging element on the second end thereof.

69. The port of claim 68, wherein the imaging element comprises a lens carried on the second end of the second arm and wherein a fiber optic element extends from the lens to a camera located in the proximal end of the port for delivering images to the camera.

70. The port of claim 69, wherein the camera comprises a CCD or CMOS device.

71. The port of claim 67, wherein the display is mounted on a proximal end of the tubular member.

72. The port of claim 69, wherein the camera is coupled to a processor is located within a housing carrying the display, the processor configured to process the signals from the camera for presentation on the display.

73. The port of claim 71, wherein the display is removable from a hub on the proximal end of the tubular member.

74. The port of claim 71, wherein the display is permanently mounted on the proximal end of the tubular member.

5 75. The port of claim 67, wherein the display is separate from the tubular member, the port further comprising a wireless communication interface carried by the tubular member for transmitting signals from the imaging device to the display.

10 76. The port of claim 67, wherein the first end of the one or more deployment arms including a ramped feature extending into lumen such that introduction of an instrument through the lumen causes the instrument to contact the ramped feature and automatically direct the one or more deployment arms from the retracted position to the deployed position.

15 77. The port of claim 67, further comprising an actuator on the proximal end of the tubular member for selectively directing the one or more deployment arms between the retracted and deployed positions.

20 78. A port for introducing one or more instruments into a patient's body, comprising:

an elongate tubular member comprising a proximal end, a distal end sized for introduction into a patient's body, and a primary lumen extending between the proximal and distal ends for receiving an instrument therethrough, and a plurality of secondary lumens positioned around the primary lumen and extending between the proximal and distal ends;

25 and

a video module comprising:

a hub;

a display; and

30 a plurality of elongate imaging elements mounted to the hub and sized for introduction simultaneously into respective secondary lumens of the tubular member such that distal tips of the imaging elements are positioned adjacent the distal end of the tubular member for acquiring images beyond the distal end.

79. The port of claim 78, wherein the display is mounted on the hub, the display coupled to the imaging elements for presentation of the images on the display.

80. The port of claim 78, wherein at least one of the imaging elements comprises an illumination source on its distal tip for delivering light beyond the distal end of the tubular member.

81. The port of claim 78, wherein at least one of the imaging elements comprises a lens on its distal tip for acquiring the images.

82. The port of claim 81, wherein the lens is coupled to an optical conductor extending to the hub for transmitting the images to a camera in the hub.

83. The port of claim 82, wherein the camera comprises a CCD or CMOS device for converting the images to signals, the camera communicating the signals to the display for presenting the acquired images.

84. The port of claim 83, wherein the camera is coupled to the display by one or more wires.

85. The port of claim 83, wherein the display is separate from the hub and wherein the camera is coupled to a communication interface carried by the hub for wirelessly transmitting the signals from the camera to the display.

86. An apparatus for performing a medical procedure, comprising:
a shaft comprising a proximal end, a distal end sized for introduction into a patient's body, and a longitudinal axis extending between the proximal and distal ends;
first and second jaws on the distal end of the shaft that are movable relative to one another between open and closed positions, thereby directing first and contact surfaces of the first and second jaws away from and towards one another, respectively, the first jaw carrying one or more staples deployable from the first contact surface;
a handle on the proximal end of the shaft comprising a first actuator for selectively moving the jaws between the open and closed positions, and a second actuator for deploying

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one or more staples from the first jaw into tissue between the first and second contact surfaces and toward the second jaw to deform the one or more staples;

an imaging sleeve disposed around the shaft comprising a hub adjacent the proximal end of the shaft and an imager adjacent the distal end of the shaft; and

5 a display mounted to the hub.

87. The apparatus of claim 86, wherein the display is mounted to the hub by an adjustable mount.

10 88. The apparatus of claim 87, wherein the mount comprises one or more ball and socket joints between the hub and the display.

89. The apparatus of claim 87, wherein the mount comprises a hinged joint between the hub and the display.

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90. The apparatus of claim 86, wherein the shaft is rotatable about the longitudinal axis relative to the imaging sleeve such that the end effector may be rotated relative to a field of view of the imager.

20 91. The apparatus of claim 86, wherein the shaft is movable axially along the longitudinal axis relative to the imaging sleeve such that the imager may be directed closer to and further from the end effector to adjust the field of view of the imager.

25 92. The apparatus of claim 91, wherein the shaft is movable axially to adjust zoom and/or focus of the imager.

93. The apparatus of claim 91, wherein the shaft is movable between proximal and distal positions.

30 94. The apparatus of claim 91, wherein the hub comprises a plurality of guides spaced apart axially from one another, the apparatus further comprising a coupler configured to slidably engage one of the guides and the shaft to prevent axial motion of the shaft once the coupler is engaged while allow rotational movement.

95. The apparatus of claim 94, wherein the plurality of guides comprise a plurality of circumferential slots in the hub, and wherein the coupler comprises a set screw or pin receivable through each of the slots into a recess in the shaft, the set screw or pin
5 slidable circumferentially within the slots to allow rotational movement of the shaft while preventing axial motion.

96. The apparatus of claim 86, further comprising a cutting element between the jaws, the handle comprising a third actuator for advancing the cutting element to sever
10 tissue between the jaws.

97. The apparatus of claim 86, further comprising:
a Doppler sensor on one of the first or second contact surfaces;
a thermal element disposed on one of the first jaw or second jaw for delivering
15 thermal energy; and
wherein the handle comprises a third actuator for activating the Doppler sensor to detect blood flow in the tissue.

98. The apparatus of claim 86, wherein the imager comprises:
20 a housing rotatably mounted on the distal end of the shaft;
an arm extending radially from the housing; and
an imaging element carried on the arm, wherein rotation of the housing causes the imaging element to travel around the axis.

99. The apparatus of claim 98, further comprising a third actuator coupled to the housing for controlling rotation of the housing.
25

100. The apparatus of claim 98 or 99, wherein the imaging element is rotatably mounted to the arm, an actuator coupled to the imaging element to rotate the imaging
30 element in a direction opposite the direction the housing is rotated to maintain a desired orientation of images acquired by the imaging element presented on the display.

101. The apparatus of claim 98, wherein the housing is movable axially relative to the distal end of the shaft e.g., to allow a focal length of the imaging element to be adjusted.

102. The apparatus of claim 98, further comprising a processor receiving signals
5 from the imaging element for presentation on the display, the processor configured to modify the images to allow for zooming or retracting the field of view of the imaging element.

103. The apparatus of claim 98, further comprising a processor for receiving
10 signals from the imaging element for presentation on the display, the processor configured to modify the images to maintain a stable field of view to compensate for the circular motion of the imaging element.

104. An apparatus for performing a medical procedure, comprising:
15 a shaft comprising a proximal end, a distal end sized for introduction into a patient's body, and a longitudinal axis extending between the proximal and distal ends;

first and second jaws on the distal end of the shaft that are movable relative to one another between open and closed positions, thereby directing first and contact surfaces of the first and second jaws away from and towards one another, respectively, the first jaw
20 carrying one or more staples deployable from the first contact surface;

a grasper comprising a distal end extendable between the first and second jaws, the grasper distal end comprising a pair of grasper elements; and

a handle on the proximal end of the shaft comprising a first actuator for selectively moving the jaws between the open and closed positions, a second actuator for deploying one
25 or more staples from the first jaw into tissue between the first and second contact surfaces and toward the second jaw to deform the one or more staples; and a third actuator for manipulating the grasper to grasp tissue with the grasper elements and pull the tissue between the first and second jaws.

30 105. The apparatus of claim 104, wherein the third actuator is configured to direct the grasper between a proximal position wherein the grasper elements are positioned within the shaft and a distal position wherein the grasper elements are positioned distally beyond the first and second jaws.

106. The apparatus of claim 104, further comprising a second grasper deployable from the distal end of the shaft adjacent the first and second jaws, the second grasper comprising a fourth actuator for manipulating the second grasper to grasp and manipulate
5 tissue.

107. The apparatus of claim 106, wherein the second grasper is slidably received within an auxiliary lumen of the shaft.

108. The apparatus of claim 107, wherein the fourth actuator is configured to direct the second grasper between a proximal position wherein the grasper elements are positioned within the auxiliary lumen and a distal position wherein the grasper elements are positioned distally beyond the first and second jaws.

109. The apparatus of claim 107, wherein the second grasper is removable entirely from the auxiliary lumen.

110. The apparatus of claim 104, wherein the shaft comprises an auxiliary lumen extending from the handle to a port in the distal end of the shaft for slidably receiving one
20 or more instruments.

111. The apparatus of claim 110, further comprising an instrument slidably received within the auxiliary lumen such that an active end of the instrument is deployable from the port to perform a procedure.

112. The apparatus of claim 104, wherein the grasper is slidably received within a lumen extending from the handle to the distal end of the shaft.

113. The apparatus of claim 112, wherein the grasper is removable entirely from
30 the lumen.

114. The apparatus of claim 113, further comprising an instrument slidably received within the lumen when the grasper is removed such that an active end of the instrument is deployable distally beyond the first and second jaws.

5 115. The apparatus of claim 114, wherein the instrument comprises a laser device.

116. The apparatus of claim 104, further comprising:
a Doppler sensor on one of the first or second contact surfaces; and
a thermal element disposed on one of the first jaw or second jaw for delivering
10 thermal energy.

117. The apparatus of claim 116, further comprising a processor coupled to the Doppler sensor for receiving signals from the Doppler sensor to identify blood flow in tissue contacting the Doppler sensor, and an output device coupled to the processor for
15 providing an output indicating whether blood is flowing in the tissue.

118. The apparatus of claim 104, wherein the first and second jaws are carried on an end effector removably coupled to the distal end of the shaft.

20 119. The apparatus of claim 104, further comprising a cartridge removably received in the first jaw, the cartridge carrying the one or more staples.

120. The apparatus of claim 104, further comprising a cutting element disposed on the distal end, the handle further comprising an actuator for advancing the cutting
25 element between the first and second jaws to sever the stapled tissue.

121. An apparatus for performing a medical procedure, comprising:
a shaft comprising a proximal end connectable to a robotic control system, a distal end sized for introduction into a patient's body, and a longitudinal axis extending between
30 the proximal and distal ends;

first and second jaws on the distal end of the shaft that are movable relative to one another between open and closed positions, thereby directing first and contact surfaces of

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the first and second jaws away from and towards one another, respectively, the first jaw carrying one or more staples deployable from the first contact surface;

a Doppler sensor on one of the first or second contact surfaces; and

a thermal element disposed on one of the first jaw or second jaw for delivering
5 thermal energy;

wherein, when the proximal end of the shaft is coupled to the robotic control system, a first actuator may be used for selectively moving the jaws between the open and closed positions, a second actuator may be used for deploying one or more staples from the first jaw into tissue between the first and second contact surfaces and toward the second jaw to
10 deform the one or more staples, and a third actuator for activating the Doppler sensor to detect blood flow in the tissue.

122. An apparatus for performing a medical procedure, comprising:

a shaft comprising a proximal end connectable to a robotic control system, a distal
15 end sized for introduction into a patient's body, and a longitudinal axis extending between the proximal and distal ends;

first and second jaws on the distal end of the shaft that are movable relative to one another between open and closed positions, thereby directing first and contact surfaces of the first and second jaws away from and towards one another, respectively; and

20 first and second sets of staples carried by the first jaw and positioned on opposite sides of a cutting element, wherein at least some of the staples are a different size than other staples,

wherein, when the proximal end of the shaft is coupled to the robotic control system,

a first actuator may be used for directing one or both of the first and second
25 jaws to the closed position to secure tissue between the first and second contact surfaces, and

a second actuator may be used for deploying the staples from the first jaw through the secured tissue towards the second jaw to deform the staples; and

a third actuator may be used for advancing the cutting element from a
30 retracted position to an advanced position aligned with the longitudinal axis to sever the stapled tissue.

123. A system for performing a medical procedure, comprising:

a robotic control system; and
an apparatus according to claim 121 or 122 coupled to the robotic control system,
the robotic control system including the actuators.

5 124. A method for performing a surgical procedure within a patient's body,
comprising:

introducing an apparatus according to any one of claims 1-13, 25-40, and 86-123
into a patient's body;

performing one or more of tubal ligation, cholecystectomy clipping, oophorectomy,
10 hysterectomy, nephrectomy, splenectomy, lung biopsy and resection, bariatric surgery,
colon and intestine surgery and vascular surgery using the apparatus.

125. A method for performing a surgical procedure within a patient's body,
comprising:

15 introducing first and second jaws on a distal end of a shaft into a region within the
patient's body;

with the jaws in an open position, placing tissue within the region between contact
surfaces of the first and second jaws;

actuating one or both of the first and second jaws to secure tissue between the
20 contact surfaces;

deploying one or more staples from the first jaw through the tissue towards the
second jaw to deform the one or more staples and staple the tissue;

activating a Doppler sensor on one of the contact surfaces to detect blood flow in the
stapled tissue; and

25 if blood flow is detected, delivering thermal energy to the stapled tissue to stop
blood flow.

126. The method of claim 125, further comprising actuating a cutting element to
sever the stapled tissue from adjacent tissue at the region.

30

127. The method of claim 125, wherein delivering thermal energy comprises
activating a thermal element on one of the first and second jaws to deliver thermal energy to
the stapled tissue.

128. The method of claim 127, wherein the thermal energy is delivered until the Doppler sensor confirms that blood is no longer flowing in the stapled tissue.

5 129. The method of claim 127, wherein the thermal element comprises an electrode, and wherein electrical energy is delivered to the electrode to deliver thermal energy to the stapled tissue.

10 130. The method of claim 126, wherein the first jaw carries first and second sets of staples positioned on opposite sides of the cutting element, and wherein an actuator enables delivering one or more staples from each of the first and second sets of staples into the tissue.

15 131. The method of claim 130, wherein the first and second sets of staples are positioned in a plurality of rows aligned with the longitudinal axis of the shaft, and wherein the cutting element advanced from a retracted position to an advanced position aligned with the longitudinal axis to sever the stapled tissue between the staples delivered into the tissue.

20 132. The method of claim 130, wherein each of the first and second sets of staples includes one or more rows of staples aligned with the longitudinal axis, and wherein one or more staples from each of the rows are delivered into the tissue when the second actuator is actuated.

25 133. The method of claim 125, further comprising delivering light from a light source on the distal end of the shaft or end effector to facilitate imaging the region during the procedure.

30 134. The method of claim 125, further comprising acquiring images of the region using an objective on the distal end of the shaft or end effector to facilitate performing the procedure.

135. The method of claim 125, wherein the tissue comprises an appendix.

136. A method for performing an appendectomy within a patient's body, comprising:

introducing first and second jaws on a distal end of a shaft into an abdominal cavity of the patient's body;

5 with the jaws in an open position, placing an appendix and appendicular artery within the abdominal cavity between contact surfaces of the first and second jaws;

actuating one or both of the first and second jaws to secure the appendix and artery between the contact surfaces;

10 deploying one or more staples from the first jaw through the appendix and artery and towards the second jaw to deform the one or more staples and staple the appendix and artery;

activating a Doppler sensor on one of the contact surfaces to detect blood flow in the stapled appendix and artery;

15 if blood flow is detected, activating a thermal element to deliver thermal energy to stop blood flow;

actuating a cutting element to simultaneously sever the appendix and artery.

137. The method of claim 136, wherein the one of the appendix and the artery is positioned distal to the other between the contact surfaces.

20

138. The method of claim 136, wherein the Doppler sensor and thermal element are activated alternately to deliver thermal energy and then detect resulting blood flow until the blood flow stops.

25

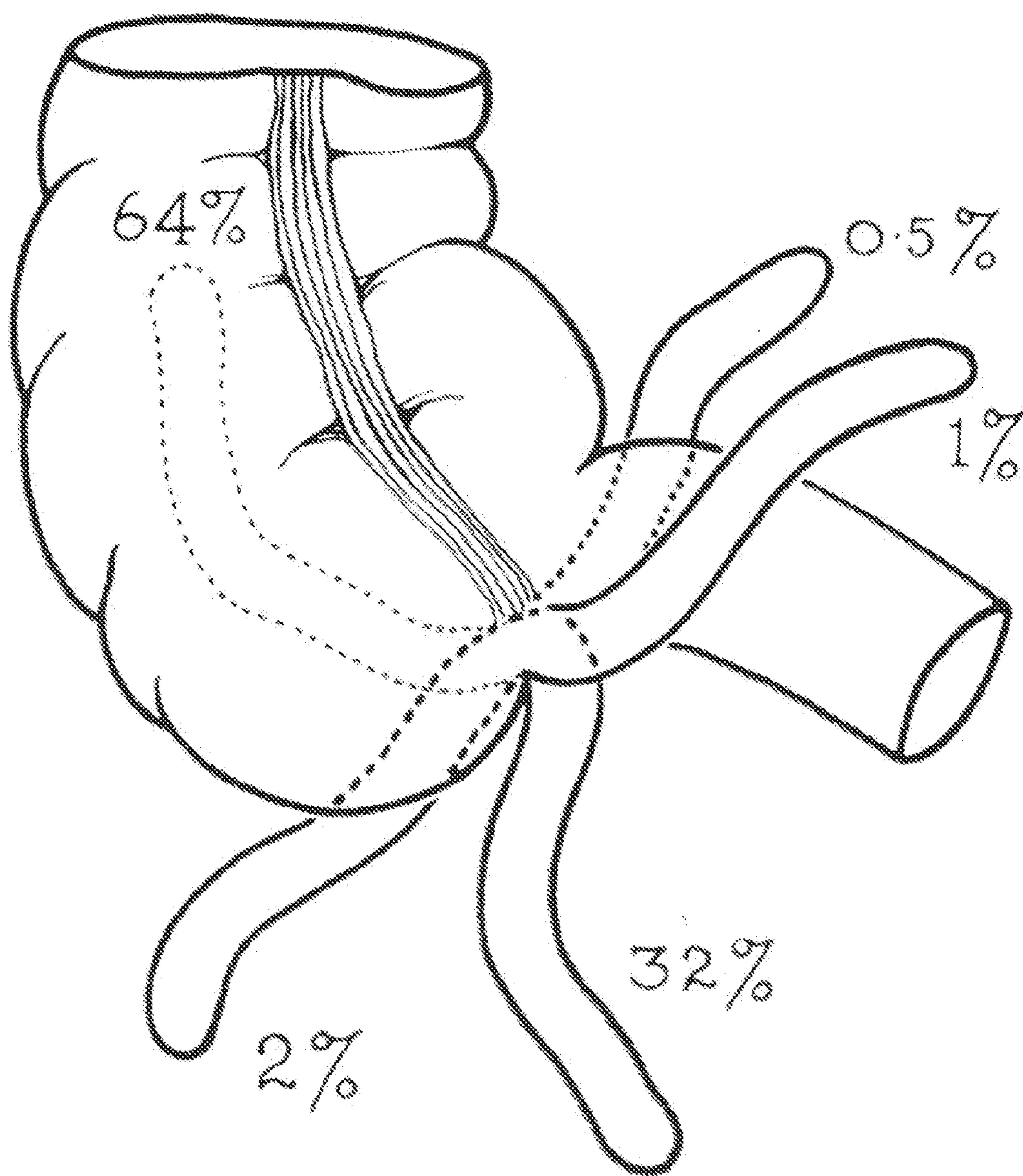


FIG. 1

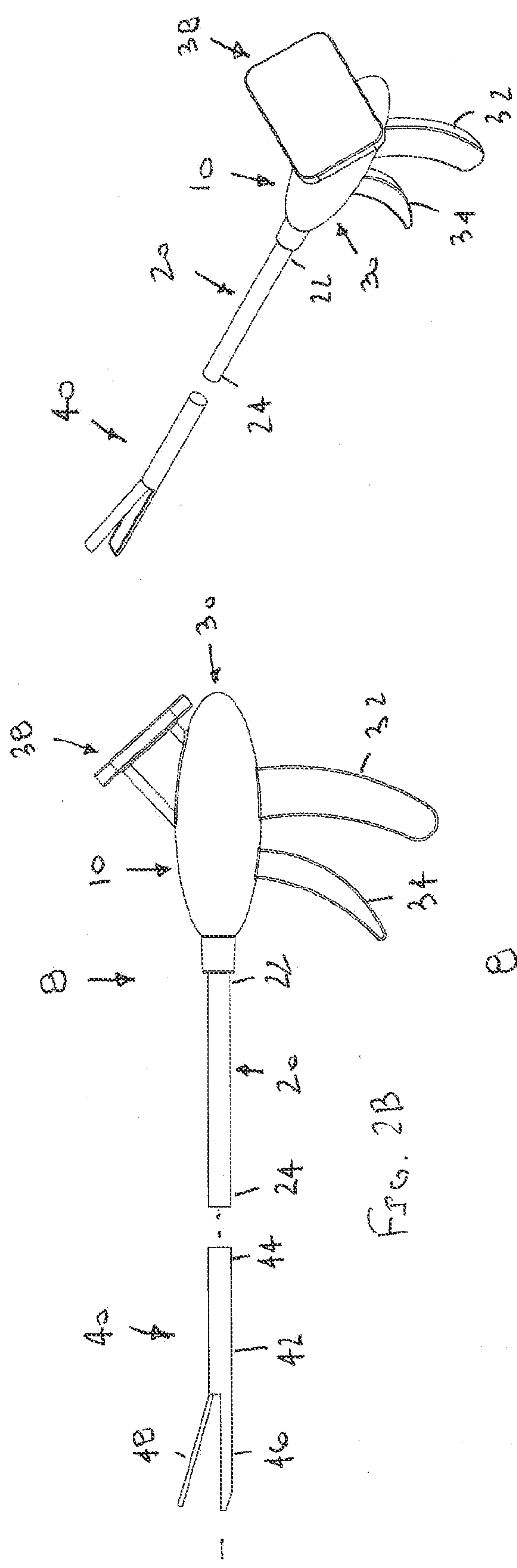


FIG. 2B

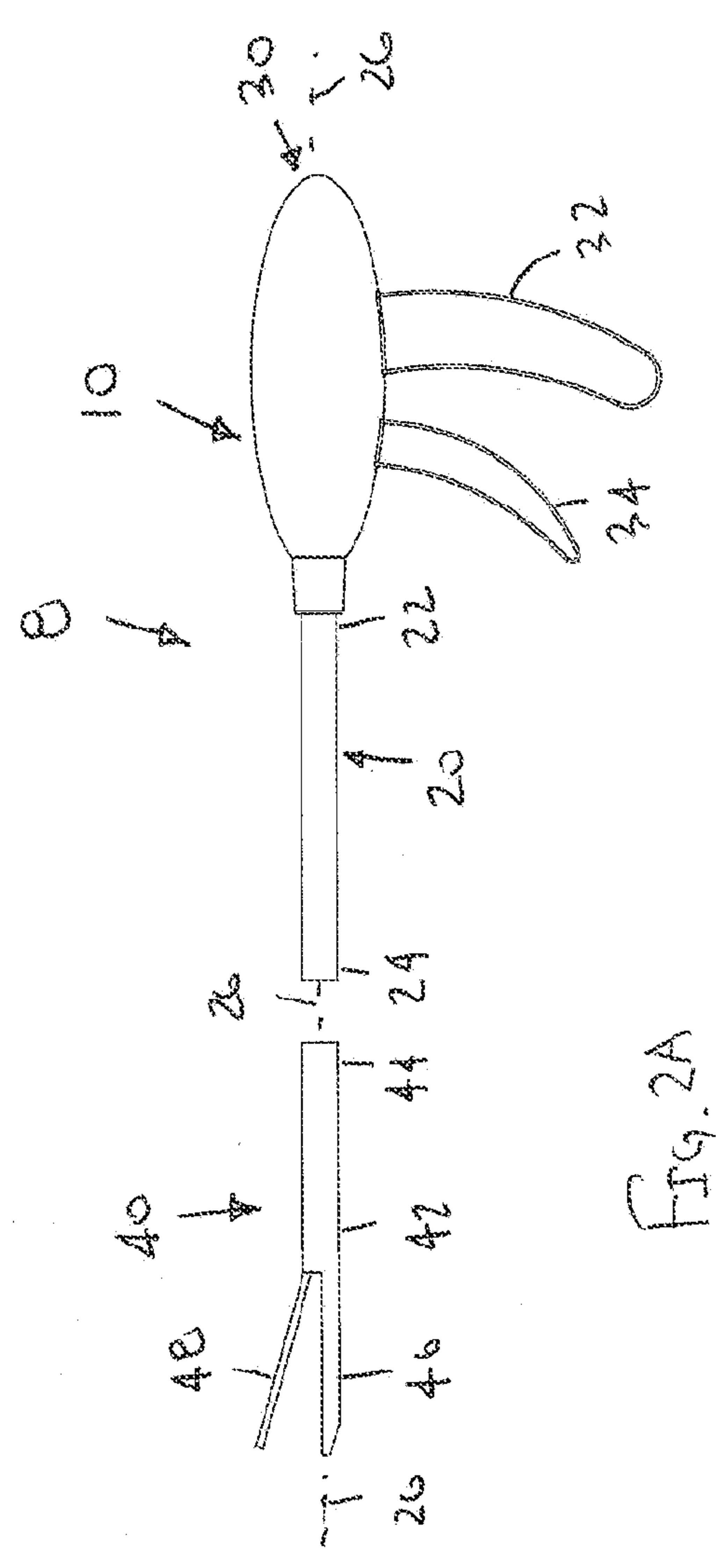
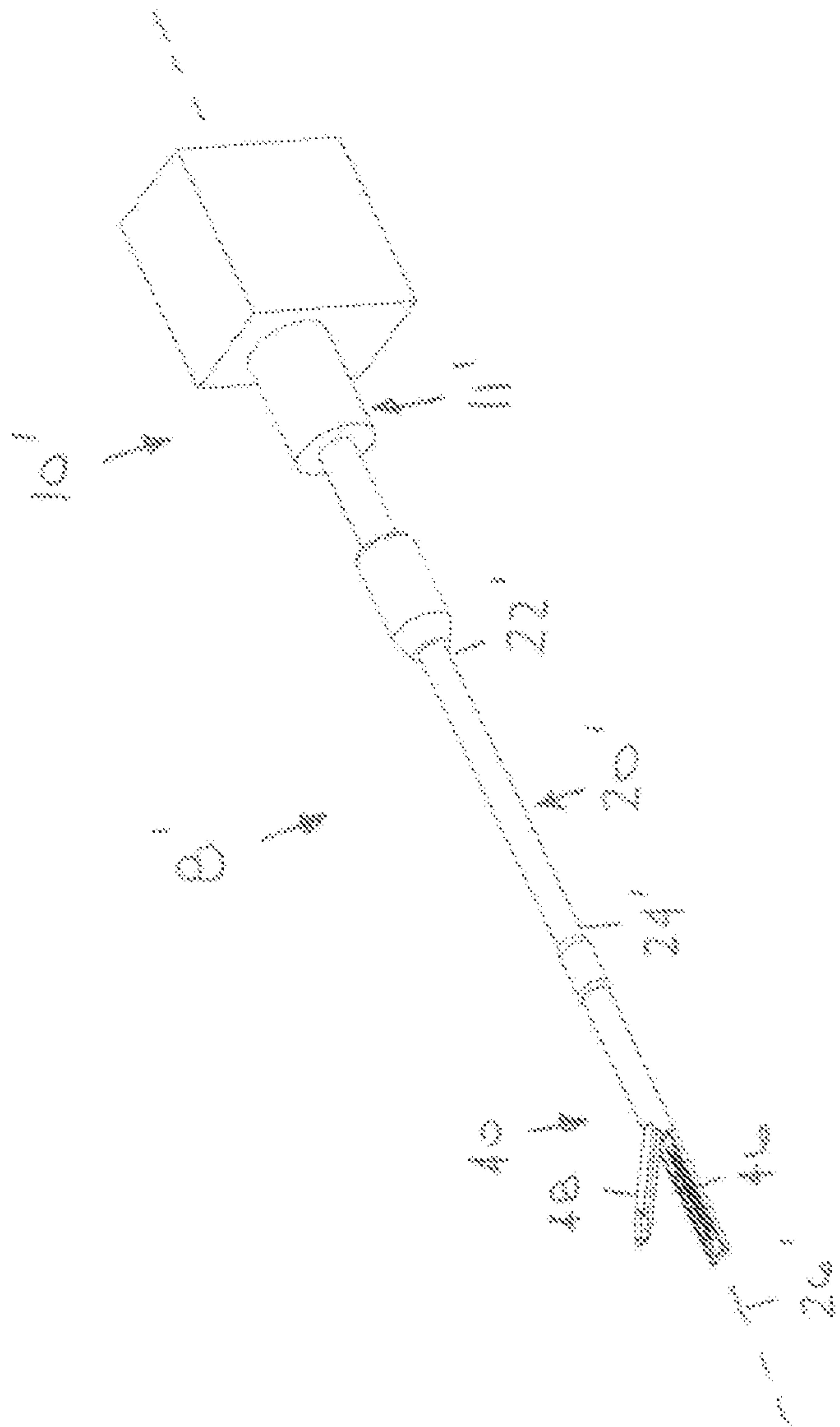
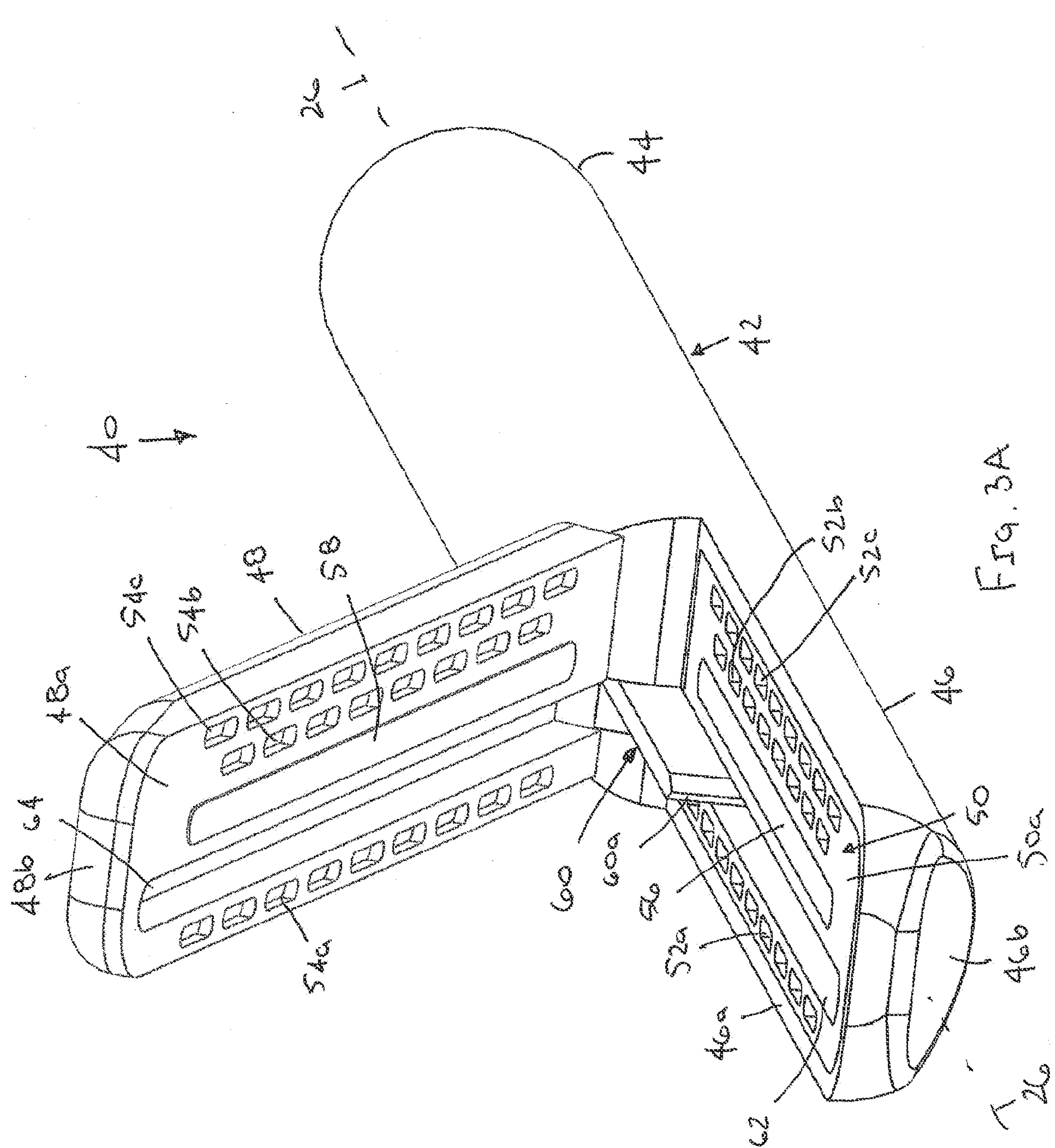


FIG. 2A

FIG. 2C





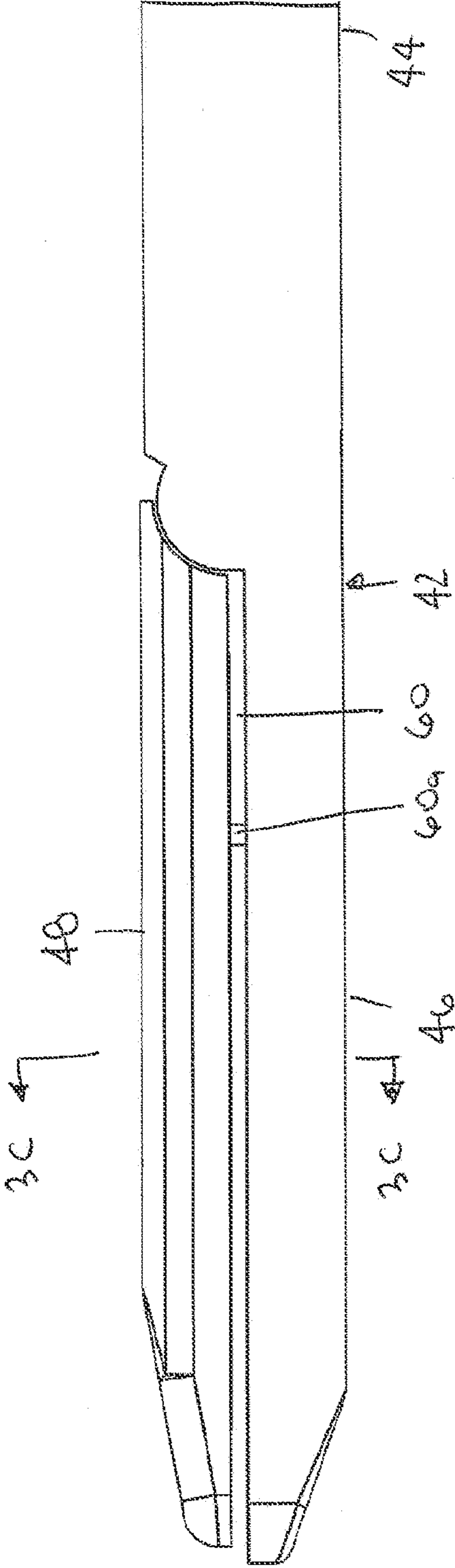


Fig. 3B

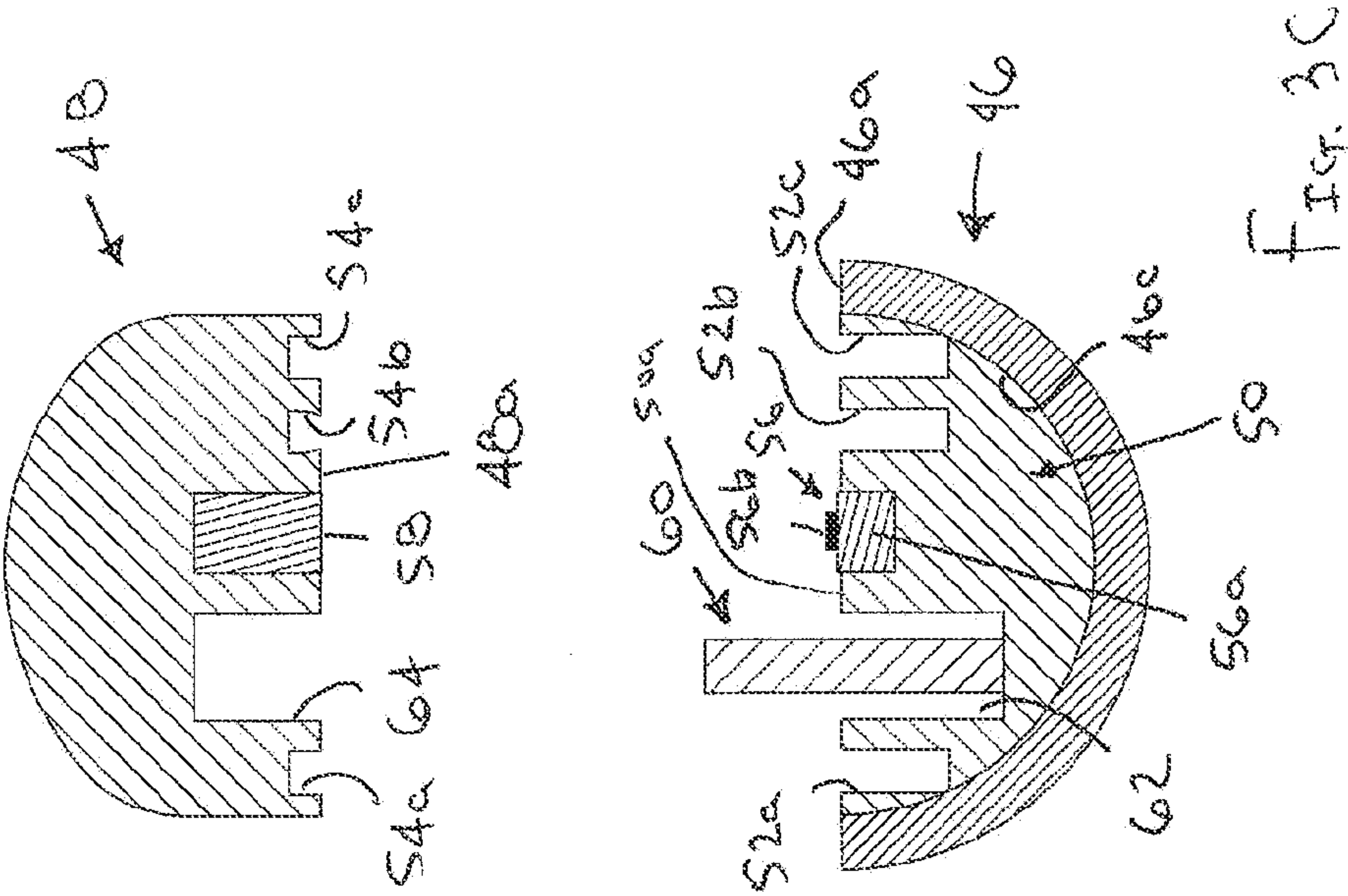
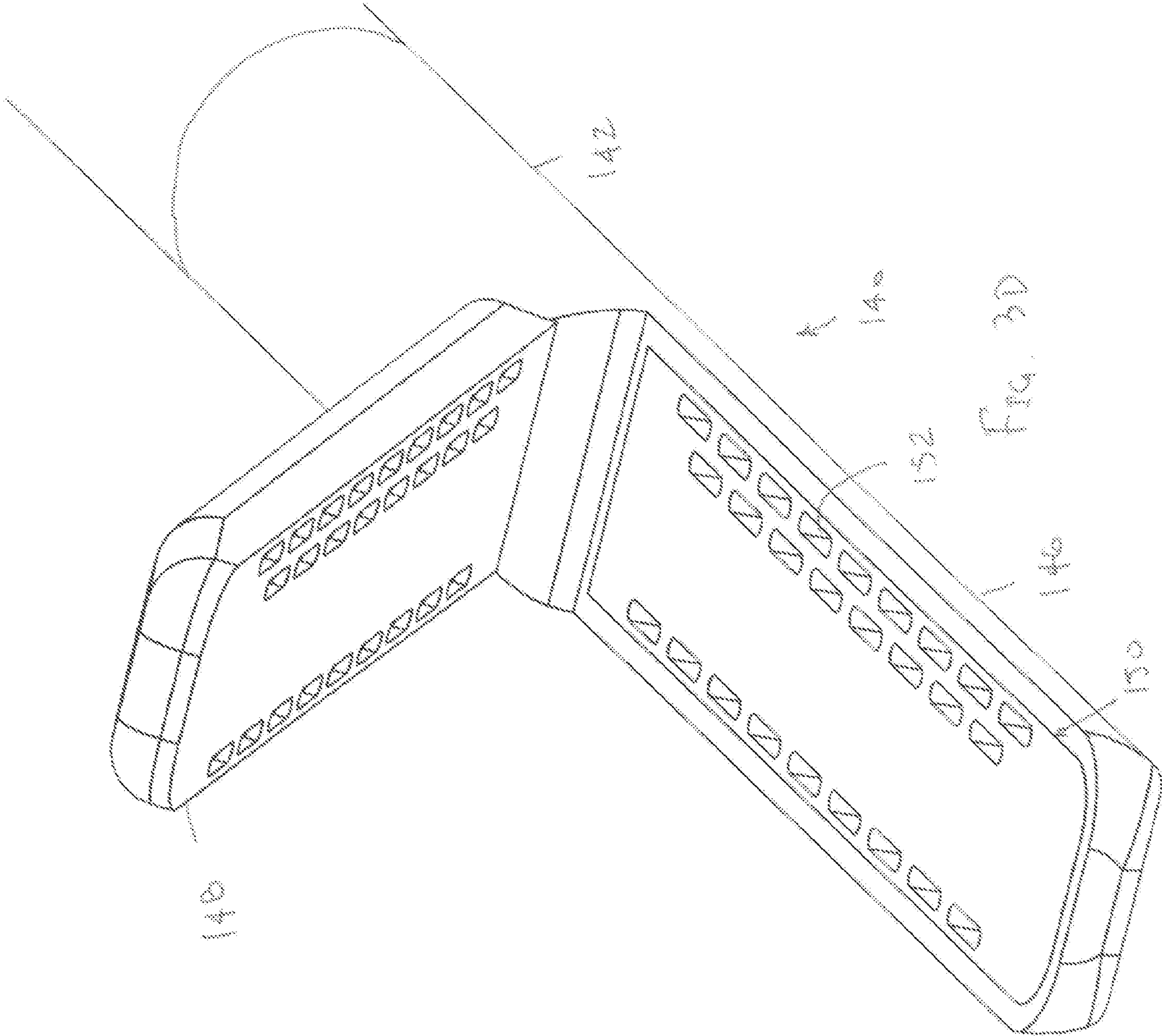


Fig. 3C



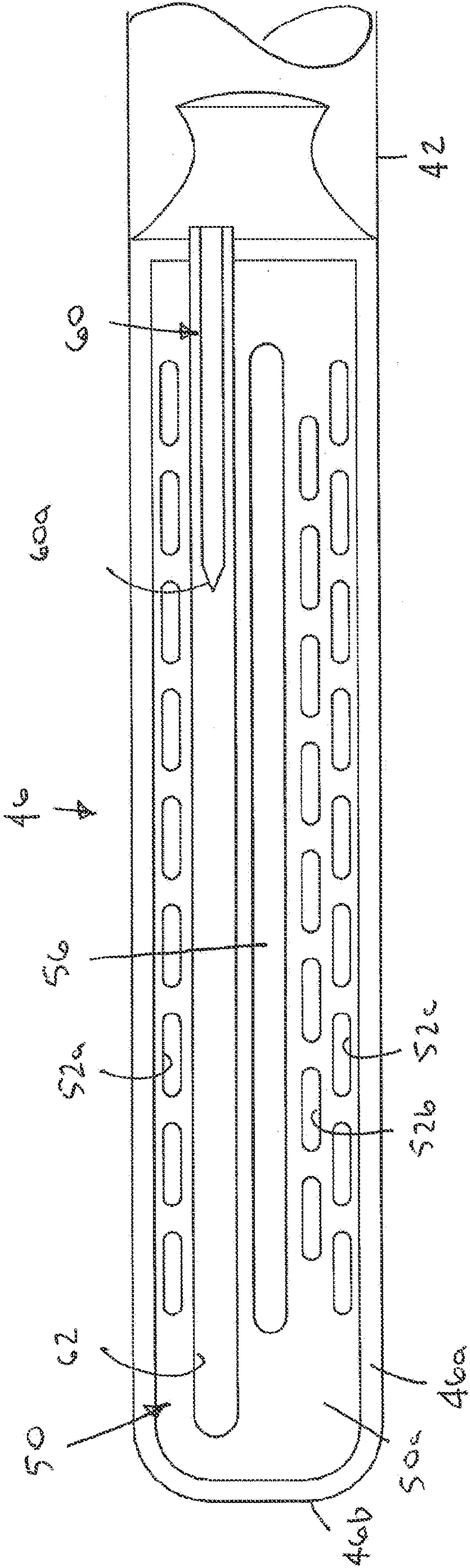


FIG. 4A

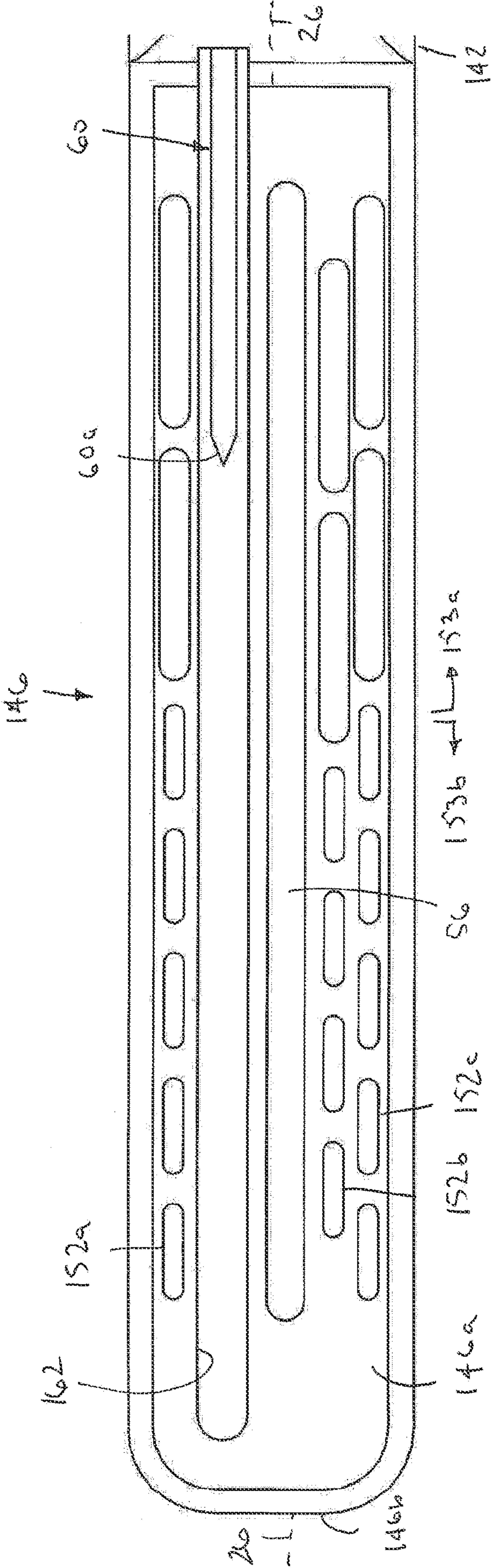
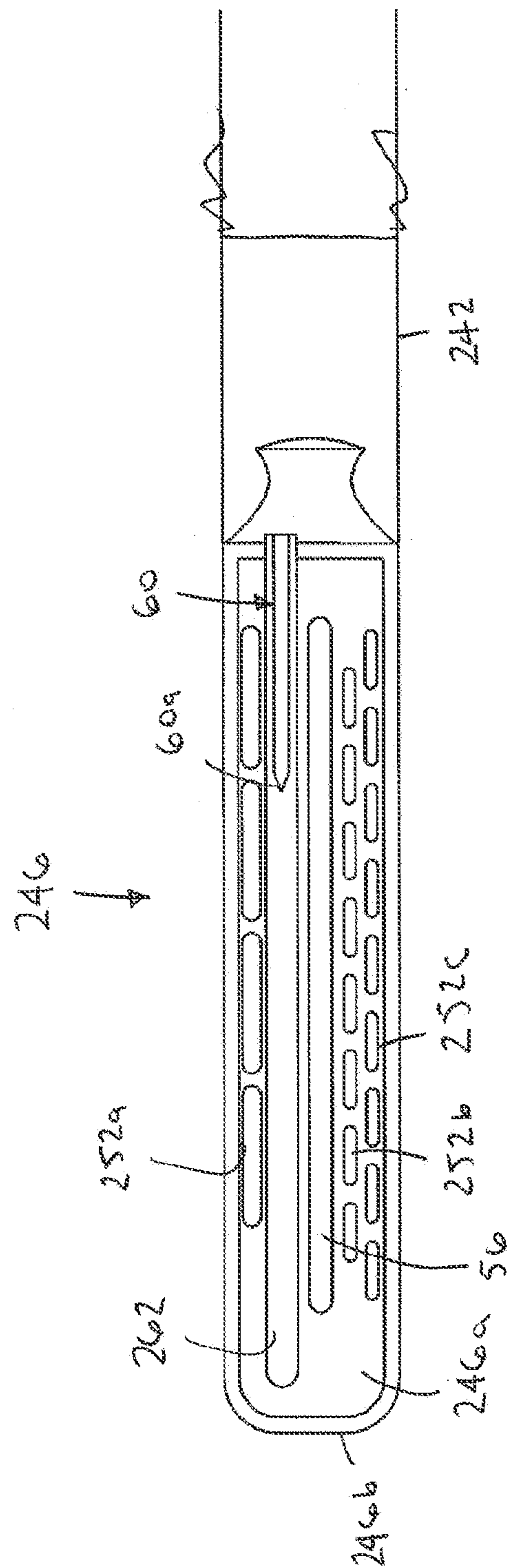
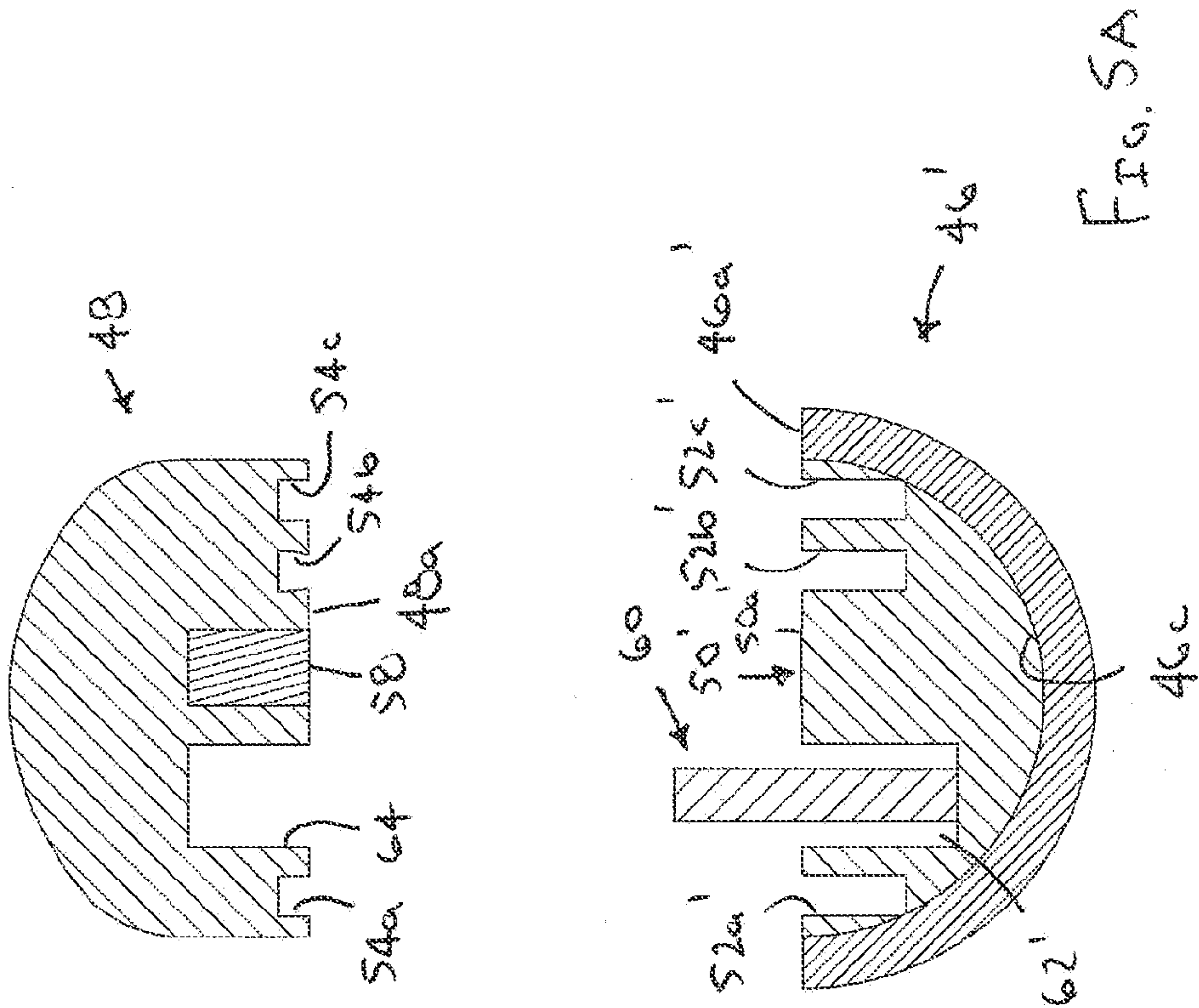


Fig. 4B



245



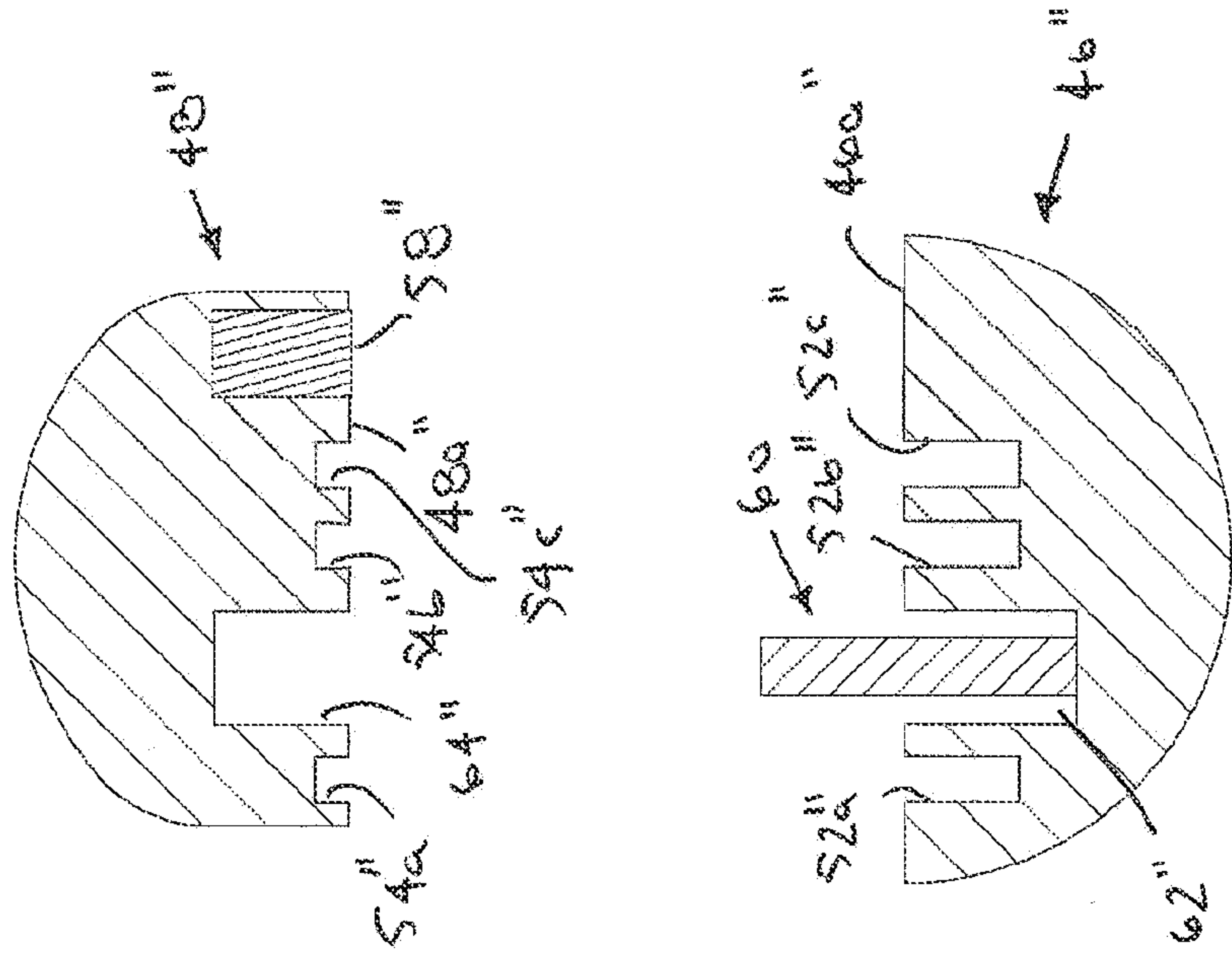
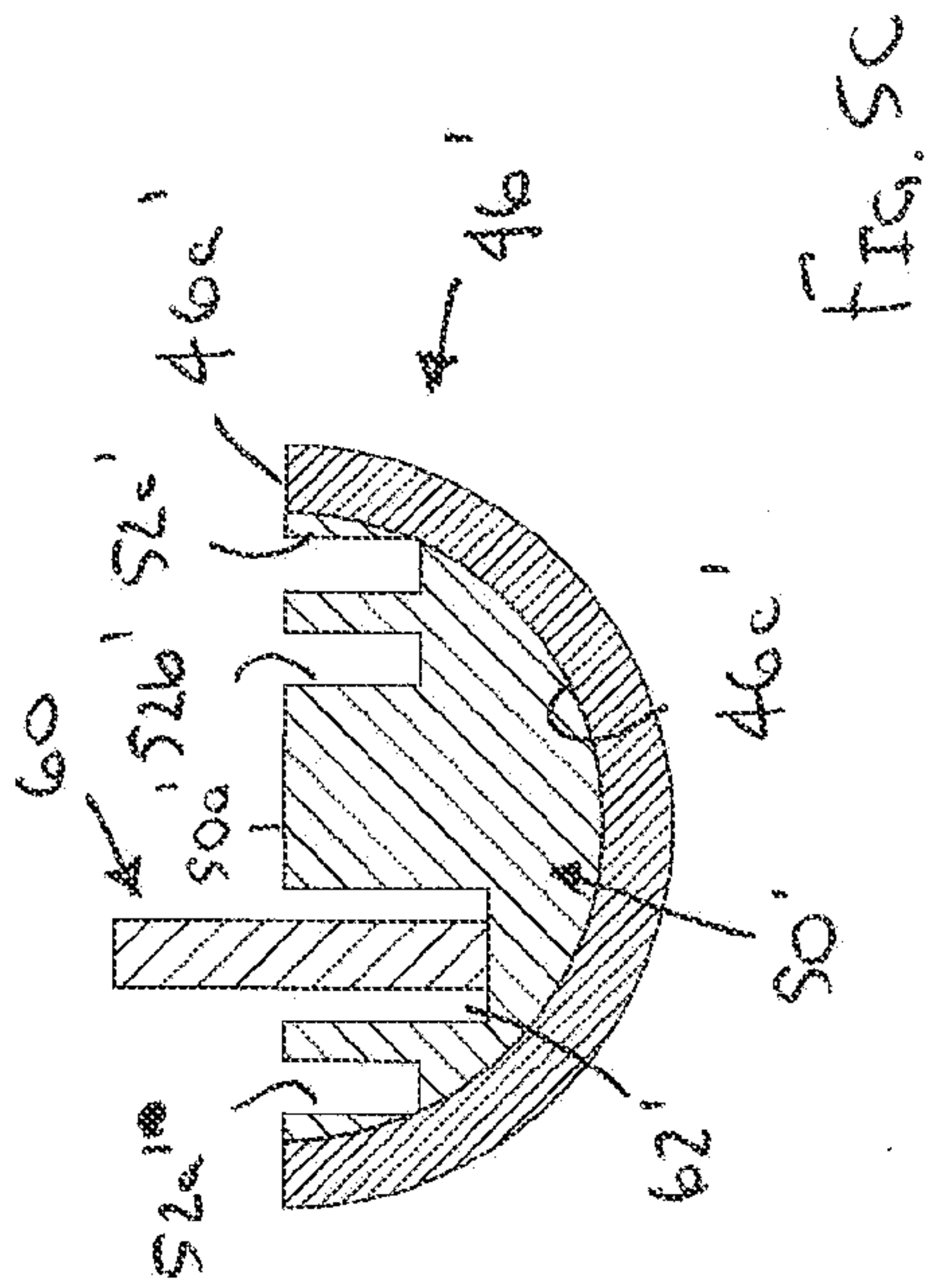
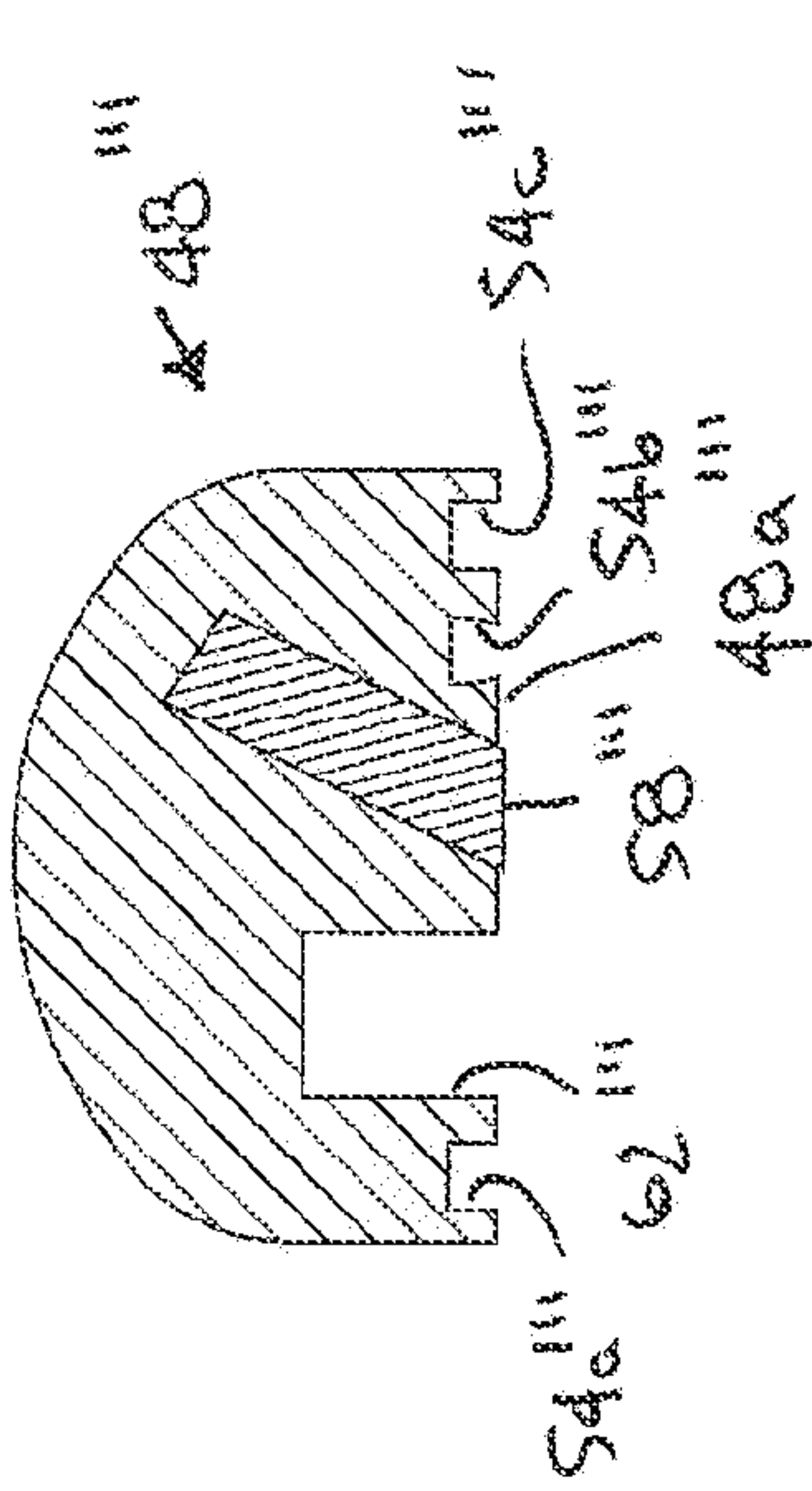
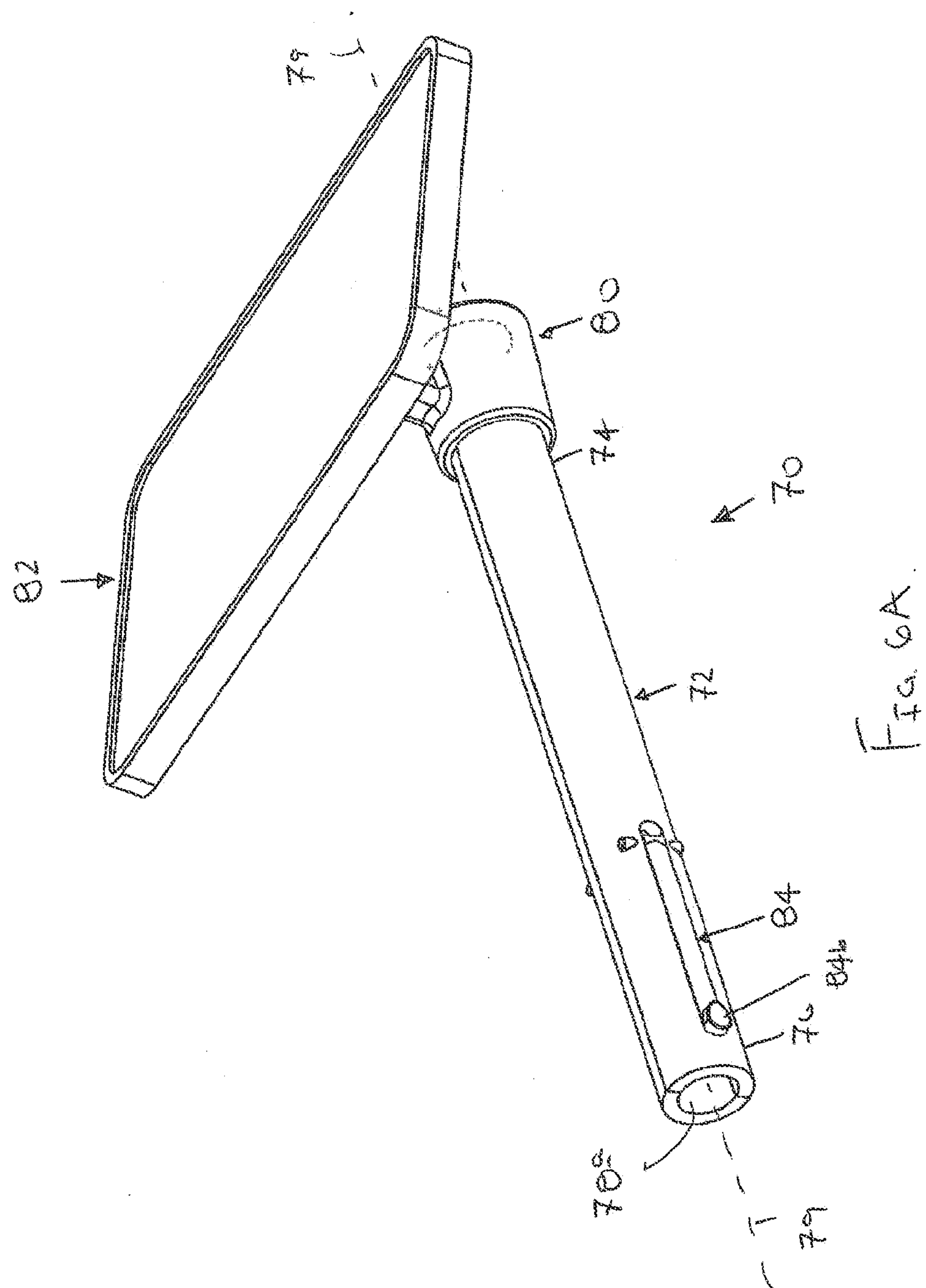


Fig. 5B





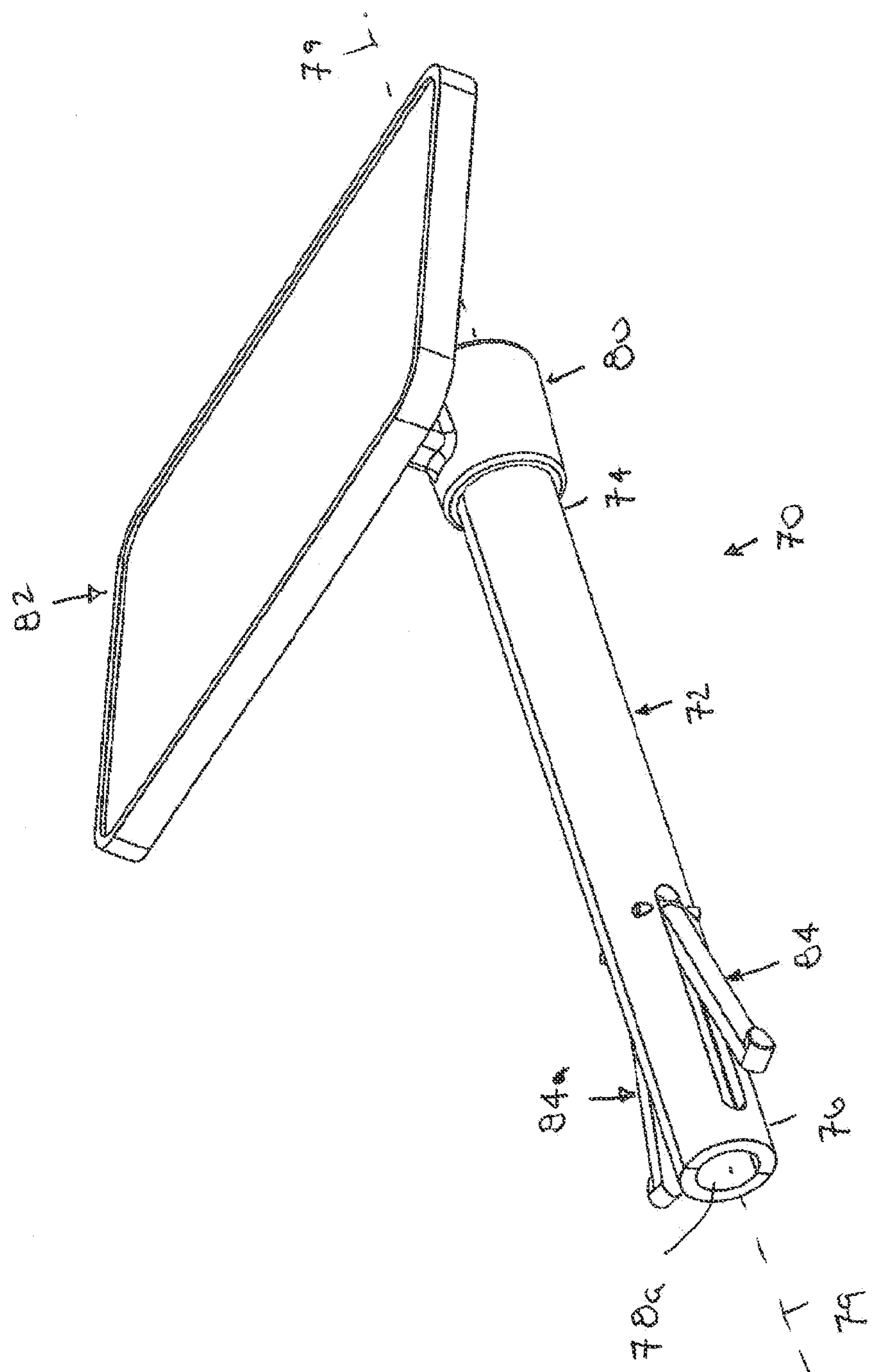


Fig. 6B

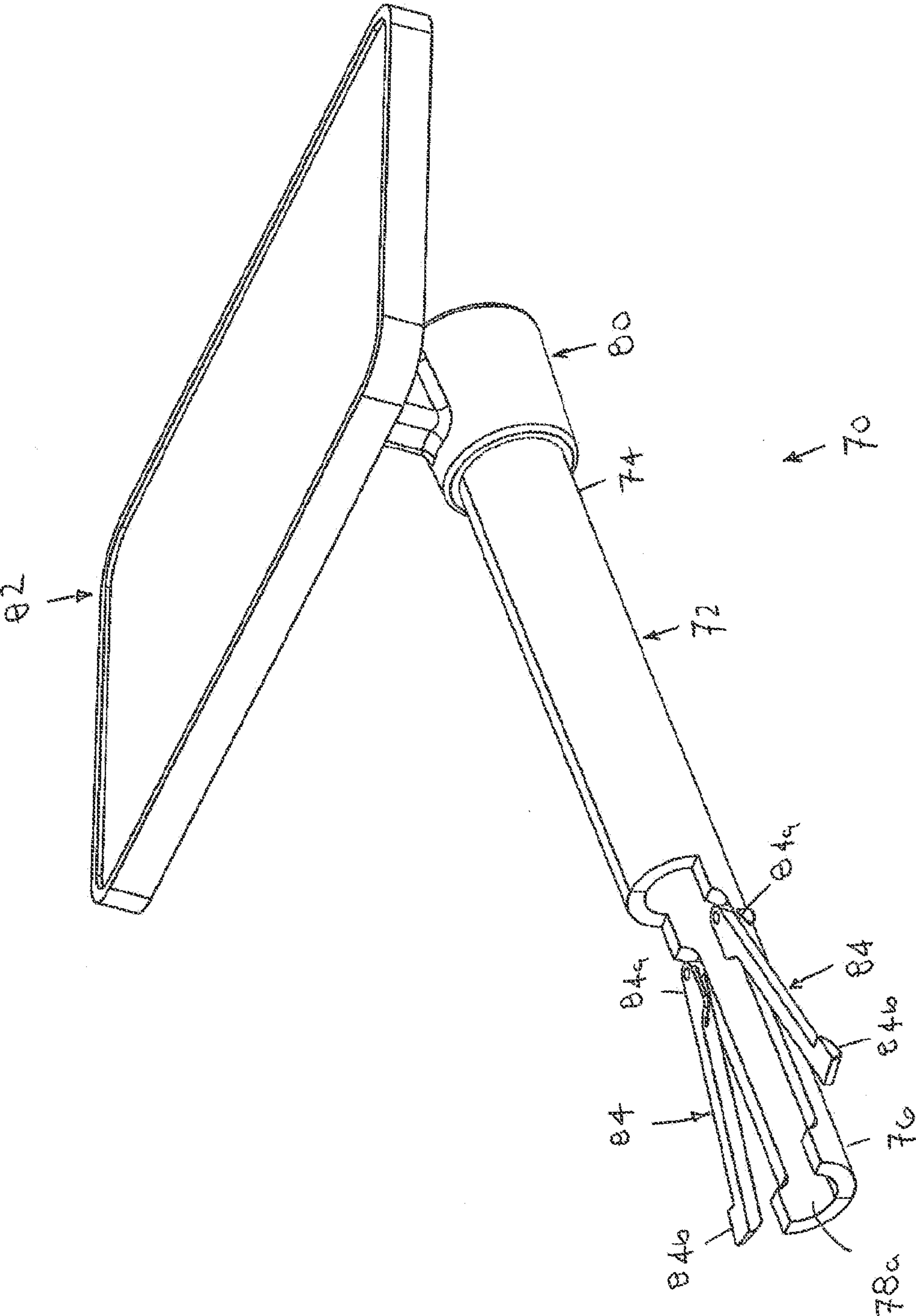
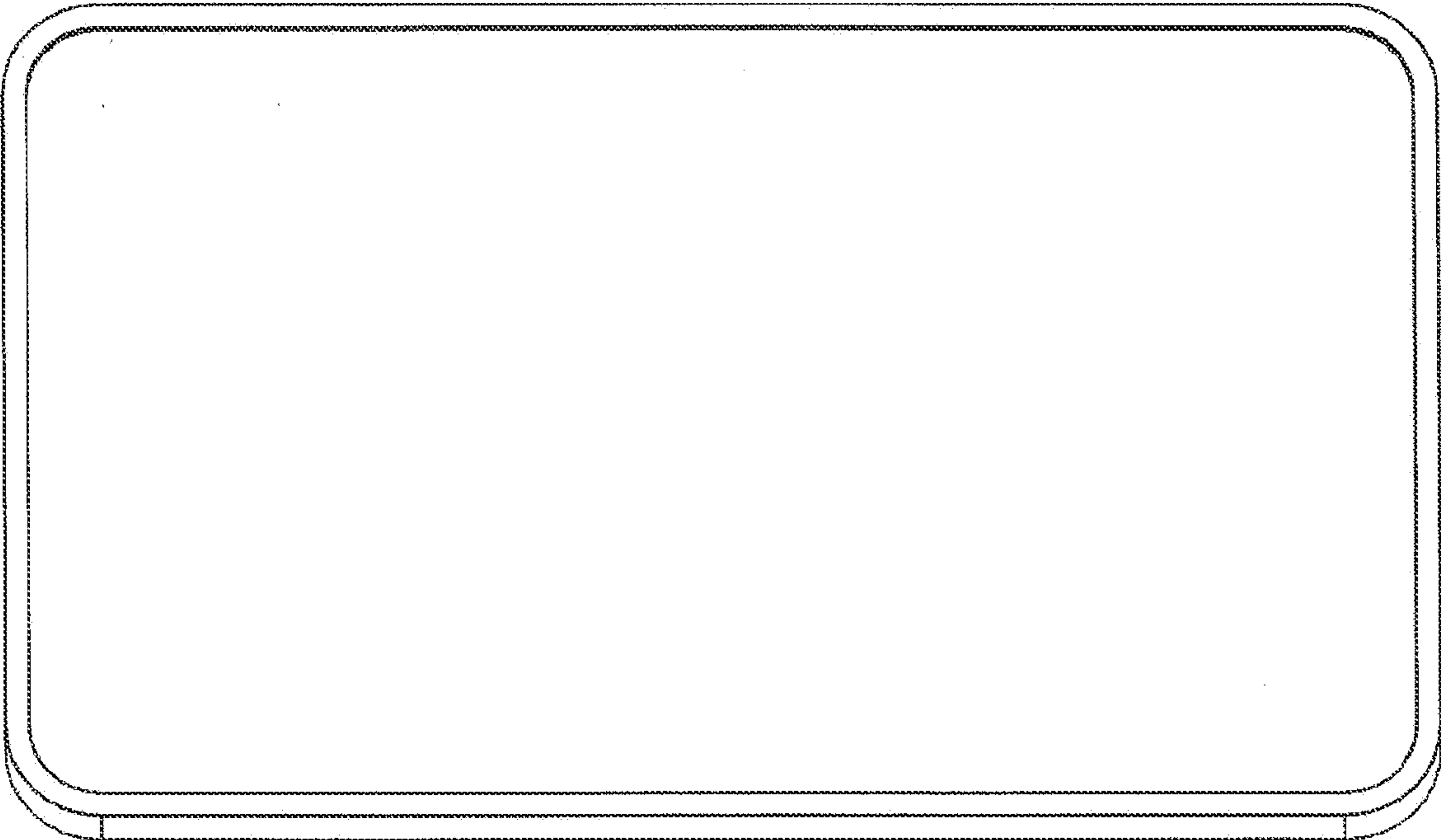


Fig. 6c



70

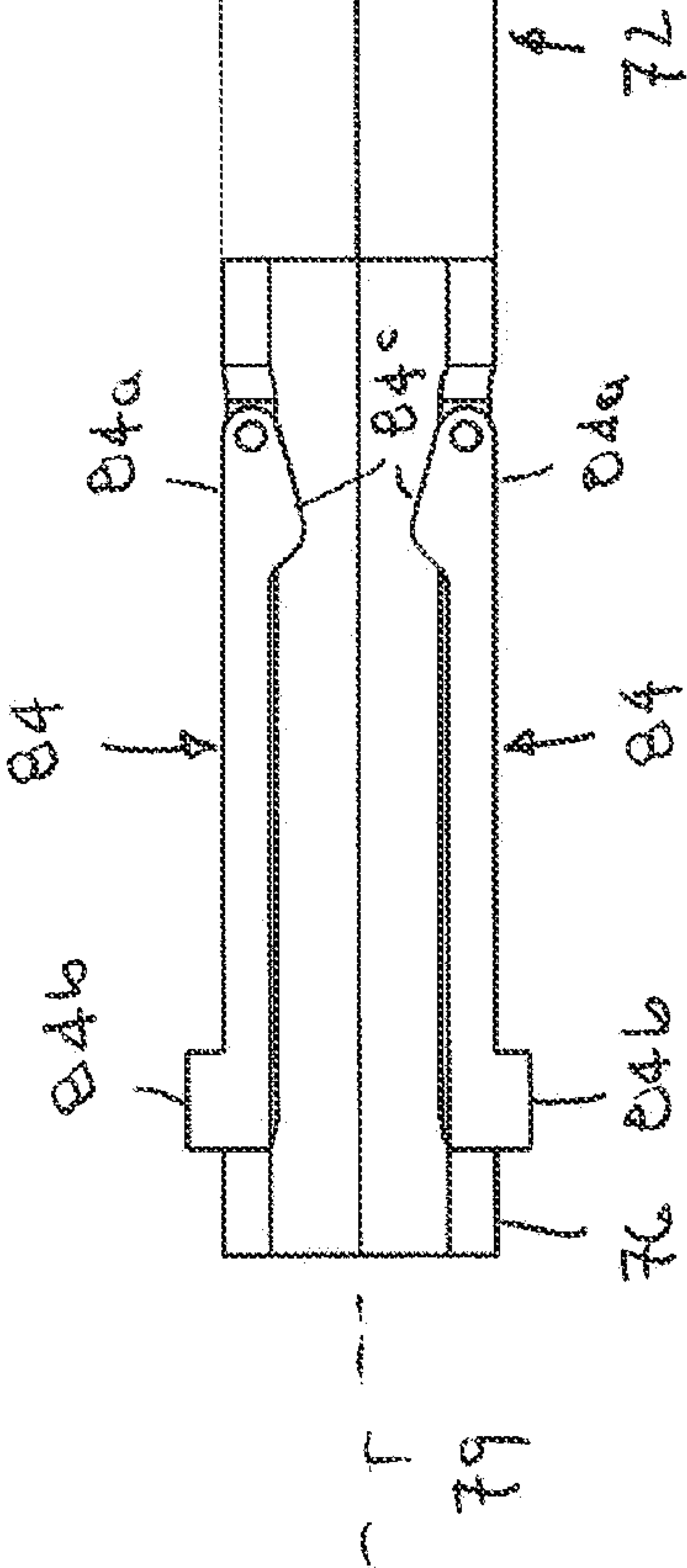
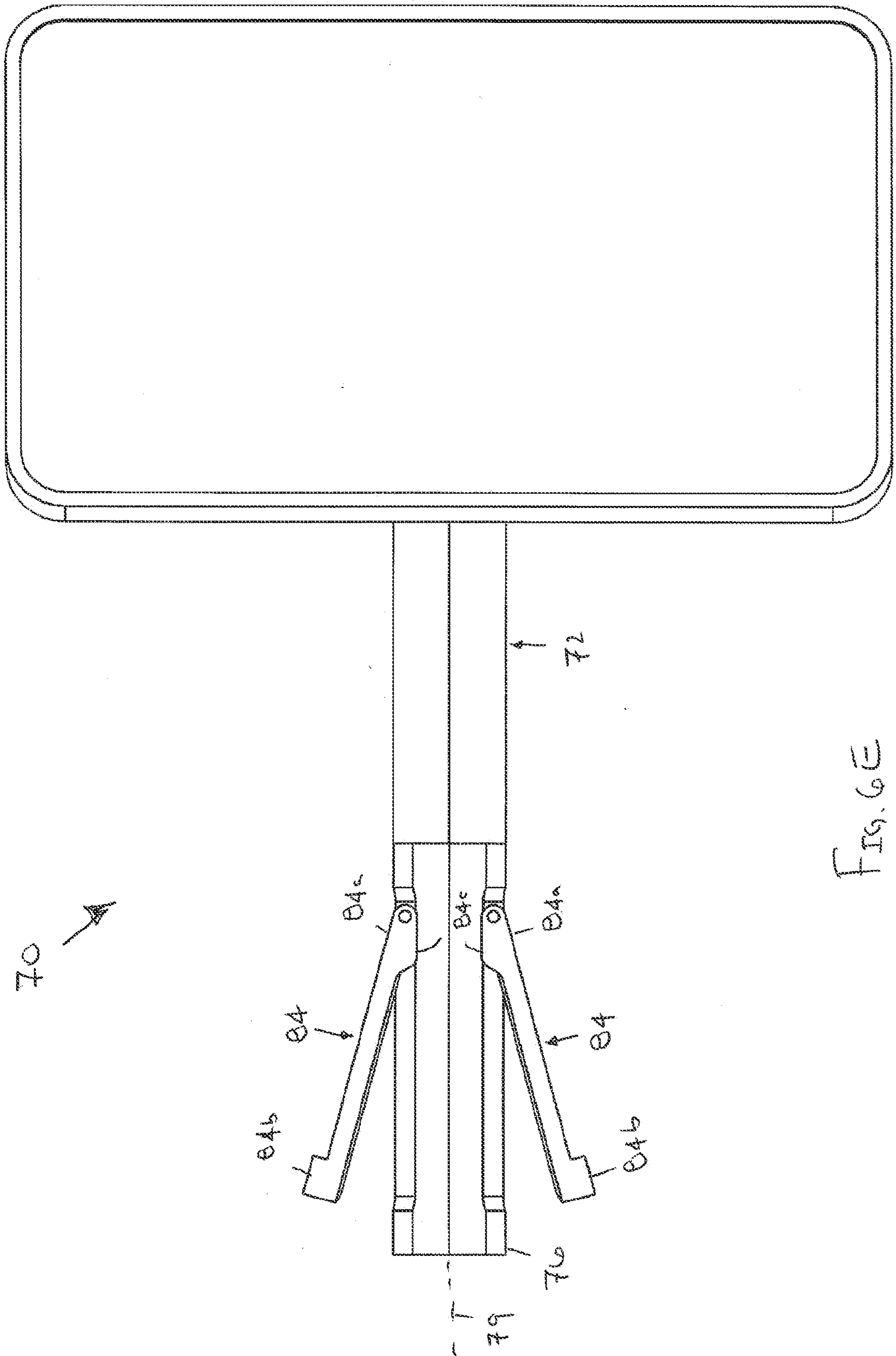
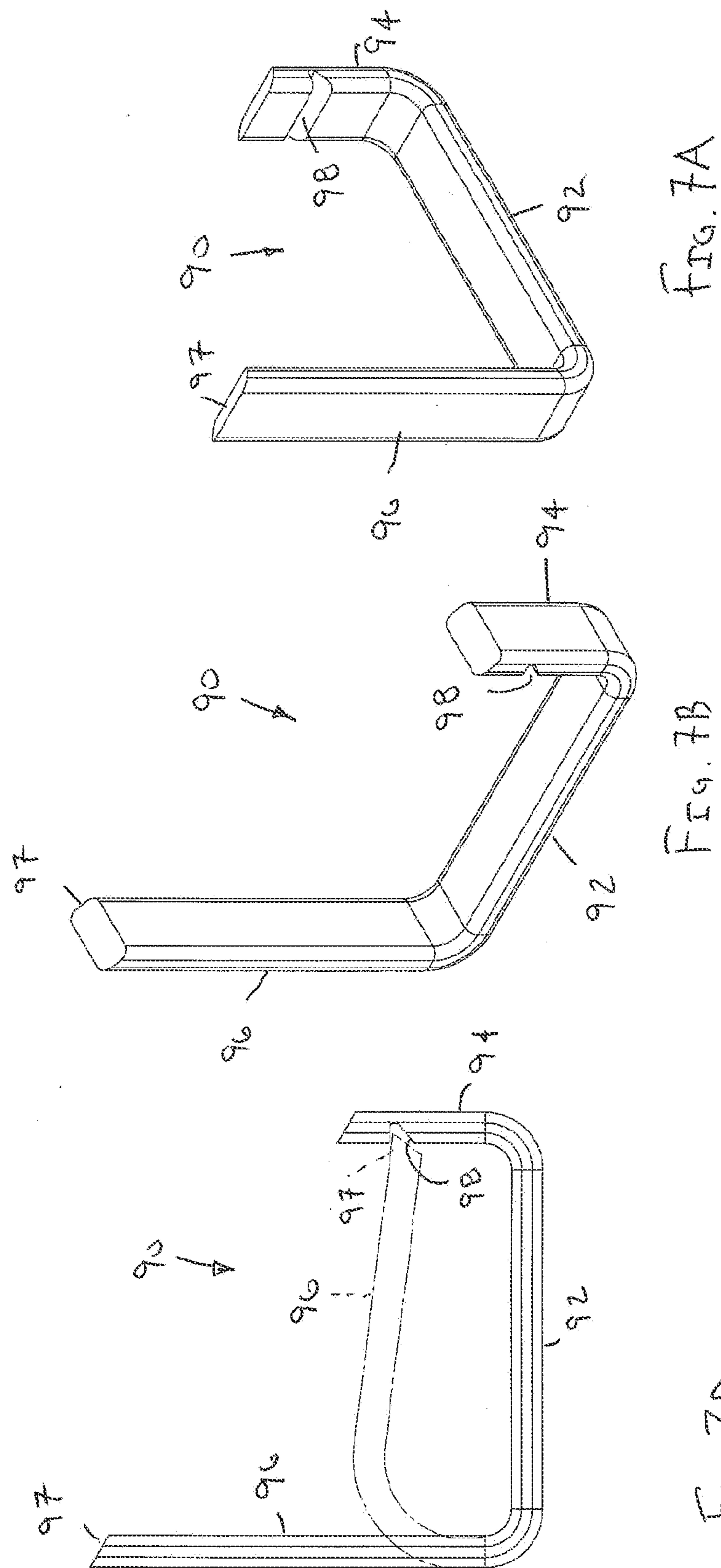


FIG. 6D





ATC

37544

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A

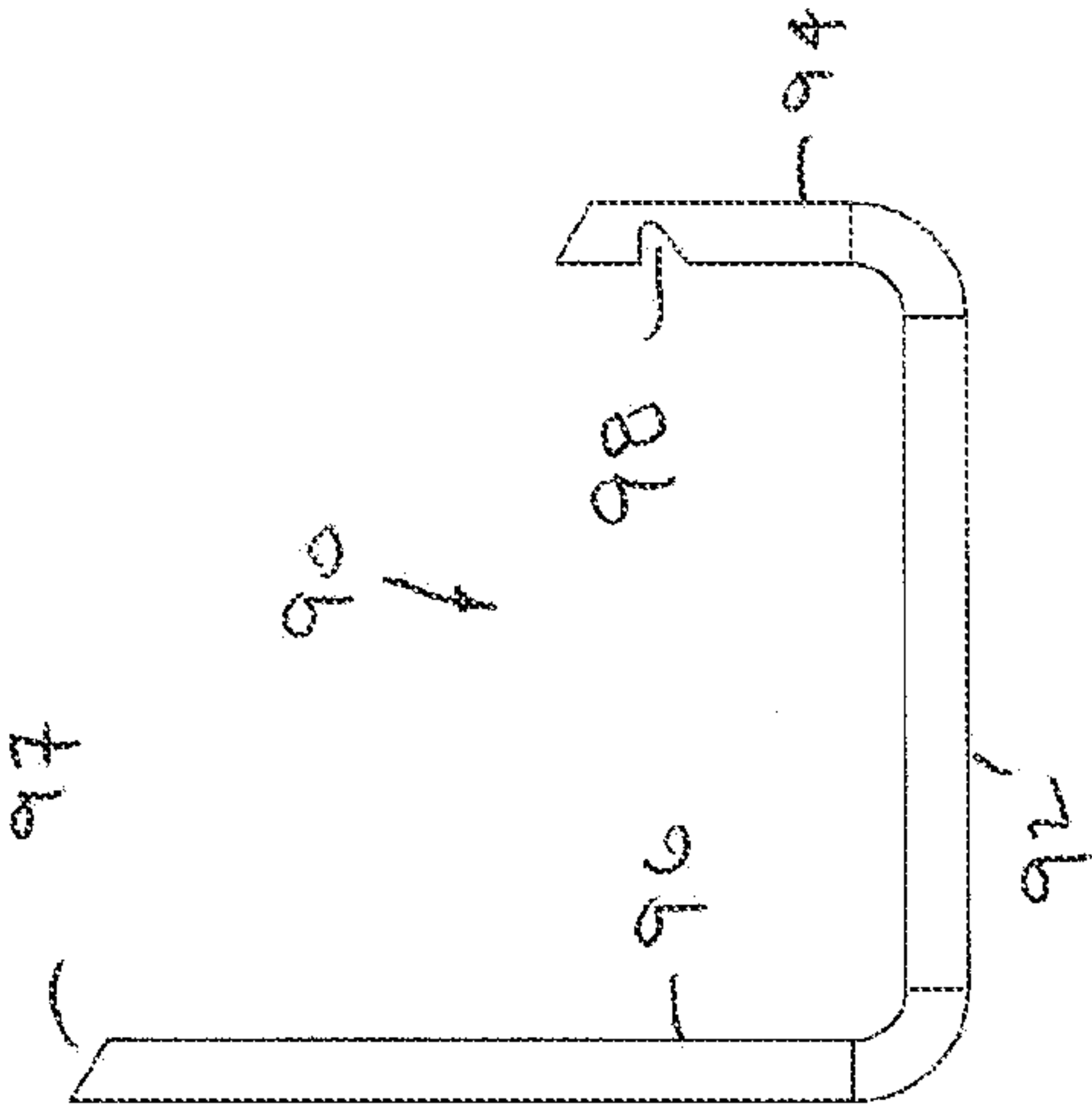


FIG. 7C

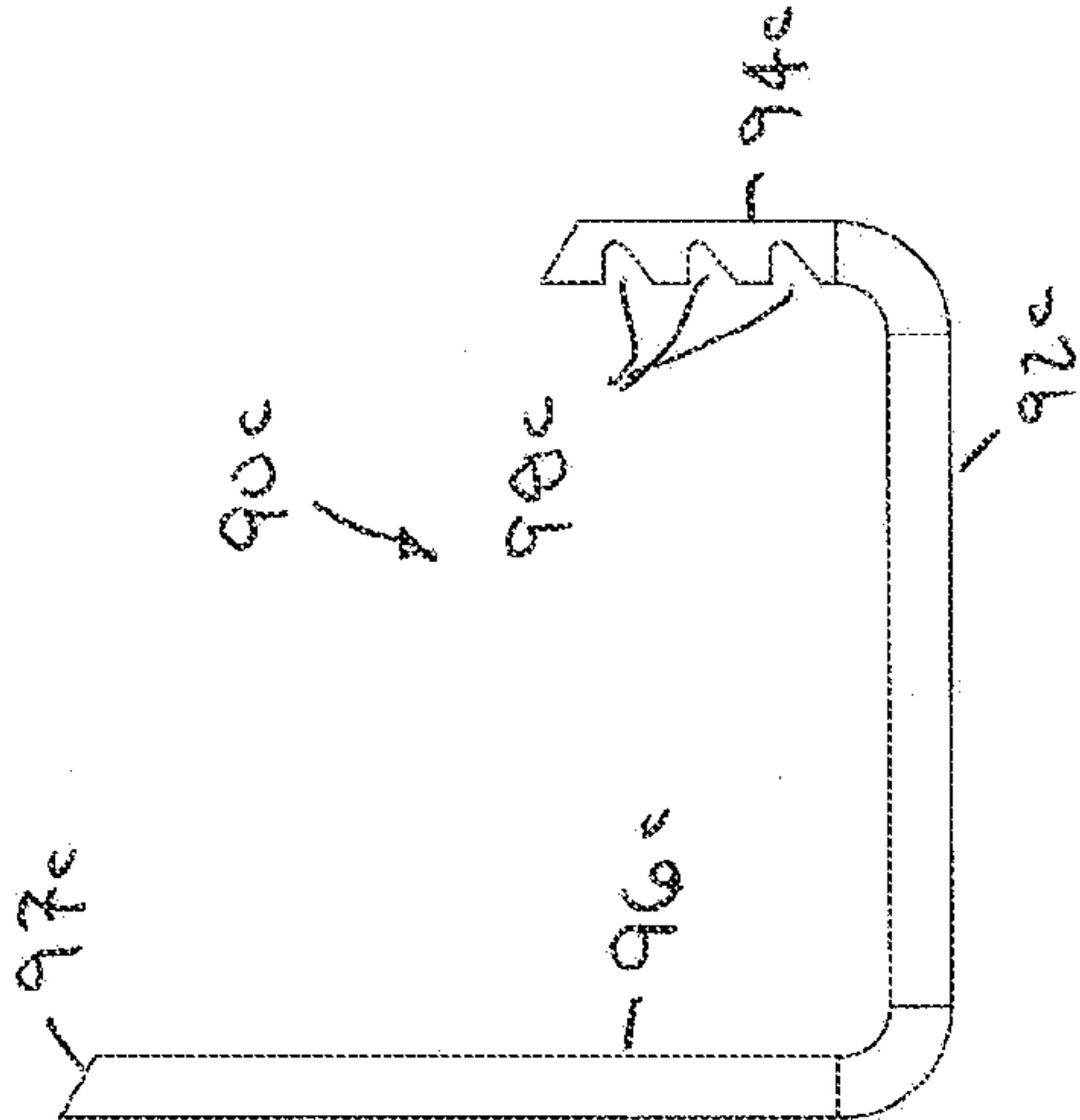


FIG. 8C

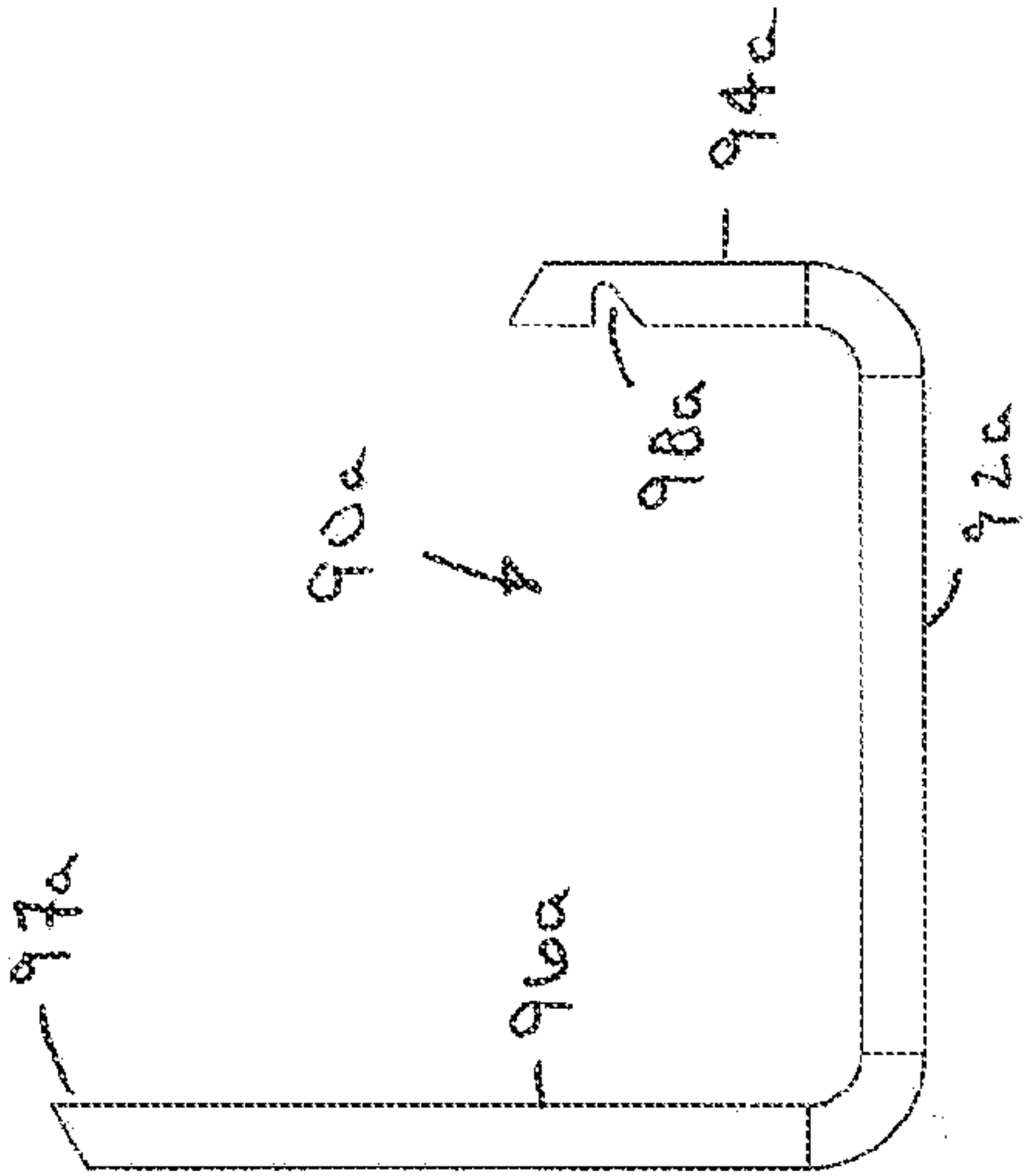


FIG. 8A

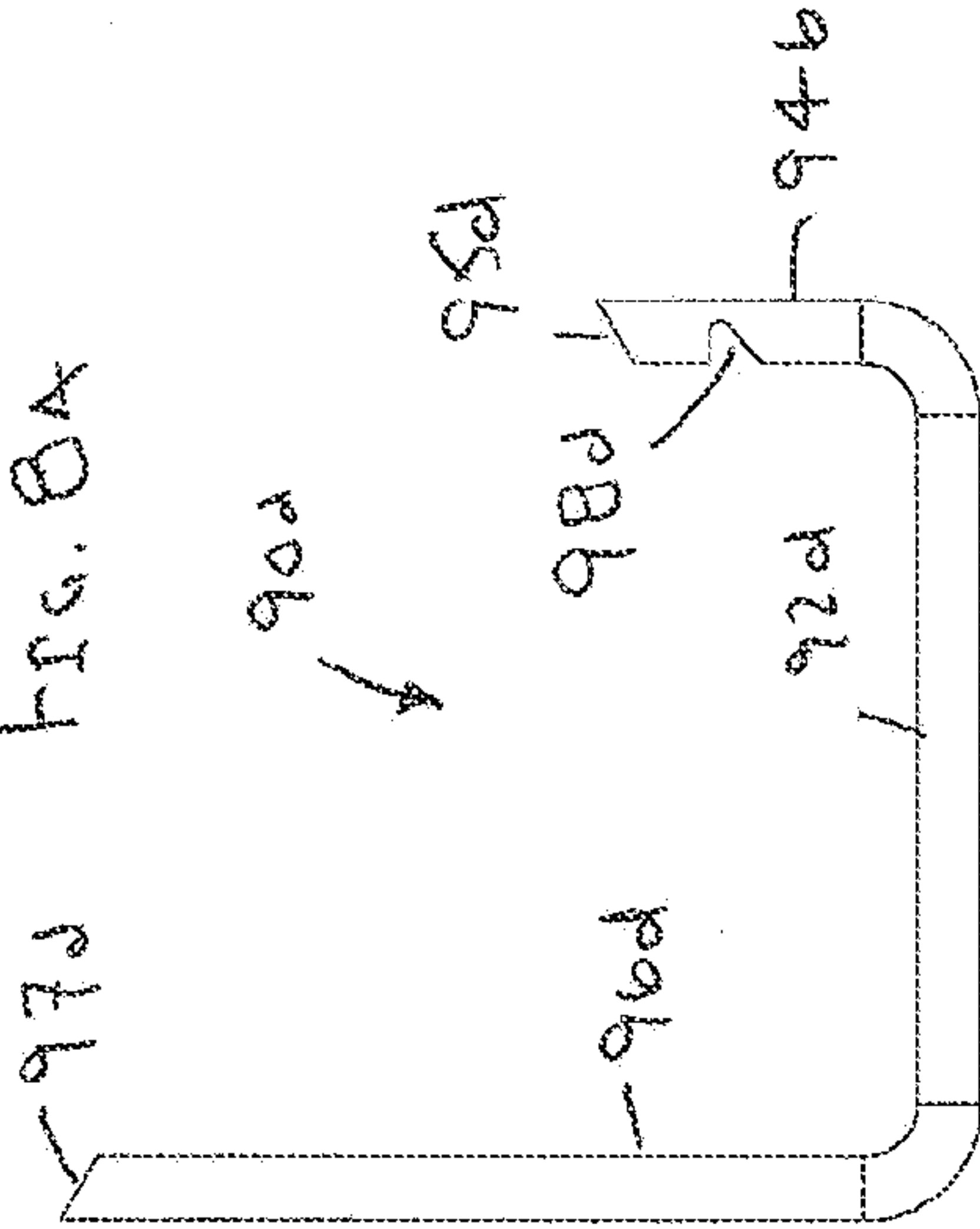


FIG. 8D

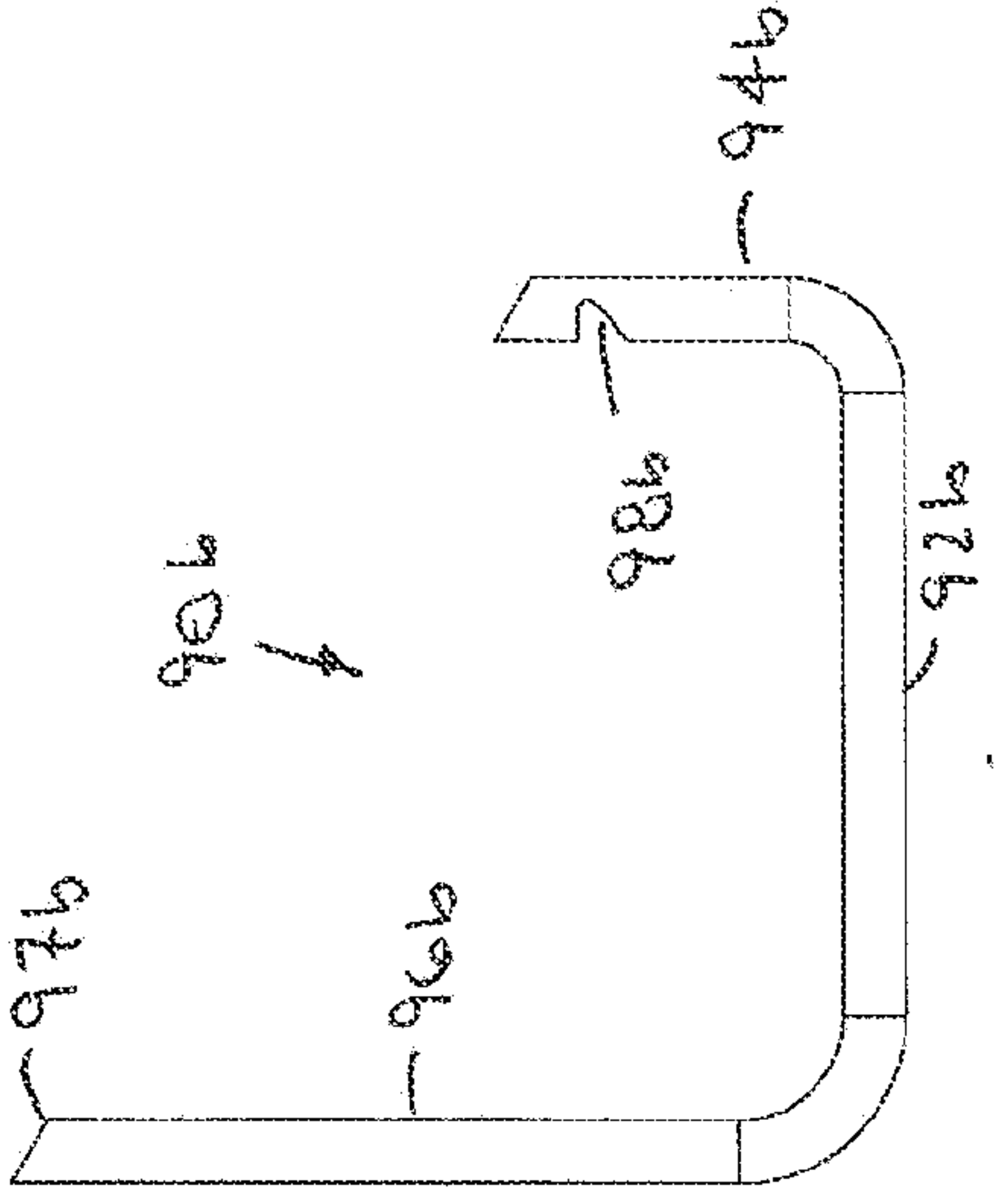


FIG. 8B

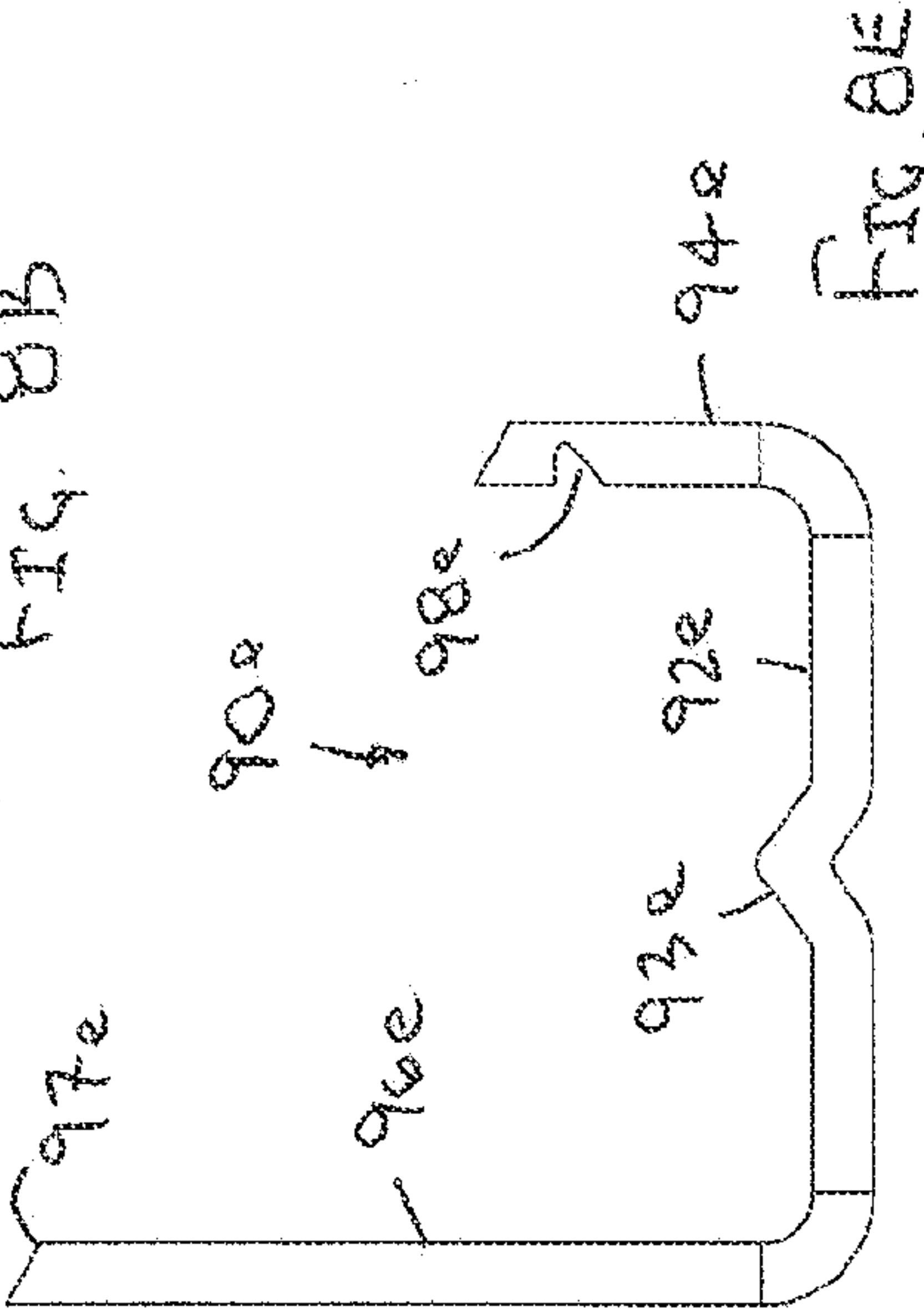


FIG. 8E

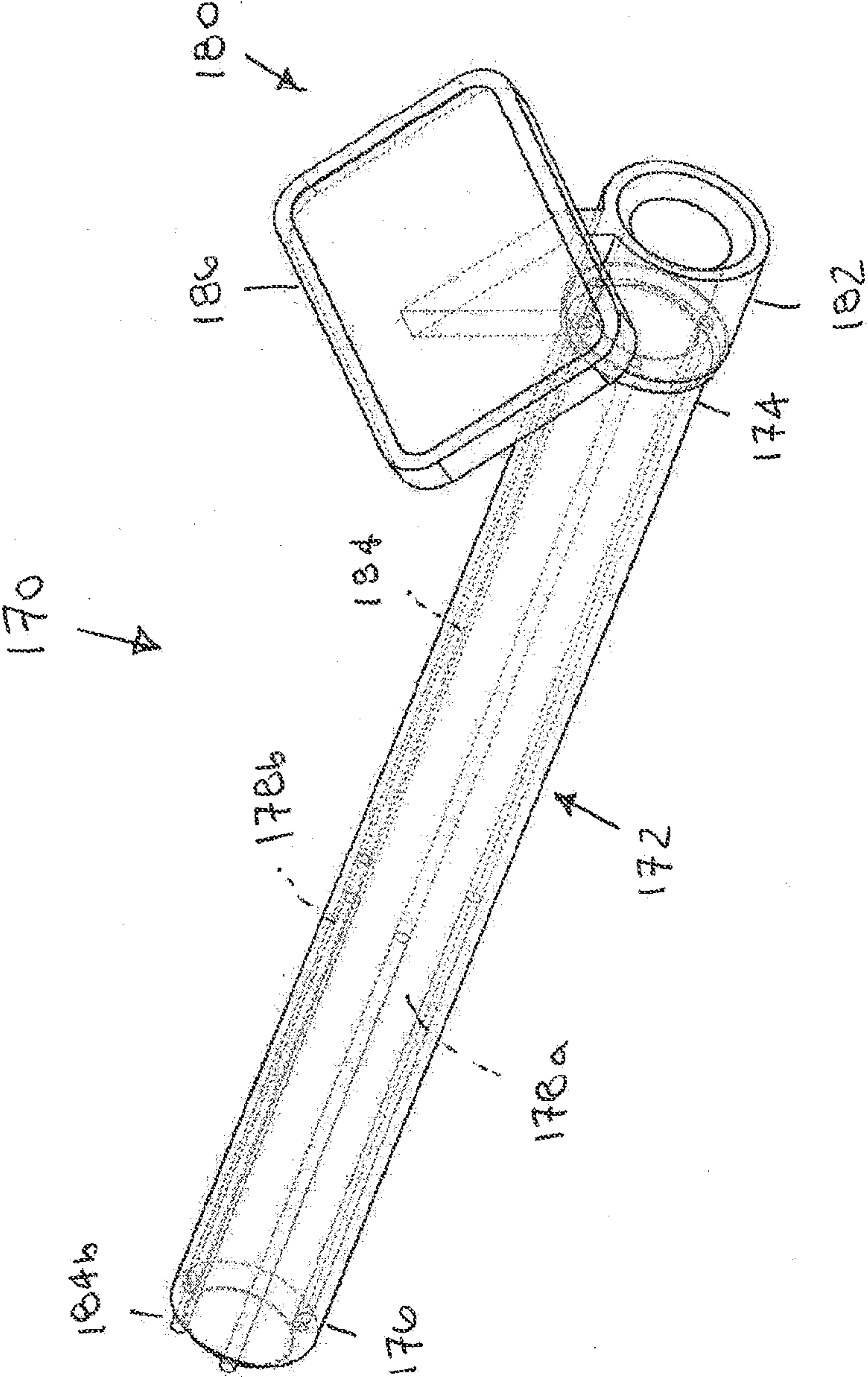


Fig. 9A

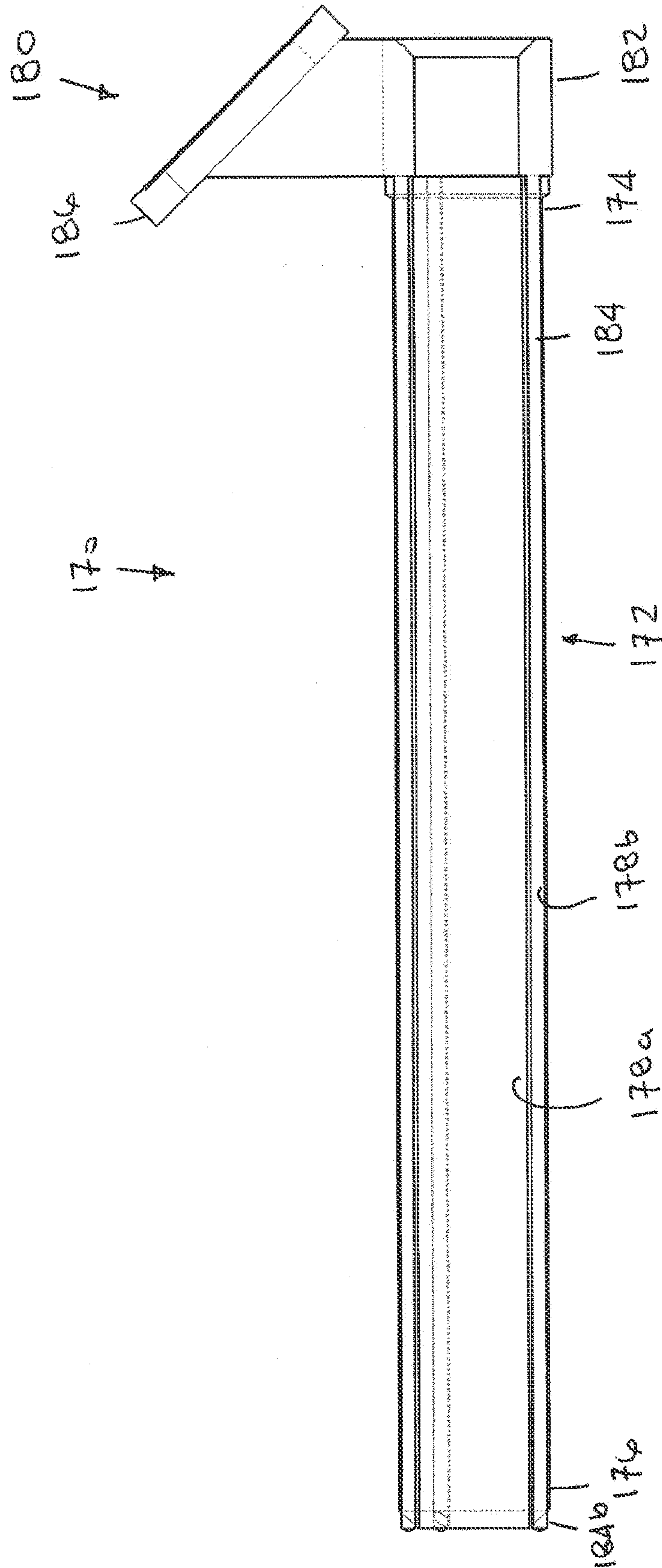


Fig. 9B

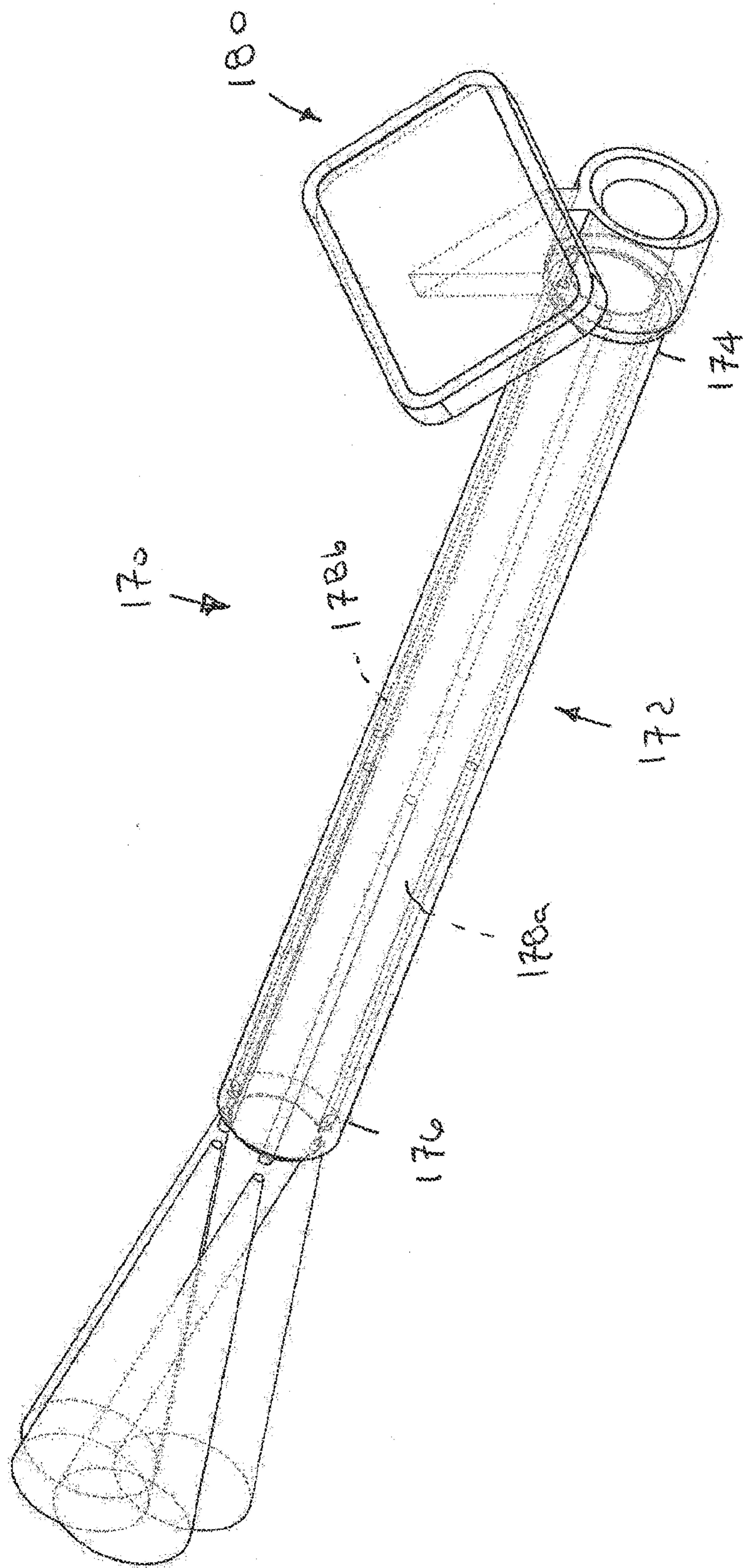


Fig. 9C

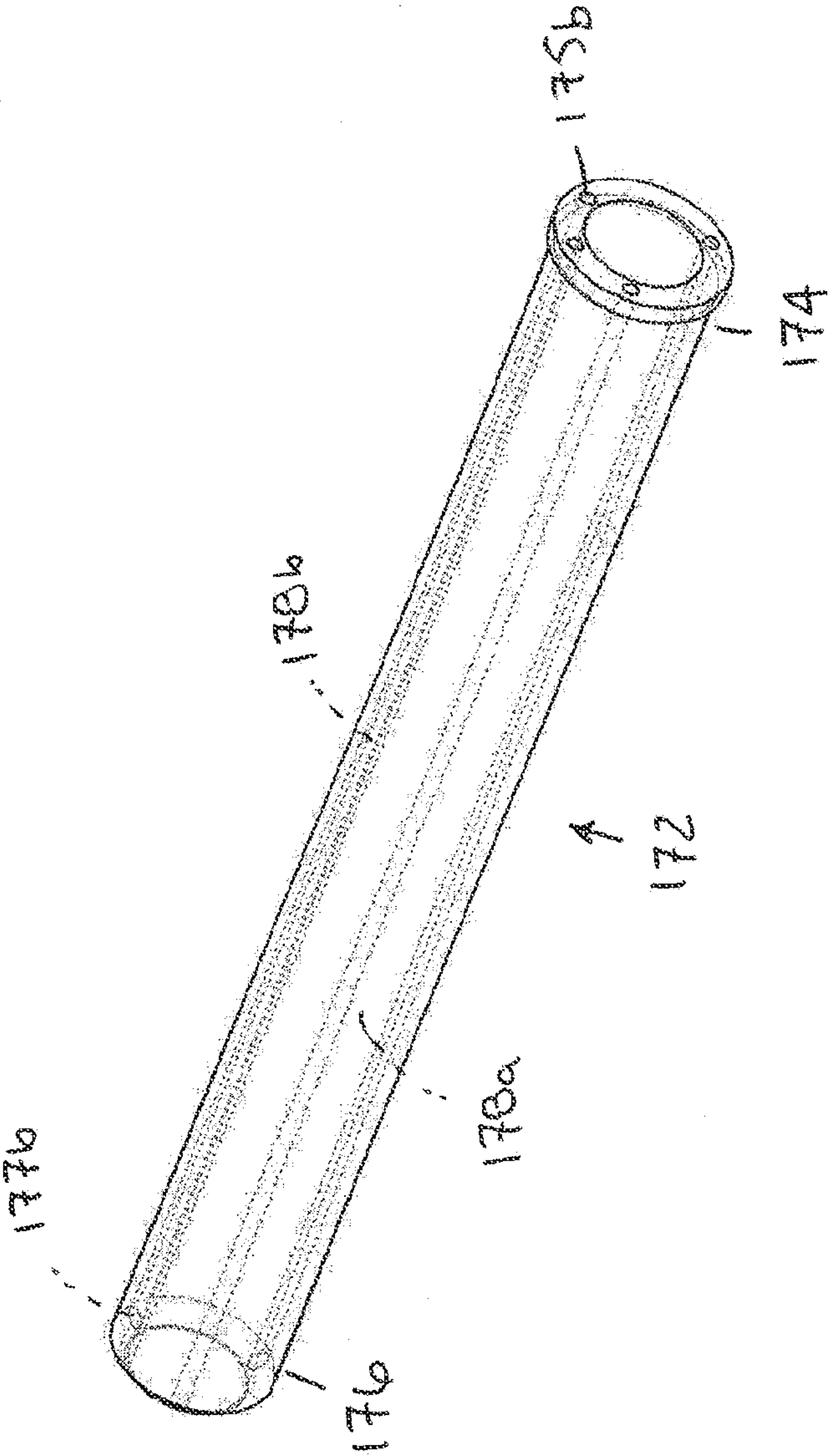


Fig. 10

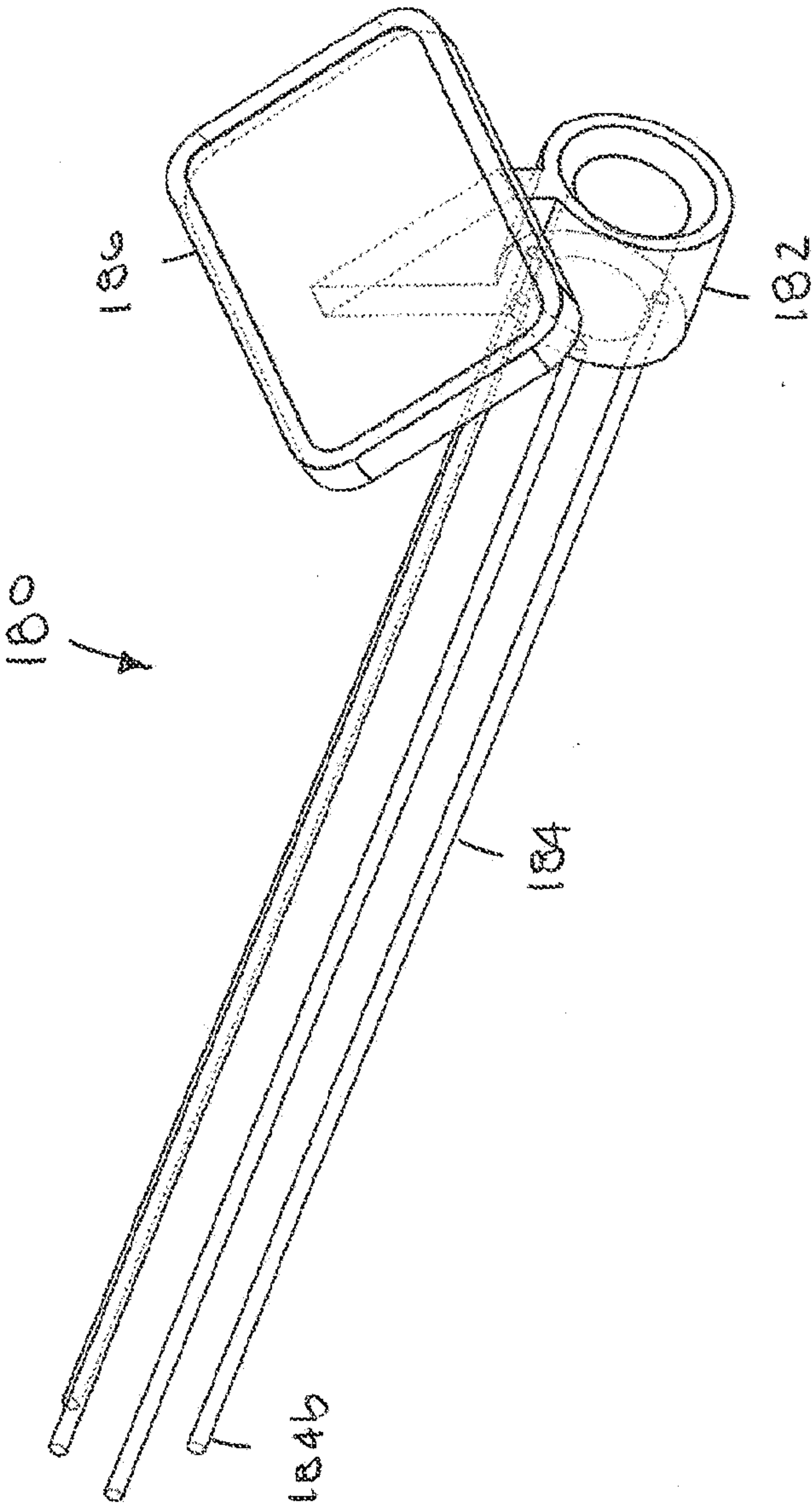


Fig. 11

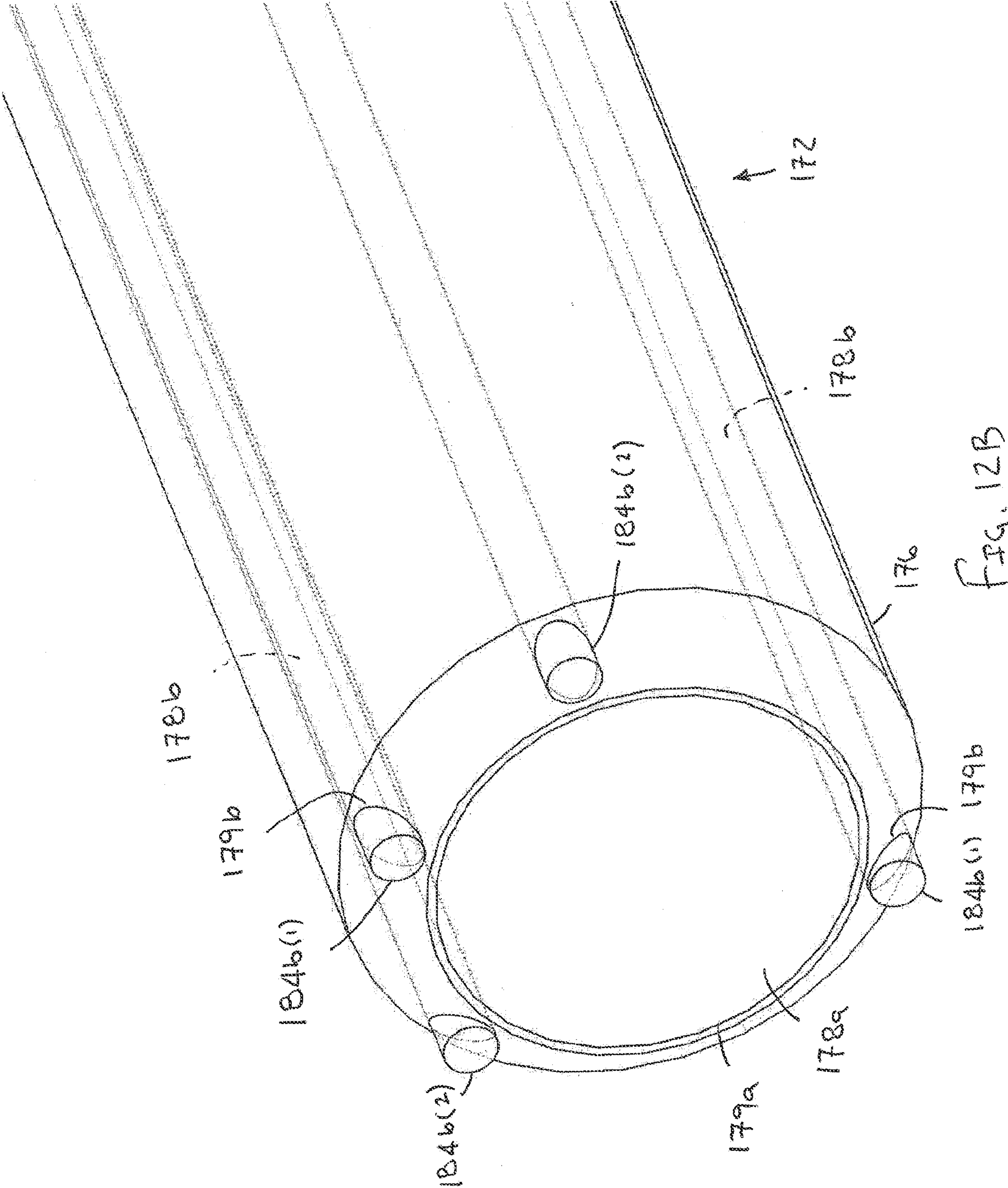


Fig. 12B

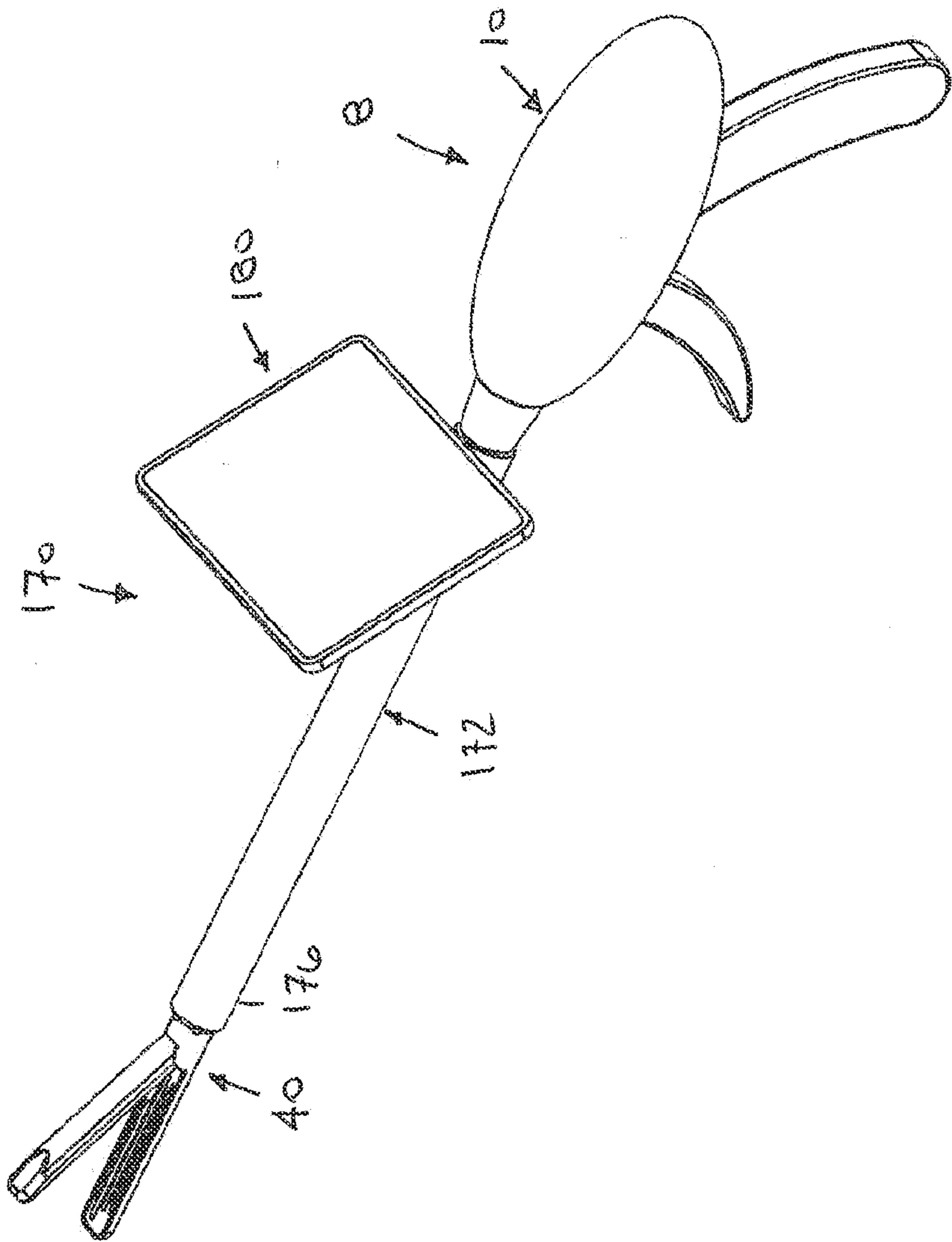


Fig. 13A

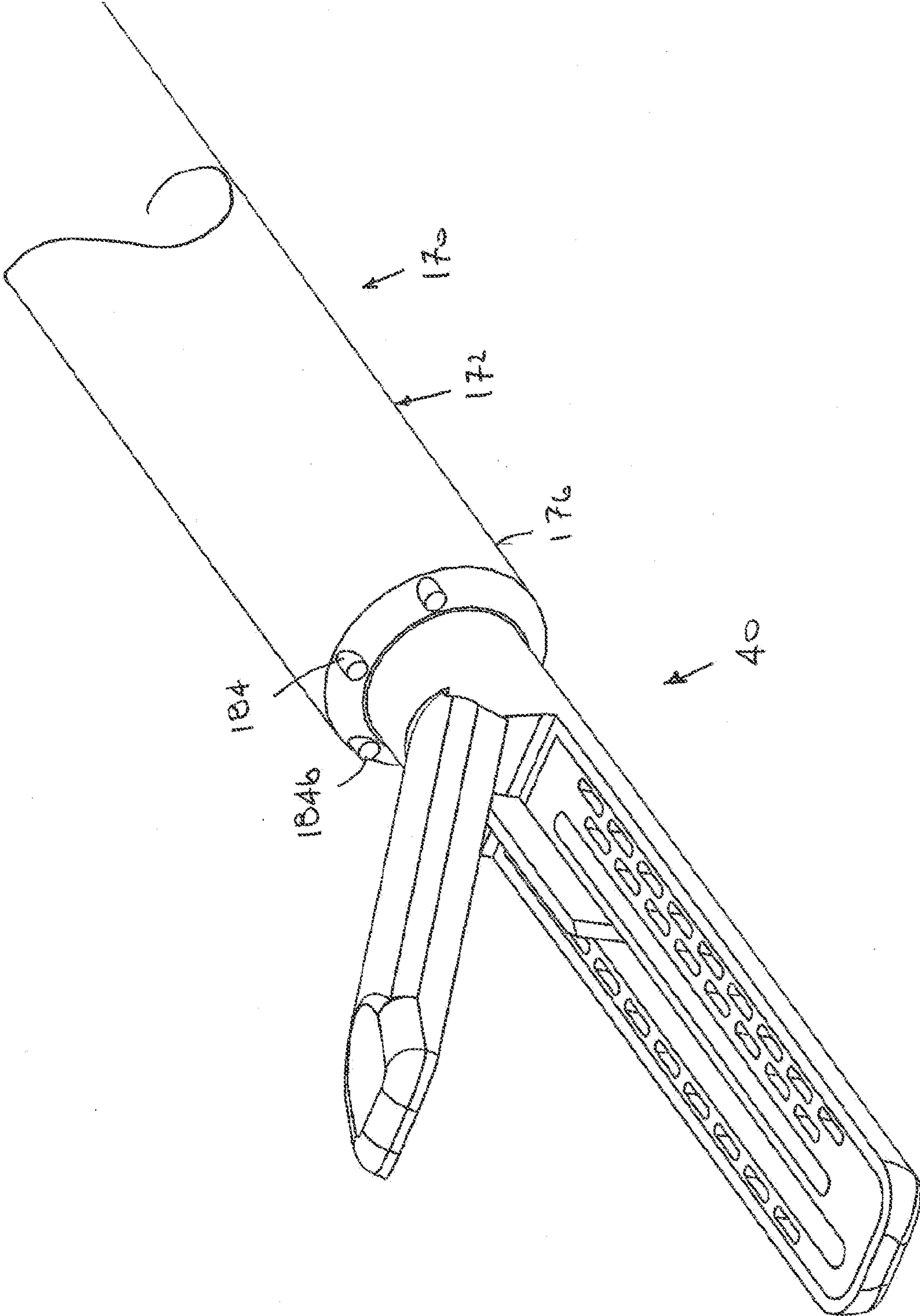


FIG. 13B

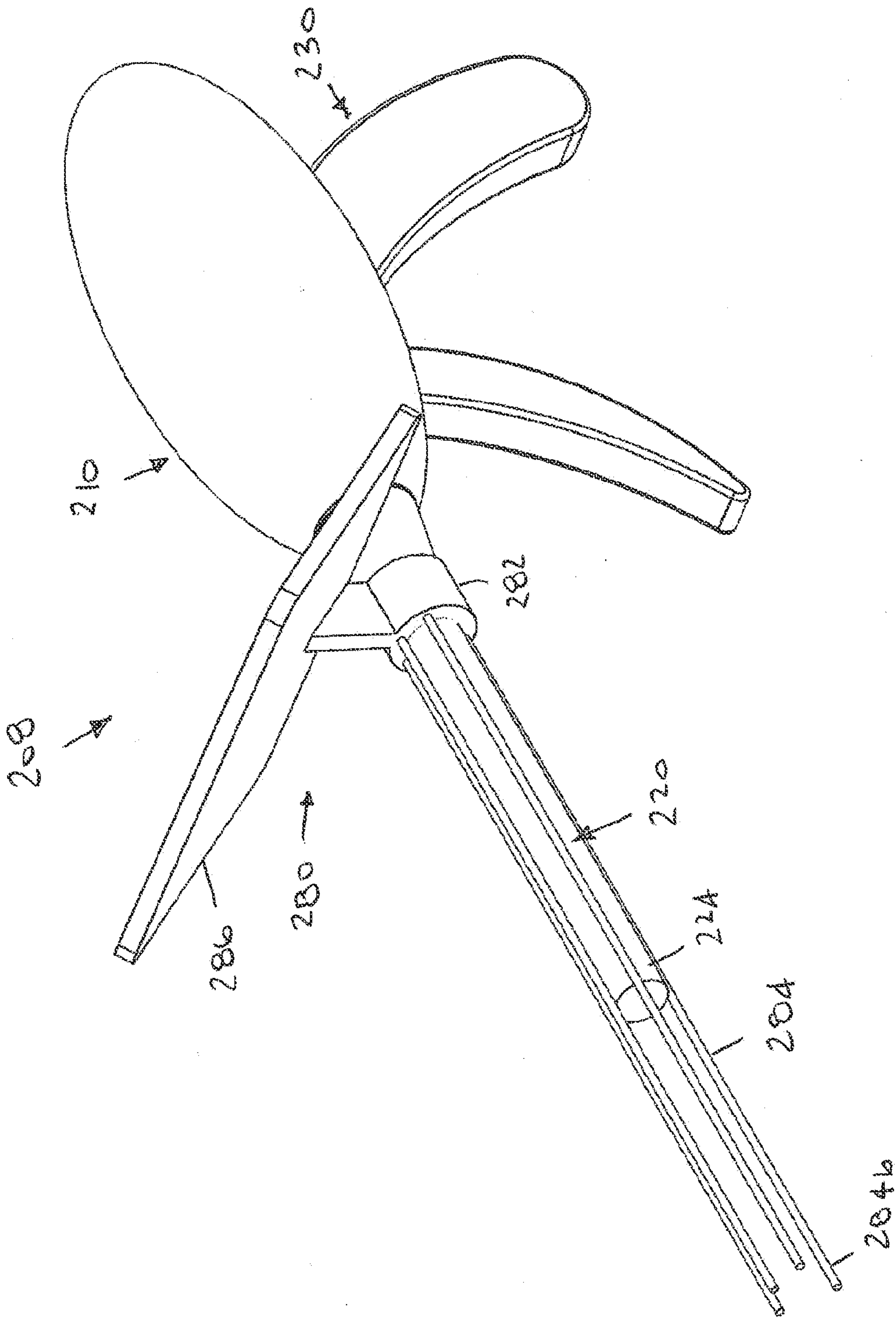
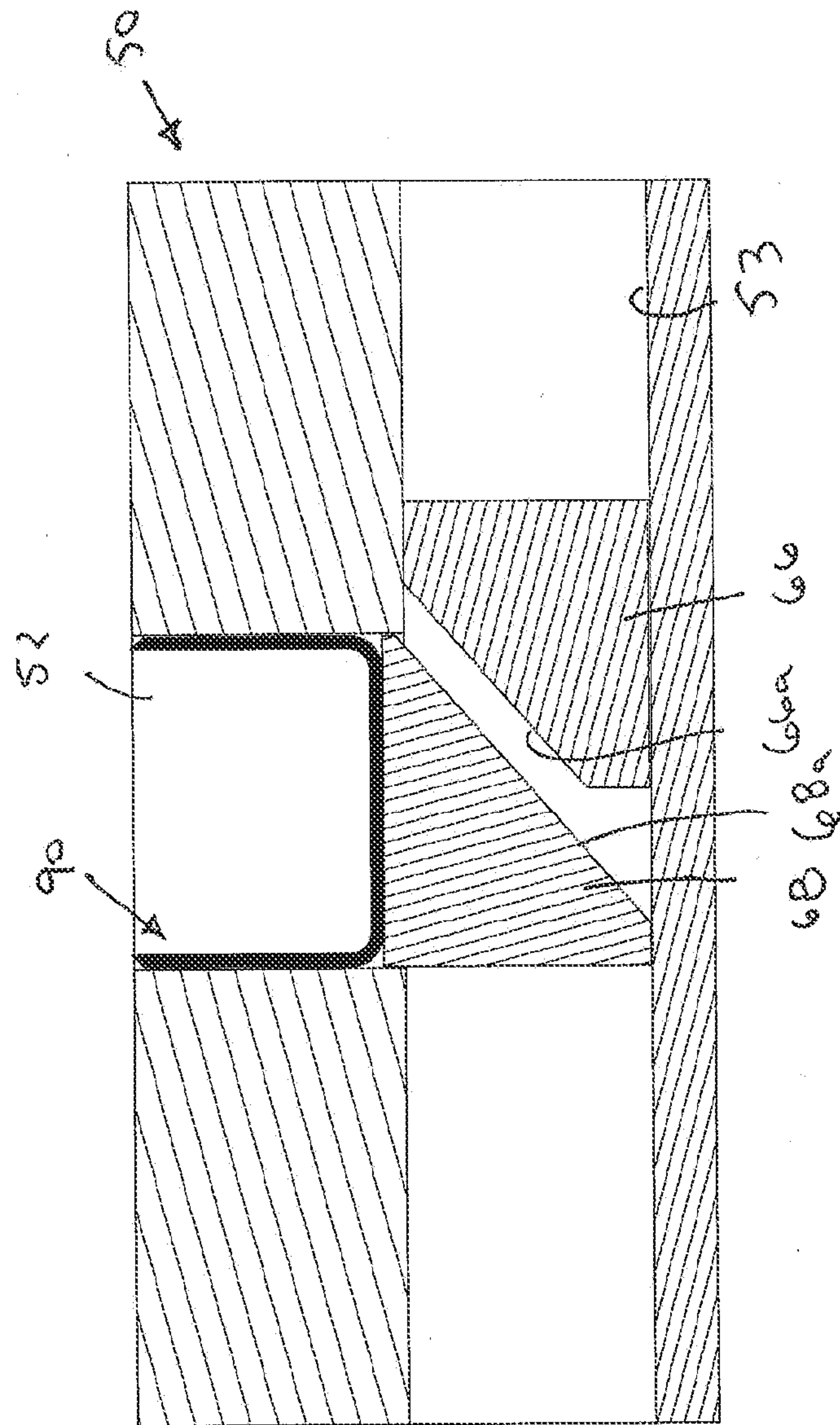


Fig. 14



15A

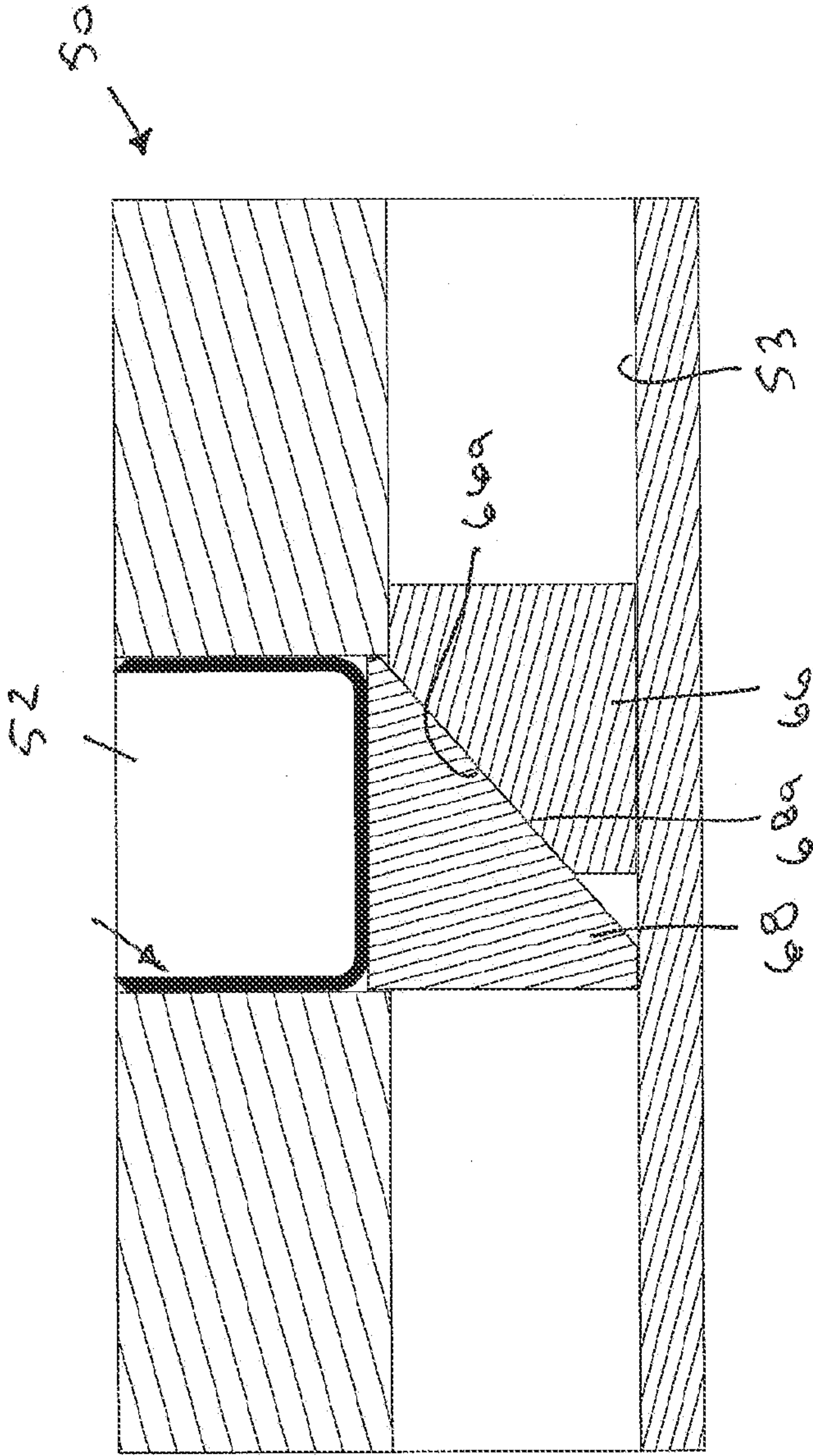


FIG. 15B

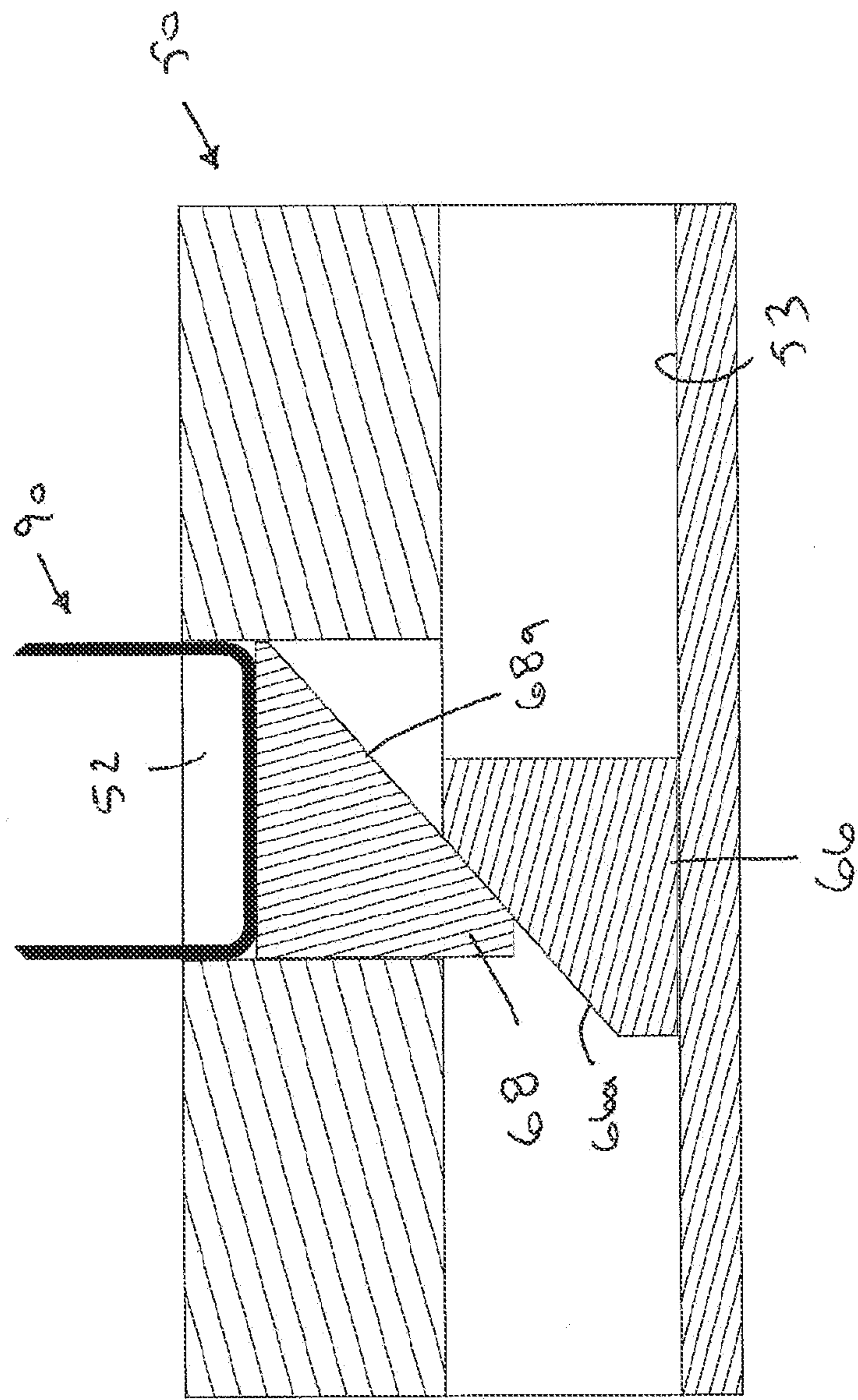
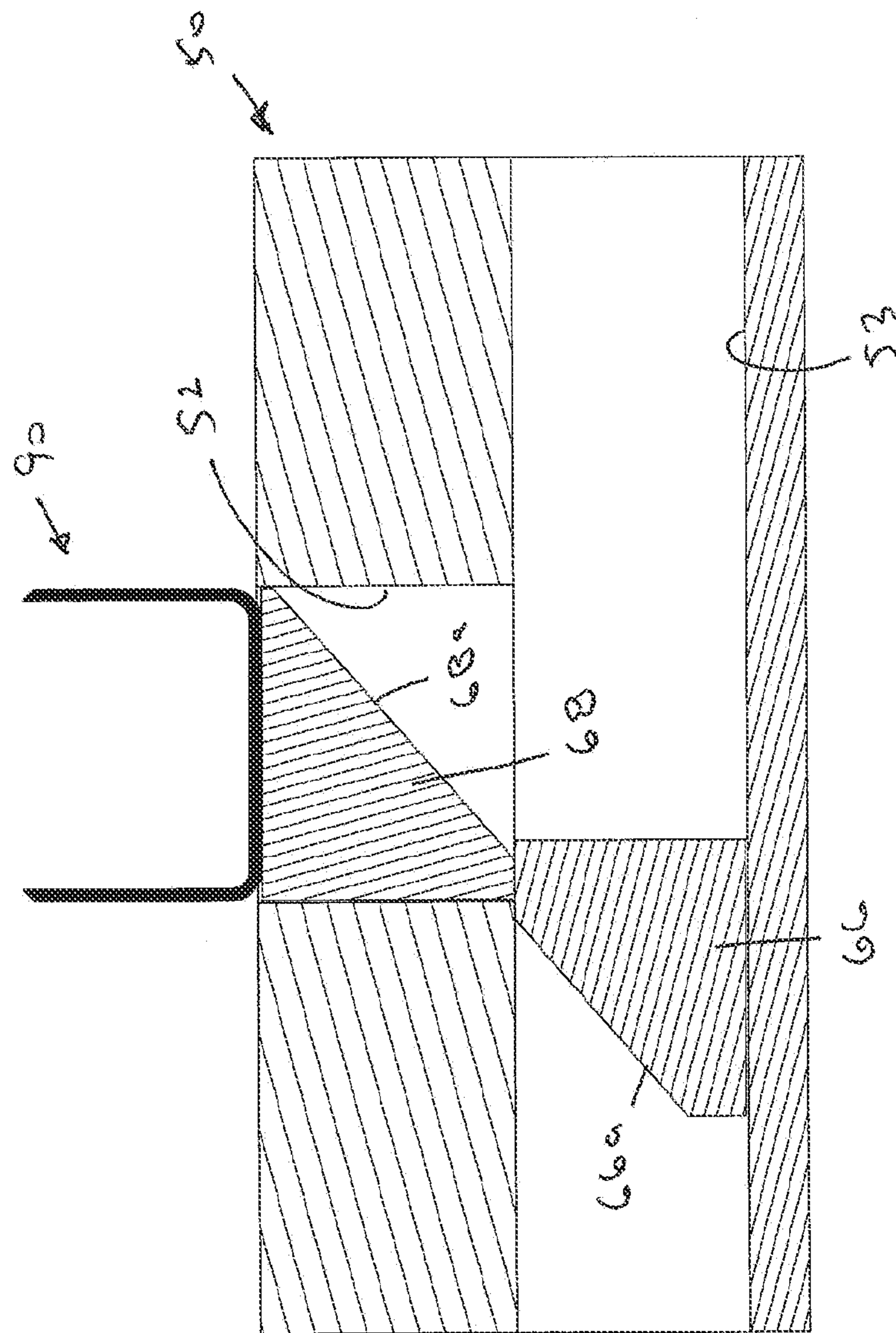


Fig. 15C



54

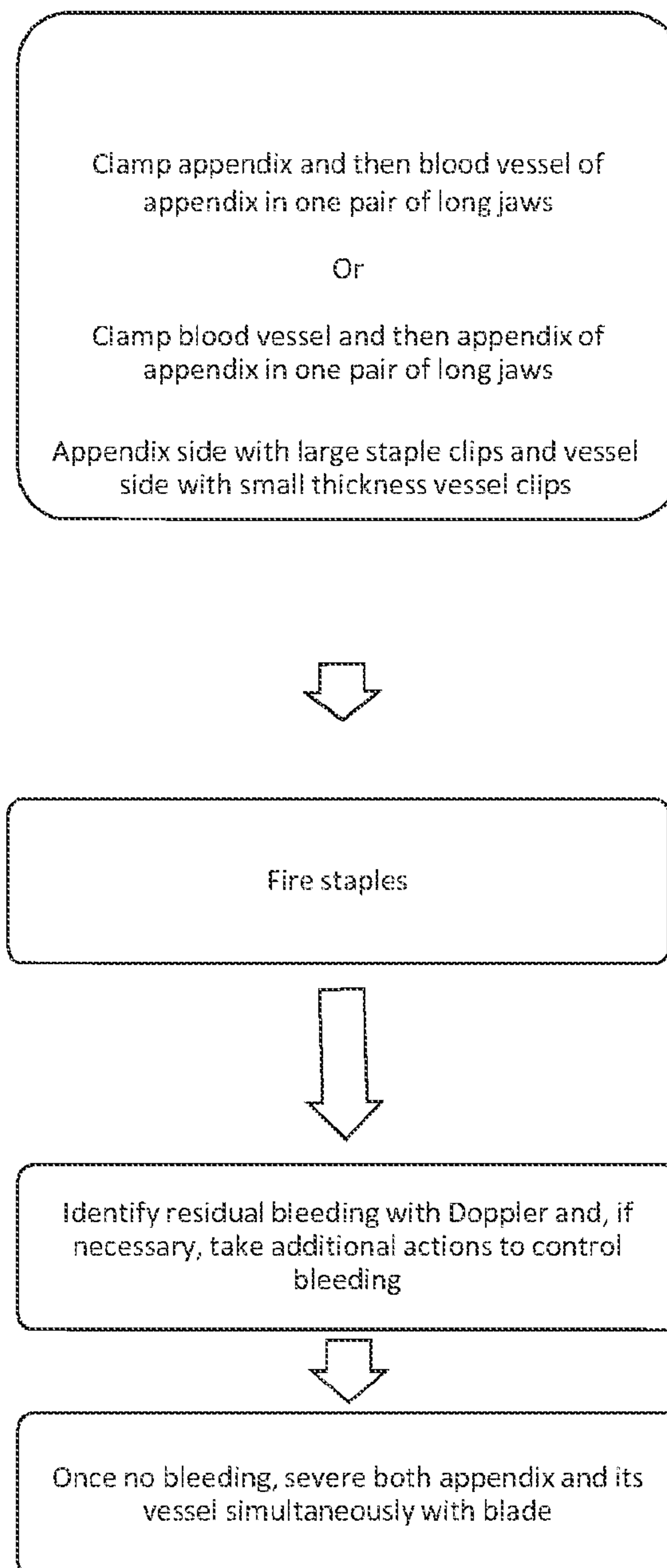


FIG. 16

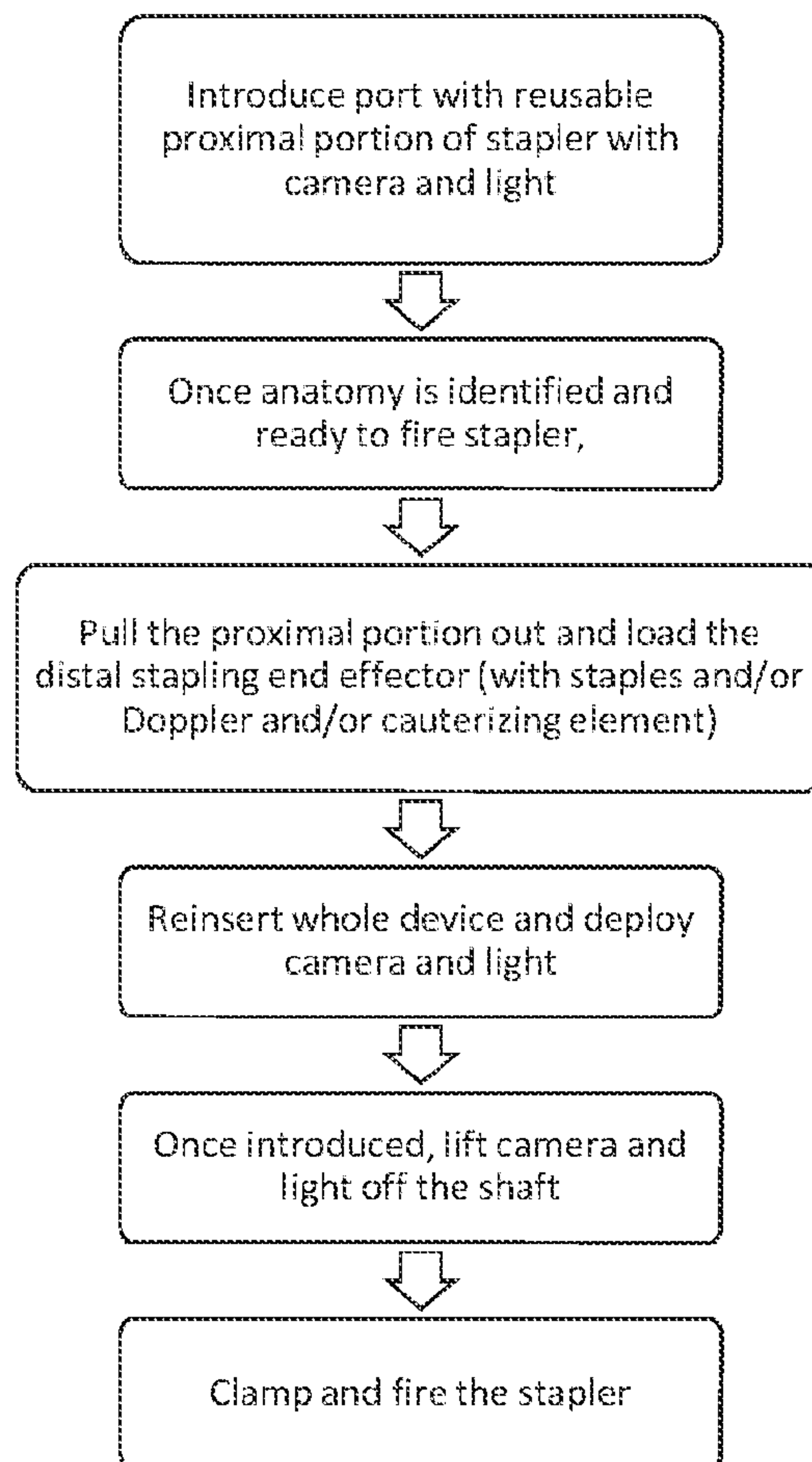


FIG. 17

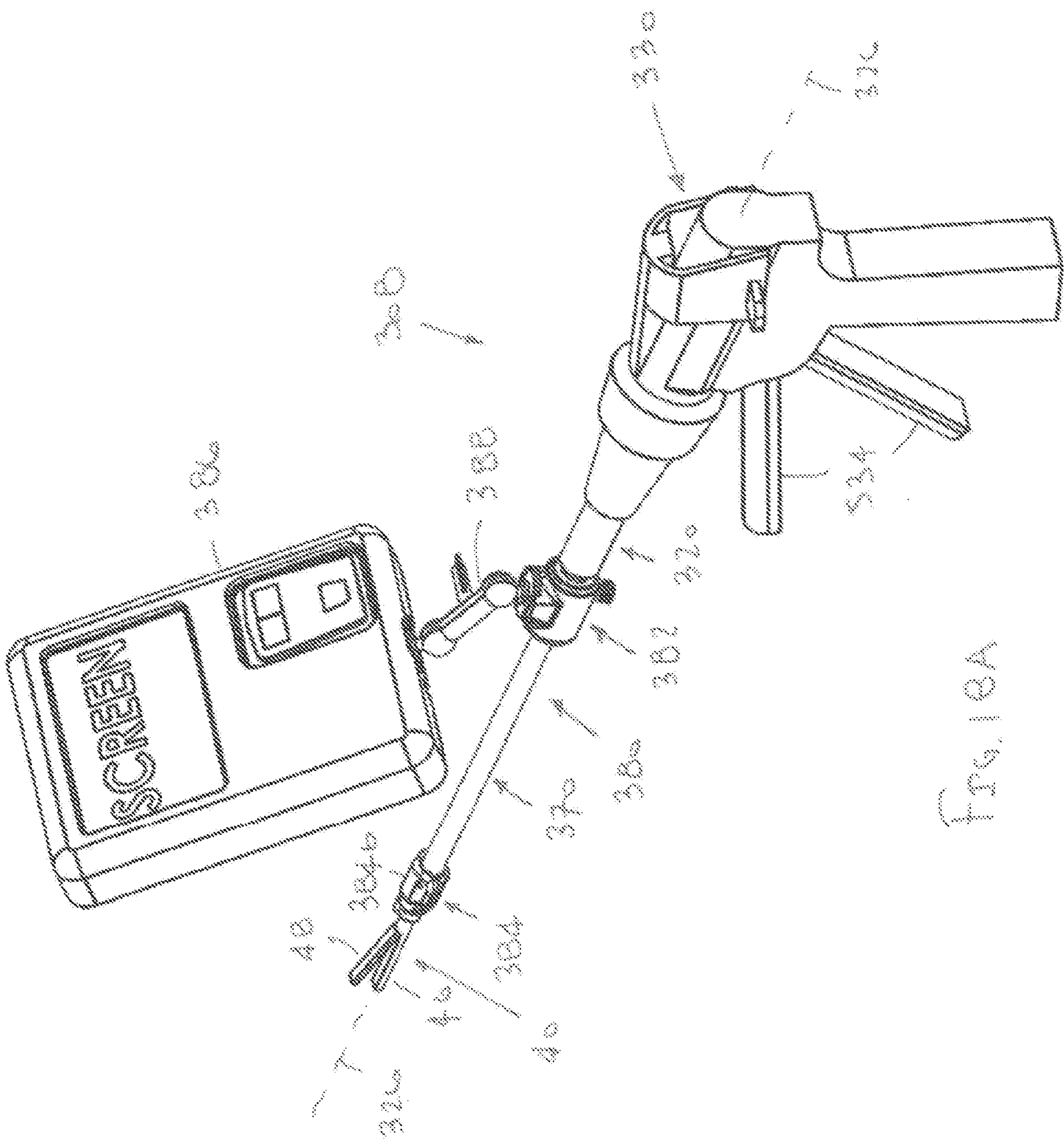


Fig. 18A

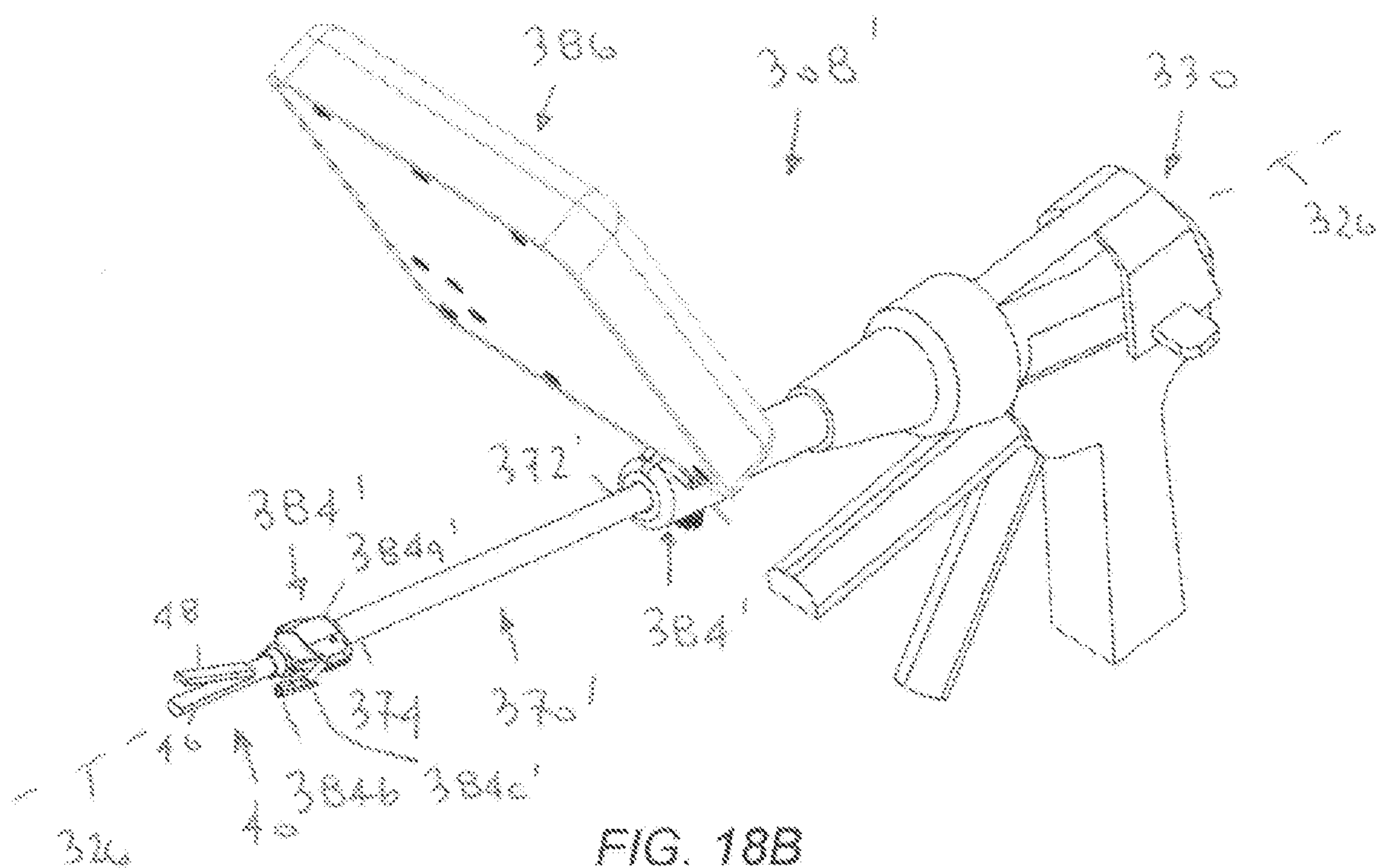


FIG. 188

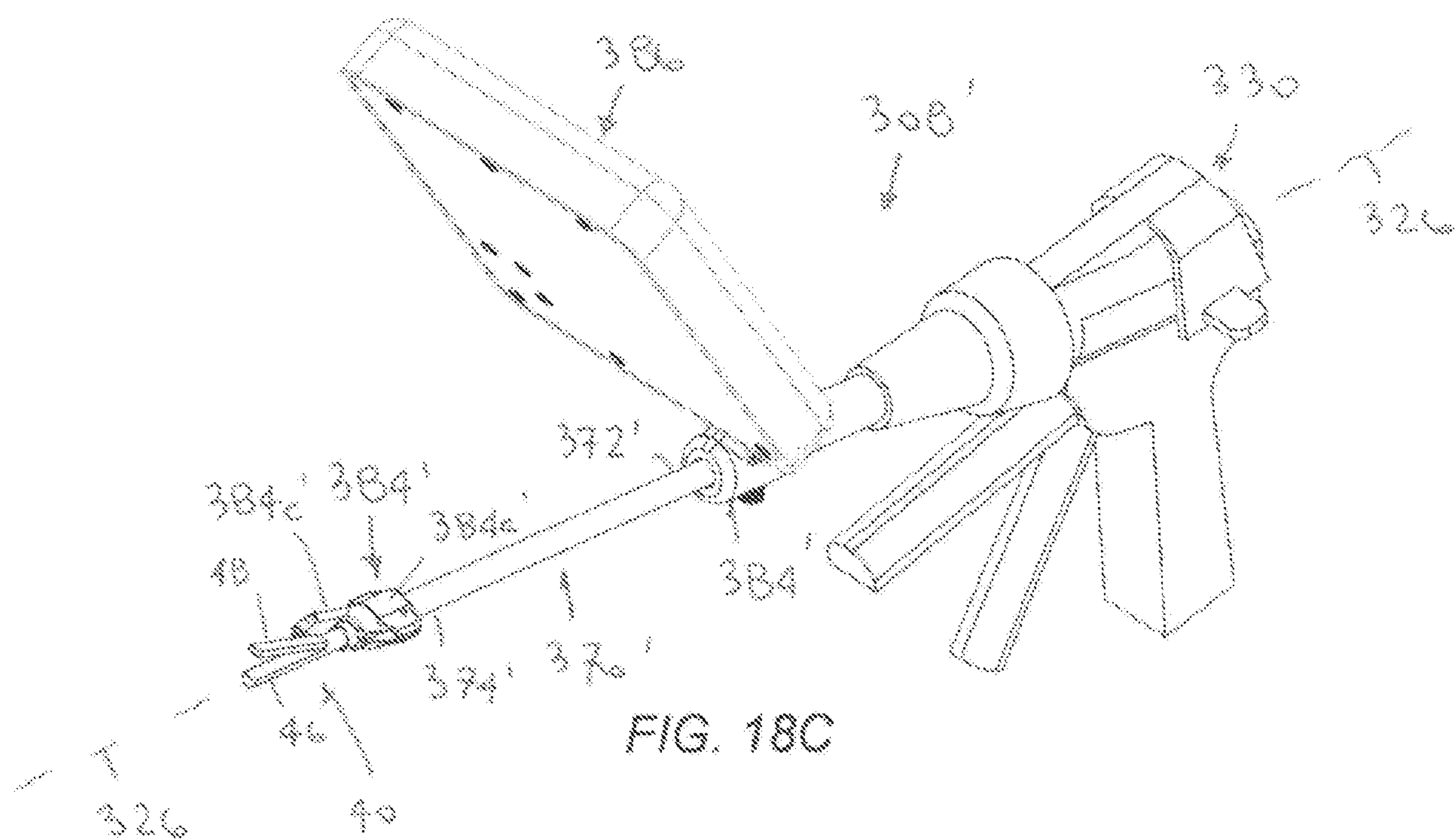


FIG. 18C

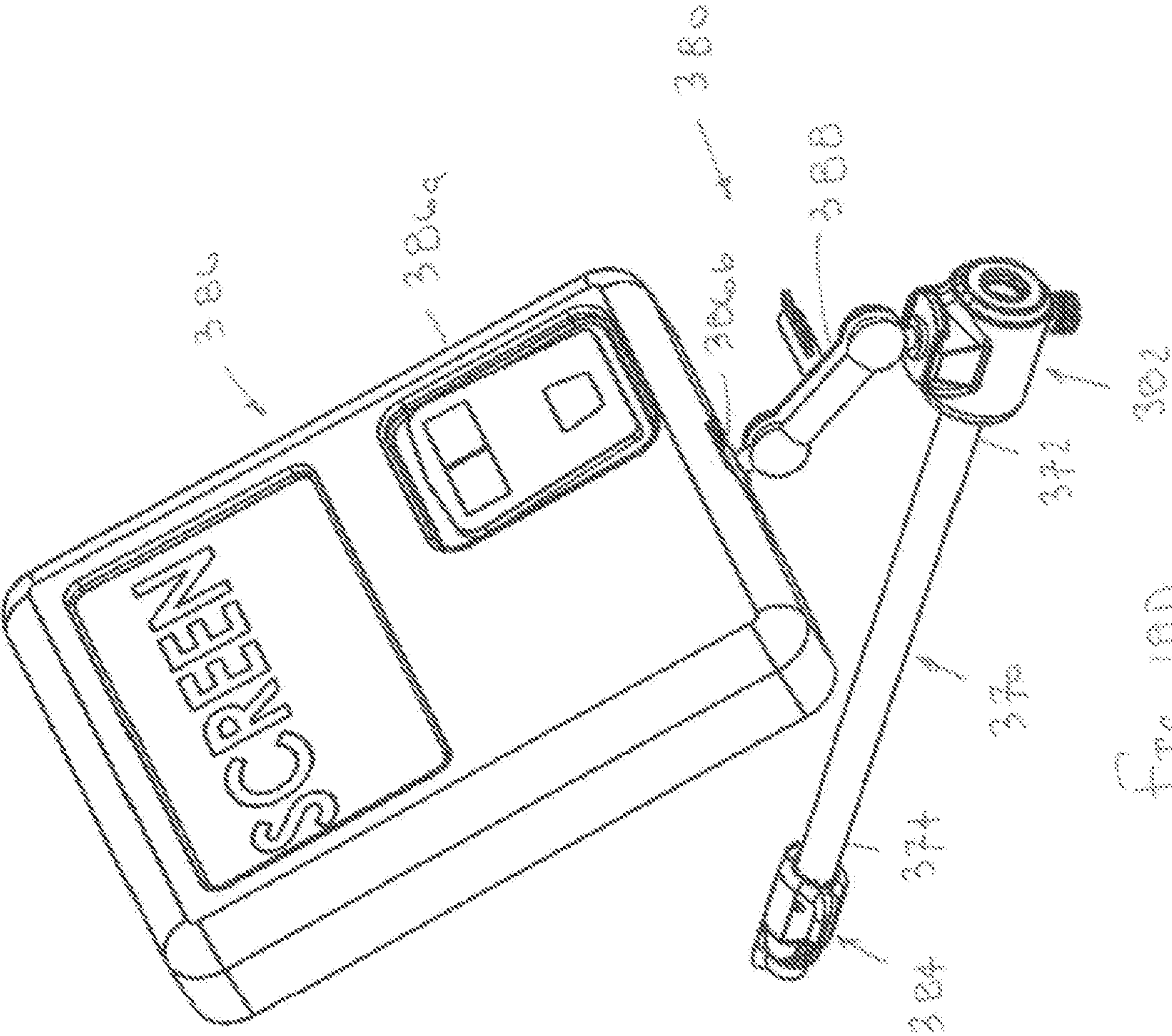
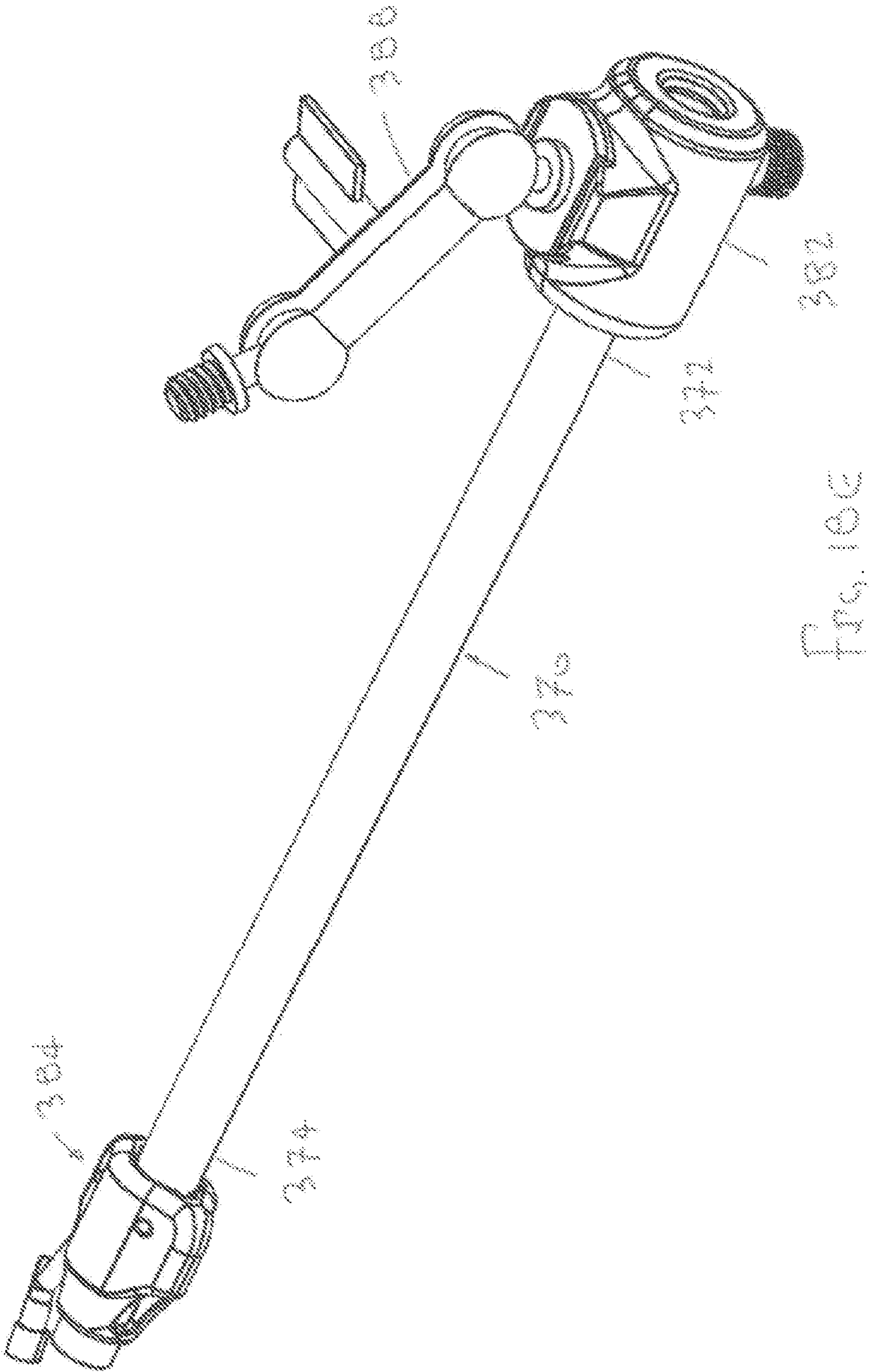


FIG. 10D



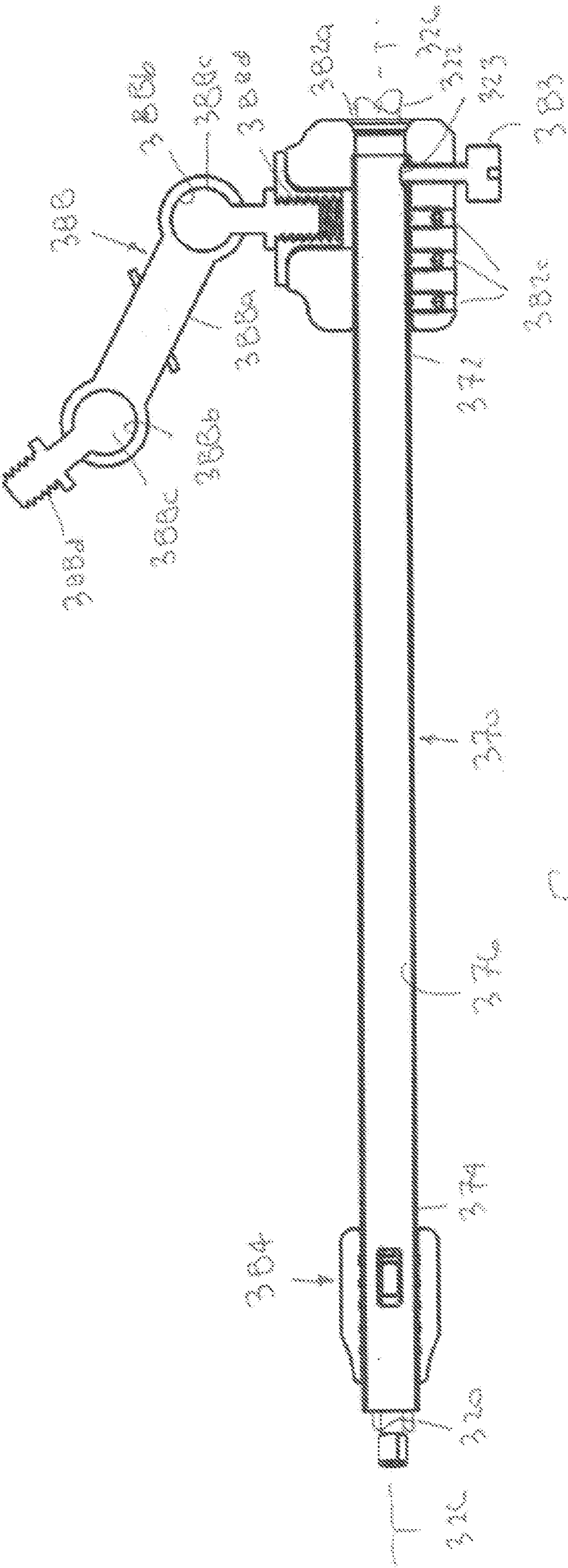


Fig. 10f

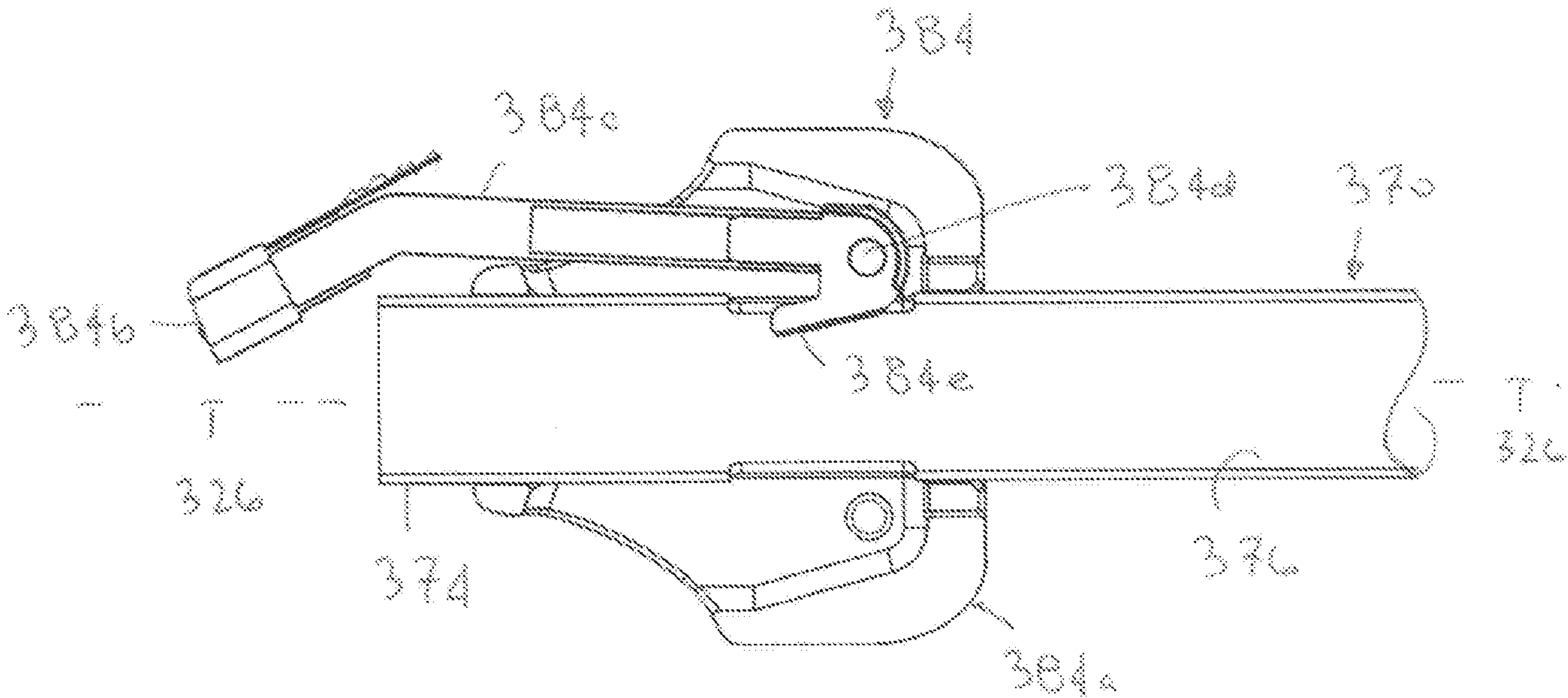


FIG. 18G

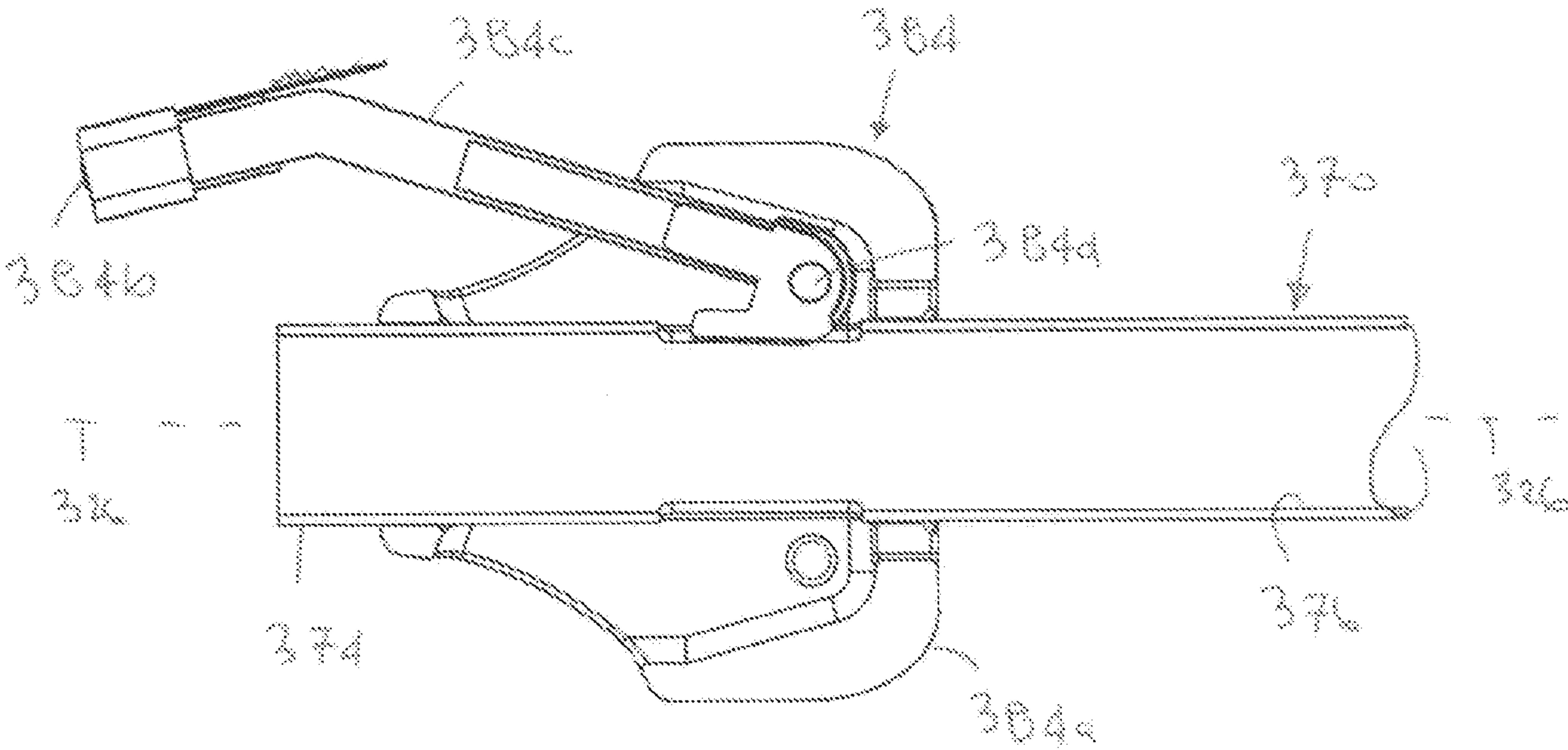


FIG. 18H

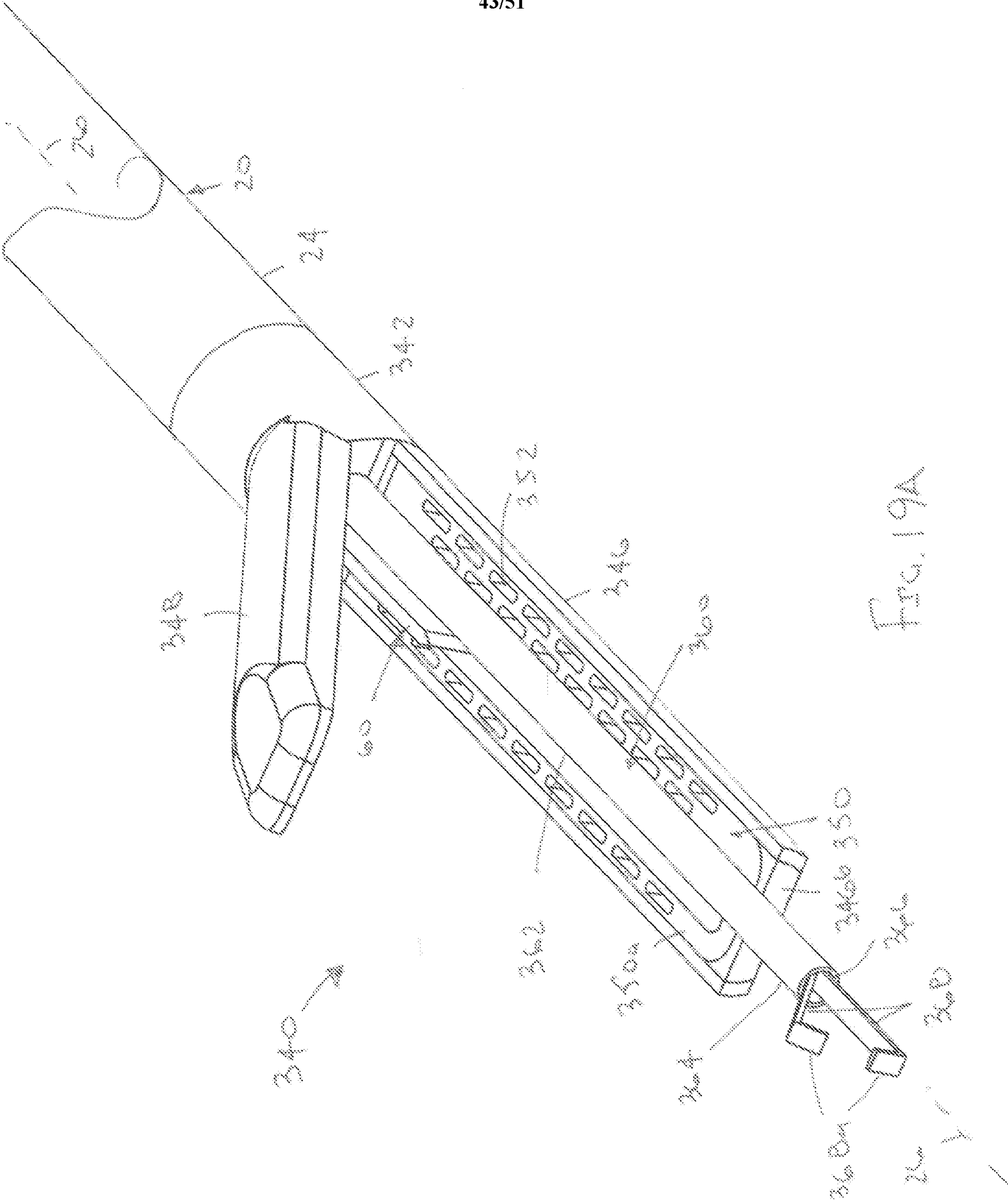


FIG. 19A

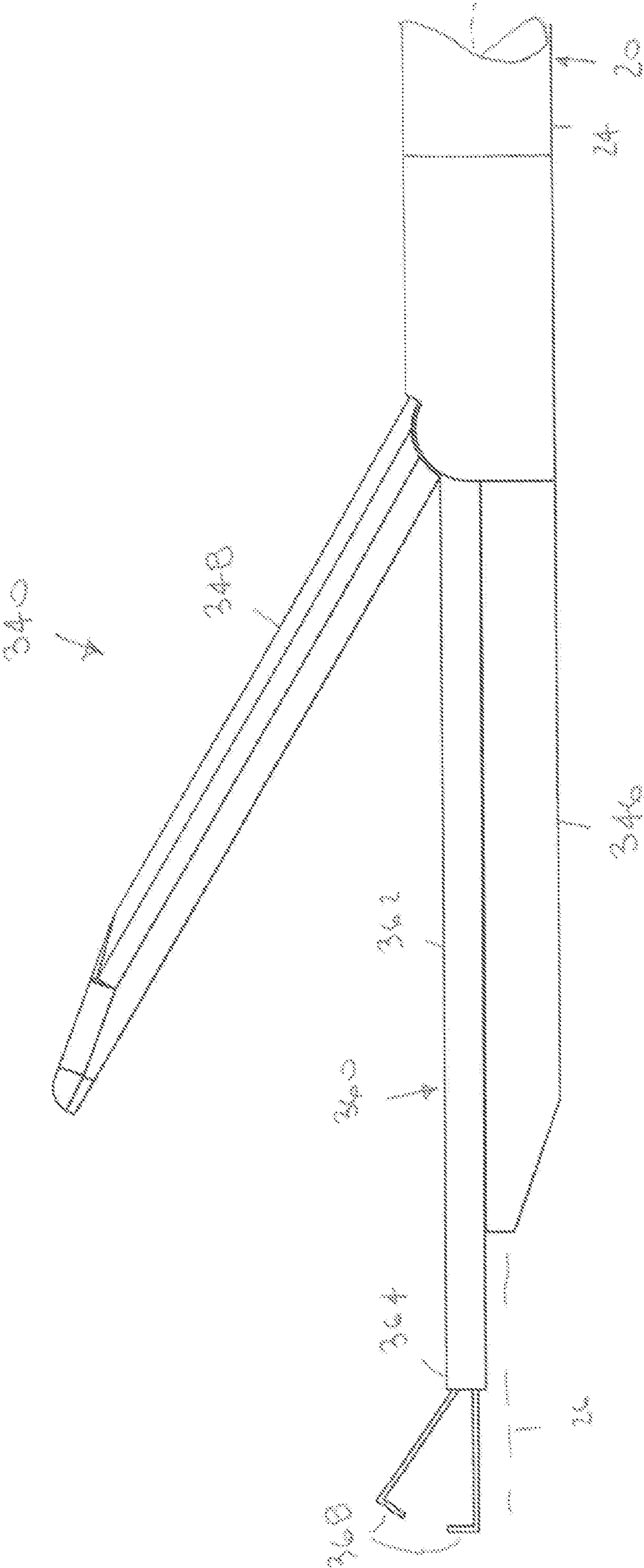


FIG. 19B

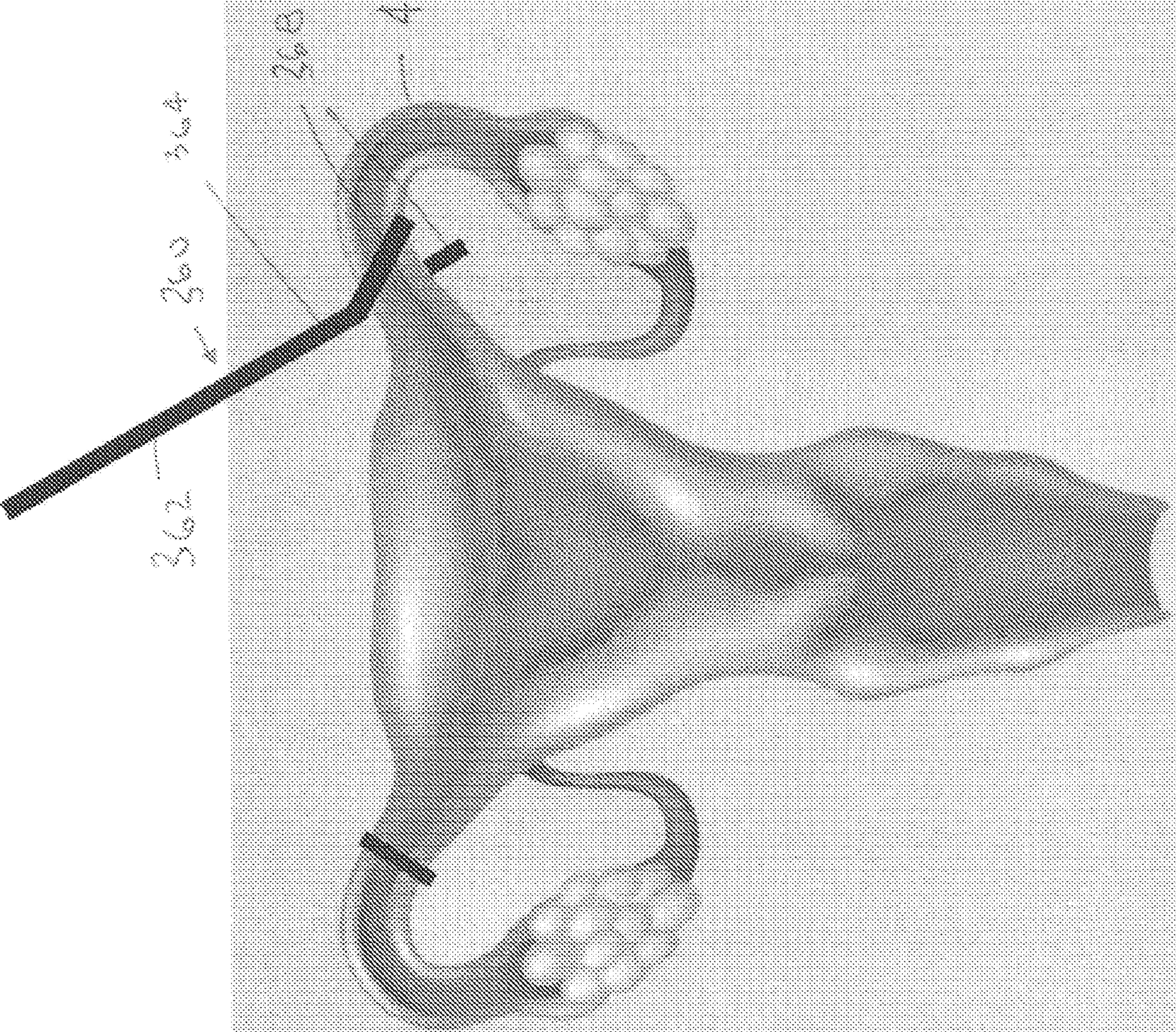
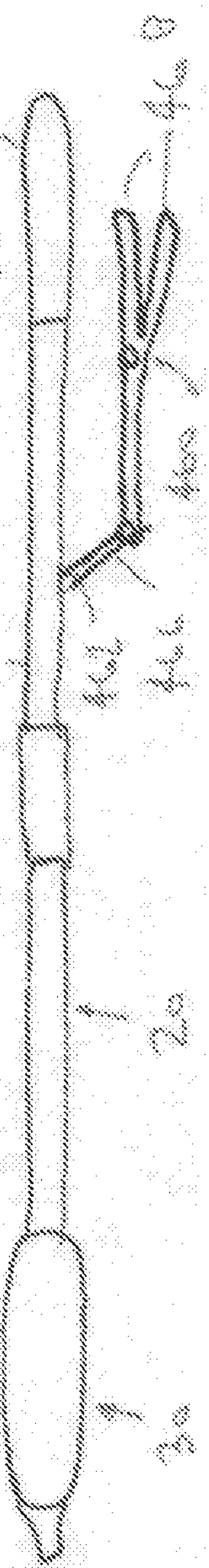
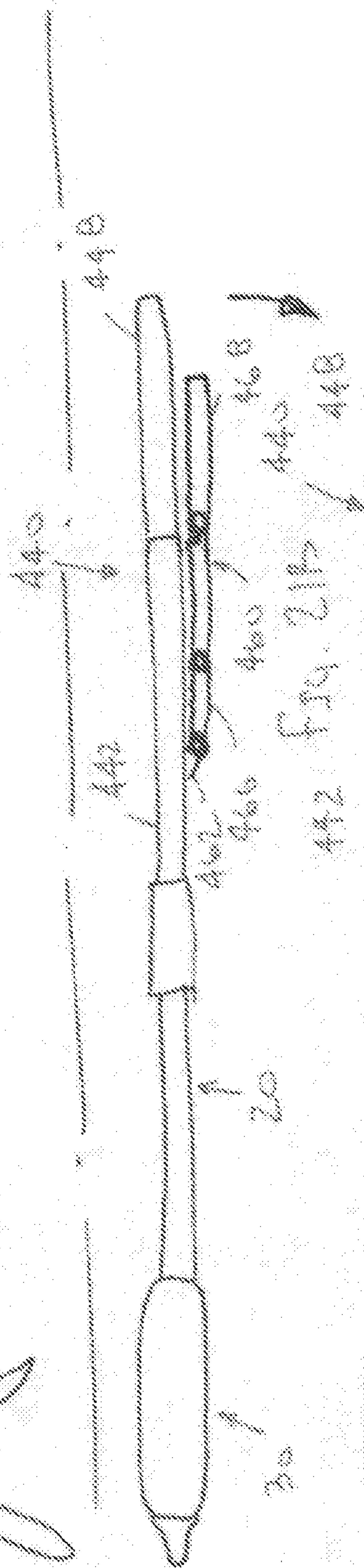
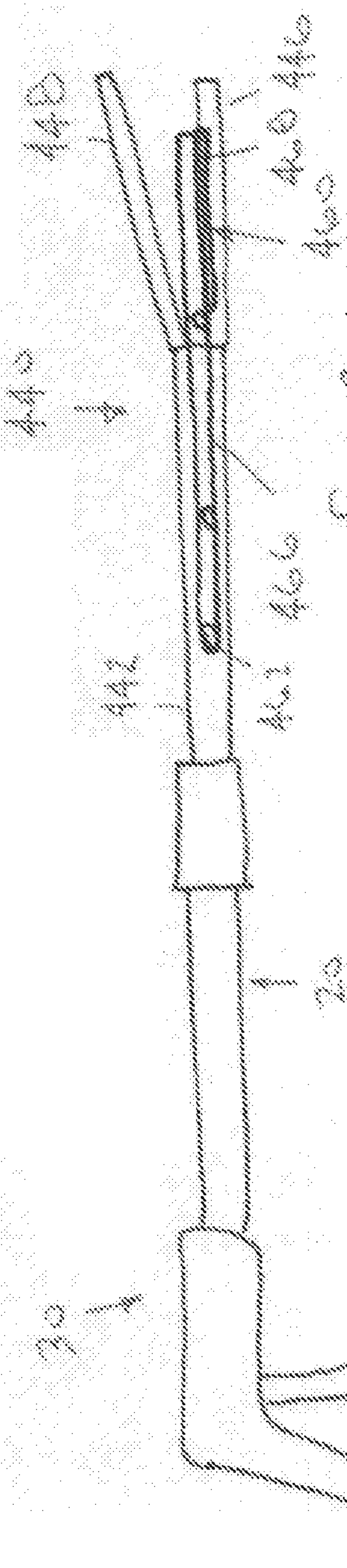
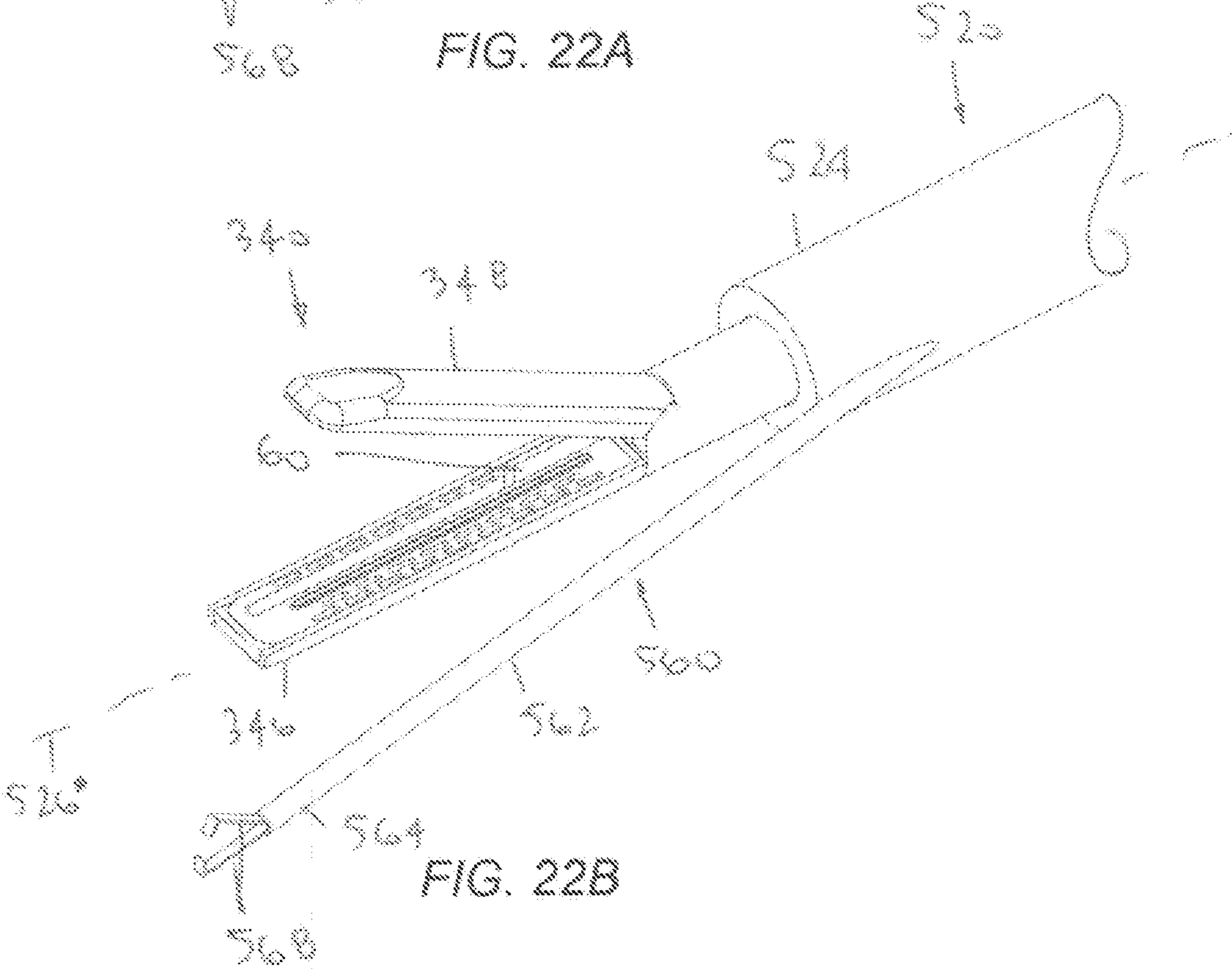
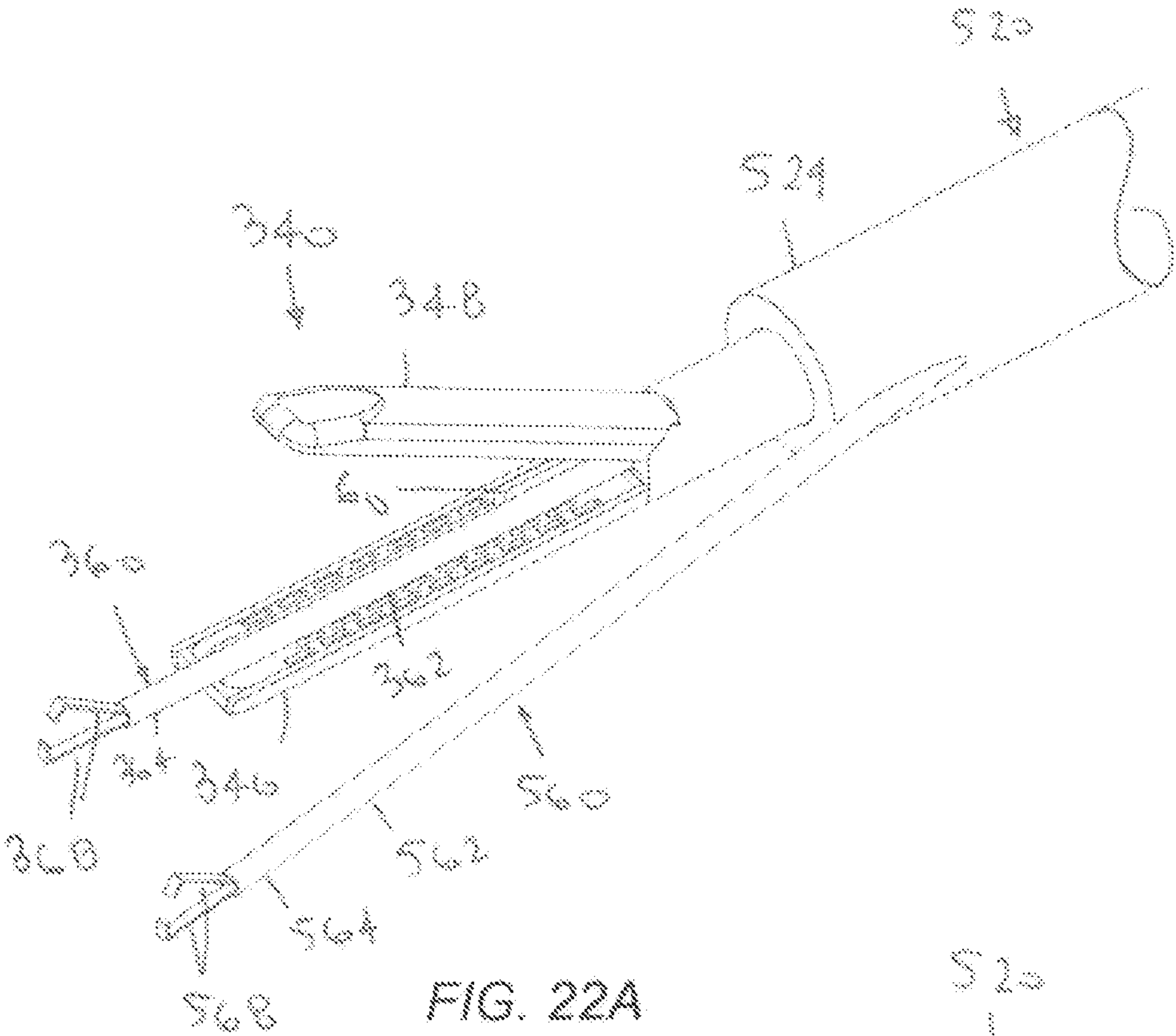


Fig. 20





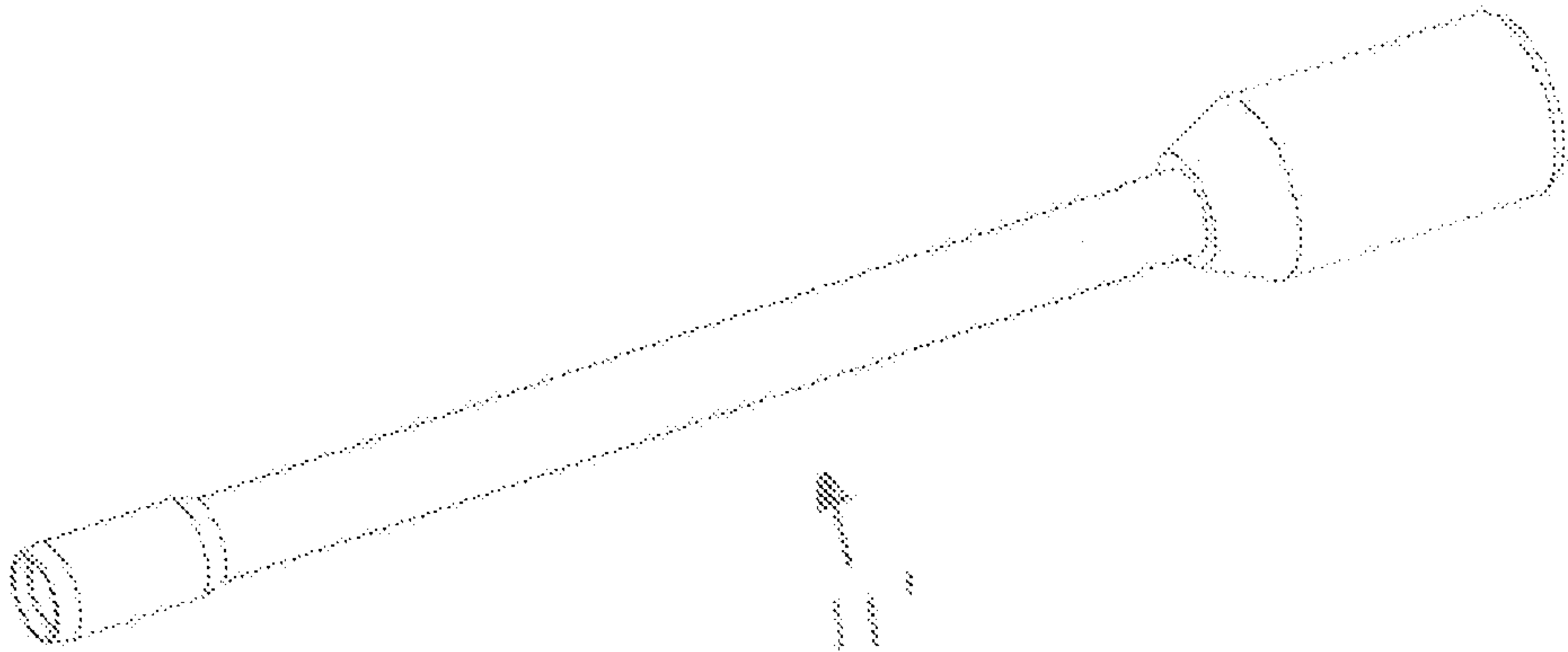


FIG. 2E

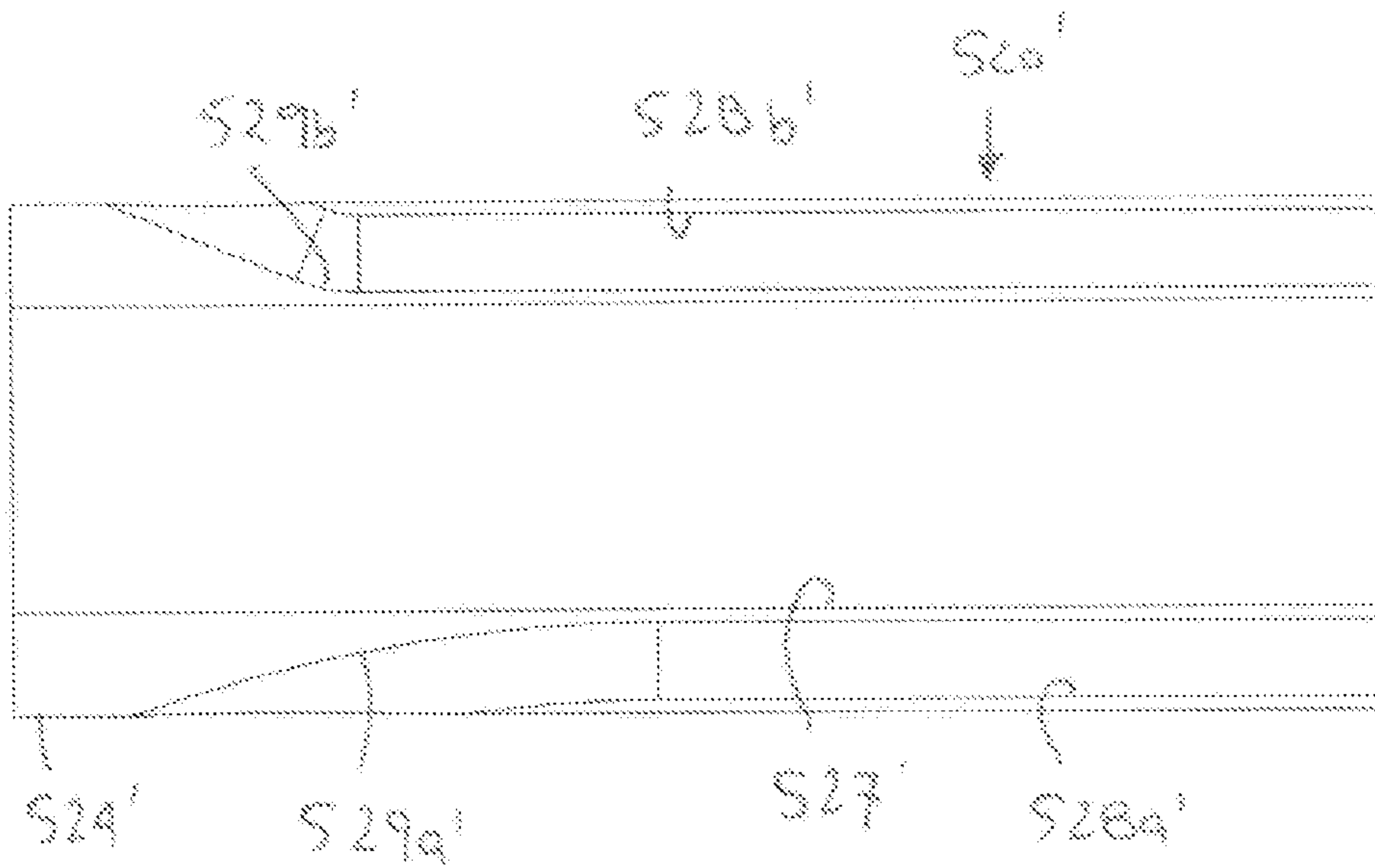


FIG. 22C

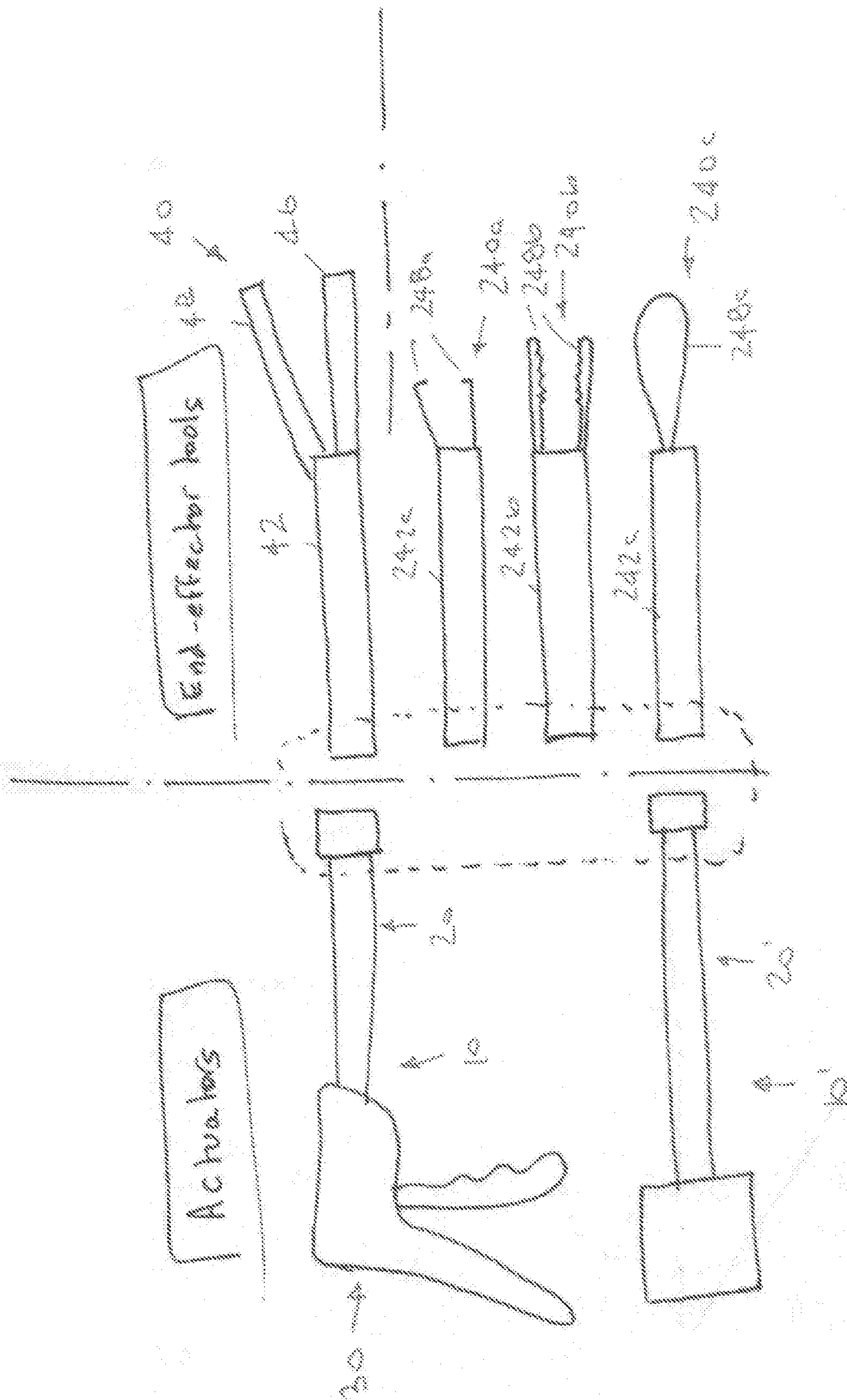


Fig. 23

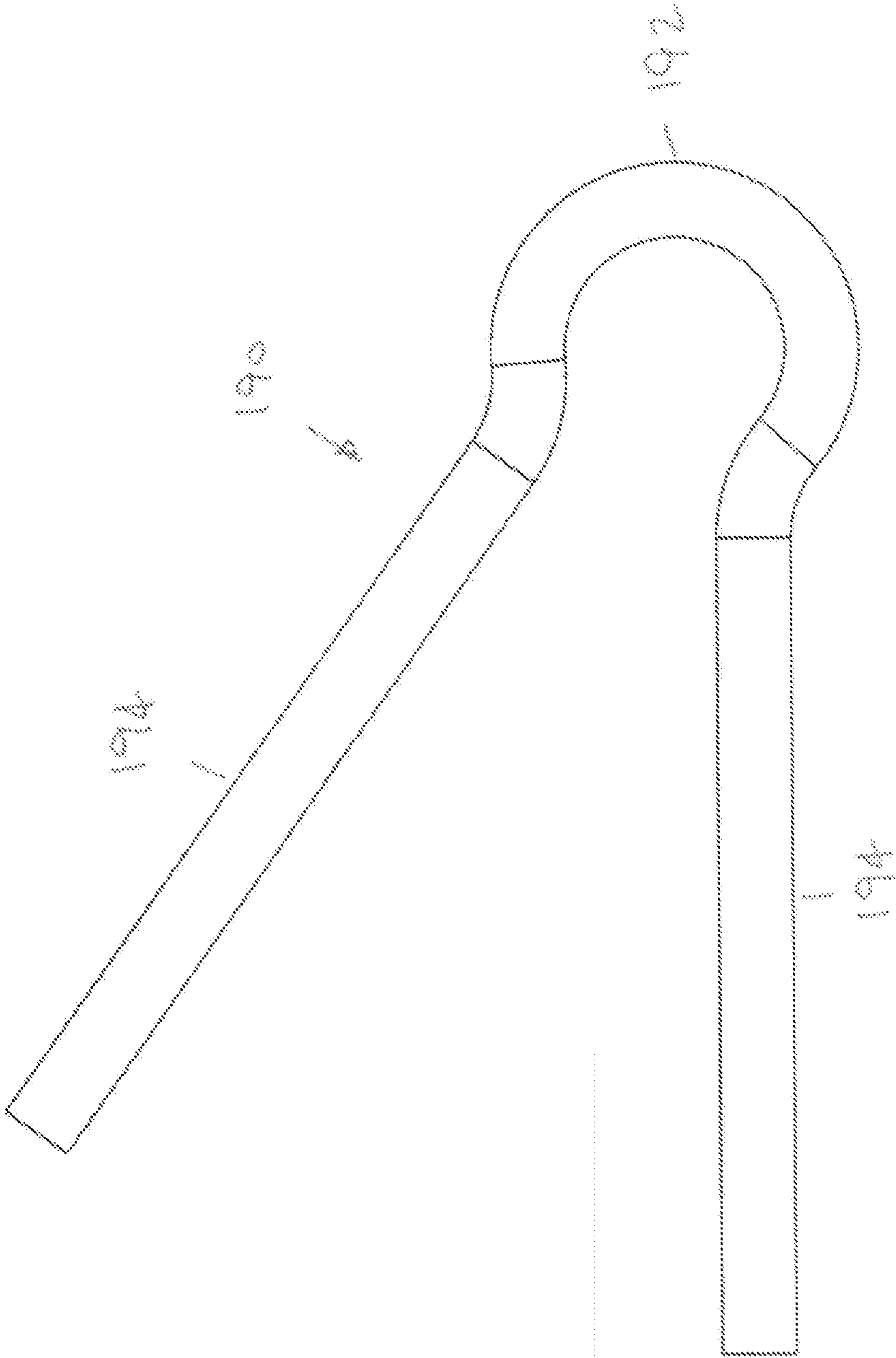


Fig. 24

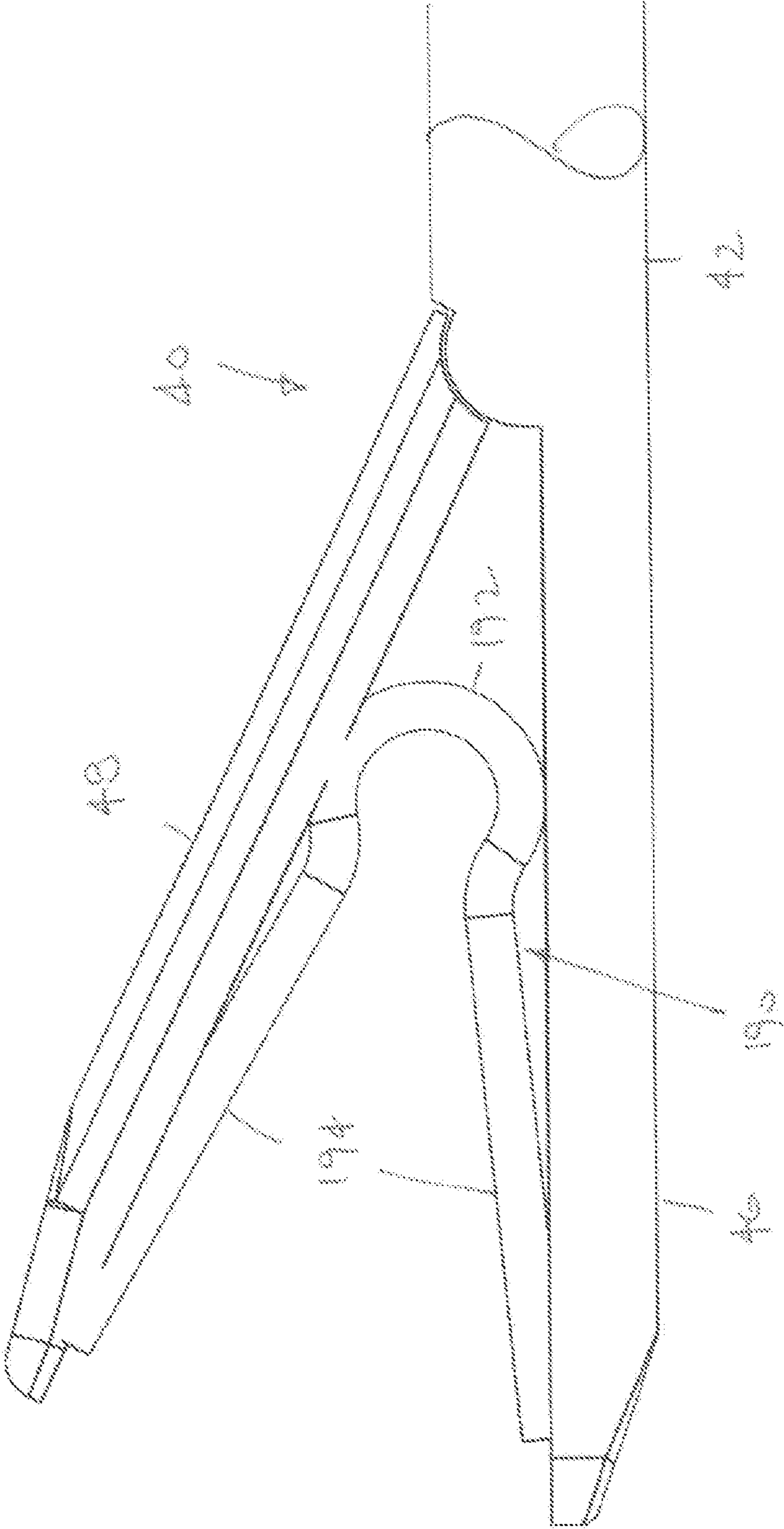


Fig. 25