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An agency of Industry Canada

CA 2143012 C 2002/12/10

(11)(21) 2 143 012

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(22) Date de dépôt/Filing Date: 1995/02/21

(41) Mise à la disp. pub./Open to Public Insp.: 1995/09/03

(45) Date de délivrance/Issue Date: 2002/12/10

(30) Priorité/Priority: 1994/03/02 (08/205,042) US

(51) Cl.Int.^{6}/Int.Cl.^{6} A61B 17/062, A61B 17/06

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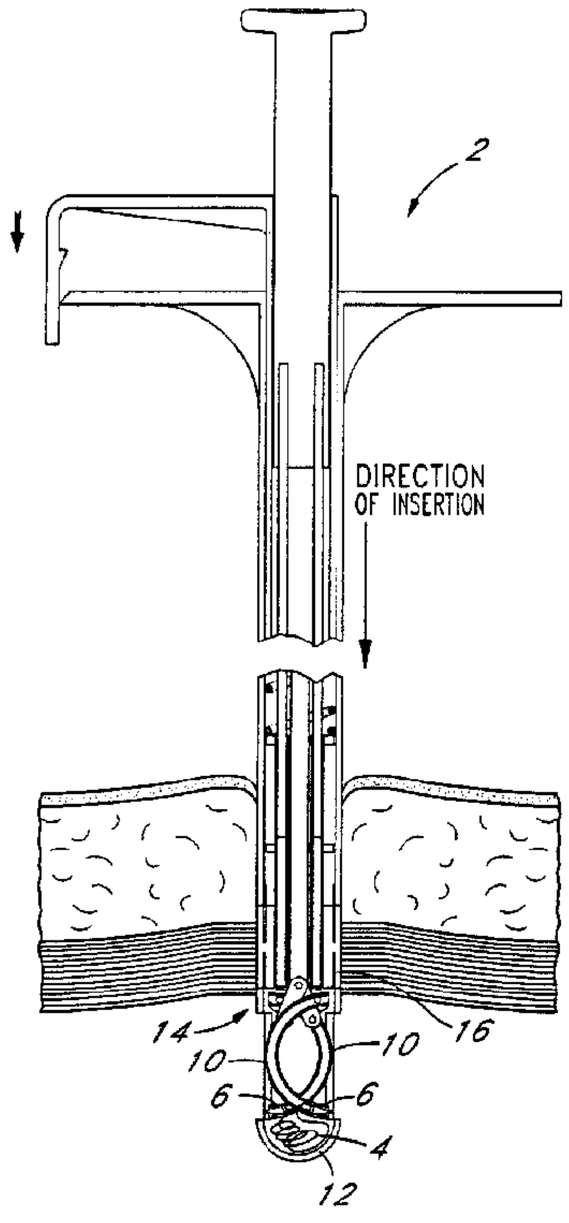
(54) Titre : SYSTEME ENDOSCOPIQUE DE SUTURE
(54) Title: ENDOSCOPIC SUTURE SYSTEM



(57) Abrégé/Abstract:
A method and device for the placement of sutures and for the purpose of approximating tissue. A particular utility is effected in the approximation of the tissue separated by means of an endosurgical trocar being inserted into a body cavity. The invention provides for the loading of suture material including needles into the device, introduction and placement of the device into the body cavity, with the distal end having deployable needle guides, extending the needle guides either simultaneously or individually to the periphery of the wound, engaging the wound with the needle guides, driving the needles and suture material through the tissue to be approximated into a catch mechanism, retracting the needle guides and withdrawing the device, leaving a loop of suture material in the margin of tissue. The suture may then be tied to approximate the wound and excess suture material cut off.

Endoscopic Suture System

Abstract

A method and device for the placement of sutures and for the purpose of approximating tissue. A particular utility is effected in the approximation of the tissue separated by means of an endosurgical trocar being inserted into a body cavity. The invention provides for the loading of suture material including needles into the device, introduction and placement of the device into the body cavity, with the distal end having deployable needle guides, extending the needle guides either simultaneously or individually to the periphery of the wound, engaging the wound with the needle guides, driving the needles and suture material through the tissue to be approximated into a catch mechanism, retracting the needle guides and withdrawing the device, leaving a loop of suture material in the margin of tissue. The suture may then be tied to approximate the wound and excess suture material cut off.

DHE-3823
LAURUS.01ACP2
[DHE-3224;DHE-2448]
940301/2038

LAURUS.01ACP2 PATENT

ENDOSCOPIC SUTURE SYSTEM

Field of the Invention

The invention relates to devices for approximation, ligation and fixation of tissue using a suture, and particularly to the tissue separated by means of an endosurgical trocar being inserted into a body cavity.

Background of the Invention

Suturing of body tissues is a time consuming aspect of most surgical procedures. Many surgical procedures are currently being performed where it is necessary to make a large opening to expose the area of, for instance, the human body that requires surgical repair. There are instruments that are becoming increasingly available that allow the viewing of certain areas of the body through a small puncture wound without exposing the entire body cavity. These viewing instruments, called endoscopes, can be used in conjunction with specialized surgical instrumentation to detect, diagnose, and repair areas of the body that were previously only able to be repaired using traditional "open" surgery.

In the past, there have been many attempts to simplify the surgeons' task of driving a needle carrying suture through body tissues to approximate, ligate and fixate them. Many prior disclosures, such as described in Drake et al, U.S. Patent Number 919,138 issued April 20, 1909, employ a hollow needle driven through the tissue with the suture material passing through the hollow center lumen. The needle is withdrawn

leaving the suture material in place, and the suture is tied, completing the approximation. A limitation of these type of devices is that they are particularly adapted for use in open surgical procedures where there is room for the surgeon to manipulate the instrument.

Others have attempted to devise suturing instruments that resemble traditional forceps, such as Bassett, U.S. Patent Number 3,946,740 issued March 30, 1976. These devices pinch tissue between opposing jaws and pass a needle from one jaw through the tissue to the other jaw, where grasping means pull the needle and suture material through the tissue. A limitation of these designs is that they also are adapted primarily for open surgery, in that they require exposure of the tissues to be sutured in order that the tissue may be grasped or pinched between the jaws of the instrument. This is a severe limitation in the case of endoscopic surgery.

The term "endosurgery" means endoscopic surgery or surgery performed using an endoscope. In conjunction with a video monitor, the endoscope becomes the surgeons' new eyes from which they operate. Operations using an endoscope are significantly less invasive when compared to traditional open surgery. Patients usually return home the next day or in some cases the same day of the endosurgical procedure. This is in contrast to standard open surgical procedures where a large incision divides the muscle layers and allows the surgeon to directly visualize the operative area. Patients may stay in the hospital for 5 to 6 days or longer following open surgery. In addition, after endosurgical procedures, patients return to work within a few days versus the traditional 3 to 4 weeks at home following open surgery.

Access to the operative site using endosurgical or minimally invasive techniques is accomplished by inserting small tubes called trocars into a body cavity. These tubes have a diameter of, for example, between 3mm and 30mm and a length of about 150mm (6 inches). There have been attempts to devise instruments and methods for suturing within a body cavity through these trocar tubes. Such an instrument is disclosed by Mulhollan et al, U.S. Patent Number 4,621,640 issued November

11, 1986. Mulhollan describes an instrument that may be used to hold and drive a needle, but makes no provision for retrieval of the needle from the body cavity, nor the completion of the suture by tying. Mulhollan's instrument is limited in that the arc through which the needle must be driven is perpendicular to the axis of the device. Another such instrument intended for endoscopic use is described by Yoon, U.S. Patent Number 4,935,027, issued June 19, 1990. This instrument uses oppositional hollow needles or tracks pushed through the tissue and coapted to create a tract through which the suture material is pushed. It is not clear how these curved tracks would be adapted to both be able to pierce the tissue planes illustrated, parallel to the tips of the tracks, and be curved toward each other to form the hollow tract.

The invention herein described may be used for final closure of umbilical and secondary trocar puncture wounds in abdominal tissues including the fascia and other layers. The umbilical puncture is routinely a puncture site of 10mm to 12mm. Future procedures may require trocar puncture sites up to 18mm and greater in size. Due to the large size of the puncture wound, it is important that the site be closed or approximated at the interior abdominal wall following removal of the large trocar cannula. An improper or non existent closure can lead to a herniation of the bowel and/or bowel obstruction. The present mode for closure is to reach down to the desired tissue layer with a pair of needle drivers holding a needle and suture material and secure a stitch. Many patients are obese and present considerable fat in this region. Because the abdominal wall may be several inches thick, it is extremely difficult, tedious and time consuming to approximate the fascial tissues with a suture. Often times, following removal of a large trocar, the puncture site needs to be enlarged to accomplish this, thus negating some of the advantages of endoscopic surgery previously discussed.

One of the embodiments described herein may be of particular advantage in performing a surgery for correction of female stress incontinence, which affects over 5 million women in the United States. Stress incontinence is caused when the

structures defining the pelvic floor are altered by aging or disturbed by the process of childbirth or other trauma. These structures in the pelvic floor normally hold the urinary bladder such that maintenance of a volume of urine in the bladder is accomplished by a combination of muscle tone and bladder positioning.

There are a number of surgical procedures that may be performed in order to restore the normal anatomical position of the urinary bladder. The classic open Burch suspension procedure is one such procedure and is a straightforward surgical treatment for correction of female stress incontinence. During this procedure, sutures are precisely placed in the wall of the vagina on each side of the urethra, with care being taken to avoid puncturing either the urethra or the mucosal layer of the vagina. These sutures are then looped through a ligament, called Cooper's ligament, which runs along the posterior ridge of the pubic bone. These sutures are then pulled taut, and carefully tied to suspend the urinary bladder in a more anatomically sound position, restoring normal urinary function and continence.

One of the problems with the procedure described above is that it is normally done only in conjunction with other scheduled abdominal surgical procedures such as a hysterectomy. This is because, as described earlier, an open surgical approach requiring a large abdominal incision must be used, and it is not very common for a patient to elect to have a major abdominal surgical procedure just for the treatment of incontinence.

Consequently, of late, a procedure known as a laparoscopic Burch suspension procedure has begun to find favor among physicians. The laparoscopic approach to the Burch procedure has all of the advantages described earlier with respect to post operative pain, hospital stay and recovery time. There are three difficulties associated with the laparoscopic approach; access, suture placement, and knot tying. The present invention addresses the problems surrounding the placement of the sutures in the appropriate structures and in the optimal position, and also addresses particular aspects of needle retrieval and knot tying when using endoscopic techniques.

Currently, the placement of sutures while using endoscopic techniques involves placing a semi-circular needle, attached to and carrying a suture, in a pair of endoscopic needle holders. These needle holders, which resemble a pair of pliers with an elongated shaft between the handles and the jaws, must be placed down through one of the surgical trocars into the body cavity containing the structure to be sutured. The needle carrying the suture may then be driven by pronation of the wrist, causing rotation of the elongate shaft, and subsequent arcuate rotation of the semi-circular needle.

It may be seen that a limitation of this type of needle driver is that the needle may only be driven or rotated in a plane perpendicular to the axis of rotation, such axis being described by the elongate shaft and the position of the surgical trocar. Thus the current endoscopic needle drivers will not allow the surgeon to swing the needle in an arc parallel to the trocar's axis. This is a severe limitation in the case of the laparoscopic Burch, because of the orientation of the anatomy relative to the planes of access. The vaginal wall and the Cooper's ligament require the sutures to be placed in a orientation that makes the procedure extremely difficult and time consuming with the use of currently available instrumentation.

It may also be seen that the surgeon must be able to retrieve the needle trailing the suture material back through the same surgical trocar through which the needle driver is placed. This allows a knot to be tied in the suture outside of the body, and pushed down the trocar to the structure being sutured. Thus the needle driver must be able to retrieve the needle and bring the needle trailing the suture back up through the same trocar through which it is introduced allowing the tied knot to be pushed back down into the operative site.

Because of the number of sutures placed during a laparoscopic Burch suspension procedure, which may be from 2 to 4 sutures, and because of the fact that the sutures must be tied outside of the body in a particular sequence after all of the sutures have been placed, it may be seen that the number of individual strands of suture draped through and exiting the

trocars may be as many as eight. Thus having a means to tag and keep track of where each suture has been placed would be helpful.

It is well known in the art that the use of particular suture materials for specific applications is desirable. In the case of closure of abdominal wall defects caused by operative wounds, trauma, or spontaneous separation, e.g. hernias, it is generally desirable to use an absorbable suture material. Such sutures may be made from synthetic materials such as polyglycolic acid, designed to be absorbed into the body by means of hydrolysis. As a result, these materials require specialized packaging and sterilization methods, known in the art as "bone dry" packaging. Such packaging processes are described by Glick in U.S. Patent Number 4,135,622 issued January 23, 1979 and assigned to American Cyanimid Corporation. Essentially, because of the sensitivity of these materials to degradation of tensile strength in the presence of moisture, they need to be sterilized and packaged in an environment that guarantees that they remain bone dry.

Due to these packaging constraints, it is desirable that the suture material along with the needles be packaged separately from the suture applicator. As a result, it is desirable to have a loading system that allows the user to quickly and easily place the needles and suture material into the applicator and prepare the applicator for use in the body. It will be clear to those skilled in the art that this loading system would be adaptable to include any of the available suture materials, such as silk, polyester, polypropylene, catgut and the like, even though these materials may not require the specialized packaging that the synthetic absorbable materials do.

It would also be desirable for the needle loading system to incorporate features which allow the user to tag and keep track of the placement of the various sutures that have been introduced into tissues at the operative site. These features may be color coding or numbering or the like.

None of the prior art devices are adaptable to effect the placement of a suture in the anterior abdominal wall, nor are

they adaptable to place sutures precisely and controllably while making provision for needle retrieval when using endoscopic techniques. It is therefore an object of the present invention to provide a family of novel suturing device that overcomes the above set out disadvantages of prior known devices in a simple and economical manner.

It is a further object of the present invention to provide a suture device that will permit the approximation of the separated edges of a puncture wound without making a larger incision to expose the wound margins.

A further object of the present invention is to provide a suture device that will permit the surgeon to apply substantial force to the needle, permitting it to be driven through tough tissues, for example, a ligament or the abdominal fascia.

It is a further object of the present invention to provide a suture device that can be used in conjunction with modern day endoscopic surgical techniques.

Another object of the invention is to provide a suture device that will allow a needle to be driven in an arc which describes a plane parallel to the axis of the device.

Yet another object of the invention is to provide a suture device that may be used to approximate the edges of an internal wound. Another object of the present invention to provide a suture device that permits the penetration of two needles having suture material extending there between into and through the sides of a wound and into catches thereby creating a suture loop through the wound that may be tied to approximate the tissues.

A further object of the present invention is to provide a loading system for suture material that allows the user to quickly and easily prepare the device for use.

Yet another object of the present invention is to provide a suture storage system which is compatible with current sterilization processes and incorporates the functionality of the above suture loading system.

It is a further object of the present invention to provide a means to tag and organize the ends of the sutures placed at the operative site.

Summary of the Invention

The present invention is a new medical device that will allow the surgeon to quickly and easily place a suture in the interior wall of a body cavity to approximate the tissues separated as a result of a puncture wound made by the introduction of a surgical trocar into a body cavity during endoscopic surgery. The invention described herein may also be used to approximate the margins of an open wound in an internal organ, such as the uterus or the stomach, such as would be effected during the course of a resection for benign or malignant lesions. This may be done by adapting the device to allow for the needles to be actuated and driven independently.

The present invention includes needle holders that releasably hold a pair of needles that are in turn attached to each end of a single piece of suture material. Such needle holders are held within tubular guiding tracks housed within a hollow outer sleeve that may be introduced into a puncture wound. The needle holders and guiding tracks may be deployed outside the hollow sleeve to allow the needles to engage the tissue to be approximated. A plunger is coupled to rigid driving members that are in turn attached to flexible driving members adapted to follow the shape of the guiding tracks. The flexible driving members are suitably attached to the needle holders. The plunger is pushed, simultaneously driving the needle pair into opposite sides of the puncture wound and into catches also disposed within the hollow sleeve. The needle holders are retracted into the guiding tracks, and the tracks pulled back into the hollow sleeve trailing the suture material. The device may then be withdrawn, leaving a loop of suture material precisely placed in the selected tissue, for example, in the interior wall of the body cavity. The needles are removed from the ends of the suture, and the suture material is tied to complete the approximation of the tissue.

In one aspect, the present invention differs from the prior art in that it allows a suture to be placed in a retrograde fashion in the puncture wounds created during the introduction of trocars used for endoscopic surgery. These puncture wounds have margins perpendicular to the plane of tissue dissection,

unlike the wounds that are addressed by prior art in which the tissues generally overlap. Presently all the existing instruments are designed to either approximate tissues to which direct visual and physical access may be gained during open surgery, or to approximate tissues that may be pinched between the jaws of a forceps like instrument. Wounds in body organs such as the uterus or the stomach which are created during the resection or removal of benign or malignant lesions may also have wound margins which require end to end approximation instead of overlapping. The present invention allows the surgeon to independently pass a needle through each side of the wound to allow the two sides to be drawn together, approximating the tissue.

The needle driver apparatus of the present invention may be constructed in a number of different ways. Several of the preferred ways are described herein. One embodiment uses needle guides which are semicircular in shape, holding either a semicircular needle, or a semicircular needle holder with a small needle tip. These guides are disposed across their diameter within a hollow tubular sleeve when in the retracted mode, and are rotated about one end to deploy them outside the bounds of the hollow sleeve for engaging the tissue to be sutured. The needles, or the needle holders, are driven through the tissue by axial movement of a rigid cylindrical member which contacts a flexible cylindrical member that follows the semicircular shape of the guide tracks. The needles are caught in catches placed within the hollow tubular sleeve that capture the needle by means of a leaf spring disposed to flex, preferably in one direction, and squeezing into grooves or recesses in the needles, thereby retaining the needles to the hollow tubular sleeve. The needle guides may be retracted, and the instrument removed from the wound, thus trailing the suture material. The needles are removed, the suture is tied, and the approximation is completed.

Another version of the device uses similar semicircular needle holders to the previous version, but the needle guides are eliminated. The needle holders are instead rotated about their axes such that the needles attached to the ends of the

holders describe an arc that encompasses the tissue to be sutured.

Yet another embodiment of the device uses elongated guides with hooked ends, the ends describing semicircles, housed within a hollow tubular member. Into the hooked ends are placed needles with the suture material between. The needle guides are translated axially and then radially to dispose them outside the bounds of the hollow tubular member. The catches are attached directly to the needle guides, to allow for their precise placement relative to the needle path.

It is contemplated that the above embodiments may be modified to include needle paths other than circular, such as helical, elliptical or straight, by modification of the needles, the needle holders and the needle guides. It is also possible to adapt the above configurations to allow each of the needles to be actuated and driven independently by dividing the deployment controls and the needle drivers into separate left and right hand members. Further, it is possible to utilize a tool that would use only a single needle and guide it through both sides of the wound as opposed to the double needle configuration described above.

Accordingly, another embodiment of the device uses a single needle which eliminates the deployment aspect of the needle guides. The needle guide track is incorporated directly into the cannular body which is particularly adapted for use in endoscopic procedures. The cannular body is of a diameter such that it may be placed through, for example, a standard 10mm - 12mm trocar. The needle may be a long shouldered needle such as described previously, or may be a standard 1/2 circle, or 180 needle, with a length of, for example, 22 to 28 mm and crimped onto a length of standard suture material. As previously discussed, those skilled in the art will understand that various needle wire diameters, needle bend radii, needle cross sections, and suture materials are all adaptable to be used in the devices described herein. The needle may be loaded into the preformed needle guide track in the cannular body. It should be noted that the needle is placed in the cannular body across its diameter such that the point of the needle lies substantially

perpendicular to the axis of the cannular body. As in previous embodiments, axial movement of a flexible drive member drives the needle out of the guiding track into and through tissue placed adjacent to the exit opening in the cannular member.

After having driven the needle into tissue, if the needle is a shouldered needle, it may be retrieved by using a keyhole shaped slot incorporated into the side of the cannular body. If the needle is a standard, non-shouldered needle, standard laparoscopic graspers, which have been introduced into the operative site via a secondary trocar, pull the needle trailing the suture up a short distance. The needle driver may then be used to retrieve the needle and suture combination by either pinching the suture material in a groove fashioned for that objective, or clamping the needle with a means adapted for that purpose. The needle trailing the suture may then be withdrawn through the surgical trocar.

This basic method of driving and retrieving the needle may be used in a number of ways at the surgeon's discretion to effect approximation, ligation, or fixation of tissue. Approximation involves the placement of one to multiple sutures in order to pull the edges of a wound together to effect healing. Ligation involves placing a suture circumferentially about a vessel or duct in order to tie it off. In the case of ligation, only a single suture is placed, and a knot tied to strangulate the encompassed structure. Fixation involves the placement of sutures to positionally secure tissues in a particular orientation, and may require multiple sutures placed. Fixation may also require that each end be driven through the tissue more than once.

As it may be apparent, provisions for needle retrieval, the capability of the needle to be reloaded into the needle guide track, and the positioning and orientation of the needle are important to being able to efficiently and effectively place sutures for various therapeutic reasons. The invention herein described solves these problems.

The above described embodiment may be modified to include a needle carrier adapted as described before to hold a short barbed needle. This carrier may be disposed within the

preformed needle guide track in the cannular body. A similar catch mechanism as described previously is incorporated into the side of the cannular body at the end of the arcuate path described by the short needle/needle carrier combination when axial movement of the flexible drive member drives the needle and carrier combination out of the guide and through the tissue to be sutured. Use of this embodiment for closure of trocar puncture wounds would be accomplished by loading one end of a suture prepared with short needles at both ends into the needle carrier. The instrument is inserted into the puncture wound by means of the trocar placed therein. The instrument is located such that the tip of the needle is placed directly against the inside of the abdominal wall.

The needle is driven up into the abdominal fascia by the flexible needle driver coupled to the needle driver button, and into the catch. The short needle stays in the catch, the needle carrier is withdrawn back into the needle guide track, and the entire device is withdrawn from the surgical trocar. The needle is removed from the catch, the opposite end of the suture with its attached short needle is loaded into the instrument, and the entire process is repeated with the second end of the suture being driven into the tissue on the opposite side of the puncture wound, 180° from the initial stitch. The instrument and trocar are removed from the wound, and the remaining loop of suture is tied to approximate the tissues, thus closing the wound.

In one embodiment, the present invention comprises a surgical suture device for applying a suture to approximate tissue surrounding a trocar puncture wound in a body cavity wall. The suture device comprises a first needle and a second needle attached to opposite ends of a length of suture material; a needle catch; a needle deployment mechanism for moving the first and second needles along first and second paths which terminate in the needle catch; and a cannular body member for inserting the first needle, the second needle, the suture material, the needle catch and the needle deployment mechanism into a body cavity through a puncture wound in a wall of the body cavity. The needle deployment mechanism transports the

needles to regions outside of the cannular body member, into the body cavity wall and back into the cannular body member, thereby forming a loop of the suture which approximates tissue on opposing sides of the puncture wound when the cannular body member, along with the first needle, the second needle, the suture material, the needle catch and the needle deployment mechanism are extracted from the body cavity. This device may further include first and second needle guides for directing the first and second needles and/or first and second needle carriers for holding the first and second needles. For some applications, the needle carriers and needle guides have a substantially semi-circular shape. The device may further include a first flexible cylindrical member for pushing the first needle through the first needle guide.

Another embodiment of the invention is in the form of a suture device having a first needle having a suture attachment point; a second needle having a suture attachment point; a suture having a first end attached to the first needle suture attachment point and a second end attached to the second needle suture attachment point; a capture system for receiving and retaining the first and second needles; a needle deployment system for: a) moving the first needle along a first path which initially diverges away from the capture system and subsequently converges toward the capture system; and b) moving the second needle along a second path which initially diverges away from the capture system and subsequently converges toward the capture system; and a cannular body member having a chamber for containing the first and second needles; the suture; the needle deployment system; and the capture system.

In yet another embodiment, the invention describes a suture device comprising: a first needle and a second needle attached to opposite ends of a length of suture material contained within a tubular body member; and a needle deployment mechanism contained within the tubular body member for moving the first and second needles along first and second paths which traverse regions external to the body member and return to a catch mechanism on the body member. Additionally, first and second needle guides may be included which define the shape of the

first and second paths traversed by the first and second needles.

An additional embodiment includes a suture application apparatus comprising: a needle attached to a suture; and a needle deployment mechanism which transports the needle along a path which first intercepts one side of a plane of reference, passes through the plane, reverses direction and then intercepts the opposite side of the plane.

The invention encompasses a method of approximating a trocar puncture wound in the wall of a body cavity. The method includes the following steps: 1) inserting a cannular body member having a chamber into the body cavity through the puncture wound, wherein the chamber contains a first needle and a second needle attached to opposite ends of a length of suture material, a needle catch device and a needle deployment mechanism; 2) extending the first needle into a first region of the wall of the body cavity adjacent the puncture wound and the second needle into a second region of the wall of the body cavity adjacent the puncture wound with the needle deployment mechanism; 3) capturing the first and second needles in the needle catch device; and 4) extracting the body member from the body cavity through the puncture wound, thereby forming a loop of the suture which is secured to opposing regions of the puncture wound.

The invention also incorporates a method of approximating a wound in a body organ within a body cavity. The method includes the following steps: 1) inserting a cannular body member having a chamber into the body cavity through a puncture wound, wherein the chamber contains a first needle and a second needle attached to opposite ends of a length of suture material, a needle catch device and a needle deployment mechanism; 2) extending the first needle into a first region of the wound of the body organ; 3) driving and capturing said first needle in the needle catch device; 4) extending the second needle into a second region of the wound of the body organ; 5) driving and capturing said second needle in the needle catch device; and 6) extracting the body member from the body cavity through the

puncture wound, thereby forming a loop of the suture which is secured to opposing regions of the wound in the body organ.

In one embodiment, the present invention is for a suture device comprising: an elongate cannular body member which defines an internal chamber; a first actuator located near a proximal end of the cannular body member and extending into the internal chamber, the first actuator having a retracted position and a deployed position; and a first needle deployment mechanism comprising a needle carrier pivotally mounted within the internal chamber near a distal end of the elongate cannular body member, the first needle deployment mechanism connected to the first actuator and having a retracted configuration when the first actuator is in the retracted position wherein substantially all of the first needle deployment mechanism is contained within the internal chamber and a deployed configuration when the first actuator is in the deployed position wherein the first needle deployment mechanism transports the needle carrier outside of the internal chamber along a path having an initial direction away from the cannular body member as the first actuator begins to move from the retracted position toward the deployed position followed by a direction toward the cannular body member as the first actuator approaches the deployed position. This embodiment may further comprise a needle having a suture attachment point inserted in the needle carrier; a suture attached to the needle suture attachment point; and a needle capture system located on the cannular body member at a location which intercepts the portion of the needle carrier path which approaches toward the cannular body member. Alternatively, this embodiment may further comprise a second actuator and a second needle deployment mechanism which are deployable independently of the first actuator and the first needle deployment mechanism. A second alternative embodiment further comprises a second needle deployment mechanism which is deployable simultaneously with the first needle deployment mechanism by the first actuator, wherein the first and second needle deployment mechanisms are deployed on opposite sides of the cannular body member. In yet a third alternative embodiment, the suture device first actuator

comprises a first sub-actuator and a second sub-actuator, each having a retracted position and a deployed position which is independent of the other, wherein the first needle deployment mechanism transports the needle carrier outside of the internal chamber along the path having an initial direction away from the cannular body member as the first sub-actuator moves from the retracted position toward the deployed position followed by the direction toward the cannular body member as the second sub-actuator moves from the retracted position toward the deployed position.

The invention also encompasses a suturing apparatus for securing a suture at a location within a confined space, wherein the apparatus comprises: a cartridge, wherein the cartridge further comprises: a cartridge body member having an attachment point; and a first needle and a second needle attached to opposite ends of a length of suture material mounted on the cartridge body member; and an applicator tool, wherein the applicator tool further comprises: an applicator tool body member which defines an internal cavity, the applicator tool body member including an attachment point which joins with the cartridge body member attachment point; and a needle deployment mechanism contained within the applicator tool body member internal cavity, the needle deployment mechanism holding the first and second needles and having a first position wherein the first and second needles are contained within the body member internal cavity and a second position wherein the first and second needles are located outside of the body member internal cavity. In this embodiment, the needle deployment mechanism may further comprise first and second needle carriers for holding the first and second needles. Additionally, the first and second needle carriers may have a substantially semi-circular shape.

The invention also includes a surgical needle comprising an elongate body section with a substantially uniform cross sectional area having a distal end, a pointed proximate end and a shoulder located intermediate the distal end and the pointed proximate end, the shoulder defined by an abrupt change in the cross sectional area of the body section, the transition between

the body section and the shoulder defining a plane which is substantially perpendicular to a longitudinal axis of the elongate body section. In this embodiment, the elongate body section may take on a variety of cross section shapes including but not limited to conical, rectangular, or triangular. The surgical needle of this embodiment may further comprise a means for attaching a suture to the body section distal end. Additionally, this means for attaching a suture to the body section distal end may further comprise an eye formed in the body section.

Yet another embodiment of the invention includes a suture cartridge for use with a suture applicator, the suture cartridge comprising: a needle; a suture attached to the needle; and a support which holds the needle and suture in a predetermined configuration with respect to the support, the support further including a means for attaching the suture cartridge to the suture applicator. Additionally, the suture cartridge may further comprise an alignment element which aligns the cartridge with the suture applicator in a predetermined configuration. In another variation, the suture cartridge may further comprise a needle loader for loading the needle into the suture applicator, the loader comprising a body member having a needle pocket and a needle retainer which holds the needle in the pocket, the loader body member further including an alignment feature which positions the needle in a predetermined configuration with respect to the suture applicator.

The invention further includes a needle loading device for loading a surgical needle into a suturing tool, the loading device comprising a body member having a needle pocket and a needle retainer which holds the needle in the pocket, the loading device body member further including an alignment feature which positions the needle in a predetermined configuration with respect to the suturing tool.

Another embodiment of the invention is a suturing apparatus comprising: a suture cartridge comprising: a needle; a suture attached to the needle; and a support which holds the needle and suture in a predetermined configuration with respect to the support, the support further including a tool attach fixture;

and an applicator tool, wherein the applicator tool further comprises: an applicator body member which defines an internal cavity, the applicator body member including an attachment fixture which, in combination with the cartridge support tool attach fixture, mounts the suture cartridge to the applicator tool; and a needle deployment mechanism contained within the applicator body member internal cavity, the mechanism having a first position wherein the needle is contained within the body member internal cavity and a second position wherein the needle is located outside of the body member internal cavity. This embodiment may further include a needle loader comprising a body member having a needle pocket and a needle retainer which holds the needle in the pocket, the needle loader body member further including an alignment feature which positions the needle in a predetermined configuration with respect to the needle deployment mechanism.

Another embodiment of a suturing apparatus is characterized by a needle comprising a point which is connected to a shoulder by means of a tapered section wherein the connection of the tapered section to the shoulder defines a first cross sectional transverse dimension of the shoulder, the shoulder further connected to a distal portion of the needle immediately adjacent the connection of the tapered section with the shoulder, wherein the connection of the distal section to the shoulder defines a second cross sectional transverse dimension of the shoulder which is smaller than the first cross sectional transverse dimension of the shoulder thereby forming a shoulder ledge; a suture attached to the distal portion of the needle; and a needle catch comprising a flexible aperture having a first relaxed dimension which is smaller than the first cross sectional transverse dimension of the shoulder but allows insertion of the needle into the aperture along an insertion direction by expansion of the flexible aperture first relaxed dimension to a stretched dimension which is substantially equal to the first cross sectional transverse dimension of the shoulder by the passage of the tapered section, the aperture returning to a second relaxed dimension, also smaller than the first cross sectional transverse dimension of the shoulder, the

shoulder ledge thereby preventing removal of the needle from the catch in a direction which is the reverse of the insertion direction. In this embodiment, the needle catch may further comprise a removal aperture, contiguous with the flexible aperture, the removal aperture having a dimension which is larger than the first cross sectional transverse dimension of the shoulder, thereby allowing the needle to be removed from the needle catch when the needle is moved from the flexible aperture to the removal aperture.

The invention also describes a passive needle catch for receiving and retaining a shouldered surgical needle, the catch comprising a flexible aperture which expands to allow passage of the needle shoulder into the aperture and contracts after the needle shoulder has passed through the aperture. This passive needle catch may further comprise a removal aperture, contiguous with the flexible aperture, the removal aperture having a dimension which is larger than the needle shoulder, thereby allowing the needle to be removed from the needle catch when the needle is moved from the flexible aperture to the removal aperture.

The invention further includes a passive needle catch for a shouldered surgical needle, the catch comprising an aperture having a first region which has a dimension which is at least as large as the needle shoulder thereby allowing passage of the shoulder through the aperture, the catch further having a second region which has a dimension which is smaller than the needle shoulder, thereby preventing passage of the shoulder through the aperture.

One embodiment of the invention is a suturing instrument comprising: an elongate body member having a longitudinal axis; a deployment controller having a proximal end and a distal end, the deployment controller extending substantially along the longitudinal axis of the elongate body member to a distal end of the elongate body member, wherein the deployment controller has a retracted position and a deployed position; and a needle deployment system located within the distal end of the elongate body member and coupled to the deployment controller, the needle deployment system comprising: a curved surgical needle slidably

positioned in a curved needle channel within the elongate body member, the curved needle channel located substantially in a plane which is substantially parallel to the elongate body member longitudinal axis; and a flexible pusher coupled to the distal end of the deployment controller, the needle deployment system having a retracted configuration when the deployment controller is in the retracted position wherein substantially all of the curved surgical needle is contained within the elongate body member and a deployed configuration when the deployment controller is in the deployed position, wherein the flexible pusher pushes the curved surgical needle through the curved needle channel outside of the elongate body member along a path having an initial direction away from the elongate body member longitudinal axis as the deployment controller begins to move from the retracted position toward the deployed position followed by a direction toward the elongate body member longitudinal axis as the deployment controller approaches the deployed position. This embodiment may further comprise: a suture channel which intersects the curved needle channel at the distal end of the elongate body member; and a suture capture projection positioned adjacent the suture channel and the curved needle channel such that a suture lying in the suture channel is captured between the projection and the flexible pusher as the deployment controller moves from the retracted position to the deployed position. Additionally, the suturing instrument may further comprise a needle catch at the distal end of the elongate body member. In one configuration, the curved surgical needle has a shoulder near a distal point and the needle catch further comprises a first opening dimension sized to allow the shouldered needle to pass therethrough and a second opening dimension sized smaller than the shoulder, thereby capturing the needle at the shoulder. Another configuration has a needle capture channel at the distal end of the elongate body member; and a cam positioned in the needle capture channel so as to wedge a needle inserted in the needle capture channel between the cam and the channel. Additionally, the cam may be coupled to the flexible pusher and as the deployment controller moves from the retracted position to the deployed position, the cam

increases the capture force applied to the needle. This embodiment may further comprise a suture channel formed at the distal end of the elongate body member for pushing a knot tied extracorporeally into a body cavity.

Another embodiment of the present invention is a suturing instrument comprising: an elongate body member having a longitudinal axis; a deployment controller having a proximal end and a distal end, the deployment controller extending substantially along the longitudinal axis of the elongate body member to a distal end of the elongate body member, wherein the deployment controller has a retracted position and a deployed position; and a needle deployment system located within the distal end of the elongate body member and coupled to the deployment controller, the needle deployment system comprising: a curved needle carrier channel and a curved needle carrier movably positioned therein and having a needle point mounted on a distal end thereof, the curved needle channel located substantially in a plane which is substantially parallel to the elongate body member longitudinal axis; and a flexible pusher coupled to the deployment controller, the needle deployment system having a retracted configuration when the deployment controller is in the retracted position wherein substantially all of the curved needle carrier is contained within the elongate body member and a deployed configuration when the deployment controller is in the deployed position, wherein the flexible pusher pushes the curved needle carrier along the curved needle channel outside of the elongate body member along a path having an initial direction away from the elongate body member longitudinal axis as the deployment controller begins to move from the retracted position toward the deployed position followed by a direction toward the elongate body member longitudinal axis as the deployment controller approaches the deployed position. Furthermore, this embodiment may include a bullet needle having a suture attachment point, the bullet needle inserted in the curved needle carrier; a suture attached to the bullet needle suture attachment point; and a needle capture system located on the elongate body member at a location

which intercepts the portion of the needle carrier path which approaches toward the elongate body member.

Yet another embodiment is for a suturing instrument for placing sutures inside a body cavity comprising: an elongate body member having a longitudinal axis; needle deployment means for deploying a surgical needle outside a distal end of the elongate body member along a path having an initial direction away from the elongate body member longitudinal axis followed by a direction toward the elongate body member longitudinal axis; and needle capture means attached to the elongate body member for capturing the surgical needle after deployment. This embodiment may further include a knot pushing means located at the distal end of the elongate body member for pushing a knot tied extracorporeally into the body cavity.

These and other characteristics of the present invention will become apparent through reference to the following detailed description of the preferred embodiments and accompanying drawings.

Brief Description of the Drawings

These and other objects and advantages of the subject invention will become more fully apparent from a reading of the following description in conjunction with the drawings wherein:

FIGS. 1A through 1H illustrate the general structure and operation of the present invention.

FIG. 2 is a cross sectional plan view showing a single needle guide inside a cannula.

FIG. 3 is a cross sectional plan view showing the needle guide in the deployed position.

FIG. 4A is a detailed perspective view showing that there are two needle guides.

FIG. 4B is a detailed perspective view showing only one of the needle guides in the deployed position.

FIG. 5 is a detailed perspective view of the top section of the device showing the deployment catch mechanism.

FIG. 6 is a detailed plan view of a swinging needle guide positioned in the cannula and a phantom view showing the needle guide in the deployed position.

FIG. 7 is an exploded perspective view of the major components of the present invention.

FIG. 8 is a cross sectional side view of the abdomen with a trocar inserted, showing the wound in the abdominal wall.

FIG. 9 is a cross sectional side view of the present invention in place in the abdomen.

FIG. 10 is a detail cross sectional side view of the present invention in place in the abdomen with the needle guides deployed.

FIG. 11 is a detail plan view similar to view 6 showing a needle in a guide with the guide deployed.

FIG. 12 is a detail plan view similar to view 6 showing a flexible member being pushed into the guide.

FIG. 13 is a detail plan view similar to view 6 showing a needle being pushed into a catch.

FIG. 14 is a detail plan view similar to view 6 showing the needle carrier being retracted, the needle secured in the catch and trailing a suture.

FIG. 15 is a detail plan view similar to view 6 showing the needle guide retracted back into the housing.

FIG. 16 is a detail plan view similar to view 6 showing the suture left in place in the wound before tying.

FIG. 17 is a detail plan view of an elongate needle guide design with the guides contained within a cannula.

FIG. 17A is an enlargement of the end of the embodiment shown in FIG. 17.

FIG. 18 is a detail plan view of the elongate needle guide design with the guides in the deployed position.

FIG. 18A is an enlargement of the end of the embodiment shown in FIG. 18.

FIG. 19 is a detail perspective view of a needle showing ridges on the needle to secure the needle in the catch.

FIG. 19A is a detail plan view of an alternate needle.

FIG. 19B is a detail plan view of another alternate needle.

FIG. 19C is a detail perspective view of an alternate catch mechanism with a needle.

FIG. 19D is a detail perspective view of another catch mechanism with a needle.

FIG. 20 is a detail plan view of the semicircular needle holder without a needle guide with the holder positioned within the cannula.

FIG. 20A is a detail sectional view of the needle holder and needle assembly.

FIG. 21 is a detail plan view of the semicircular needle holder being deployed.

FIG. 22 is a detail plan view of the semicircular needle holder pushing the needle into the catch.

FIG. 23 is a detail plan view of the semicircular needle holder with the holder being retracted.

FIG. 24 is a exploded perspective view of an alternate embodiment of the present invention which allows each of the guide tracks to be actuated independently.

FIGS. 24A through 24D illustrate the general operation of the independent guide deployment.

FIG. 25 is an exploded perspective view of the general structure of a suture loading system.

FIG. 26 is a perspective view of the assembly described in FIG. 25

FIG. 27 is a detail cross sectional plan view of an alternate embodiment of a suture loading system.

FIGS. 28A through 28C are detail cross sectional plan views which illustrate the insertion of the needle into the needle carrier.

FIG. 29 is a detail cross sectional plan view of an alternate embodiment of a suture loading system.

FIGS. 30A through 30C are detail cross sectional plan views of an alternate embodiment which illustrate the insertion of the needles into the needle carriers.

FIG. 31 is a detail perspective view of an alternate embodiment of the present invention for a suture application device which includes a cannular body and a keyhole shape needle catch.

FIGS. 32A through 32C show sectional detail plan views of a suture device interlock assembly in its initial, first stage of deployment and second stage of deployment configurations, respectively.

FIG. 33 shows a detail perspective view of a lockout pawl in the interlock assembly.

FIG. 34 is a perspective view of an embodiment of a needle loader for a long curved needle.

FIG. 35 is a detail perspective view of the distal end of a needle driver showing the alignment track for the needle loader.

FIGS. 36A through 36C are detail plan views illustrating the insertion of a needle into a needle guide using the needle loader described in FIG. 34.

FIG. 37 is a detail perspective view of an alternate embodiment of needle loader for short needles.

FIG. 38 is a detail plan view illustrating the use of the needle loader described in FIG. 37.

FIG. 39 is an exploded perspective view of an alternate embodiment of a suturing device.

FIGS. 40A and 40B are plan views of the suturing device described in FIG. 39 illustrating the operation thereof.

FIGS. 41A and 41B are detail plan views of the distal end of the suturing device described in FIGS. 40A and 40B illustrating the use of a shouldered needle.

FIG. 41C is a detail plan view of the distal end of the suturing device described in FIGS. 40A and 40B illustrating the use of a standard non-shouldered needle.

FIG. 42 is a detail perspective view of an alternate catch mechanism with a needle.

FIG. 43 is a detail perspective view of a suture catch mechanism with a length of suture.

FIG. 44 is a perspective view of a needle catch mechanism with a needle and phantom view of the cannula body

FIGS. 45A through 45C are detail sectional plan views illustrating the operation of the active needle catch mechanism depicted in FIG 44.

FIG. 46 is a perspective view of the needle catch actuation lever with needle and a phantom view of the cannula body

FIGS. 47A through 47C are detail sectional plan views illustrating the operation of the active needle catch mechanism shown in FIG. 46.

FIG. 48 is a detail sectional plan view of the a needle catch mechanism showing the flexible needle driver actuating the needle retainer mechanism.

FIGS. 49A and 49B are detail sectional views taken along the lines of section 49-49 of FIG. 48 illustrating the operation of the mechanism shown in FIG. 48.

FIG. 50 is an exploded detail perspective view of the of the needle retainer plates and pivot pin .

FIG. 51 is a perspective view of an alternate embodiment of a needle capture and holder mechanism.

FIG. 52 is a cross sectional view of the needle holder and needle of the embodiment taken along the lines of section 52-52 of FIG. 53.

FIG. 53 is a detailed cross sectional view illustrating the general structure and operation of the needle delivery and capture system described in FIGS. 51 and 52.

FIG. 54 is a detailed perspective view of the end of the suturing device illustrating its use for pushing knots tied in suture.

FIG. 54A is a detailed plan view of an alternate embodiment of a suture device illustrating features for use for pushing knots tied in suture.

FIGS. 55A and 55B are detailed cross sectional views illustrating the general structure and operation of an alternate embodiment of a needle delivery and capture system.

FIG. 56 is a projected detail view taken along the lines of view 56-56 of FIG. 55A illustrating the needle catch.

Detailed Description of the Preferred Embodiments

Although the principles of the present invention are applicable to any device suitable for use in surgical procedures, whether performed on humans or animals, particular utility is effected in human abdominal surgery performed using endoscopic techniques for closure of the wounds created during the introduction of trocars into the abdominal cavity, and particularly the puncture wounds created thereof, as well as closure or approximation of the wounds created either during the resection of benign or malignant lesions, or during the

performance of other therapeutic procedures on an organ or organs within a body cavity.

FIGURES 1A through 1H illustrate the general structure and operation of the present invention. FIGURES 1A and 1B show a device 2, according to the present invention, which incorporates a length of standard suture material 4 with a needle 6 on each end. The needles 6 are held by a needle carrier 8 (FIG. 1D) and loaded into two guiding tracks 10. The guiding tracks 10, containing the needle carriers 8 and needles 6, are deployable outside a housing 12 of the device 2 to allow the suture material 4 to be placed outside the limits of a puncture wound 14 (FIGS. 1B and 1C). After deployment of the guiding tracks 10 (with the needle carriers 8 and needles 6 contained within) the needle carriers 8 and needles 6 are driven out of the guiding tracks 10 and into tissue surrounding the puncture wound 14 (FIGS. 1C and 1D). The needles 6 are driven into a catch mechanism 16 (FIG. 1D). The needle carriers 8 are retracted back into the guiding tracks 10 (FIG. 1E). The guiding tracks 10 (now containing only the needle carriers 8 without the needles 6) and the catch mechanism 16 with the captured needles 6, are retracted as shown in FIGS. 1F, 1G and 1H. With a loop of suture 4 having thus been placed in the tissue surrounding the puncture wound 14, the suture device 2 is removed from the wound 14, thereby pulling the ends of the suture 4 with it (FIG 1H). Closure of the puncture wound 14 is accomplished by cutting the suture 4 to remove the needles 6, tying a knot in the suture 4, and pushing it into the wound 14. Superficial closure is then performed by normal means according to the surgeon's preference.

Detailed drawings of an illustrative embodiment of the invention are shown in FIGS. 2, 3, 4A, 4B, 5, 6 and 7 wherein a suture application device 30 includes an outer housing 32, with finger grips 34a and 34b, and a deployment catch 36. The outer housing 32 is preferably made of injection molded plastic such as polycarbonate, as are many other of the components described herein. A deployment sleeve 38, slidably disposed within the outer housing 32, has a retention catch 40 and is attached to a pushrod 42, constructed for example, of stainless steel. A driver shaft 44 includes a button 46 and has a hole 48a, into

which is bonded an elongate rigid shaft 50a. The rigid shaft 50a, which may be made of music wire, passes through outer housing ribs 52a, 52b and 52c, and as best shown in FIG. 4A, terminates slidably disposed within a hollow cylinder 54a. The hollow cylinders 54a and 54b, preferably made from stainless hypodermic tubing, are held in recesses in the outer housing ribs 52b and 52c. An elongate flexible tubular member 56a, that may be made of polypropylene or other suitable material, is also slidably disposed within the hollow cylinder 54a. As shown in FIG. 6, needle guide 58a may also be constructed from stainless hypodermic tubing, and has pivot pins 60a and 60b pivotally disposed within outer housing bosses 62a and 62b. A driving link 64a is attached by a link pin 66 to the pushrod 42 and to the needle guide 58a by a pivot pin 68a, with the entire mechanism preferably made of stainless steel so as to maximize the biocompatibility as well as the strength of the actuating members. It may be appreciated from FIG. 4A that, as described, there are two needle guides 58a and 58b oppositionally disposed within the outer housing 32.

Referring again to FIGS. 2 and 3, a driver retainer 70 is slidably disposed within the outer housing 32, and is fixably attached to rigid shafts 50a and 50b, with a hole 72 to allow the pushrod 42 to pass slidably therethrough. A driver spring 74, preferably wound from stainless steel wire is compressed between the driver retainer 70 and the outer housing rib 52b. A deployment spring 76, also made of stainless steel wire is compressed between an end 77 of the deployment sleeve 38 and outer housing rib 52a. A needle catch 78a is housed within a recess 80a in the outer housing 32.

Referring now to FIG. 6, a retraction line 82a that is preferably made of kevlar, is slidably threaded through the flexible tubular member 56a and is attached to a needle carrier 84a by means of a crimp 86a or other means that would bind the retraction line 82a to the needle carrier 84a. The distal end of the retraction line 82a is attached to the rigid shaft 50a by means of another crimp 98a or other means. The needle carrier 84a is slidably disposed within the needle guide 58a, and holds a needle 88a, typically constructed of surgical grade stainless

steel in a recess 90a, such needle having a suture 92a attached thereto. The suture material is preferably polyglycolic acid, but may be made of polypropylene, nylon*, silk, catgut*, or any other materials known in the art selected for their biocompatibility and tensile strength to be used in the body for the approximation of tissue. The suture 92a exits the needle guide 58a by means of a groove 94a (groove 94a is hidden from view in FIGS. 4A and 4B, however, groove 94b in the opposing needle guide 58b is visible), and is stored in a recess 96 in outer housing 32.

Referring to FIG. 7, it may be seen that outer housing 32 may comprise two halves, 32a and 32b which are joined by pins 100 and holes 102. The pins 100 and holes 120 are preferably molded into the outer housing halves 32a and 32b to encompass an inner assembly 104.

Use and operation of this embodiment of the invention will be described beginning with reference to FIG. 8 which shows a trocar assembly 106 inserted into the abdominal wall 108, which includes a layer of skin 110, a fat layer 112, a muscle layer 114 and a fascial layer 116. The trocar assembly 106 includes a hollow tube 118 that is inserted through the abdominal wall 108 and into an abdominal cavity 122 using techniques well known to those skilled in the art, creating a puncture wound 120. As shown in FIG. 9, the suture application device 30 of the present invention is inserted through the hollow tube 118 into the trocar assembly 106 until it passes into the abdominal cavity 122. Referring to FIG. 3, arm 124 of deployment sleeve 38 is pushed so that the sleeve slides within the outer housing 32, compressing spring 76, and in turn sliding pushrod 42. As can be seen in FIGS. 4A and 4B, when the pushrod 42 slides relative to the outer housing 32, driving links 64, which are pivotally attached to both pushrod 42 and needle guides 58, force the needle guides 58 to pivot about the pins 60 that are retained in outer housing bosses 62. The ultimate deployed position of one of the needle guides 58a is shown in perspective view in FIG. 4B and in cross sectional plan view in place in the body in FIG. 10. Referring to FIG. 10, it can be seen that the suture device 30 is in place through the hollow tube 118 and in the abdominal

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cavity 122, with needle guides 58 deployed and engaging the fascial layer 116 and the muscle layer 114.

Operation of the needle driver portion of this embodiment will be described by referring to FIGS. 11 through 15. It should be understood that in the interest of clarity only one half of the instrument is being shown. In FIG. 11, the needle guide 58a has been deployed by movement of the pushrod 42 attached to the deployment link 64a. As shown in FIG. 12 and FIG. 13, the rigid shaft 50a within the hollow cylinder 54a is slidably moved and in turn pushes the flexible tubular member 56a, thereby displacing the needle carrier 84a along an arc described by the needle carrier 58a. The needle carrier 58a pushes the needle 88a carrying the suture 92a through the tissue and into the catch 78a as best shown in FIG. 13. The needle catches 78 are preferably made of thin gauge surgical grade stainless steel which allows the leaves to be flexible yet create a gripping force on the needles 88. Referring to FIG. 14, the rigid shaft 50a is retracted, and because of the retraction line 82a, the needle carrier 82a is retracted back into needle guide 58a and the flexible tubular member 56a is retracted back into the hollow cylinder 54a. As shown in FIG. 15, the pushrod 42 is retracted, by which the linkage previously described rotates the needle guide 58a back into the outer housing 32. Referring to FIG. 16, the suture application device 30 and the trocar assembly 106 are completely withdrawn from the abdominal wall 108, leaving the suture 92 in the abdominal wall 108, to be tied, completing the approximation of the wound 120.

Another embodiment of the described invention is shown in FIGS. 17, 17A, 18 and 18A. It should be understood that in the interest of clarity only one half of the instrument is being shown. The second half is a virtual copy of the first half in both function and structure. Typical materials used in this embodiment are injection molded materials such as polycarbonate, and surgical grade stainless steel.

A suture application device 126 includes an outer housing 128, with finger grips 130a and 130b, and a deployment catch 132. A deployment sleeve 134, slidably disposed within the outer housing 128, has a retention catch 136. A driver shaft

138, which is slidably disposed within the deployment sleeve 134 includes a button 140 and has a hole 142, into which is bonded an elongate rigid shaft 144. The rigid shaft 144 passes through a hole 146 in the deployment sleeve 134, through a hole 148 in an outer housing rib 150, through another hole 152 in the deployment sleeve 134 and terminates slidably disposed within a hollow cylinder 154. The hollow cylinder 154 is pivotally attached to the deployment sleeve 134 by means of a pivot pin 156 disposed on either side of the hollow cylinder 154, and inserted into holes 158 in deployment sleeve 134. An elongate flexible member 160 is also slidably disposed within the hollow cylinder 154. A needle guide assembly 162 includes: a needle guide 164, secured within the hollow cylinder 154 so as to allow the flexible member 160 to slidably transition from the hollow cylinder 154 to the curved needle guide 164; a needle 166 to which is secured a suture 168; and a needle catch 174 secured between a boss 170 and another boss 172.

Use and operation of this embodiment of the invention will be described beginning with reference to FIG. 18. The suture application device 126 is introduced into the abdomen through a trocar assembly in the same manner as described in the previous embodiment. Subsequently, a deployment arm 177 is pushed such that the retention catch 136 snaps past the deployment catch 132. Deployment sleeve 134 slides within the outer housing 128 and compresses deployment spring 176 between a wall 178 of the deployment sleeve 134 and the outer housing rib 150. The needle guide assembly 162 is forced to slide along with the deployment sleeve 134 with a cam 182 riding in a track 184, deploying the needle guide assembly as shown in FIGS. 17, 17A, 18, and 18A. Similar to the previously described embodiment, the needle 166 is driven out of the needle guide 164 by pushing the button 140, thereby pushing the rigid shaft 144, which in turn pushes the flexible member 160, which follows the curvature of needle guide 164 and pushes the needle into the catch 174. As seen in FIG. 18, the length of travel permitted button 140 is restricted by a slot 194 in driver shaft 138 sliding past a pin 192 secured to the deployment sleeve 134.

The needle guide assembly 162 is retracted back into the outer housing 128 by releasing the catch 132. The spring 176 forces the deployment sleeve 134 back to its original position, thereby causing the cam 182 to follow the track 184 such that the position of the needle guide assembly 162 is once again as shown in FIGS. 17 and 17A.

FIG. 19 shows a detail view of the needle 166 secured to the suture 168 as it enters the catch 174 through a slot 186 created by spring leaves 188a and 188b. The catch 174 is preferably made of thin gauge spring steel to allow the leaves to be flexible yet create a gripping force on the needle. Ridges 190 on needle 166 enable the catch 174 to capture and hold the needle 166. The capture and holding of the needle 166 by the catch 174 is facilitated by the spring leaves 188 being disposed to bend away from the axis of needle penetration, thus snapping into the ridges 190.

FIGS. 19A through 19B show detail plan views of alternate needle embodiments. Referring to FIG. 19A, a needle 234 comprises a body 236, and a shoulder 238 tapering to a point 240. A length of suture material 242 is inserted into a hole 244 and attached to the needle 234 thereby. Referring now to FIG. 19B, a needle 246 comprises a body 248 and a shoulder 250 formed by a groove 252 which tapers to a point 254. A length of suture material 256 is inserted into a hole 258 and attached to the needle 246 thereby.

FIGS. 19C through 19D show detail perspective views of alternate catch embodiments and illustrate their operation. A catch 260 is preferably constructed of thin stainless steel of high temper, such as ANSI 301 full hard. Referring to FIG. 19C, a catch 260 includes openings 262 defined by ribs 264. As the needle 234 enters the opening 262, the ribs 264 deflect slightly to allow the shoulder 238 to pass through. After the shoulder 238 has passed the ribs 264, the ribs spring back to their original position defining the openings 262. The openings 262 are chosen to be smaller in dimension than the shoulder 238. This causes the catch 260 to retain the needle 234 by the interference between the shoulder 238 and the ribs 264 around the body 236. When it is necessary to remove the needle 234

from the catch 260, it may be moved toward an opening 265 which is sized to allow the needle shoulder 238 to pass through without resistance.

Referring now to FIG. 19D, a catch includes a frame 268 to which is attached a woven mesh 270. Threads 272 creating the woven mesh 270 may be made out of nylon or polyester or the like woven in a common over/under pattern. The weaving of the threads 272 creates holes 274 in the mesh through which a needle 246 may be passed. The needle 246 is constructed such that the shoulder 250 defined by the groove 252 is larger than the holes 274, or conversely, the holes 274 are chosen to be smaller than the shoulder 250. The point 254 of the needle 246 pushes the threads 272 aside creating room for the shoulder 250 to pass through the holes 274. As the threads 272 return to their original positions, the catch 266 holds onto the needle 246 by means of the mismatch in the size of the holes 274 and the shoulder 250.

It may be seen and should be understood that catches 260 and 266 are capable of catching either needle 234 or 246. The examples of needle 234 coupled with catch 260 and needle 246 coupled with catch 246 are given purely to illustrate the concepts of each embodiment and do not exclude their coupling with alternate designs.

Yet another embodiment of the present invention is shown in FIGS. 20, 20A, 21, 22 and 23. It should be again understood that in the interest of clarity only one half of the instrument is being shown. The other half is quite similar in function and structure as the half described herein. The upper portion of the device is similar in construction and materials to the previously disclosed embodiments, and is not repeated here.

A suture application device 196 includes an outer housing 198 having bosses 200 into which a pin 202 is rotatably inserted. The pin 202 is secured to an arm 204, which is attached to a needle carrier 206. A pin 208 on needle carrier 206 is rotatably inserted into a hole 210 in a link 212. Another pin 214 is secured to a pushrod 216 and is rotatably inserted into another hole 218 in the link 212. The pushrod 216 is

attached to a sleeve 220 slidably disposed within the outer housing 198.

FIG. 20A shows a detail view of a needle 222 held in a recess 224 in the needle carrier 206. A suture 226 is attached to the needle 222 and is threaded through a slot 228 in the needle carrier 206. All components in this mechanism are preferably constructed of surgical grade stainless steel, chosen for its biocompatibility and strength.

Use and operation of this embodiment of the invention will be described beginning with reference to FIG. 20. The suture application device 196 is introduced into the abdomen through a trocar assembly in the same manner as described in a previous embodiment. Sleeve 220 slides within the housing 198 in the direction indicated by the arrow. As shown in FIG. 21, as the sleeve 220 moves, it pushes the pushrod 216 which causes the link 212 to cause the needle carrier 206, along with the needle 222 and the suture 226, to rotate about the axis defined by the pin 202. Referring to FIG. 22, it may be seen that the needle 222 is driven into a catch 230 through an opening 232 in the outer housing 198. Accordingly, in reference to FIG. 23, it is seen that as the pushrod 216 is retracted, the link 212 is also retracted, causing the needle carrier 206 to rotate about the pivot pin 202 and back through the opening 232 into the outer housing 198, the same position as shown in FIG. 20.

Another embodiment of the present invention is described in FIGS. 24, 24A, 24B, 24C, and 24D. FIG. 24, shows an exploded perspective view of a suture device which is similar in construction to the previously described suture application device 30 and includes an outer housing 32, comprised of two halves 32a and 32b, with finger grips 34a and 34b, and a deployment catch 36. Residing within the outer housing 32, are independent needle driver assemblies 278a and 278b. For purposes of discussion, only one of the needle driver assemblies 278 will be described, although it should be understood that both are substantially identical in structure and function.

A deployment sleeve 280a, slidably disposed within the outer housing 32, has a retention catch 282a and is attached to a pushrod 284a, constructed for example, of stainless steel. A

driver shaft 286a includes a button 288a and has a hole 290a, into which is bonded an elongate rigid shaft 50a. The rigid shaft 50a, which may be made of music wire, passes through outer housing ribs 52a, 52b and 52c. In construction similar to and as best shown in FIG. 4A, the rigid shaft 50a terminates slidably disposed within the hollow cylinder 54a, which is held in recesses in the outer housing ribs 52b and 52c. Elongate flexible tubular member 56a, that may be made of polypropylene or other suitable material, is also slidably disposed within the hollow cylinder 54a. As shown in FIG. 6, needle guide 58a may also be constructed from stainless hypodermic tubing, and has pivot pins 60a and 60b pivotally disposed within outer housing bosses 62a and 62b. A driving link 64a is attached by a link pin 66 to the pushrod 42 (284a in FIG. 24) and to the needle guide 58a by a pivot pin 68a, with the entire mechanism preferably made of stainless steel so as to maximize the biocompatibility as well as the strength of the actuating members. It may be appreciated from FIG. 24 that, as described, there are two needle guides 58a and 58b oppositionally disposed within the outer housing 32.

Referring again to FIG 24, driver retainer 70 is slidably disposed within the outer housing 32, and is fixably attached to rigid shafts 50a and 50b, with a hole 72 to allow the pushrod 284a to pass slidably therethrough. Driver spring 74, preferably wound from stainless steel wire is compressed between the driver retainer 70 and the outer housing rib 52b.

It may be appreciated by the foregoing that the needle driver assemblies 278a and 278b may be actuated independently. The internal mechanisms and components are similar in construction to the embodiment described in FIG. 1A through 1H.

FIGS 24A through 24D illustrate the use and operation of this embodiment of the invention. The use of this embodiment will be described beginning with reference to FIG. 24A which shows a suture device 276 inserted through the abdominal wall 108, which includes a layer of skin 110, a fat layer 112, a muscle layer 114 and a fascial layer 116. Within the abdominal cavity 122 lies a hollow organ 292, which may be, for example, a uterus. The organ includes walls 294 into which an opening

296 has been made. The opening 296 would generally have been created by a surgeon using traditional surgical tools such as a scalpel or scissors, and may have been made in order to excise a fibroid tumor or the like. The suture device 276 is inserted into the opening 296. Referring to FIG. 24B, the deployment sleeve 280a is depressed, rotating the needle guide 58a outside the bounds of the housing 32. The deployment sleeve 280a is locked down by deployment catch 282a. The needle 88a is attached to the suture material 92, and rests in the recess 90a in the needle carrier 84a (also see FIG. 6 for a more detailed view). Needle driver button 288a is depressed, driving the needle carrier 84a holding the needle 88a through the organ wall 294a and into the needle catch 78a. The needle driver button 288a is returned to its original position, and the deployment sleeve 280a retracted, leaving the suture 92 placed through one wall 294a of the hollow organ 292 utilizing needle driver assembly 278a. FIG. 24C illustrates a similar process on the opposing wall 294b of the hollow organ 292 utilizing needle driver assembly 278b. Referring to FIG 24D, it can be seen that the suture 92 is withdrawn through the abdominal wall where the suture 92 is cut away from the suture device 276. A knot is then tied in the suture 92 to approximate the walls 294 of the hollow organ 292, and additional sutures 92 are placed as necessary.

Other embodiments of the present invention comprise modifications of the above embodiments which include a single needle driver, either with or without a catch system. The single needle driver embodiments perform the same function as the dual needle driver embodiments described herein, with minor operational modifications. For example, the single needle driver embodiments require that the suture application device be removed from the body cavity to load the second needle. In some applications, however, this is not a severe operational limitation, and single sided needle drivers or suturing devices should be understood to be contemplated in addition to the above described dual needle embodiments.

In some applications, such as for the placement of sutures for suspension of the bladder for the treatment of female

incontinence, it may be desirable to use a single sided device. This is due to the limited space for deployment and visualization of the instrument. For bladder suspension, the device may be used as follows. After loading a semi-circular needle similar to that shown in FIG. 19B into a single guiding track, the suture application device is introduced into the body cavity via a surgical trocar, and a suture is driven into the vaginal wall just below the urinary bladder neck. The suture application device is manipulated to catch the needle, and the device withdrawn from the body cavity carrying the needle and suture. The opposite end of the suture, which also has an attached needle, is then loaded into the suture application device, and introduced back into the body cavity. This needle is driven through one side of Cooper's ligament, and again the device withdrawn from the body. The surgeon may then repeat the same sequence, driving through the opposite side of Cooper's ligament. The surgeon may then tie the sutures at his discretion, placing the proper amount of tension on the sutures to effect the suspension of the bladder.

A similar sequence may be contemplated for use in other applications such as the previously mentioned closure of a body organ, or of the fascial puncture wounds. It may also be contemplated for use in the placement of gastrostomy tubes, or in the approximation of tissue flaps such as that accomplished in gastric fundoplication.

Referring now to FIG. 25, there may be seen the tip of a suture application device 304 which includes a cannular body 306, a hinged tip 308 and a suture carrier plate 310. The suture carrier plate 310 may be molded from polyethylene or other suitable material which may be adapted for the "bone dry" sterilization process previously described. A piece of suture material 312 has needles 314a and 314b, which as before are preferably constructed from surgical grade stainless steel, attached to each end 316 to form a suture 318. The suture 318 is wound to fit over pegs 320 on the suture plate 310. Tabs 322 are molded into the plate 310 and are constructed to fit into recesses 324 molded or otherwise placed in the walls of the cannular body 306. Hollow posts 326 formed in the cannular body

306 are sized appropriately to fit snugly into holes 328, and post 330 is concomitantly sized to fit into hole 332 and along with the tabs 322 and the recesses 324, provide guidance and retention of the plate 310 within the cannular body 306. As may be seen by referring to FIGS. 25 and 26, when the hinged tip 308 is pivoted about a hinge 334, projections 336 are made to fit into recesses 338 in the cannular body 306 simultaneously causing posts 340 to mate with the hollow posts 326. The suture material 312 is guided in channels 342 on each side of the cannular body 306, and the needles 314 are loaded within the needle guides 58.

An example of an embodiment of a needle loading system is shown in FIG. 27 and includes a cannular body 344 and a needle loader 346. The needle loader 346 includes two arms 348a and 348b which terminate in needle recesses 350a and 350b, respectively, and are commonly attached to crossbar 352. FIGS. 28A through 28C are detail cross section plan views which illustrate and describe the operation of the needle loader. As may be seen in FIG. 28A, the needle recess 350 attached to the arm 348 contains a needle 354 to which is attached a piece of suture material 356. The needle 354 is held within the recess 350 by fingers 358. The fingers 358 are bent inward such that a deflective force causes them to hold the needle by shank 360, butting up against shoulder 362. Referring now to FIG. 28B, it may be seen that as the needle recess 350 is moved in the direction indicated by the arrows, the fingers 358 are deflected even further by needle guide 364 causing the fingers 358 to release the needle shank 360 and clear the needle shoulder 362. This movement forces the needle shank 360 to slide into slot 366 in needle carrier 368, as best shown in FIG. 28C. Referring back to FIG. 27, it may be seen that the force indicated by the arrows in FIGS. 28A and 28B may be provided by a thumb 370 and finger 372. It may be clearly seen that the suture carrier plate 310 may be loaded into the cannular body 344 as previously described in reference to FIGS. 25 and 26.

An alternate embodiment of the needle loading system is shown in FIG. 29 wherein a needle loader 374 includes arms 376a and 376b and needle recesses 378a and 378b. As may be clearly

seen, the needle recesses 378 are similar in construction and operation to those described in FIGS. 28A through 28C. However, in this embodiment, the needle loader 374 is constrained to glide along cannular body 380, aligning recesses 378 with needle guides 382, and subsequently loading needles 384 as previously outlined. As before, it may be clearly seen that the suture carrier plate 310 may be loaded into the cannular body 380 as previously described in FIG. 25 and FIG. 26.

FIGS. 30A through 30C are detail section views which describe yet another embodiment of a needle loading system 386 which includes a cartridge 388 and a needle loader 390. The cartridge 388 is preferably molded out of polycarbonate or the like, and includes a flange 392 on which are projections 394 which are sized and designed to fit into recesses 396 in the cannular body 398. The needle loader 386 which is preferably molded out of a malleable plastic such as polypropylene, includes arms 400a and 400b and needle recesses 402a and 402b. As may be clearly seen, the needle recesses 402 are similar in construction and operation to those described in FIGS 28A through 28C. In this embodiment, and as shown in FIG. 30B, the needle loader 386 is constrained to be engaged with the cartridge 388. As the flange 392 is snapped into the cannular body 398, projections 394 are engaged into recesses 396, aligning the needle recesses 402a and 402b with needle guides 404a and 404b, respectively. Referring now to FIGS. 30B and 30C, it may be clearly seen that by squeezing the needle recesses 402 and deflecting arms 400, the needles 406 are loaded into openings 408 in the needle guides 404 and subsequently into needle carriers 410 as previously outlined in FIGS. 28A through 28C. FIG. 30C shows that the needle loader 386 has been removed from the cartridge 388 leaving the needles 406 loaded and ready for use.

Referring now to FIG. 31, there may be seen a detail perspective view of a suture application device 412 which includes a cannular body 414 and a needle catch 416. The needle catch 416 includes slots 418 and openings 420. Needle 422 includes a point 424 and a shoulder 426. The needle catch 416 is designed such that the openings 420 are large enough for the

point 424 and the shoulder 426 of the needle 422 may easily pass through. After the needle 422 has been driven into tissue, the suture application device 412 may be manipulated to allow the point 424 and the shoulder 426 of the needle 422 to enter the opening 420. The suture application device 412 may then be moved to allow the shoulder 426 to slide down in the slot 418 which is sized such that the shoulder 426 may not pass through. Thus the needle 422 may be captured selectively at the discretion of the user.

It may also be desirable to have an interlock assembly to prevent the user of these devices from improper sequencing of the controls. It is necessary for the needle guides previously described to be deployed prior to the needle driver control being activated. Improper sequencing may cause a malfunction of the device. We therefore now describe an interlock system which prevents improper control sequencing.

Referring to FIG. 32A, a sectional detail plan view of a suture device interlock assembly 430 which includes a needle driver button 432 attached to a shaft 434 which is slidably disposed within a guide deployment sleeve 436. The guide deployment sleeve 436 includes a button 438 and a hollow shaft 440 with keyhole slot 442 and is slidably disposed within outer housing 444. Residing on the inside diameter of hollow shaft 440 is a housing 446 dimensioned to allow the shaft 434 to move slidably within it's inside diameter. At the end of the shaft 434 is a recess 448 in which sits a bent wire 450. The housing 446 is ultimately attached to the previously described pushrod 42 (see Fig. 6), and the bent wire 450 is attached to the previously described flexible members 56a, 56b (Fig. 6). The outer housing 444 contains a pocket 452 in which is slidably disposed a lockout pawl 454 which is forced by spring 456 to ride up into notch 458 in the shaft 434.

Referring now to FIG. 33, which is a detail perspective view of the lockout pawl 454 and the hollow shaft 440, it may be seen that the lockout pawl 454 has a head 460 which has a dimension larger than a smaller slot section 462 of the keyhole slot 442. This dimensional difference restrains the head 460

from passing down through the smaller slot section 462, thereby preventing the needle driver button 432 from being depressed.

Moving to FIG. 32B, it may be seen that as the button 438 is depressed, the keyhole slot 442 moves relative to the lockout pawl 454. As previously described in other embodiments, this movement of button 438 deploys the needle guides. Referring back to FIG 33, it may be seen that the larger slot section 464 of the keyhole slot 442 is moved into a position which aligns the lockout pawl 454 with the larger slot section 464. As may be seen in FIG. 32C, as the needle driver button 432 is depressed, the lockout pawl 454 is driven back into the pocket 452 against the tension of the spring 456 as the notch 458 in the shaft 434 moves away from the lockout pawl 454. As previously described in other embodiments, this movement of needle driver button 432 drives the needle or needles through tissue. It should be noted that as the lockout pawl 454 drops into the larger slot section 464, it effectively prevents the movement of the hollow shaft 440. This has the effect of locking the needle guides in the deployed position during the driving of the needles. It also should be understood that the reverse movements of the controls will return the buttons to their original positions as described in FIG. 32A.

FIG. 34 illustrates a needle loader 466 and the needle 422. The needle loader 466, which may be injection molded out of a thermoplastic material or the like, includes a flange 468 with finger grips 470 and a center depression 472. The center depression 472 is for finger alignment, and may be color coded to accomplish suture tagging as described earlier. Attached to the flange 468 is a clip 474 which includes an alignment rib 476. Extending below the flange 468 is a boss 478 with a groove 480 cut along the inside diameter of the boss 478. The groove 480 is sized both in diameter and width to allow the needle 422 to be frictionally held in the groove 480. Referring to FIG. 35, there may be seen a detail perspective view of the distal end of one embodiment of the present invention and includes a cannular body 482 comprised of body halves 484a,b. An alignment slot 486 is formed by the edges 488a,b of the body halves

484a,b. A needle guide track 490 may be deployed to the position shown in preparation for needle loading.

Referring now to FIGS. 36A through 36C, the operation of the needle loader 466 will be described. The needle 422 is placed in the groove 480 in the needle loader 466 and is held in place by appropriate sizing of the diameter and width of the groove to effect a frictional fit. The needle point 424 is butted into recess 492. The alignment rib 476 is positioned such that it rides in the alignment slot 486, as the clip 474 snaps in place around the cannular body 482. This orientation and engagement of the alignment rib 476 and alignment slot 486 positions the needle 422 such that the needle 422 having a crimped end 494 is in axial alignment with the needle guide 490. It may be seen in FIG. 36B that axial movement relative to the cannular body 482 of the needle loader 466 will engage the crimped end 494 in a pocket 496 in the needle guide 490. Further, it may be seen in FIG. 36C that once the crimped end 494 is engaged in the pocket 496, rotation of the needle loader 466 about a center 498 will cause the needle 422 to be slidably engaged in the needle guide 490. Continued rotation about the center 498 will completely engage the needle 422 in the needle guide 490. The needle loader 466 is then disengaged from the needle 422.

FIG. 37 describes another embodiment of a needle loader for the short needle and carrier combination. A suture 500 is suitably attached to needles 502 a,b. A needle loader 504 which is preferably molded out of a thermoplastic material, includes a clip 506, a finger grip 508, and needle funnels 510 a,b. The clip 506 is dimensioned to snap onto a cannular body 512, and able to slide relative to a centerline 514. Recesses 516 a,b are formed at the bottom of the needle funnels 510, and suture slots 518 a,b formed in the sides of the needle funnels 510. The needle funnels 510 are spaced such that the recesses 516 match the spacing of needle guides 520 a,b, and the suture slots 518 match guide slots 522 a,b.

Use of the needle loader 504 will be described by referring to FIG. 38 which illustrates the needle loader 504 with the clip 506 snapped around the cannular body 512, and the recess 516

engaged on the needle guide 520 aligning the suture slot 518 with the guide slot 522. It is to be understood that only one side of the needle loader is illustrated in FIG. 38. Both sides function similarly and simultaneously. As the goal of using the needle loader is to place the needles into the needle carriers as previously described in FIGS. 28A through 28C, it should be noted that this is the intent of this embodiment of the needle loader as well. Suture 500 with attached needle 502 is placed into the suture slot 518 in the needle funnel 510. By pulling down on the suture 500, the needle 502 is forced to slide down into the needle funnel 510 and ultimately engage the needle guide 520. The process is repeated on the other side to load the other needle. The needle loader 504 is then removed from the cannular body 512 by gripping the finger grip 508 and disengaging the clip 506 from the cannular body 512.

Another embodiment of a suture device is described by referring to FIG. 39. A needle driver 524 is comprised of body halves 526 a,b, a needle driver button 528, a compression spring 530, a rigid tube 532, a flexible needle driver 534 and a needle catch 536. The housing half 526b includes a handle 538 and guide ribs 540 a,b,c,d for the rigid tube 532. The guide rib 540a also serves as a spring perch for the compression spring 530. A continuous pathway 542 a,b is formed in each of the body halves 526, and when mated together they form a cylindrical cross section. The flexible needle driver 534, which may be made from a suitable flexible thermoplastic material such as polyester or polypropylene, may be crimped or attached by other mechanical or adhesive means to the rigid tube 532 at end 544. The rigid tube 532 is bent at the other end to form a hook 546, which sits in a pocket 548 in the needle driver button 528, capturing the rigid tube 532. The needle driver button 528 includes a shaft 550 which has a cruciform shaped cross section to prevent rotation of the needle driver button 528 when it is slidably engaged in the annulus formed by anti rotation boss 554 a,b and a needle driver button pocket 556. The needle driver button 528 also includes a button head 552 and a shoulder 558. The shoulder 558 is dimensioned to provide a backstop such that when the needle driver button 528 is assembled into the needle

driver button pocket 556, and the compression spring 530 is loaded against the guide rib 540a, the needle driver button 528 is restrained from being pushed out of the needle driver button pocket 556 by interference between the shoulder 558 and the anti rotation boss 554. The rigid tube 532 and the flexible needle driver 534 are slidably disposed within the continuous pathway 542. A needle 560 is dimensioned to slidably and rotationally fit a needle groove 562 a,b which is part of the continuous pathway 542. When body halves 526 are assembled, the needle catch 536 clips into catch groove 564 a,b, and may be retained by heat staking, ultrasonic welding, adhesive bonding or the like. The needle catch 536 provides the end of the needle driver 524 with a means of keeping the body halves 526 from separating.

Use of the needle driver 524 shown in FIG. 39 will now be described by referring to FIGS. 40A and 40B, and FIGS. 41A, 41B, and 41C. There may be seen a needle driver 524 comprising a cannular body 566 with finger grips 568 a,b. FIGS. 40A and 41A depict the needle driver 524 as it would appear ready for use with the needle 422 loaded into the needle groove 562. A suture 570 is attached to the needle 422 as previously described. The flexible needle driver 534 rests slidably disposed within the continuous pathway 542. An end 572 of the flexible needle driver 534 rests against a crimp 574 on the attachment end of the needle 422 and the suture 570. Referring now to FIGS. 40B and 41B, it may be seen that as the needle driver button 528 is depressed by pushing on the button head 552, the rigid tube 532 is caused to move axial to the cannular body 566, sliding within the continuous pathway 542, and causing the flexible needle driver 534 to move commensurately. The needle 422 is forced to move out of the needle groove 562 trailing the suture 570 as the flexible needle driver 534 follows the continuous pathway 542. FIG. 41C illustrates a needle 560, without a shoulder such as that described for the needle 422, and a suture 576 being driven in a manner similar to that described in FIGS. 41A and 41B. The capture and withdrawal of needles both with and without shoulders is now to be described.

It is important to the successful completion of any suturing application to be able to tie a knot in the suture after it has been placed. It is particularly important in endoscopic applications to bring the suture ends back up through the same surgical trocar through which they were introduced. This allows a knot to be tied extracorporeally, i.e. external to the body, and then pushed down through the surgical trocar to the tissue being sutured. Accordingly, we now describe various means and methods for retrieving the needle and suture combination with the same device used for driving the needle, and provisions for pushing a knot back down the surgical trocar into the wound.

FIG. 42 shows a detail perspective view of an embodiment of a catch on the end of a suture application device 580 which includes a cannular body 582 and a needle catch 584. The needle catch 584, is similar in function to that described in FIG. 31, and is preferably constructed of thin hardened stainless steel of high temper, such as ANSI 301, includes slots 586 a,b and openings 588 a,b. The needle catch 584 is dimensioned such that the openings 588 are sufficiently large to allow the point 424 and the shoulder 426 of the needle 422 to easily pass through. After the needle 422 has been driven into tissue, the suture application device 580 may be manipulated to allow the point 424 and the shoulder 426 of the needle 422 to enter the opening 588 as illustrated in FIG. 42. The suture application device 580 may then be moved to allow the needle 422 to slide down in the slot 586 which is sized such that the shoulder 426 may not pass through. Thus the needle 422 may be captured selectively at the discretion of the user, and may be withdrawn from the surgical trocar to effect knot tying or other manipulation of the needle/suture combination.

Yet another embodiment of the present invention allowing the capture and withdrawal of the needle and suture combination is shown in FIG. 43, which shows a detailed perspective cross sectional view of the end of the suture application device 580 described in FIG. 42. Referring to FIG. 42, it may be seen that the cannular body 582 is comprised of housing halves 590 a,b. In the interest of clarity, FIG. 43 shows a cutaway view of the

housing halves 590, which are configured to form a needle guide track 592 and a flexible needle driver guide track 594. The needle guide track 592 and the flexible needle driver guide track 594 are continuous semi-circular grooves in the housing halves 590, and when the housing halves 590 are assembled, the flexible needle driver guide track 594 and the needle guide track 592 form a continuous pathway 596 of circular cross section in which a flexible needle driver 598 is slidably disposed and may travel to an exit opening 600. Slots 602 a,b intersect with the needle guide track 592 at path bottom 604, defining projections 610 a,b. The flexible needle driver 598 may optionally have a needle driver tip 606 which may be made from a different material than the flexible needle driver 598, such as stainless steel or a harder thermoplastic material. This may be helpful to improve the wear charactaristics of the tip of the flexible needle driver 598. When a suture 608 is positioned in the slots 602a and 602b and rests on the path bottom 604, the flexible needle driver 598 can be advanced in the needle guide track 592 to pinch the suture 608 between the needle driver tip 606 and the projections 610 a,b. The suture 608 may then be maneuvered as desired by the user, including being withdrawn through the surgical trocar. Needles of any description may be attached to the suture just described, therefore it may be seen that this mechanism and method of retrieval of a suture from the endoscopic operative field does not require a special needle with a shoulder.

Yet another embodiment of the present invention for capture and retrieval of a non-shouldered needle is shown in FIG. 44 and FIGS. 45A through FIG 45C. Referring first to FIG. 44, housing halves 612 a,b are configured to form a cannular body 614 similar to the one previously described in FIG. 42. A surgical needle 616 includes a needle tip 618 and a needle body 620, and a suture 622. A retainer lever 624 is pivotally mounted on a shaft 626 and is biased to a neutral position as shown in FIG. 45A by a spring 628. Referring now to FIGS. 45A through 45C, the general operation and structure of this embodiment is to be described. It is to be understood that only one housing half 612 is being shown for clarity. Referring now to FIG. 45A,

needle guide track 630 in body half 612 terminates in an exit opening 632. Flexible needle driver guide track 634 and the needle guide track 630 combine to form a continuous pathway 636, in which a flexible needle driver 638 with a needle driver tip 640 is slidably disposed. The needle 616 is inserted through the exit opening 632 in the body half 612 into the needle guide track 630. FIG. 45B shows the needle 616 and the suture 622 inserted into the needle guide track 630 until the needle tip 618 is positioned adjacent to the exit opening 632. It may be seen that during insertion into the needle guide track 630, the needle 616 causes the retainer lever 624 to rotate pivotally on the shaft 626 to a retracted position. As previously described in FIGS. 40A and 40B, the needle driver button 552 is depressed, advancing the flexible needle driver 638 until the needle driver tip 640 reaches the exit opening 632, driving the needle 616 out of the needle guide track 630 and through body tissue. When the flexible needle driver 634 returns to the retracted position as shown in FIG. 45A, the spring 628 is biased to return the retainer lever 624 to the neutral position as illustrated in FIG. 45A.

To retrieve the needle 616 and the suture 622 the cannular body 614, shown in FIG. 44, is placed in the surgical field and manuvered to guide the needle tip 618 and needle shaft 620 through an opening 642 in a needle catch 644, which includes the opening 642 and a catch bottom 646. Referring to FIG. 45C, the flexible needle driver 638 is advanced in the needle guide track, engaging and pivotally rotating the retainer lever 624 and pinching and capturing the needle body 620 between the retainer lever 624 and the catch bottom 646. The needle 616 and the suture 622 may then be removed from the surgical field through the surgical trocar. To release the needle 616 from being pinched by the retainer lever 624 and the catch bottom 646, the flexible needle driver 638 is retracted, allowing the retainer lever 624 to return to the neutral position as shown in FIG. 45A, thus freeing the needle 616.

An alternate embodiment of a needle catch system is shown in FIG. 46 and FIGS. 47A through 47C. Similar to that previously described in FIG. 44, FIG. 46 and plan view FIG. 47A

show housing halves 612a and 612b which are configured to form the flexible needle driver guide track 634 and the needle guide track 630, which combine to form the continuous pathway 636 and the exit opening 632. A capture lever 648 includes an elongate hole 650 and a lever tip 652. A shaft passes through the elongate hole 650 and holds a spring 656 which is biased to hold the capture lever 648 in the position shown in FIGS. 46 and 47A. Referring now to FIG. 47A , the needle 616 and the suture 622 are being inserted into the needle guide track 630 through the exit opening 632, with the capture lever 648 in the neutral position. As shown in FIG. 47B the needle 616 and the suture 622 are being inserted into the needle guide track 630 until the needle tip 618 is positioned flush to the exit opening 632. When inserted into the needle guide track 630, the needle body 620 pushes on the lever tip 652 causing the capture lever 648 to rotate about the shaft 654 and move to the retracted position. As previously described in FIGS. 40A and 40B, the needle driver button 552 is depressed, advancing the flexible needle driver 638 until the needle driver tip 640 reaches the exit opening 632, driving the needle 616 out of the needle guide track 630 and through body tissue. In this position the needle 616 exits the needle guide track 630 through exit opening 632. When the flexible needle driver 638 is returned to the retracted position as shown FIG. 47A, the capture lever 648 is returned to the neutral position by the spring 656.

The operation and structure of this embodiment of a needle catch will be described by referring to FIG. 46, where there may be seen a needle catch 658, which includes a catch opening 660 and a catch bottom 662. The cannular body 614 is positioned in the surgical field and maneuvered to guide the needle tip 618 and a portion of the needle body 620 through the catch opening 660 to facilitate the capture and retrieval of the needle 616 and suture 622 from the operative site. As illustrated in FIG. 47C, the flexible needle driver 638 is advanced forward in the needle guide track 630, with the needle driver tip 640 engaging the lever tip 652 and slidabily moving the capture lever 648 along the elongated hole 650, being guided by a lever shoulder 664 and a housing guide shoulder 666, until the capture lever

648 reaches the capture position, at which point the needle body 620 is pinched between the capture lever 648 and the catch bottom 662. The needle 616 and the suture 622 may then be removed from the surgical field. The flexible needle driver 638 is returned to the retracted position allowing the capture lever 648 to return to the neutral position, thus freeing the needle 616 for removal from the catch opening 660.

FIGS. 48, 49A, 49B and 50 describe yet another embodiment of a needle capture system. Similar to that previously described in FIG. 44, FIG. 48 shows a plan view of a housing half 612 which is configured to form the flexible needle driver guide track 634 and the needle guide track 630, which combine to form the continuous pathway 636 and the exit opening 632. These elements may be used in similar fashion to that described previously in FIGS. 41A through 41C and in FIG 43 to drive a needle through tissue.

Referring now to FIGS 49A and 49B, molded into the housing halves 612 there may be seen catch pockets 668 a,b and catch lever openings 670 a,b. Referring to FIG. 50 there may be seen catch levers 672 a,b which include lever jaws 674 a,b,c, holes 676 a,b,c and lever cams 678 a,b. A lever shaft 680 is driven through holes 676 to pivotally connect catch levers 672. Referring again to FIG. 48, the flexible needle driver 638 is shown in the retracted position. The lever cams 678 rest in guide pockets 684 and sit in the needle guide track 630. The lever shaft 680 rests pivotally mounted in lever shaft pockets 686 a,b. As also shown in FIG. 49A, the catch levers 672 a,b are pivotally mounted on the pivot shaft 680, with the lever cams 678 a,b projecting through the guide pockets 684 a,b and substantially into the needle guide track 630, while the lever jaws 674 are positioned in the catch lever openings 670. Lever springs 688 a,b bias the catch levers 672 a,b to bring the lever cams 678 a,b to the position shown in FIG. 49A.

The operation of this embodiment will be described by referring to FIG. 48. The surgeon places the cannular body 614 into the surgical field and guides the needle point 618 and the needle shaft 620 into the opening 682 until the needle point 618 and the needle shaft 620 project through the opening 682. The

flexible needle driver 638 is advanced toward the forward position, as shown in FIG. 49B, and as shown in FIG. 49B, engages the lever cams 678 a,b, causing the catch levers 672 a,b to pivotally rotate on the lever shaft 680. The lever jaws 674 a,b,c rotate inwardly and pinch the needle body 620, as shown in FIG. 49B, and then the needle 616 may be removed from the surgical field. When the flexible needle driver 638 is returned to the retracted position, the catch levers 672 a,b are forced to pivot back to the position shown in FIG. 49A by the lever springs 688 a,b. This frees the needle 616 for removal from the opening 682.

FIGS. 51 through 53 illustrate yet another embodiment of the present invention showing the general structure and operation of an alternate needle capture system. Referring first to FIG. 51, there may be seen a suture applicator tip 690 which includes housing halves 692 a,b. Similar to the embodiments previously described in FIG. 44 and as shown in FIG. 53, the housing halves 692 a,b are configured to form a flexible needle driver guide track 694 and the needle guide track 696, which combine to form the continuous pathway 698 and the exit opening 700. The flexible needle driver 638 is retained and slidabily guided in the continuous pathway 698. Referring now to FIG. 52 there may be seen a detailed cross sectional view of the end of the suture applicator tip 690 taken along the lines of 52-52 of FIG. 53. A needle passage 702 which is defined by needle openings 704 a,b, in the housing halves 692 a,b. The needle passage 702 intercepts the needle guide track 696. The upper passage guide walls 706 a,b and lower passage guide walls 708 a,b are configured to accommodate easy guidance and positioning of the suture needle 616 into the needle passage 702.

The operation of this embodiment of the device will now be shown by referring first to FIG. 51. The suture applicator tip 690 is directed into the surgical field at which point the needle tip 618 and the needle body 620 of the needle 616 are guided through the needle opening 704a. Referring to FIG. 53, the flexible needle driver 638 with the needle driver tip 640 is shown in the retracted position within the continuous pathway

698. The needle body 620 is shown in cross section, positioned within the needle passage 702. The flexible needle driver 638 is moved forward to position 638a to capture the needle body 620 as shown by the phantom view in FIG. 53, at which point the needle body 620 is pinched in the needle passage by the driver tip 640a. The needle 616 and the suture 622 may then be removed from the surgical field. The flexible needle driver 638 is retracted allowing the needle 616 to be removed from the needle passage 702. To enhance the function of needle driver tip 640, various materials may be selected for its fabrication. Soft elastometric or polymeric type materials could be more compatible for driving the suture 622, while a metallic material may provide increased traction to pinch and retain the needle 616 in the needle passage 702.

As previously mentioned, in order to complete any suturing application, a knot must be tied to secure the suture material to the tissue. We now describe a simple means for facilitating the tying of knots during endoscopic procedures. Referring to FIG. 54, there is seen a suture applicator tip 690 which includes housing halves 692 a,b. At the distal end of the suture applicator tip 690 are concave recesses 710 a,b, which may also be seen in cross section in FIG. 52. The suture 622 includes ends 712 a,b and a knot 714, and passes through tissue 716. It is to be understood that the suture applicator tip 690 has been passed into an interior body cavity, such as the abdominal cavity, through a surgical trocar. The knot 714 in the suture 622 has been tied extracorporeally, i.e. external to the body cavity, and with the use of the suture applicator tip 690, has been guided through the surgical trocar by the concave recesses 710 to the position shown in FIG 54. The user, by keeping tension on the ends 712 a,b of the suture 622, and by pushing on the suture applicator tip 690, may guide the knot 714 further down to the tissue 716. To complete the tying of a knot, the suture applicator tip 690 is removed from the surgical trocar and another loop or knot is tied extracorporeally, and pushed down the surgical trocar in like manner to that described above. Thus it may be seen that the present invention may be used to drive the needle, retrieve the needle from the tissue,

and facilitate the placement of knots to complete the approximation, ligation, or fixation.

An alternate embodiment of the knot pusher may be seen by referring to FIG. 54A. There may be seen a cannular body 756 which includes protrusions 758 a,b and a land 760. The protrusions 758 a,b and the land 760 combine to form a pocket 762, which may function in a similar manner to the concave recesses 710 described in FIG. 54. It should thus be clear that guidance of the suture for the purposes of knot tying may be accomplished by means of either a pocket formed by protrusions or other positive external features such as ribs or bumps on the end of the cannular body, or by recesses or other negative external features such as depressions, concavities, or reliefs formed in the end of the cannular body.

Yet another embodiment of the invention is an alternate needle driver and catch system as shown in FIG. 55A and FIG. 55B, which are detailed cross sectional views of the distal end of the suture application system. Referring to FIG. 55A a cannular body 718 is comprised of the housing halves 720 a,b. It is to be understood that for clarity only one of the housing halves 720 of the cannular body 718 is shown in FIG. 55A and FIG. 55B. The housing halves 720 are configured to create a guided pathway 722 which is comprised of a needle carrier guide track 724 and a flexible carrier driver guide track 726. A needle carrier 728 and flexible carrier driver 730 are joined at an end 732 of the needle carrier 728. The attachment between the needle carrier 728 and the flexible carrier driver 730 at the end 732 can be accomplished by crimping, welding, adhesive bonding or various other techniques. A bullet needle 734 includes a shoulder 736, a point 738 and a shaft 740. A length of suture material 742 is attached to the shaft 740 by placing it in a hole 744 and holding it there by suitable means, such as crimping or adhesive bonding or the like. Further incorporated in the housing halves 720 are catch pockets 746 a,b which position and retain a needle catch 748. Referring to FIG. 56, which is a detail plan view taken along the lines of 56-56 of FIG. 55A, it may be seen that the needle catch 748 includes openings 750 defined by ribs 752. The configuration and

function of the needle catch 748 is similar to that described earlier in FIG. 19C. The bullet needle 734 is inserted into an end 754 of the needle carrier 728. The shoulder 736 of the bullet needle 734 rests on the end 754 of the needle carrier 728, said end 754 dimensioned to hold and retain the bullet needle 734 in a manner previously described.

Referring now to FIGS. 55A and 55B, the operation of this embodiment will be described. It is to be understood that the function of this embodiment is similar to that previously described in FIGS. 1A through 1H, that is, to approximate and close the puncture wounds created when surgical trocars are introduced into a body cavity. For clarity, the imposition of tissue planes along the path of needle travel to be described in FIGS. 55A and 55B has not been shown, although it is implied. FIG. 55A shows the bullet needle 734 loaded into the needle carrier 728 which is depicted in the retracted position. In this position, the cannular body 718 may be passed through a surgical trocar and into a body cavity for operation of the device. As shown in FIG 55B, as the flexible carrier driver 730 is advanced into the needle guide track 724, the needle carrier 728, holding the bullet needle 734 and trailing the suture 742 is driven on a semi-circular path terminating in the needle catch 748. The bullet needle 734 is captured by the catch 748 in a manner previously described in FIG 19C. The flexible carrier driver 730 may be retracted back into the flexible carrier driver guide track 726, causing the needle carrier 728 to rotate back into the needle carrier guide track 724 in the body half 720. The instrument may be removed from the surgical trocar, and the process repeated on the other side of the wound, and after knots have been tied, an approximation of the puncture wound is accomplished. It may be seen that a knot pusher such as that described in FIG. 54 may be incorporated into the distal end of this embodiment of the suture applicator to effect the tying of knots for approximation of the puncture wounds. As such, the knots would be pushed directly into the wound, and not necessarily through the surgical trocar.

It will be understood that the apparatus and method of the present invention for an endoscopic suture system may be

employed in numerous specific embodiments in addition to those described herein. Thus, these numerous other embodiments of the invention, which will be obvious to one skilled in the art, including but not limited to changes in the dimensions of the device, the type of materials employed, the location and type of needles, driving mechanisms, catching mechanisms, needle loading mechanisms, etc., are to be included within the scope of the present invention. The apparatus and method of the present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

The Embodiments Of The Invention In Which An Exclusive Property Or Privilege Is Claimed Are Defined As Follows:

1. A suturing instrument comprising:
an elongate body member having a longitudinal axis and a substantially straight distal end portion;
a deployment controller having a proximal end and a distal end, said deployment controller extending substantially along the longitudinal axis of said elongate body member to said distal end portion of said elongate body member, wherein said deployment controller has a retracted position and a deployed position; and
a needle deployment system located within the distal end portion of said elongate body member and coupled to said deployment controller, said needle deployment system comprising:
a curved surgical needle slidably positioned in a curved needle channel within said elongate body member, said curved needle channel located substantially in a plane which is substantially parallel to said elongate body member longitudinal axis and having a laterally disposed exit port from said distal end portion of said elongate body member; and
a flexible pusher coupled to the distal end of said deployment controller, said needle deployment system having a retracted configuration when said deployment controller is in said retracted position wherein substantially all of the curved surgical needle is contained within said elongate body member and a deployed configuration when said deployment controller is in said deployed position, wherein said flexible pusher pushes the curved surgical needle through said curved needle channel and said laterally disposed exit port outside of said elongate body member along a path having an initial direction away from said elongate body member longitudinal axis as said deployment controller begins to move from said retracted position toward

said deployed position followed by a direction toward said elongate body member longitudinal axis as said deployment controller approaches said deployed position.

2. A suturing instrument as defined in claim 1 further comprising:

a suture channel which intersects said curved needle channel at said distal end of said elongate body member; and

a suture capture projection positioned adjacent said suture channel and said curved needle channel such that a suture lying in said suture channel is captured between said projection and said flexible pusher as said deployment controller moves from said retracted position to said deployed position.

3. A suturing instrument as defined in claim 1 further comprising a needle catch at said distal end of said elongate body member.

4. A suturing instrument as defined in claim 3 wherein said curved surgical needle has a shoulder near a distal point and said needle catch further comprises a first opening dimension sized to allow said shouldered needle to pass therethrough and a second opening dimension sized smaller than said shoulder, thereby capturing said needle at said shoulder.

5. A suturing instrument as defined in claim 3 further comprising:

a needle capture channel at said distal end of said elongate body member; and

a cam positioned in said needle capture channel so as to wedge a needle inserted in said needle capture channel between said cam and said channel.

6. A suturing instrument as defined in claim 5 wherein said cam is coupled to said flexible pusher and as said

deployment controller moves from said retracted position to said deployed position, said cam increases the capture force applied to said needle.

7. A suturing instrument as defined in claim 1 further comprising a suture channel formed at the distal end of said elongate body member for pushing a knot tied extracorporeally into a body cavity.

8. A suturing instrument comprising:

an elongate body member having a longitudinal axis;

a deployment controller having a proximal end and a distal end, said deployment controller extending substantially along the longitudinal axis of said elongate body member to a distal end of said elongate body member, wherein said deployment controller has a retracted position and a deployed position;

a needle deployment system located within the distal end of said elongate body member and coupled to said deployment controller, said needle deployment system comprising:

a curved surgical needle slidably positioned in a curved needle channel within said elongate body member, said curved needle channel located substantially in a plane which is substantially parallel to said elongate body member longitudinal axis;

a flexible pusher coupled to the distal end of said deployment controller, said needle deployment system having a retracted configuration when said deployment controller is in said retracted position wherein substantially all of the curved surgical needle is contained within said elongate body member and a deployed configuration when said deployment controller is in said deployed position, wherein said flexible pusher pushes the curved surgical needle through said curved needle channel outside of said elongate body member along a path having an initial direction away from said elongate body

member longitudinal axis as said deployment controller begins to move from said retracted position toward said deployed position followed by a direction toward said elongate body member longitudinal axis as said deployment controller approaches said deployed position;

a suture channel which intersects said curved needle channel at said distal end of said elongate body member; and

a suture capture projection positioned adjacent said suture channel and said curved needle channel such that a suture lying in said suture channel is captured between said projection and said flexible pusher as said deployment controller moves from said retracted position to said deployed position.

9. A suturing instrument comprising:
an elongate body member having a longitudinal axis;
a deployment controller having a proximal end and a distal end, said deployment controller extending substantially along the longitudinal axis of said elongate body member to a distal end of said elongate body member, wherein said deployment controller has a retracted position and a deployed position;

a needle deployment system located within the distal end of said elongate body member and coupled to said deployment controller, said needle deployment system comprising:

a curved surgical needle slidably positioned in a curved needle channel within said elongate body member, said curved needle channel located substantially in a plane which is substantially parallel to said elongate body member longitudinal axis;

a flexible pusher coupled to the distal end of said deployment controller, said needle deployment system having a retracted configuration when said deployment controller is in said retracted position wherein substantially all of the curved surgical

needle is contained within said elongate body member and a deployed configuration when said deployment controller is in said deployed position, wherein said flexible pusher pushes the curved surgical needle through said curved needle channel outside of said elongate body member along a path having an initial direction away from said elongate body member longitudinal axis as said deployment controller begins to move from said retracted position toward said deployed position followed by a direction toward said elongate body member longitudinal axis as said deployment controller approaches said deployed position; and

a needle catch at said distal end of said elongate body member.

10. A suturing instrument as defined in claim 9 wherein said curved surgical needle has a shoulder near a distal point and said needle catch further comprises a first opening dimension sized to allow said shouldered needle to pass therethrough and a second opening dimension sized smaller than said shoulder, thereby capturing said needle at said shoulder.

11. A suturing instrument as defined in claim 9 further comprising:

a needle capture channel at said distal end of said elongate body member;

a cam positioned in said needle capture channel so as to wedge a needle inserted in said needle capture channel between said cam and said channel.

12. A suturing instrument as defined in claim 11 wherein said cam is coupled to said flexible pusher and as said deployment controller moves from said retracted position to said deployed position, said cam increases the capture force applied to said needle.

13. A suturing instrument comprising:

an elongate body member having a longitudinal axis;

a deployment controller having a proximal end and a distal end, said deployment controller extending substantially along the longitudinal axis of said elongate body member to a distal end of said elongate body member, wherein said deployment controller has a retracted position and a deployed position;

a needle deployment system located within the distal end of said elongate body member and coupled to said deployment controller, said needle deployment system comprising:

a curved surgical needle slidably positioned in a curved needle channel within said elongate body member, said curved needle channel located substantially in a plane which is substantially parallel to said elongate body member longitudinal axis;

a flexible pusher coupled to the distal end of said deployment controller, said needle deployment system having a retracted configuration when said deployment controller is in said retracted position wherein substantially all of the curved surgical needle is contained within said elongate body member and a deployed configuration when said deployment controller is in said deployed position, wherein said flexible pusher pushes the curved surgical needle through said curved needle channel outside of said elongate body member along a path having an initial direction away from said elongate body member longitudinal axis as said deployment controller begins to move from said retracted position toward said deployed position followed by a direction toward said elongate body member longitudinal axis as said deployment controller approaches said deployed position; and

a suture channel formed at the distal end of said elongate body member for pushing a knot tied extracorporeally into a body cavity.

14. A suturing instrument comprising:

an elongate body member having a longitudinal axis;

a deployment controller having a proximal end and a distal end, said deployment controller extending substantially along the longitudinal axis of said elongate body member to a distal end of said elongate body member, wherein said deployment controller has a retracted position and a deployed position; and

a needle deployment system located within the distal end of said elongate body member and coupled to said deployment controller, said needle deployment system comprising:

a curved needle carrier channel and a curved needle carrier movably positioned therein and having a needle point mounted on a distal end thereof, said curved needle channel located substantially in a plane which is substantially parallel to said elongate body member longitudinal axis; and

a flexible pusher coupled to said deployment controller, said needle deployment system having a retracted configuration when said deployment controller is in said retracted position wherein substantially all of the curved needle carrier is contained within said elongate body member and a deployed configuration when said deployment controller is in said deployed position, wherein said flexible pusher pushes the curved needle carrier along said curved needle channel outside of said elongate body member along a path having an initial direction away from said elongate body member longitudinal axis as said deployment controller begins to move from said retracted position toward said deployed position followed by a direction toward said elongate body member longitudinal axis as said deployment controller approaches said deployed position.

15. A suturing instrument as defined in claim 14 further comprising:

a bullet needle having a suture attachment point, said bullet needle inserted in said curved needle carrier;

a suture attached to said bullet needle suture attachment point; and

a needle capture system located on said elongate body member at a location which intercepts said portion of said needle carrier path which approaches toward said elongate body member.

16. A suturing instrument for placing sutures inside a body cavity comprising:

an elongate body member having a longitudinal axis and a substantially straight distal end portion;

needle deployment means for deploying a surgical needle outside a distal end of said elongate body member along a path having an initial direction away from said elongate body member longitudinal axis followed by a direction toward said elongate body member longitudinal axis, wherein said needle deployment means further comprises a substantially semi-circular shaped needle channel located within said distal end portion of said elongate body member, said substantially semi-circular shaped needle channel having a laterally disposed exit port from said distal end portion of said elongate body member; and

needle capture means attached to said elongate body member for capturing the surgical needle after deployment.

17. A suturing instrument as defined in claim 16 further comprising a knot pushing means located at the distal end of said elongate body member for pushing a knot tied extracorporeally into the body cavity.

18. A suturing instrument comprising:

a tubular body member, said tubular body member having a substantially straight distal end portion; and

a curved needle channel located within said substantially straight distal end portion of said tubular body member configured such that a curved surgical needle may be slidably positioned therein, said curved needle channel having a laterally disposed exit port proximal to said tubular body member distal end portion.

19. A suturing instrument as defined in claim 18 further comprising:

a deployment controller having a proximal end and a distal end, said deployment controller extending substantially along a longitudinal axis of said tubular body member to said distal end portion of said tubular body member, wherein said deployment controller has a retracted position and a deployed position; and

a needle deployment system located within said distal end portion of said tubular body member and coupled to said deployment controller, said needle deployment system comprising a flexible pusher coupled to the distal end of said deployment controller, said needle deployment system having a retracted configuration when said deployment controller is in said retracted position wherein substantially all of the curved surgical needle is contained within said tubular body member and a deployed configuration when said deployment controller is in said deployed position, wherein said flexible pusher pushes the curved surgical needle through said curved needle channel and said laterally disposed exit port outside of said tubular body member along a path having an initial direction away from said tubular body member longitudinal axis as said deployment controller begins to move from said retracted position toward said deployed position followed by a direction toward said tubular body member longitudinal axis as said deployment controller approaches said deployed position.

20. A suturing instrument as defined in claim 18 further

comprising a needle catch at said distal end of said tubular body member.

21. A suturing instrument comprising:

a tubular body member having a longitudinal axis and a substantially straight distal end portion;

a deployment controller having a proximal end and a distal end, said deployment controller extending substantially along said longitudinal axis of said tubular body member to a distal end of said tubular body member, wherein said deployment controller has a retracted position and a deployed position; and

a needle deployment system located within said substantially straight distal end portion of said tubular body member and coupled to said deployment controller, said needle deployment system comprising:

a curved needle channel configured such that a curved surgical needle may be slidably positioned therein, said curved needle channel located substantially in a plane which is substantially parallel to said tubular body member longitudinal axis and having a laterally disposed exit port from said tubular body member distal end portion; and

a flexible pusher coupled to the distal end of said deployment controller, said needle deployment system having a retracted configuration when said deployment controller is in said retracted position wherein substantially all of the curved surgical needle is contained within said tubular body member and a deployed configuration when said deployment controller is in said deployed position, wherein said flexible pusher pushes the curved surgical needle through said curved needle channel and said laterally disposed exit port outside of said tubular body member along a path having an initial direction away from said tubular body member longitudinal axis as said deployment controller begins to move from said retracted position toward said deployed position followed by a direction toward said tubular

body member longitudinal axis as said deployment controller approaches said deployed position.

22. A suturing instrument as defined in claim 21 further comprising:

a suture channel which intersects said curved needle channel at said distal end portion of said tubular body member; and

a suture capture projection positioned adjacent said suture channel and said curved needle channel such that a suture lying in said suture channel is captured between said projection and said flexible pusher as said deployment controller moves from said retracted position to said deployed position.

23. A suturing instrument as defined in claim 21 further comprising a needle catch at said distal end of said tubular body member.

24. A suturing instrument as defined in claim 23 wherein said curved surgical needle has a shoulder near a distal point and said needle catch further comprises a first opening dimension sized to allow said shouldered needle to pass therethrough and a second opening dimension sized smaller than said shoulder, thereby capturing said needle at said shoulder.

25. A suturing instrument as defined in claim 23 further comprising:

a needle capture channel at said distal end of said tubular body member; and

a cam positioned in said needle capture channel so as to wedge a needle inserted in said needle capture channel between said cam and said channel.

26. A suturing instrument as defined in claim 25 wherein said cam is coupled to said flexible pusher and as said deployment controller moves from said retracted position to said deployed position, said cam increases the capture

force applied to said needle.

27. A suturing instrument as defined in claim 21 further comprising a suture channel formed at the distal end of said tubular body member for pushing a knot tied extracorporeally into a body cavity.

Fig. 1A

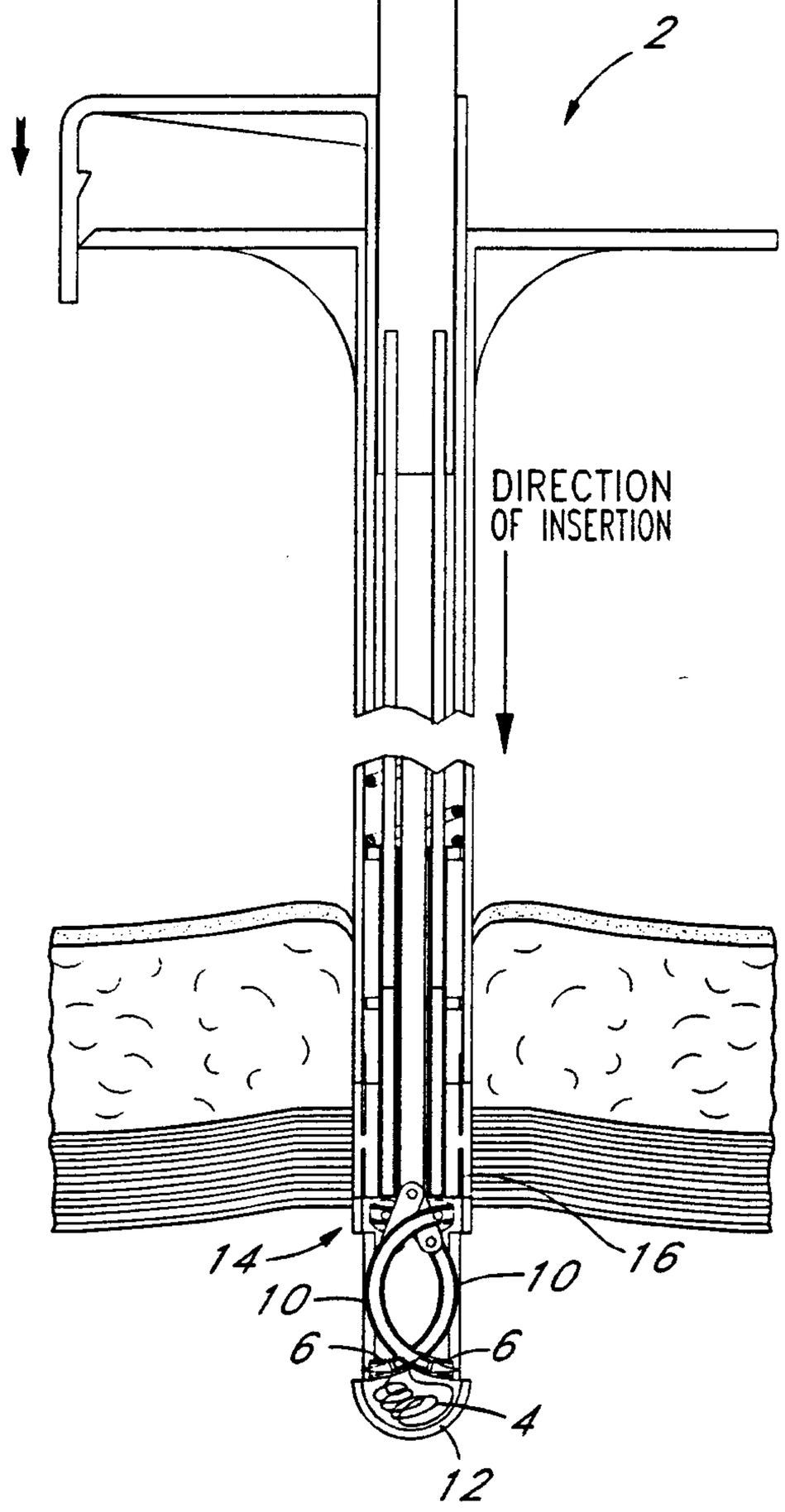

Fig. 1B

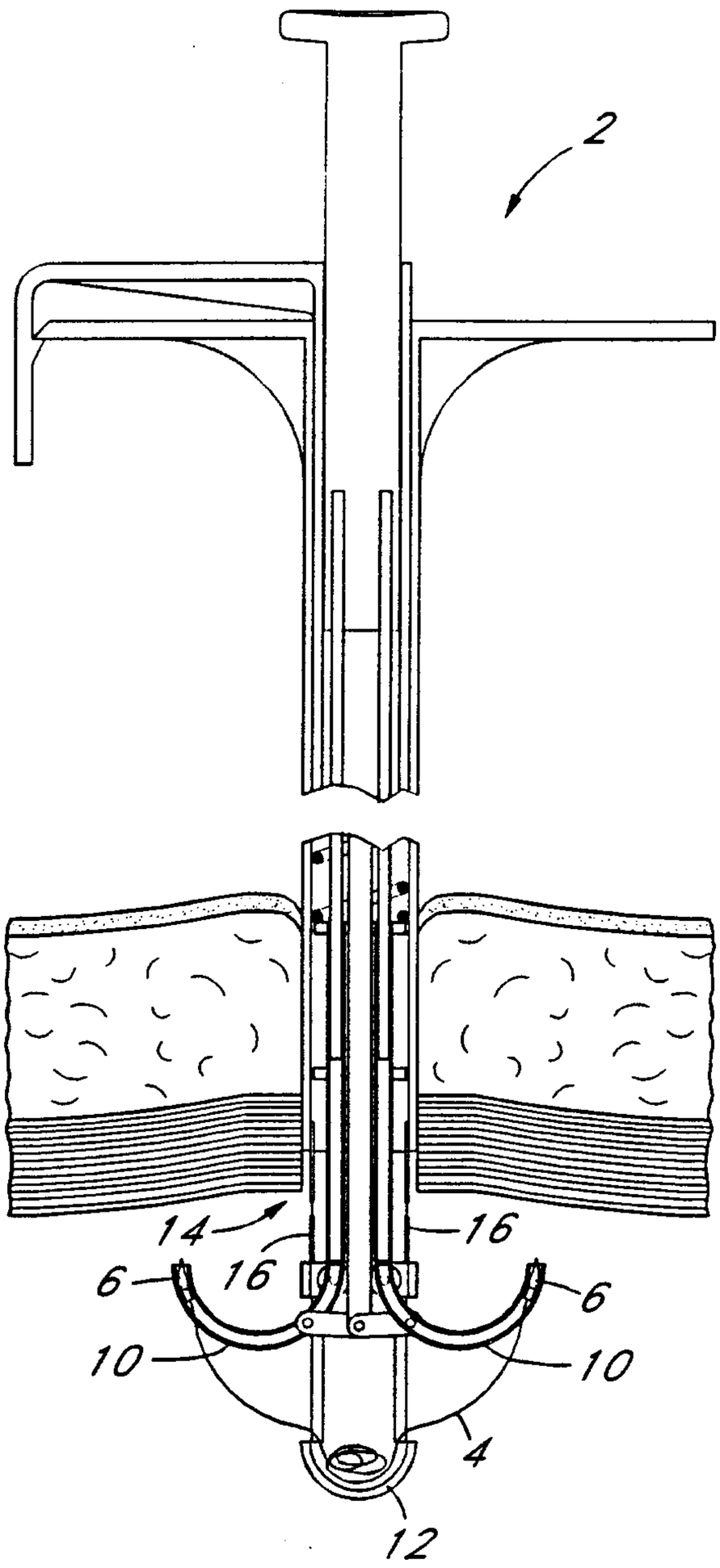

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Fig. 1C

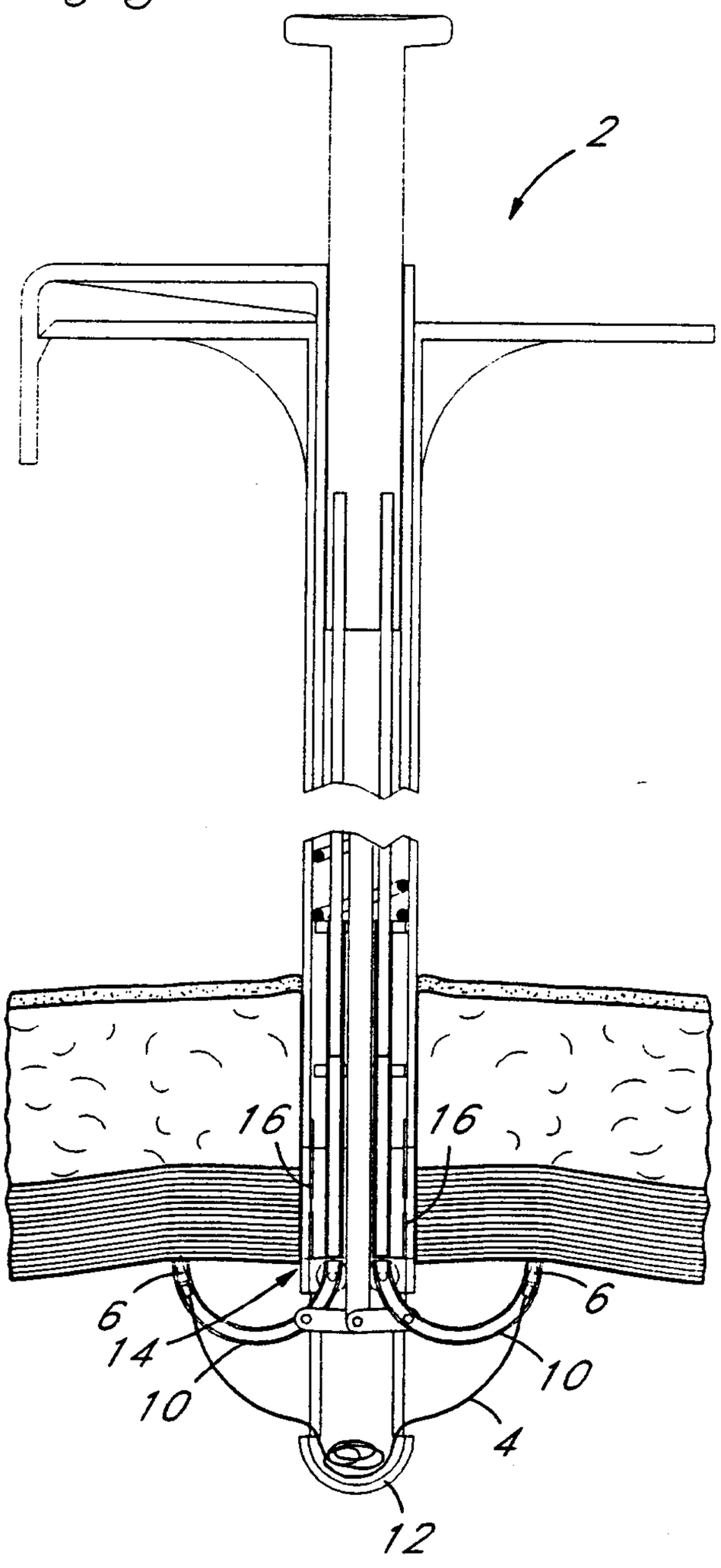

Fig. 1D

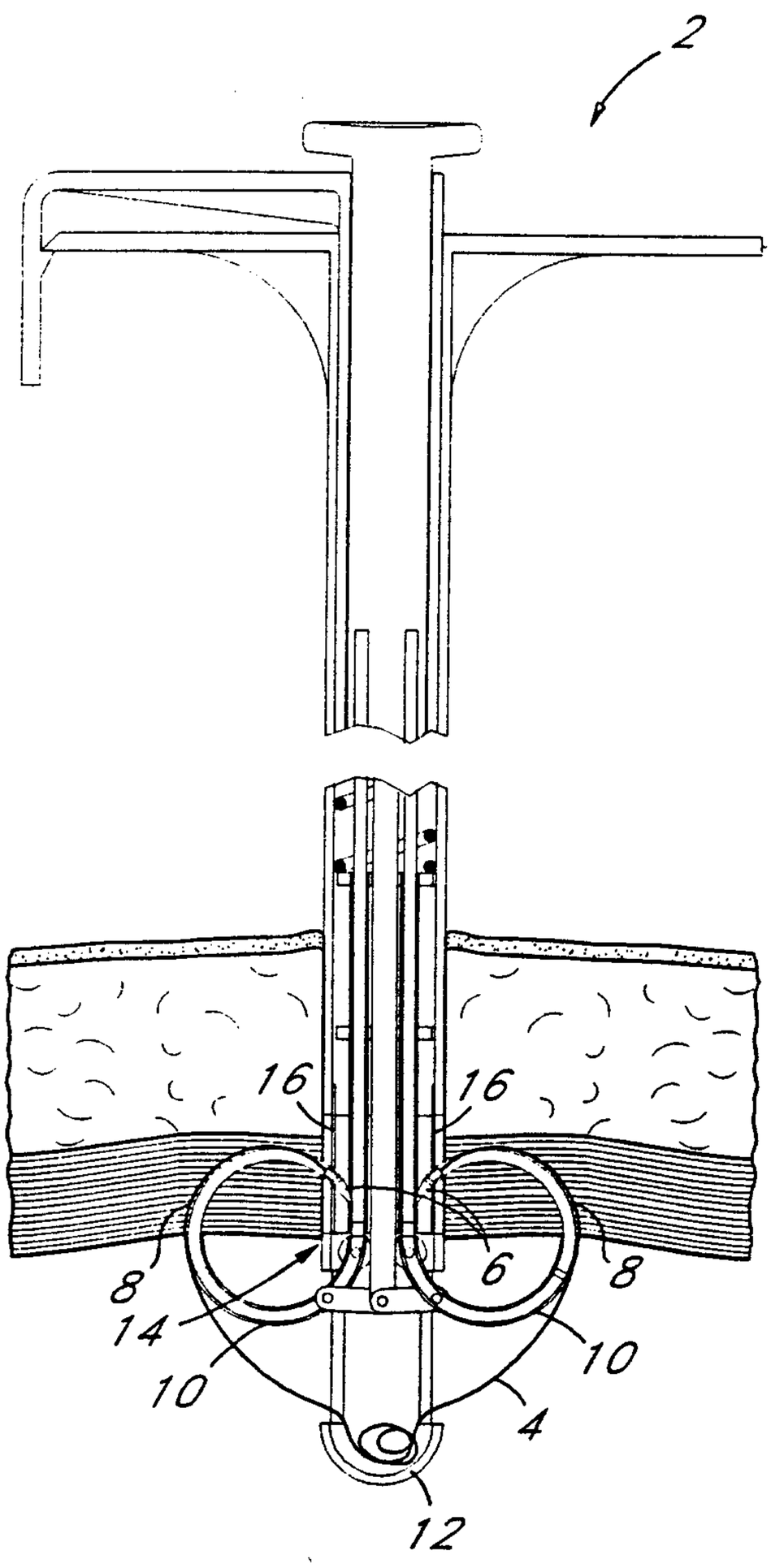

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Fig. 1E

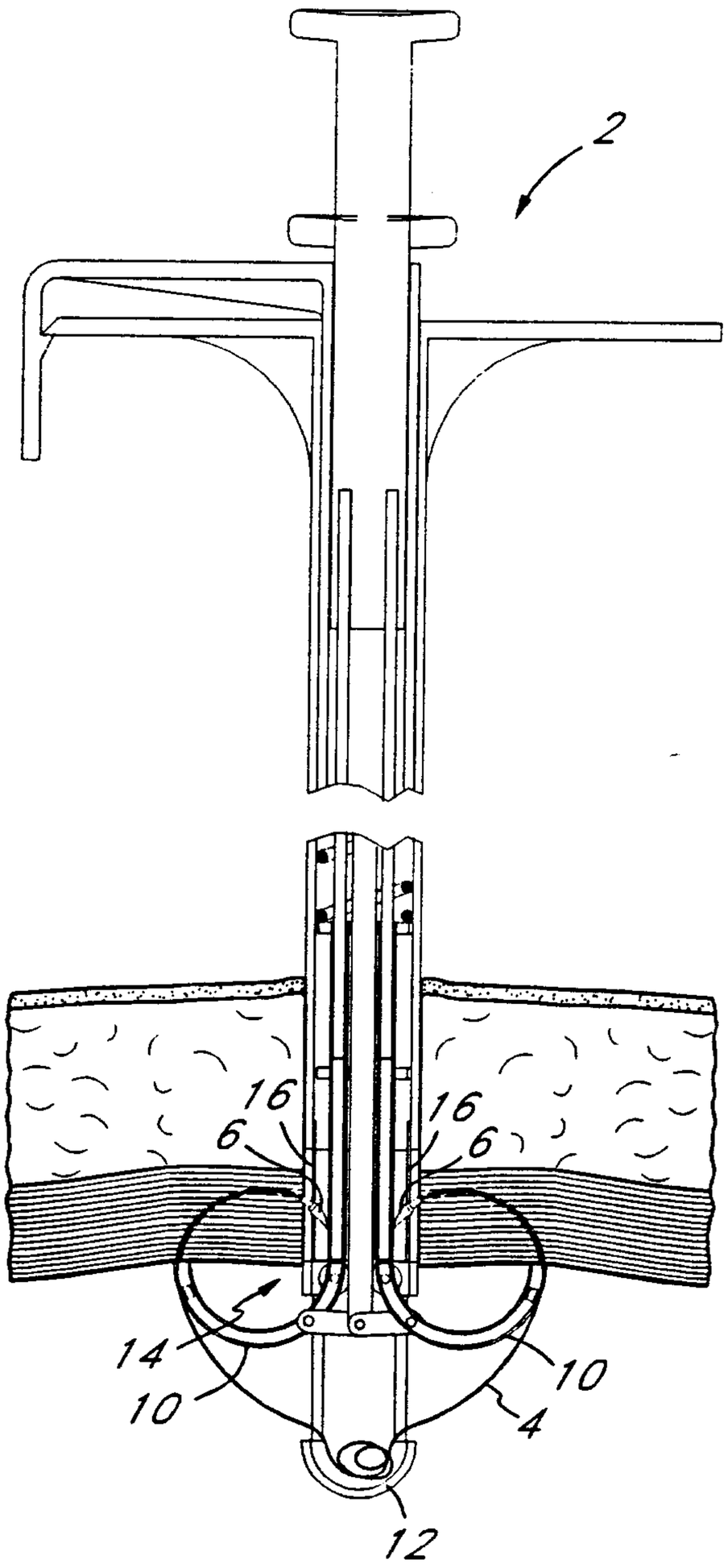

Fig. 1F

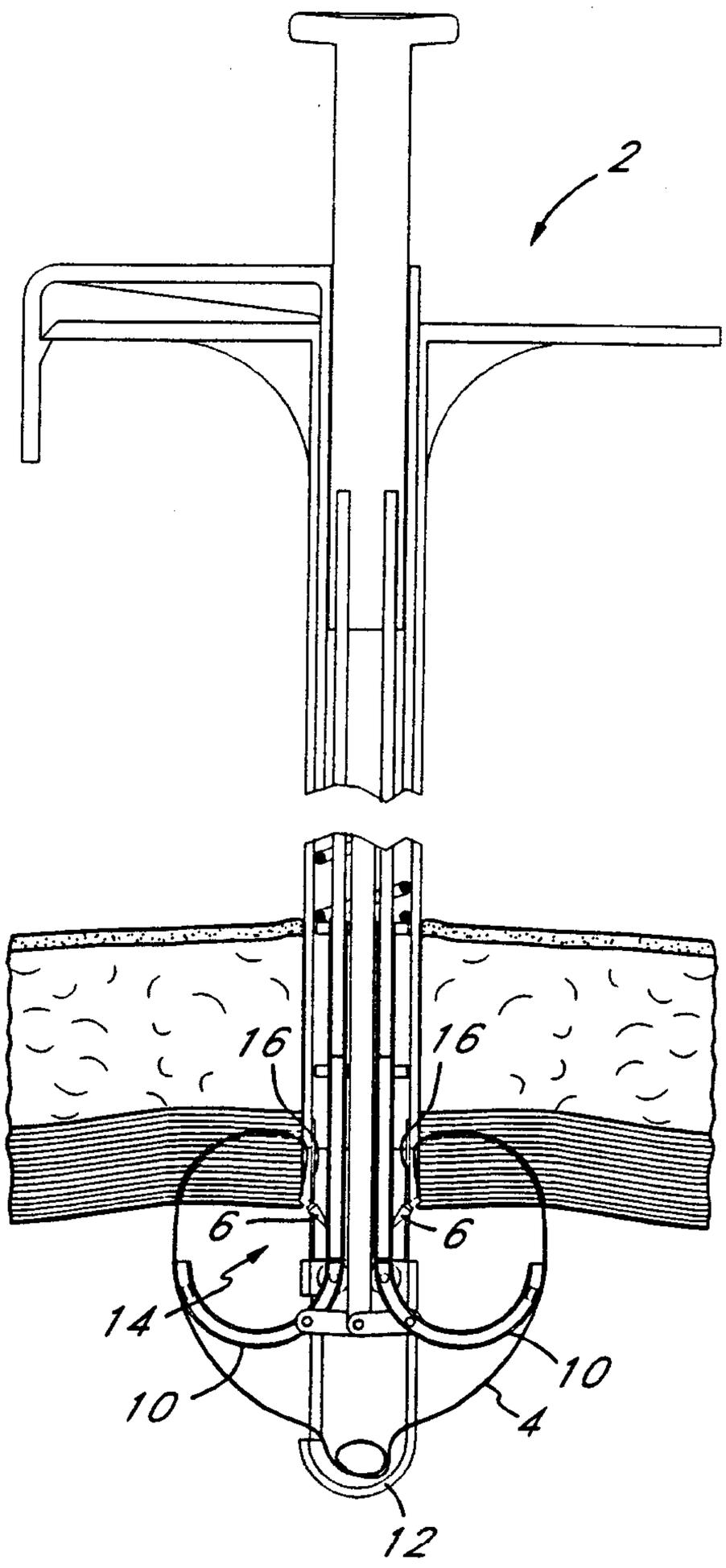

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Fig. 1G

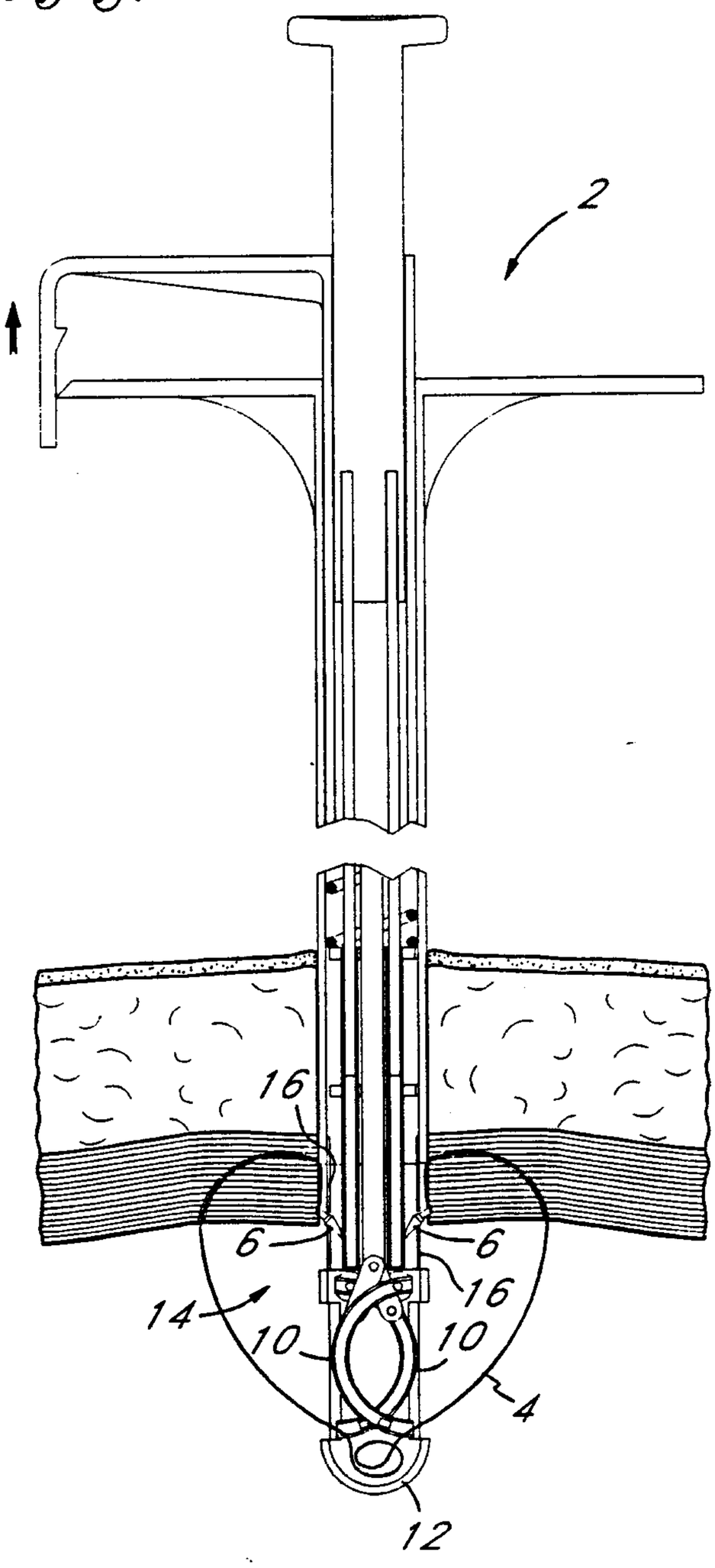

Fig. 1H

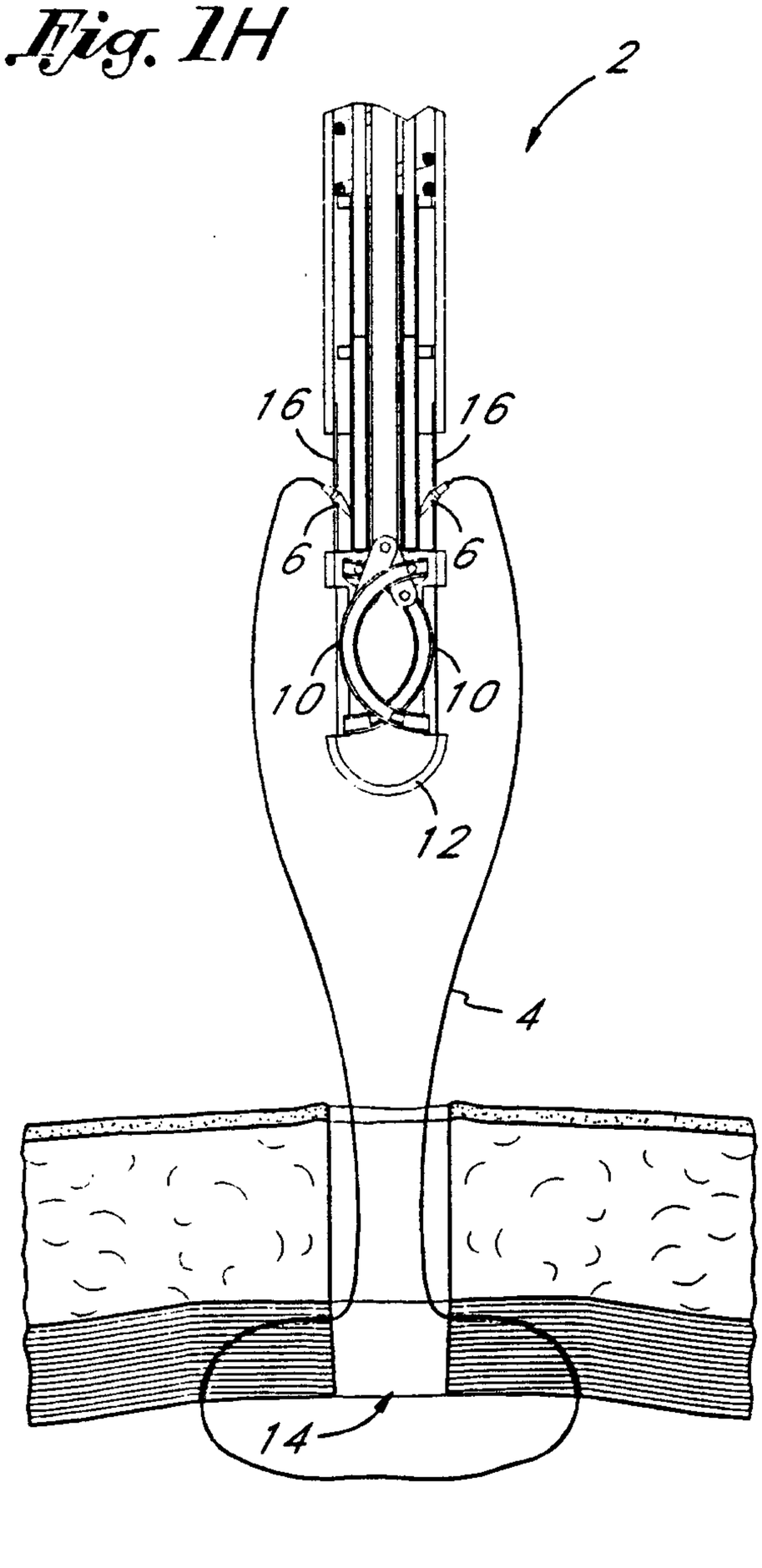

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Fig. 2

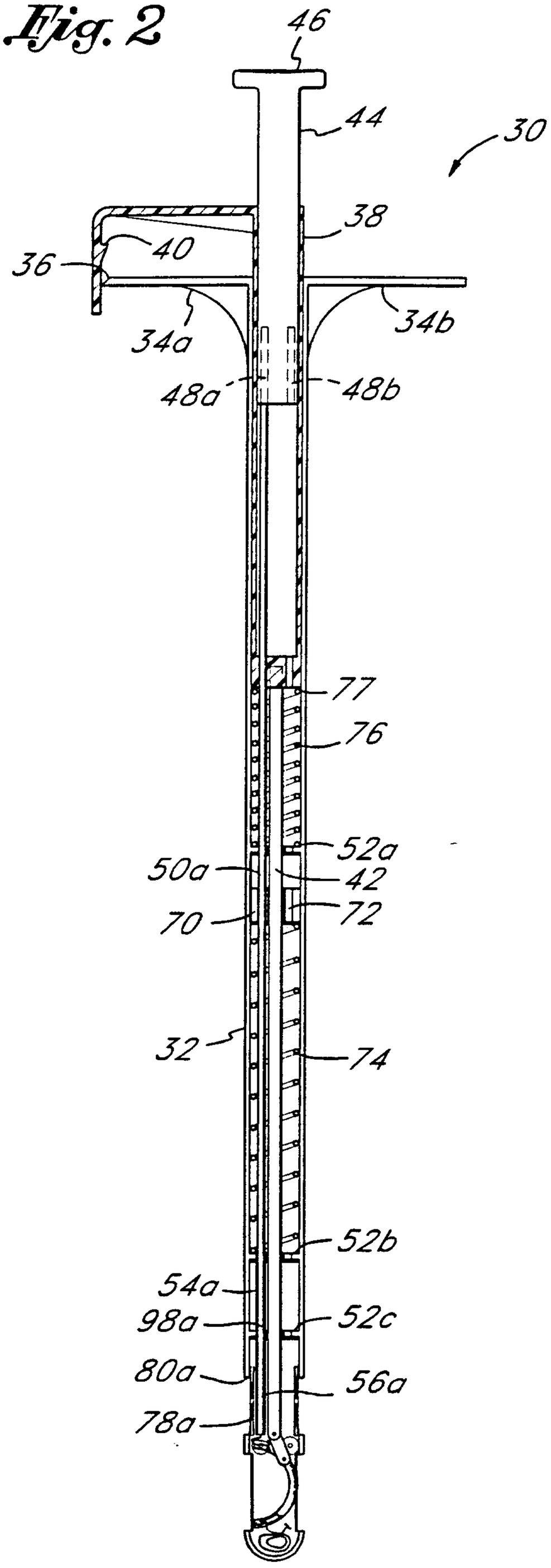

Fig. 3

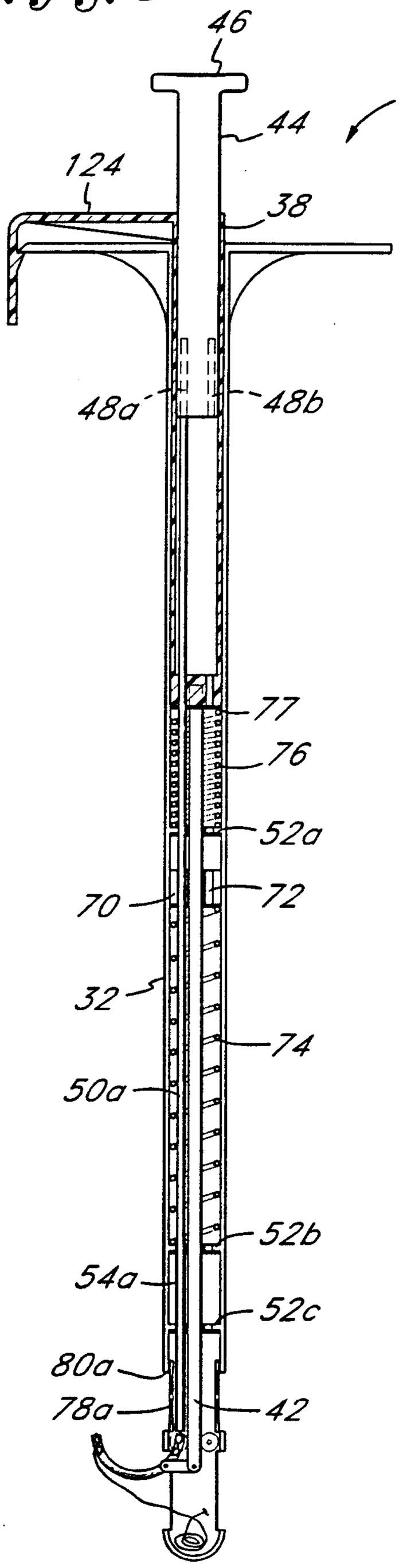

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Fig. 4A

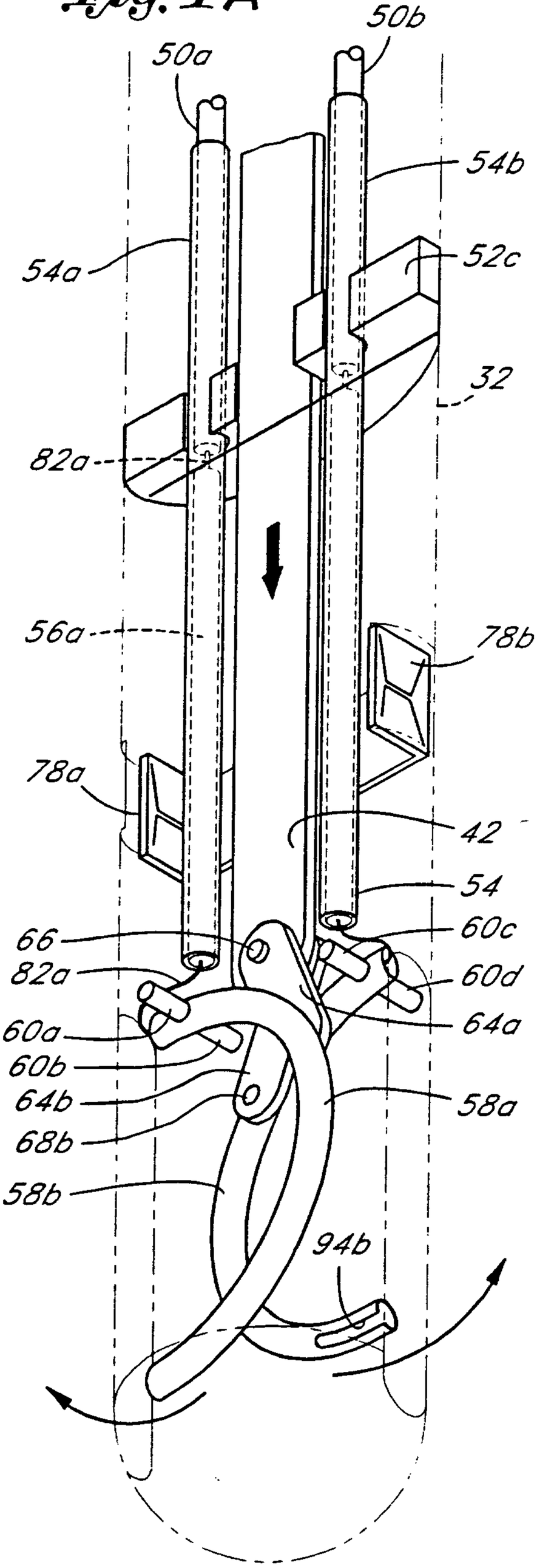

Fig. 4B

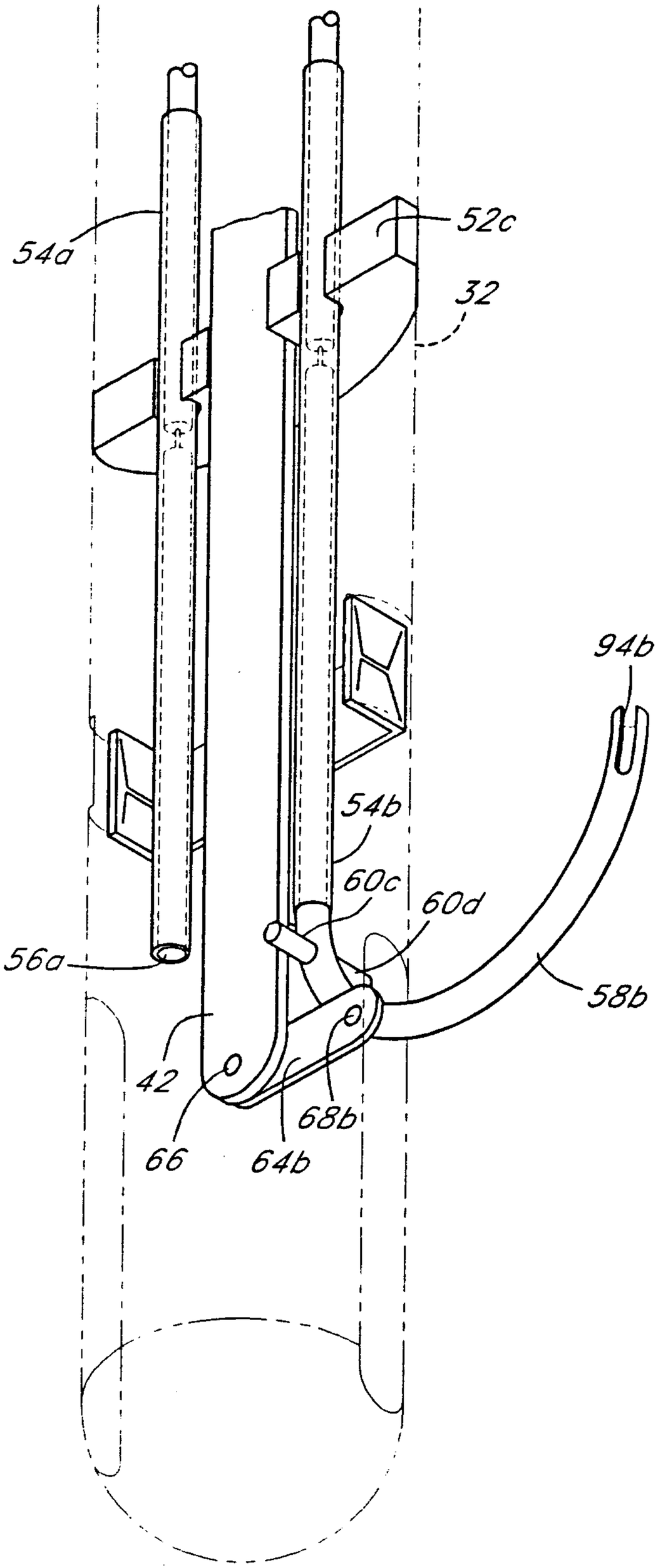

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Fig. 5

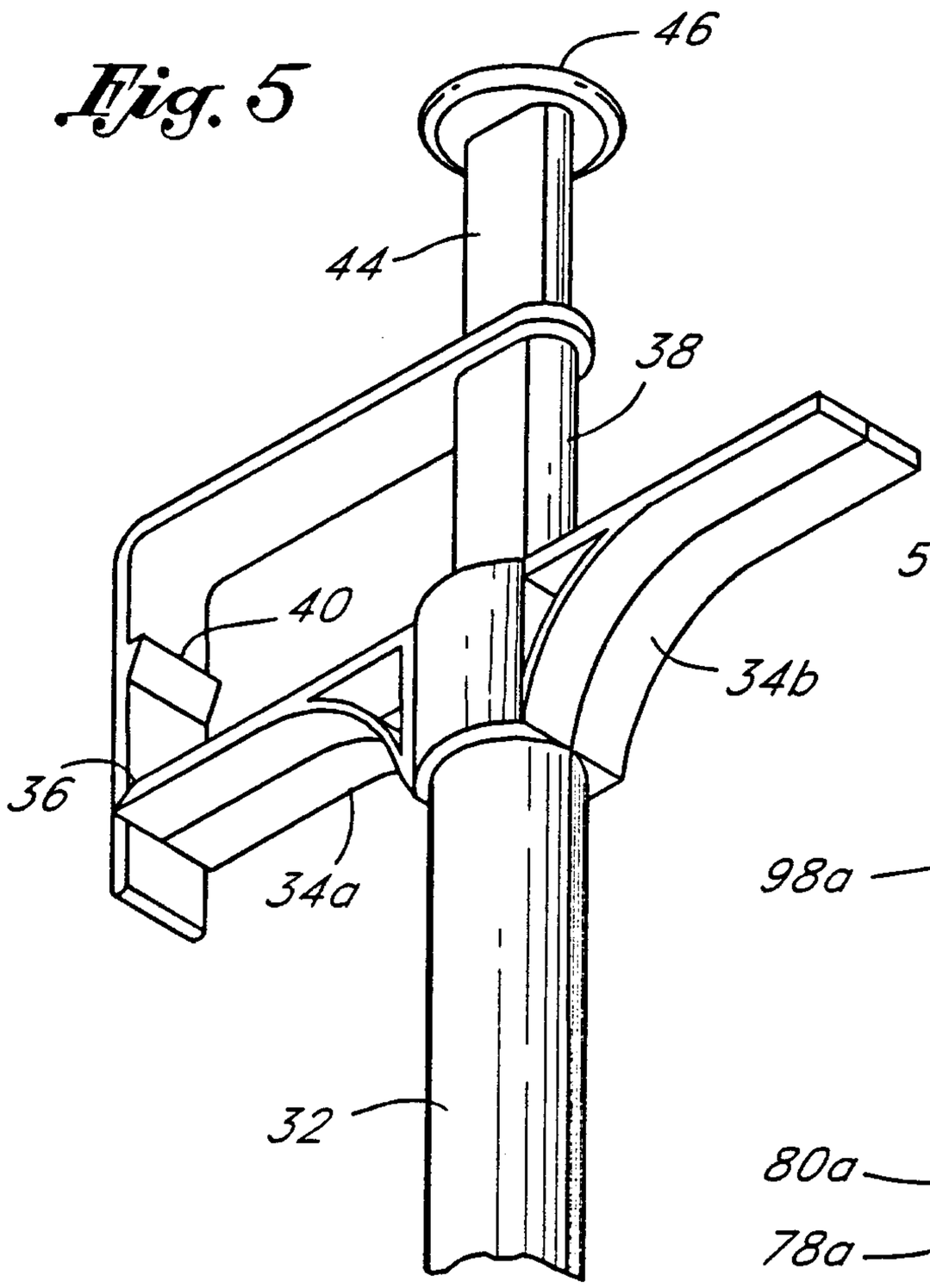
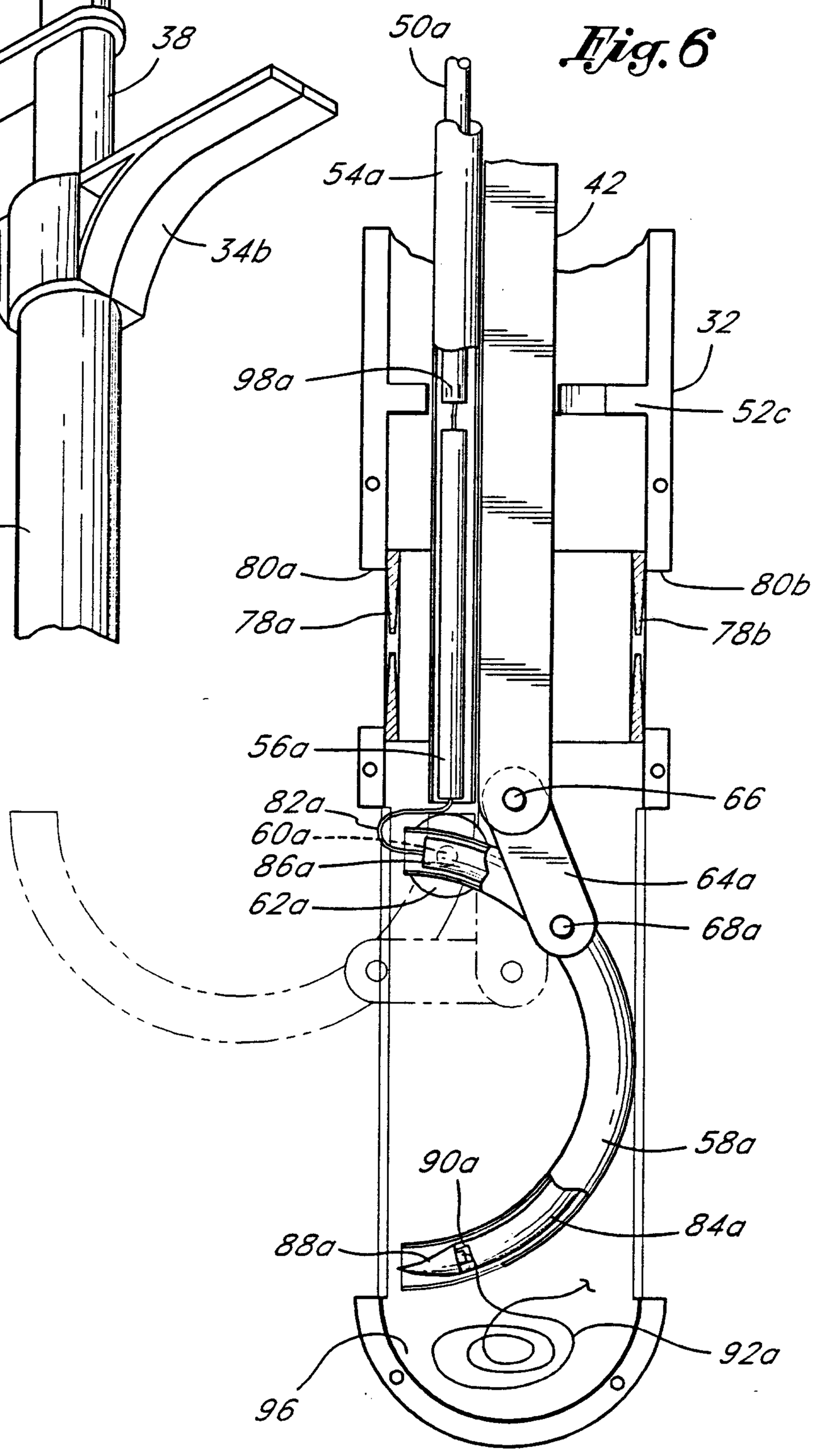


Fig. 6



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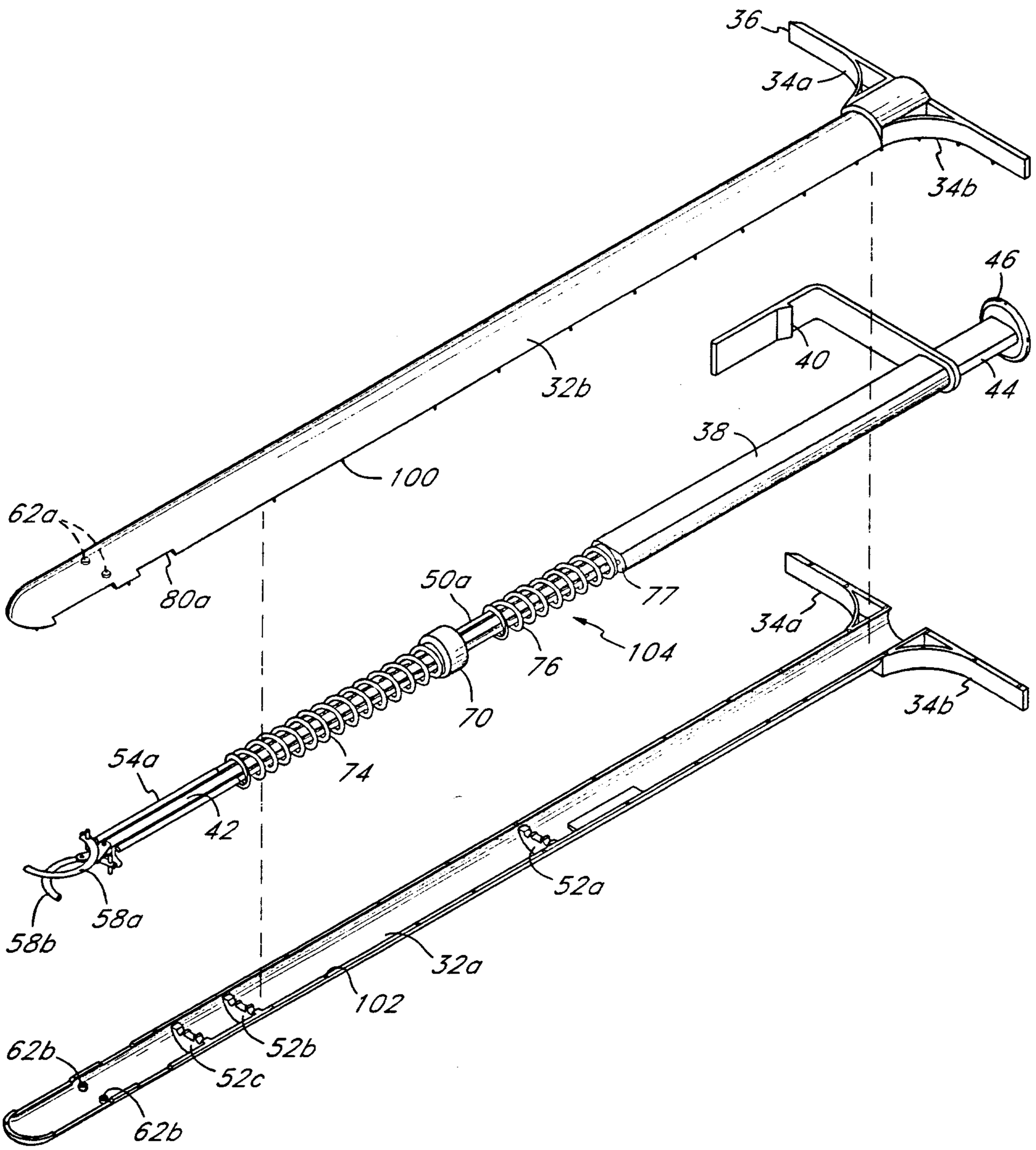

Fig. 7

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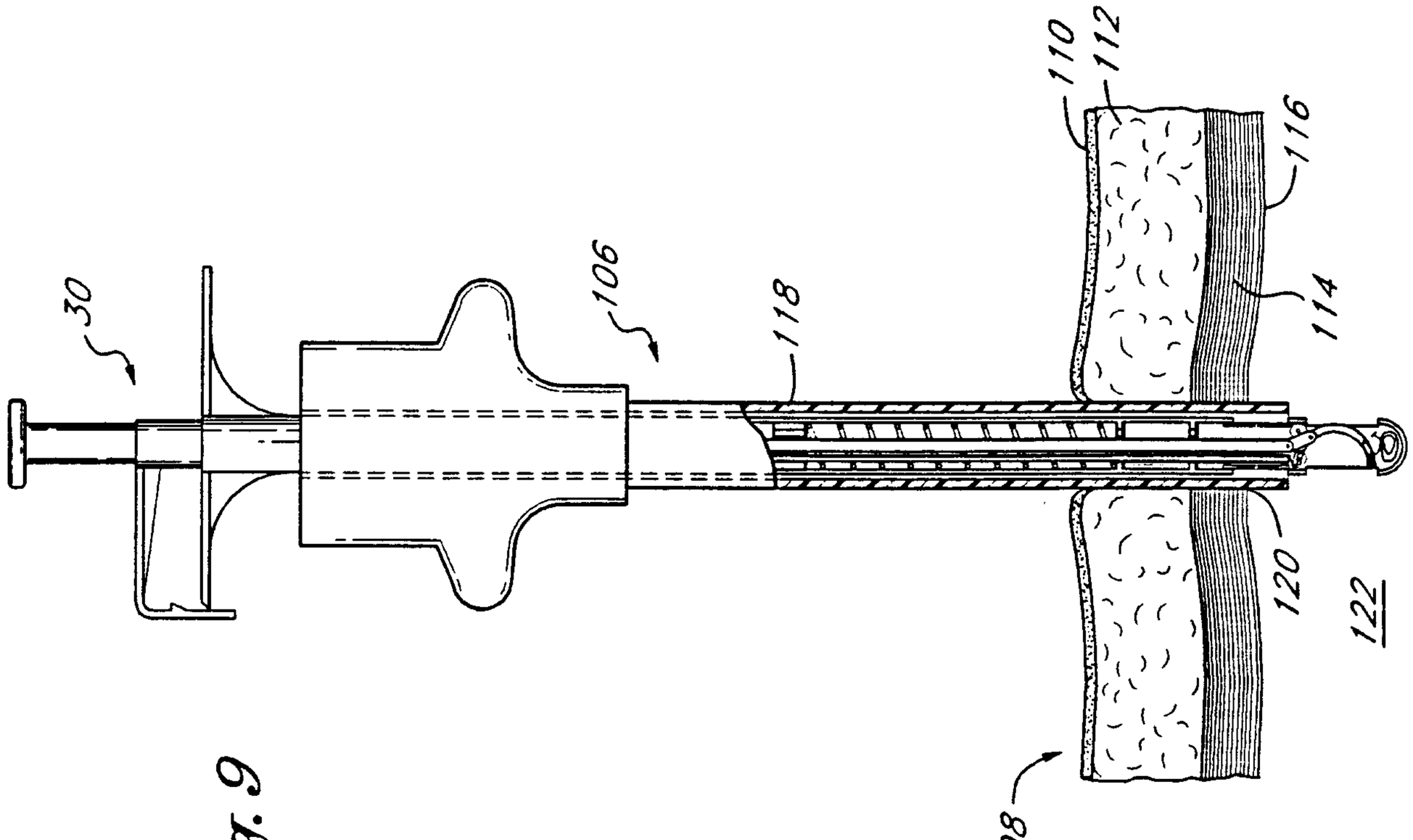
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Fig. 9

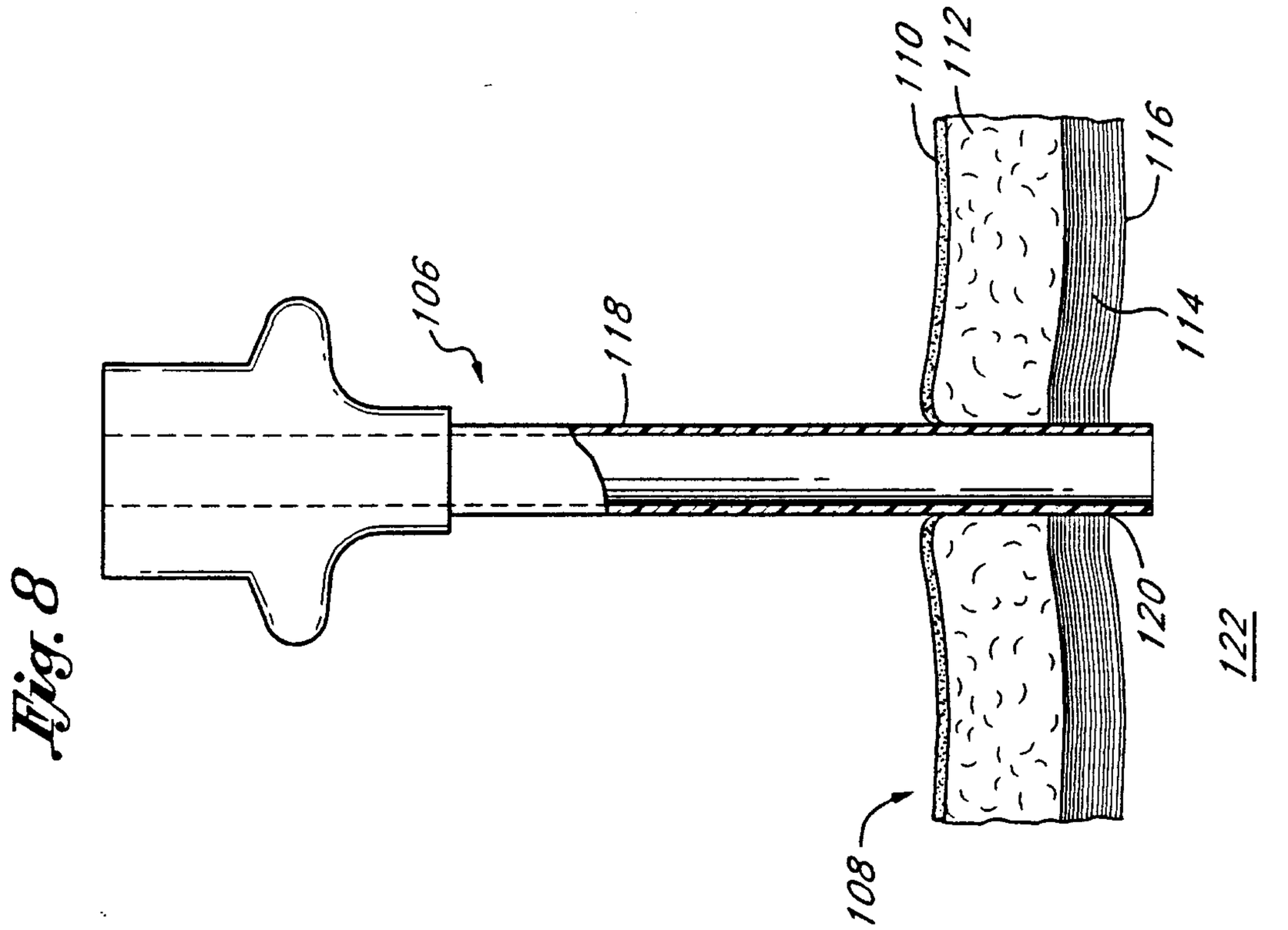
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Fig. 8

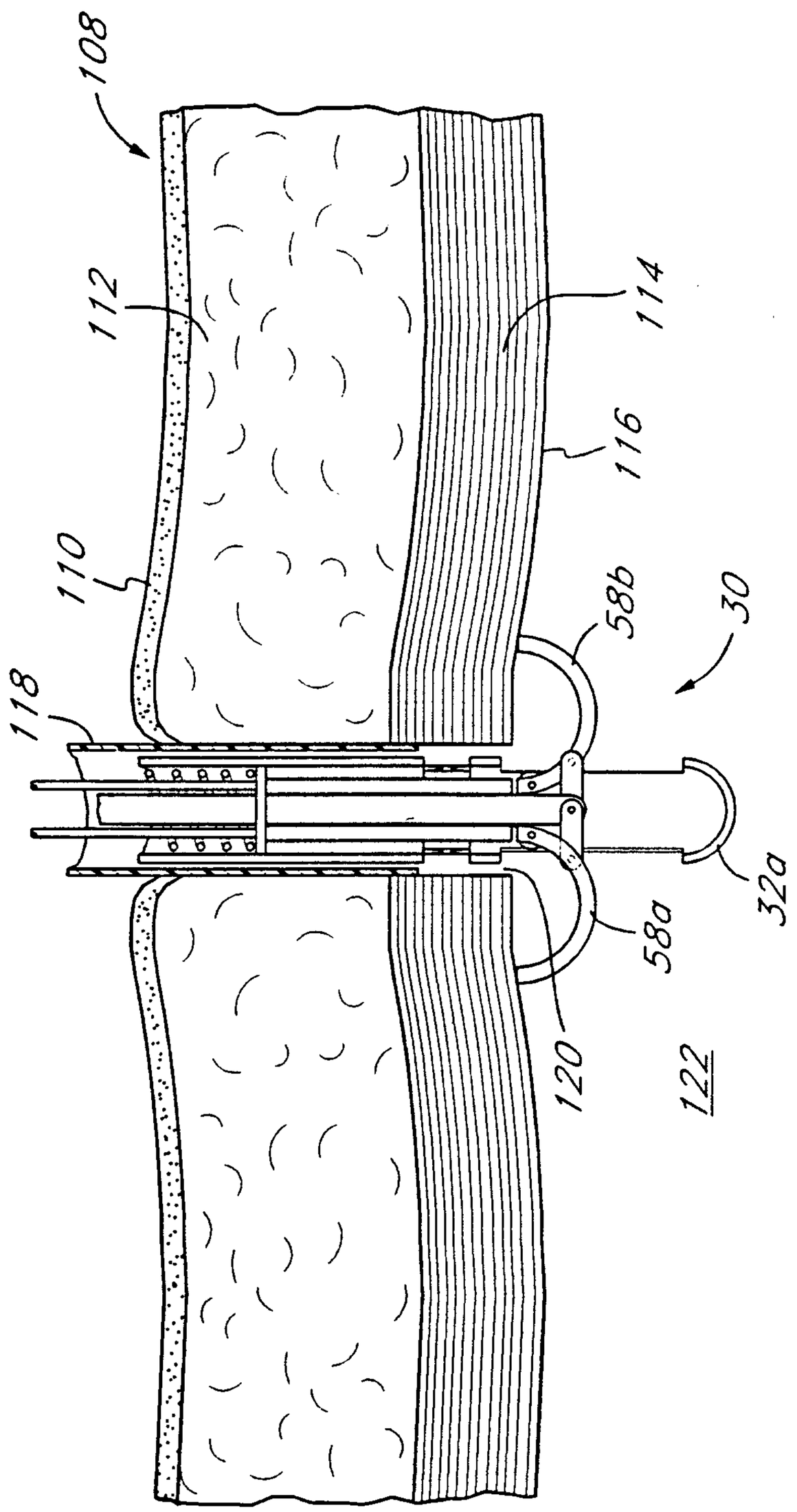

Fig. 10

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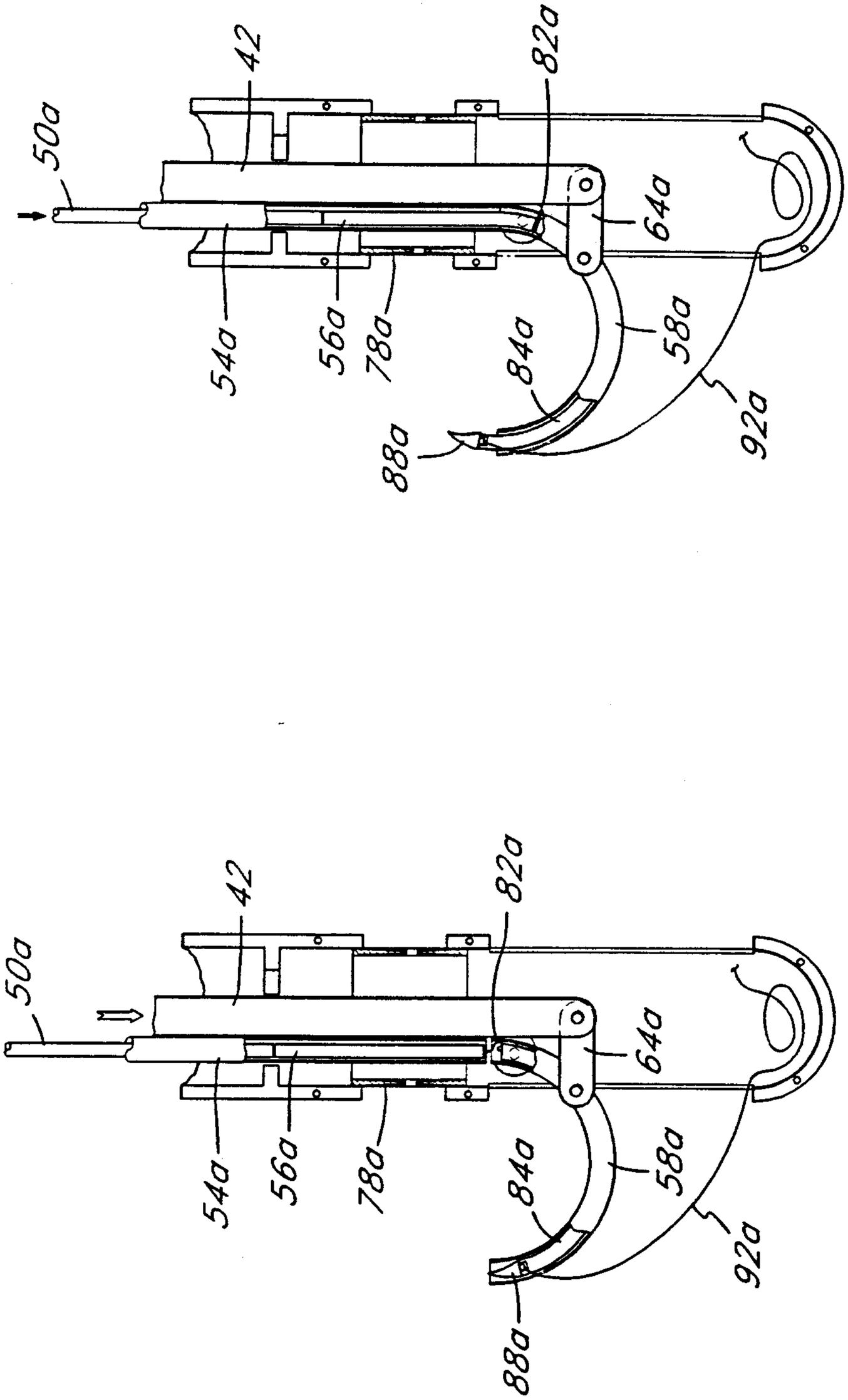

Fig. 12

Fig. 11

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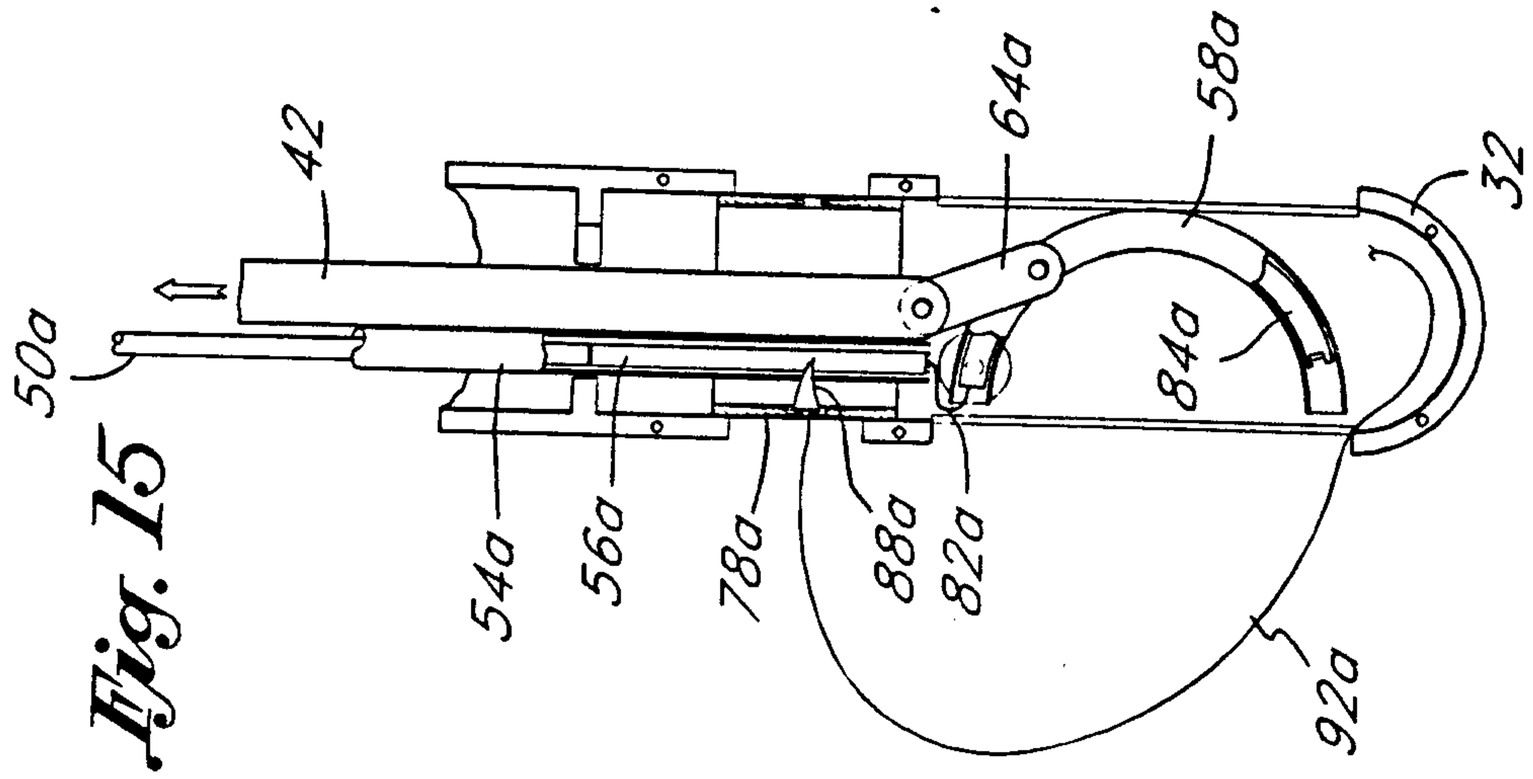


Fig. 15

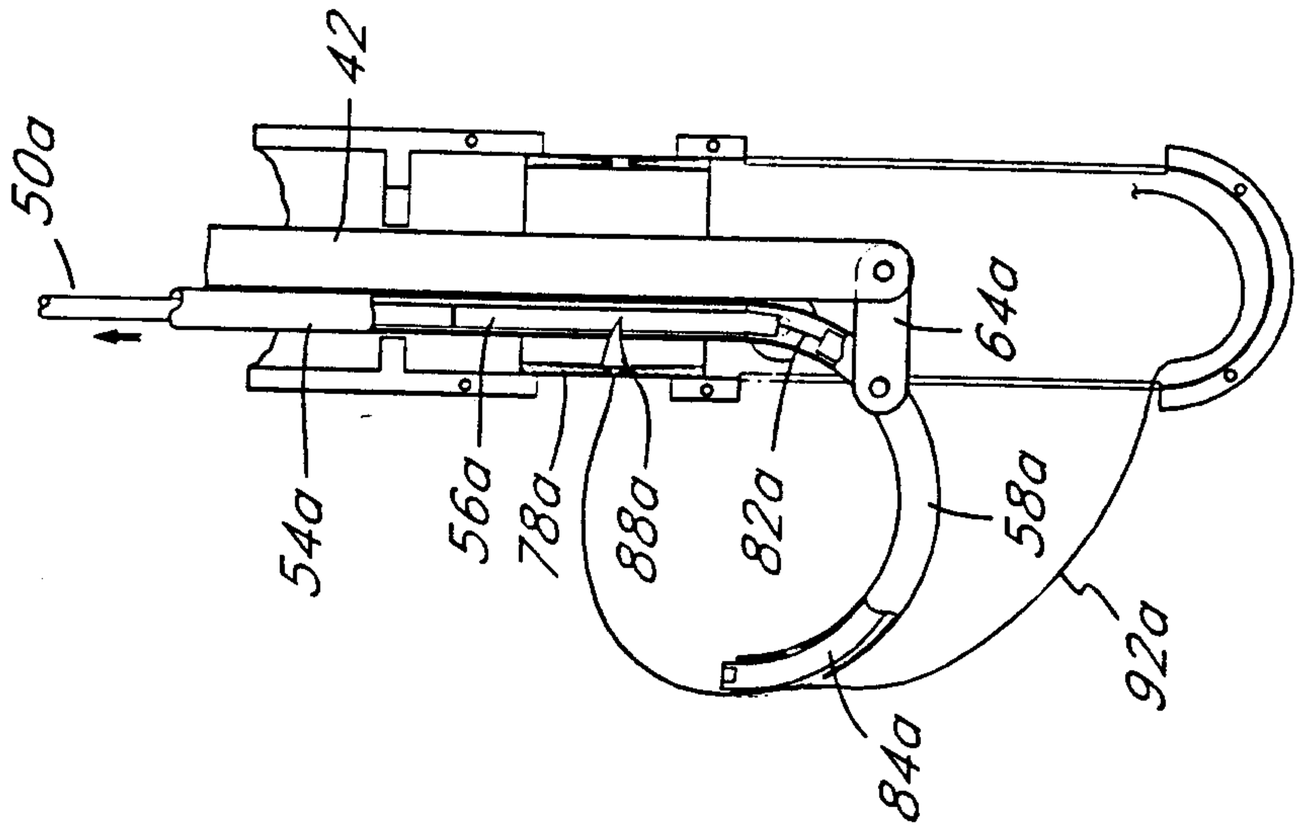


Fig. 14

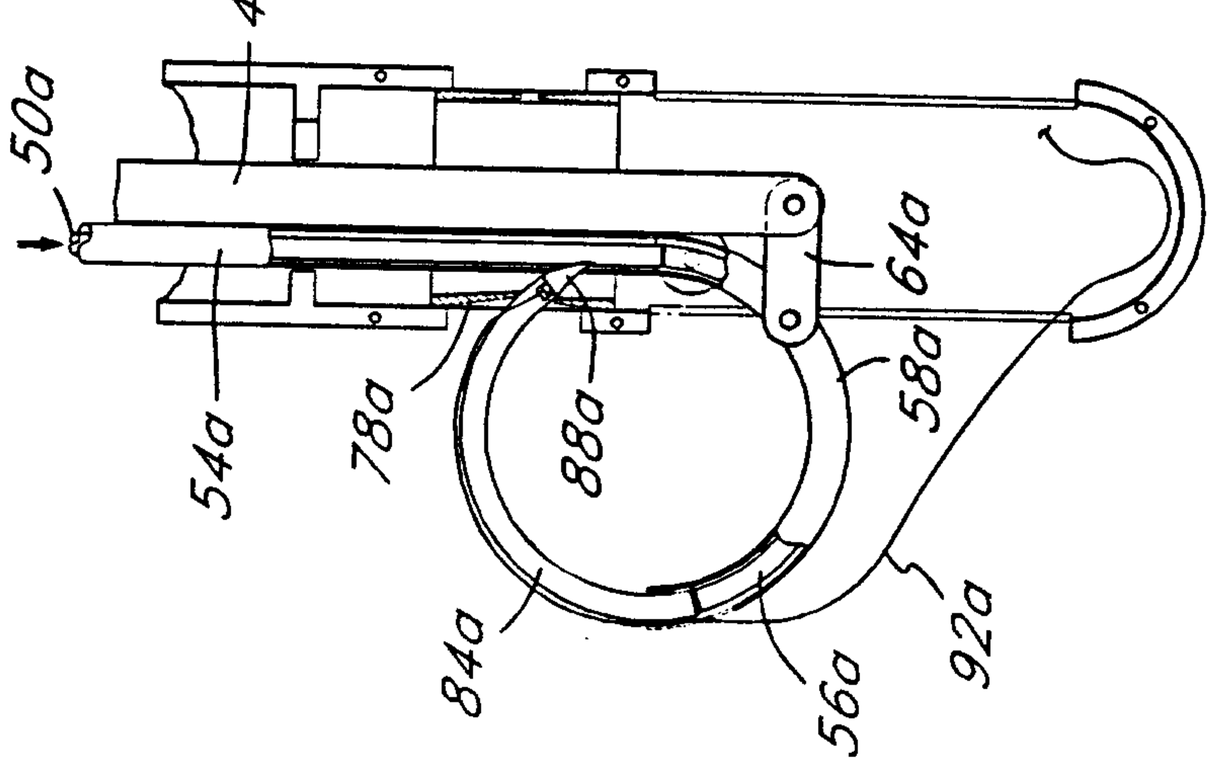
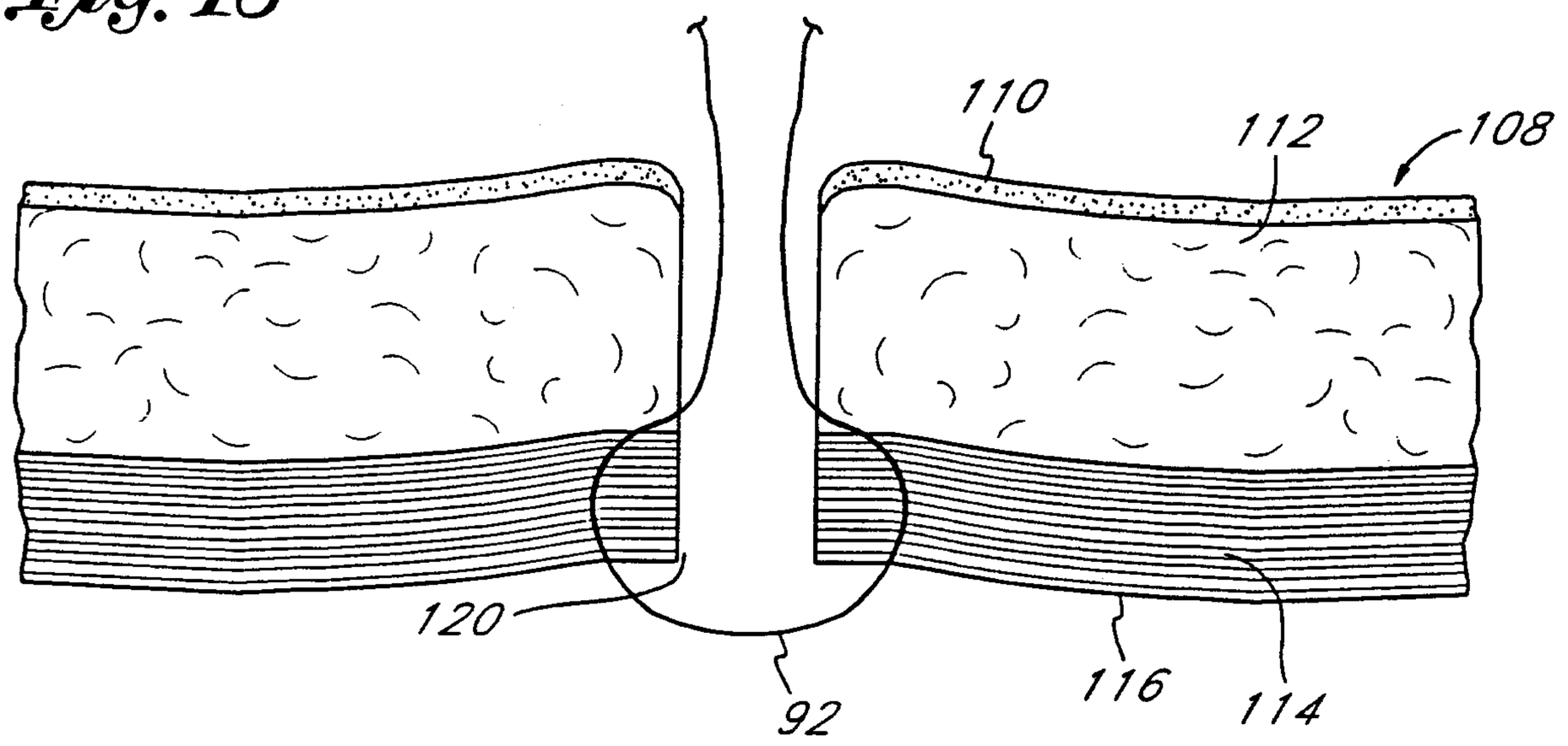


Fig. 13

Fig. 16



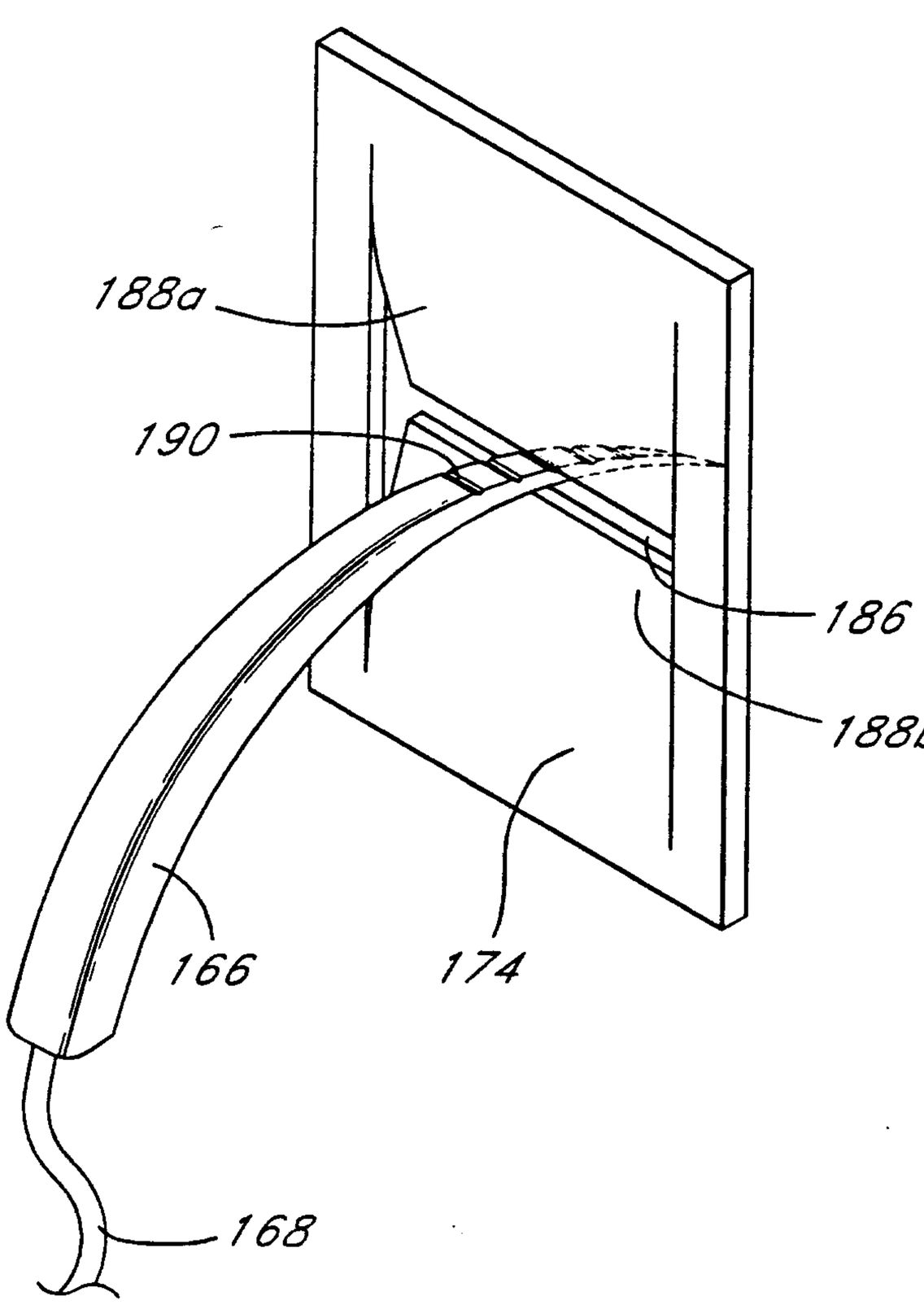


Fig. 19

Fig. 17

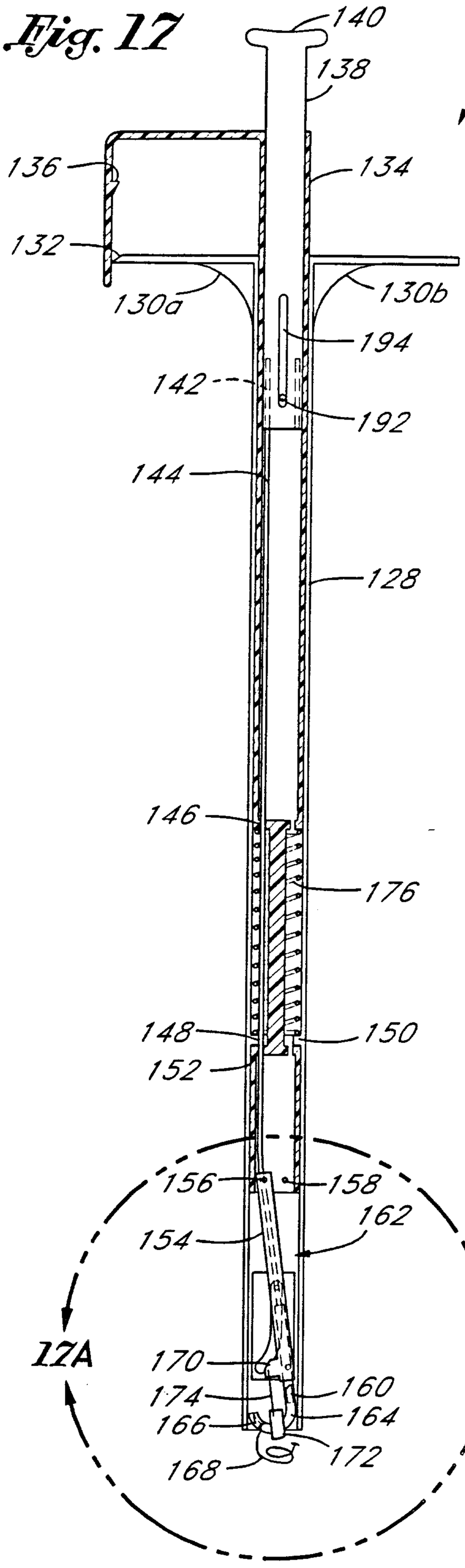


Fig. 17A

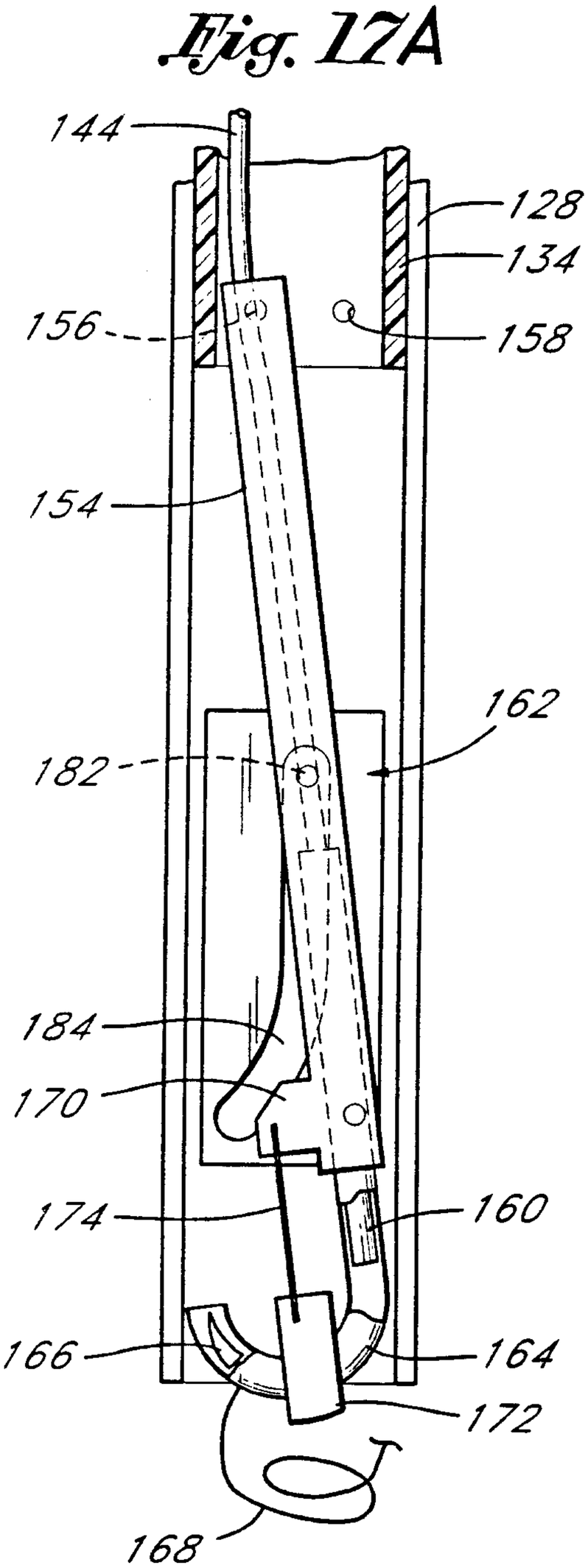


Fig. 18

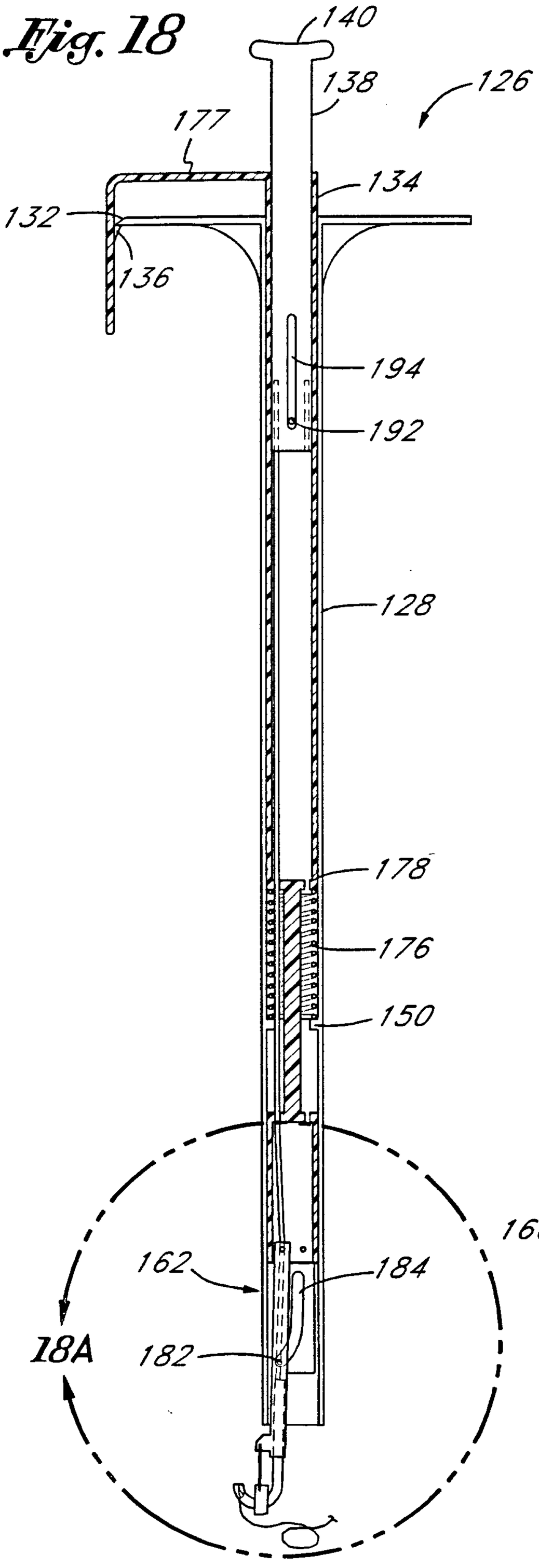
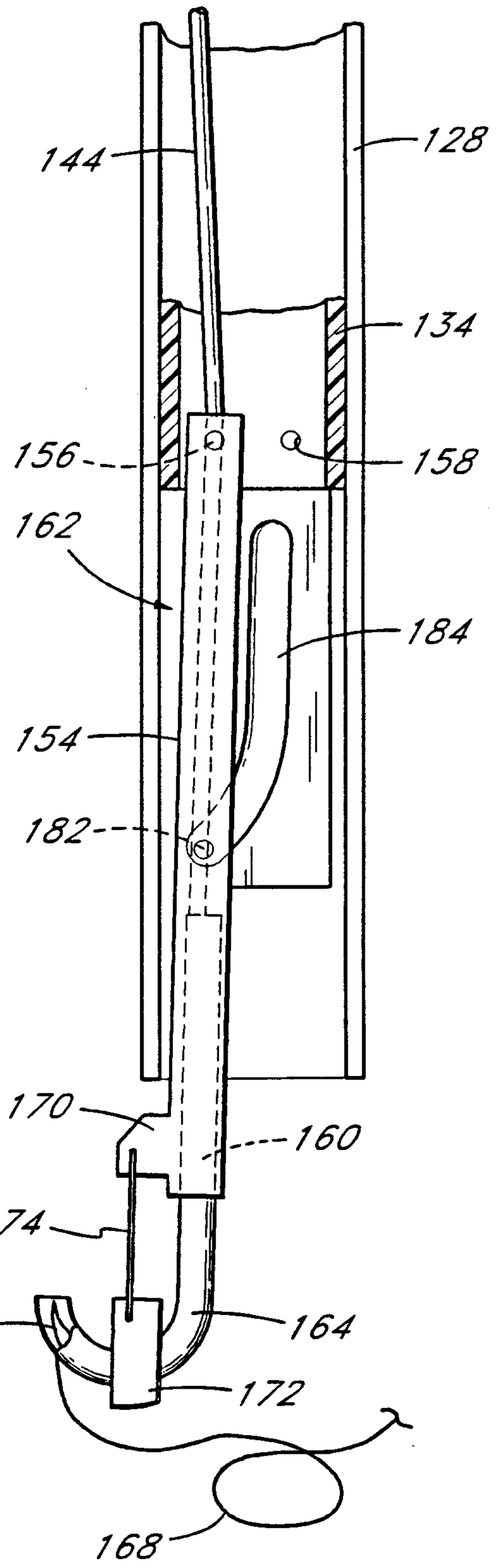


Fig. 18A



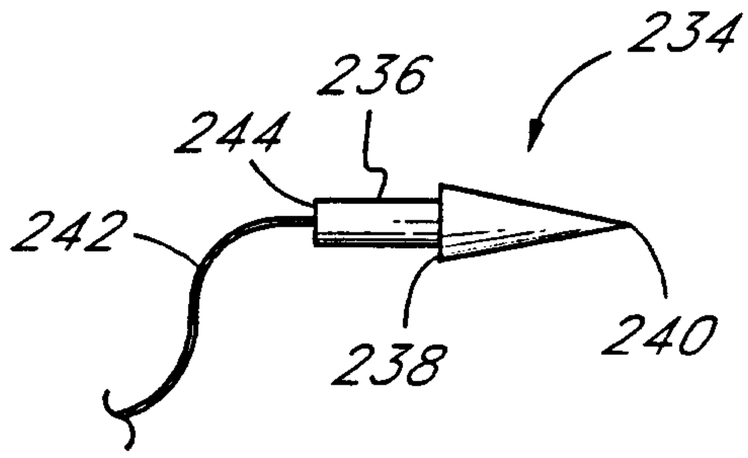


Fig. 19A

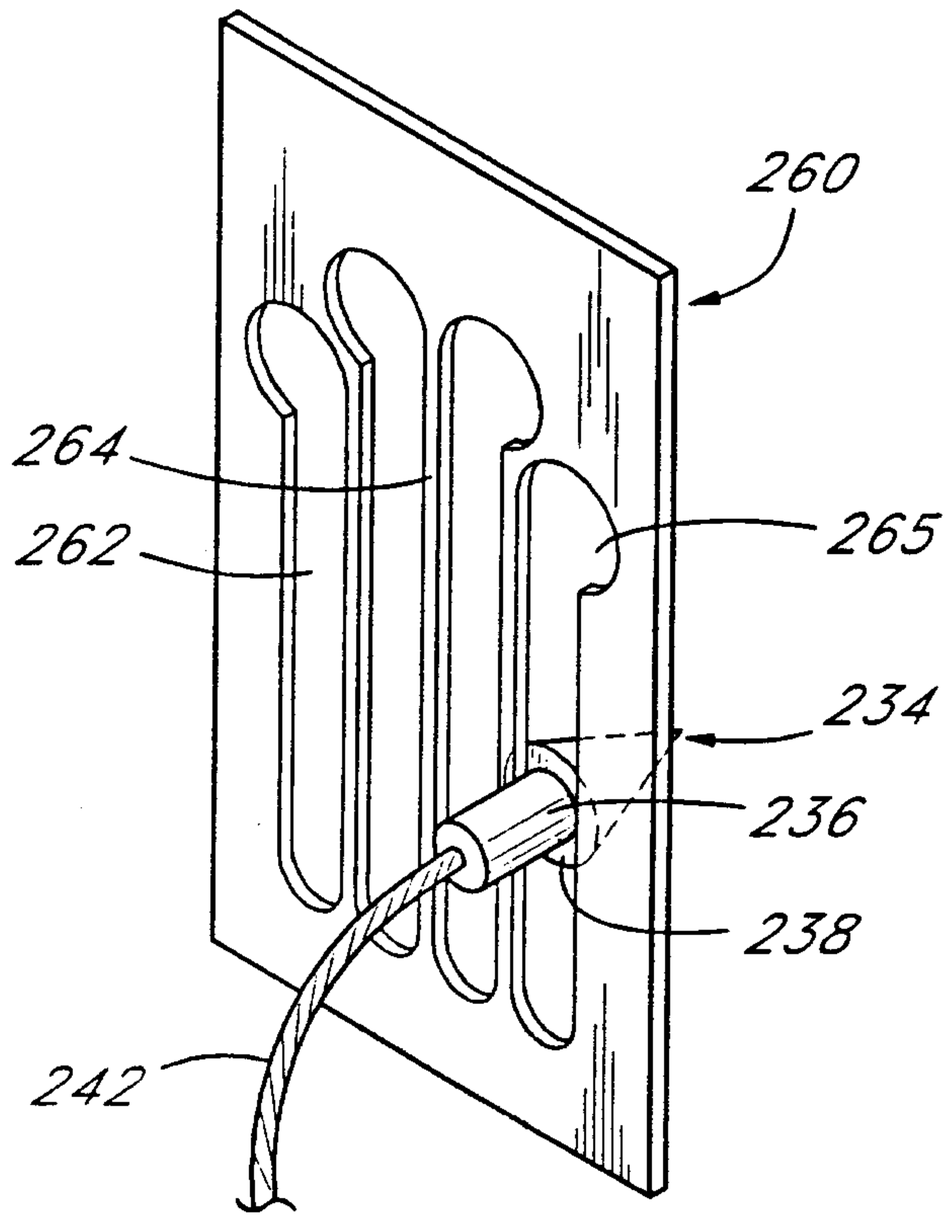


Fig. 19C

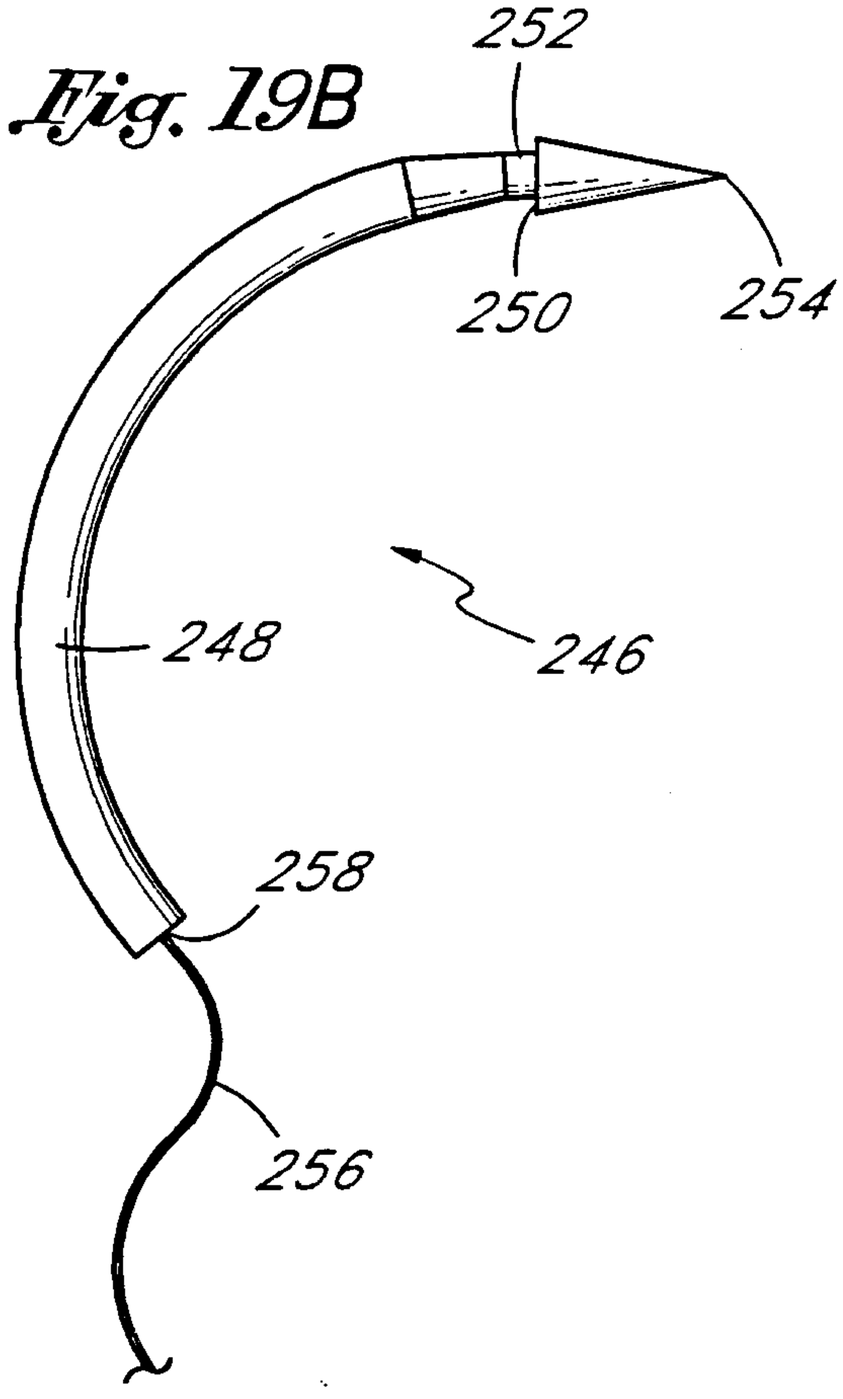


Fig. 19B

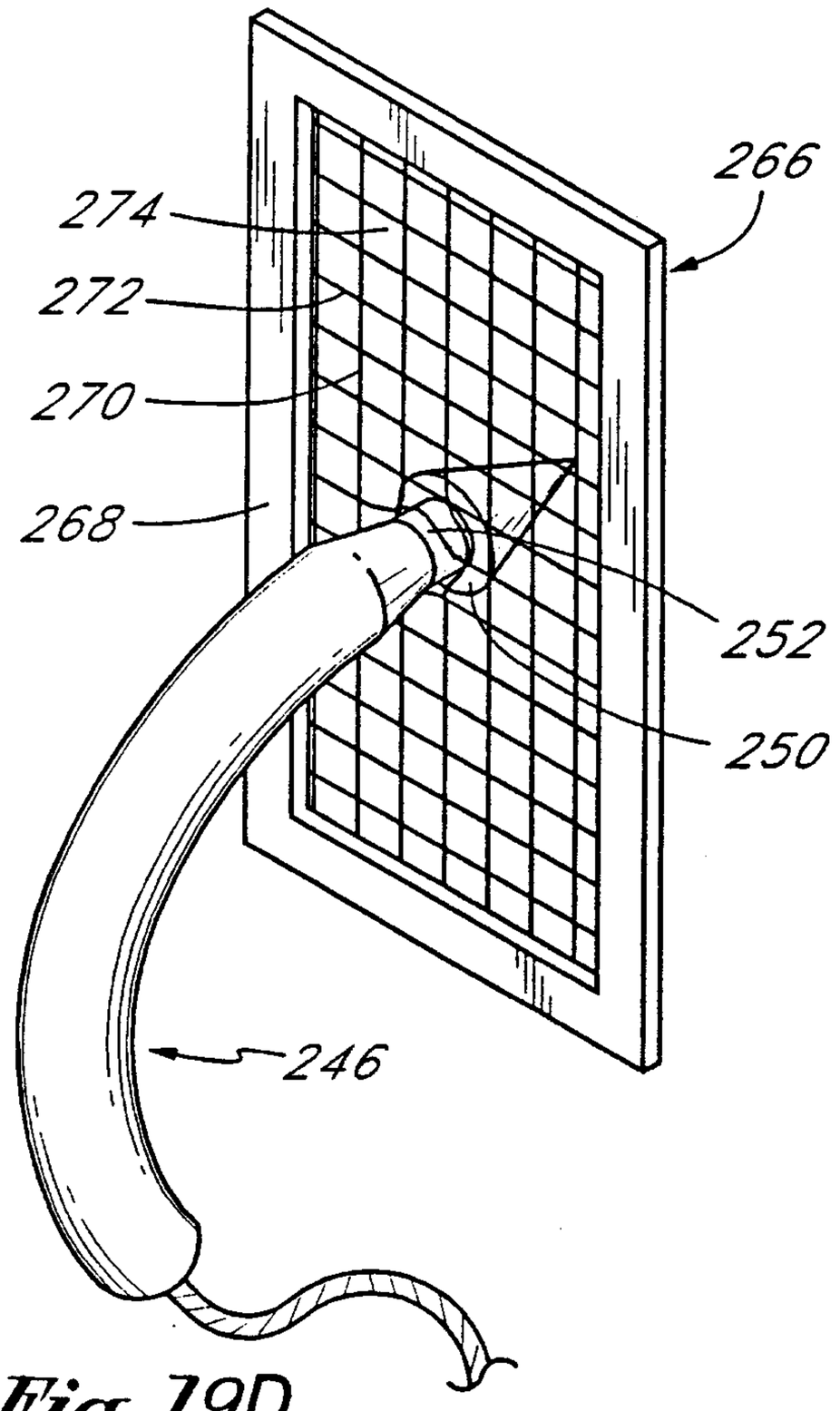


Fig. 19D

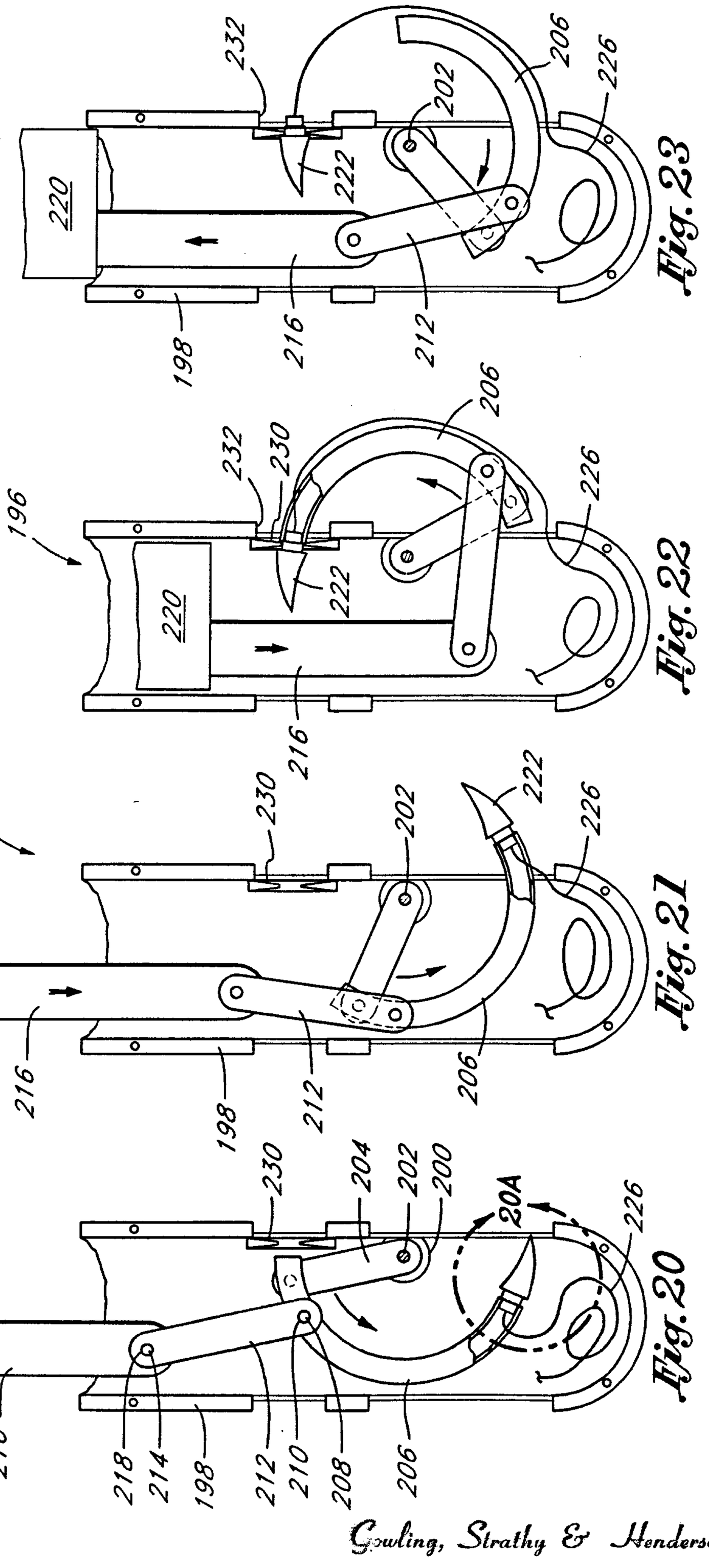


Fig. 20A

Fig. 23

Fig. 22

Fig. 21

Fig. 20

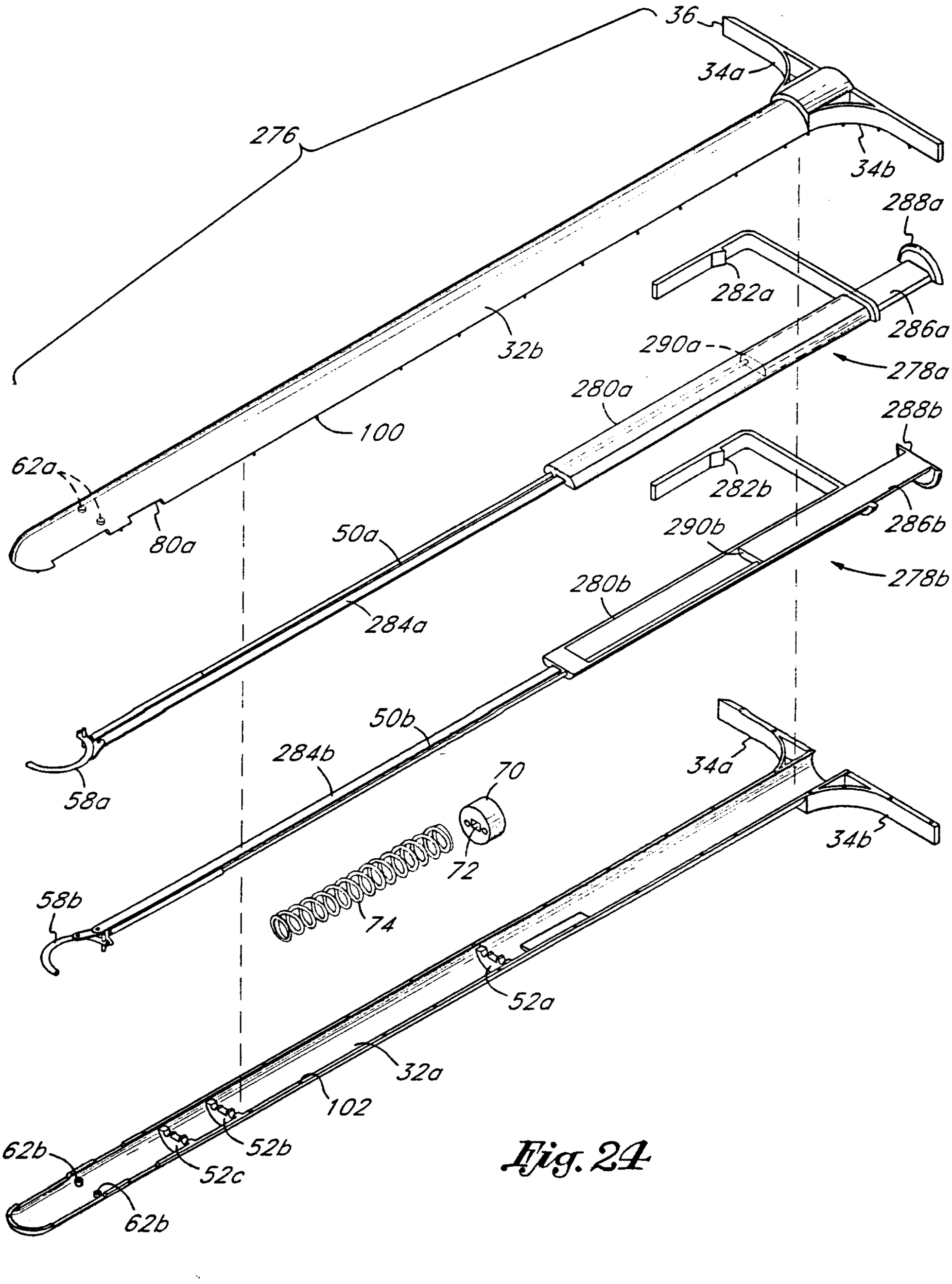


Fig. 24

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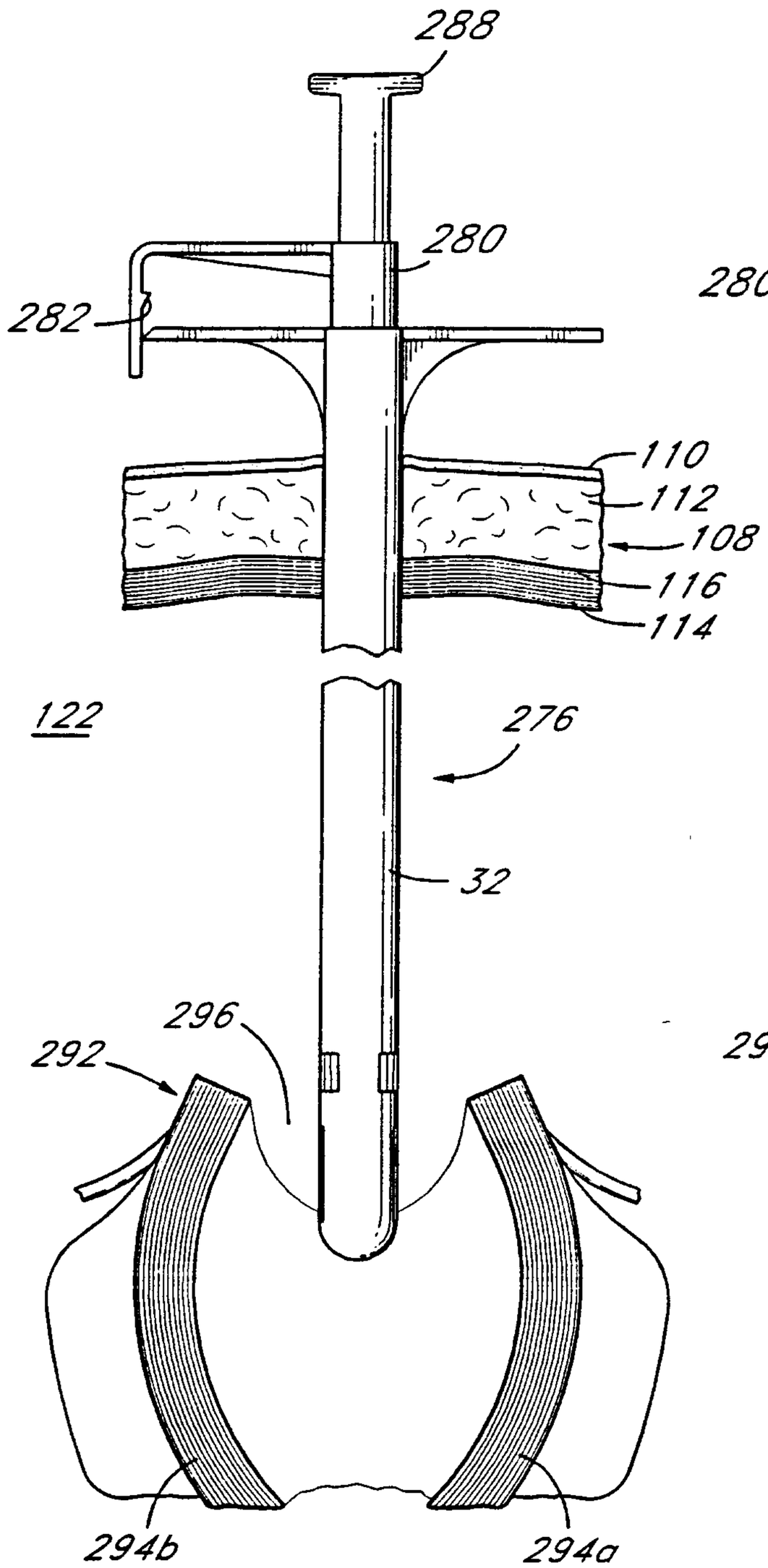

Fig. 24A

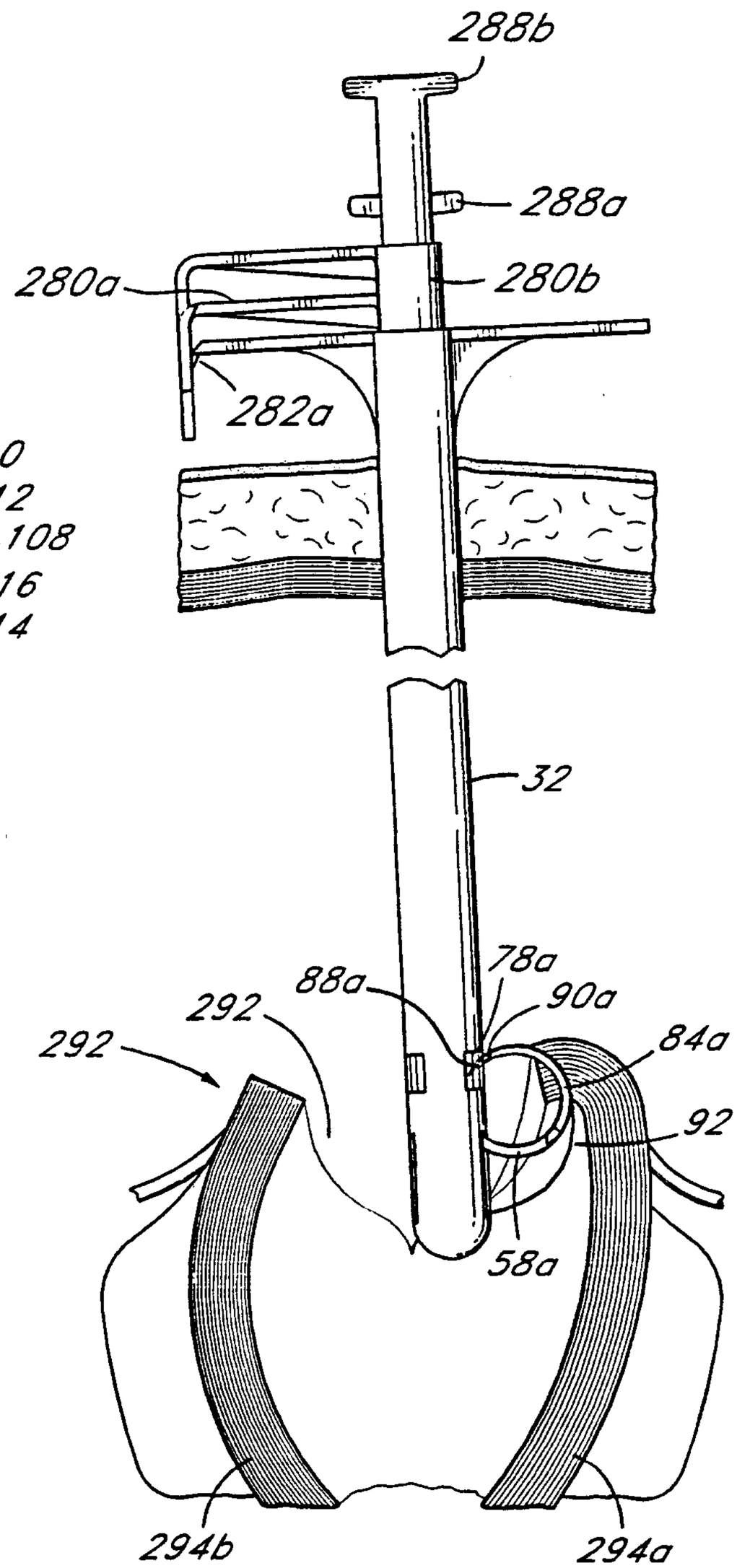

Fig. 24B

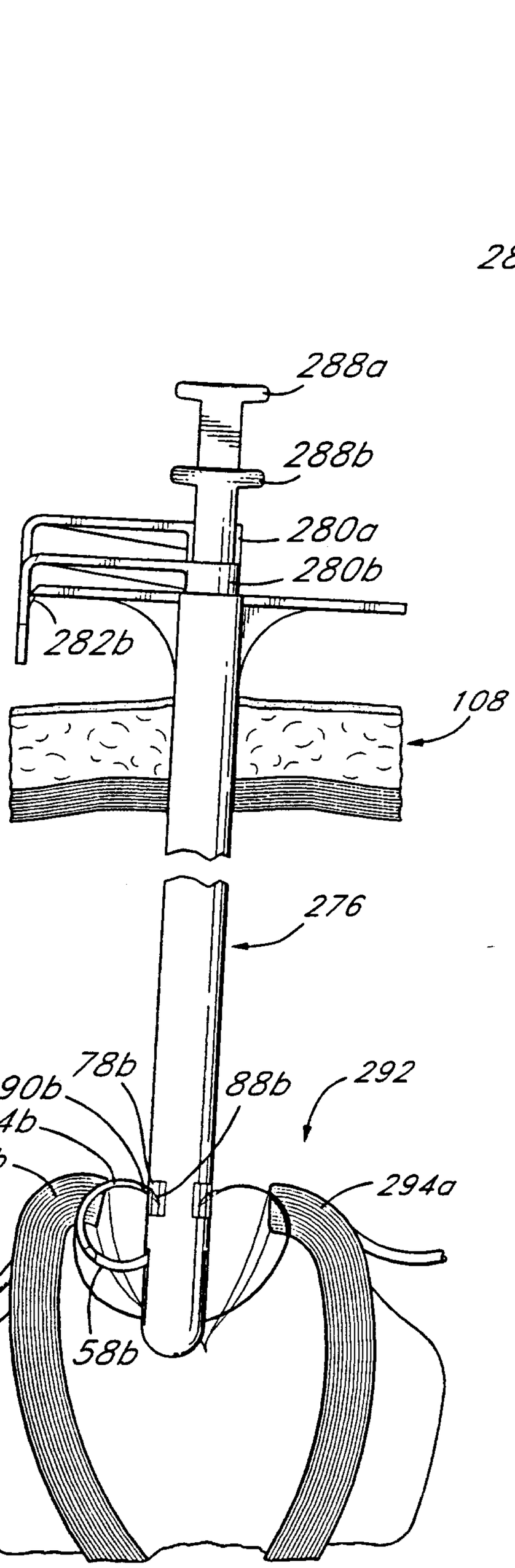

Fig. 24C

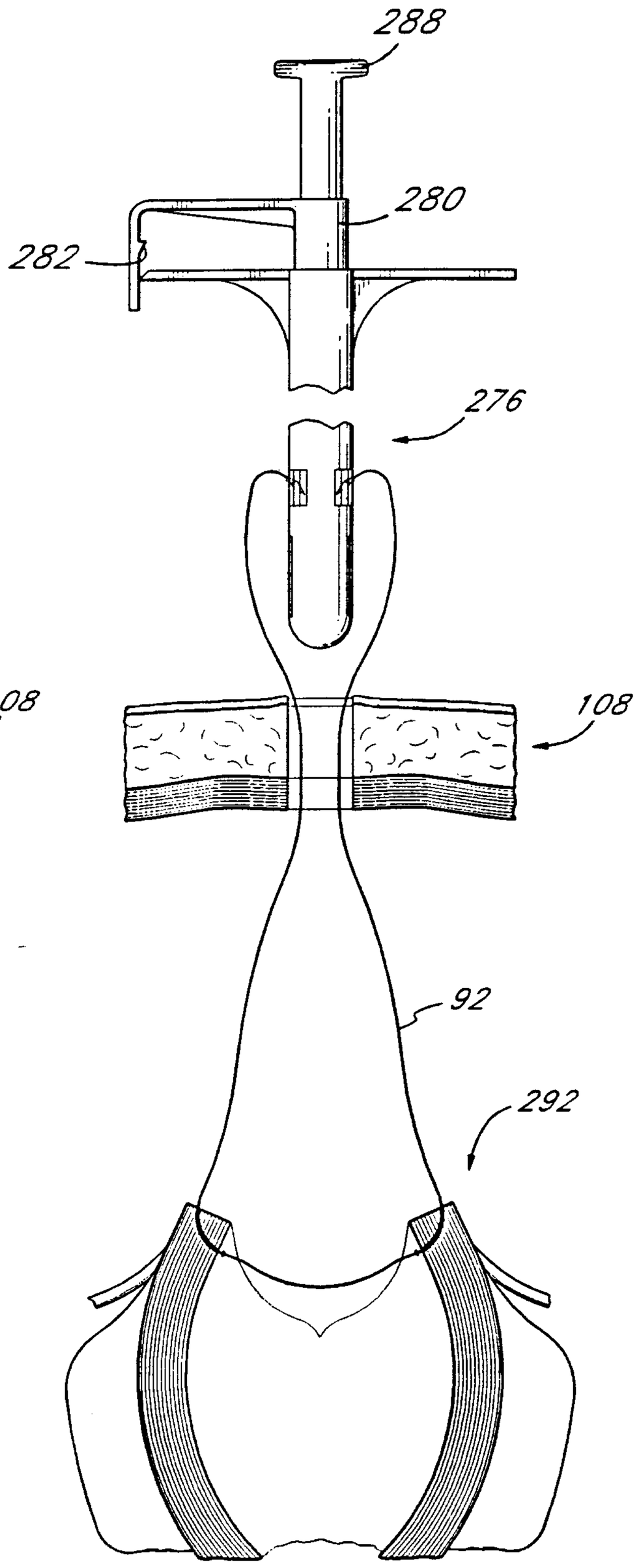

Fig. 24D

Fig. 25

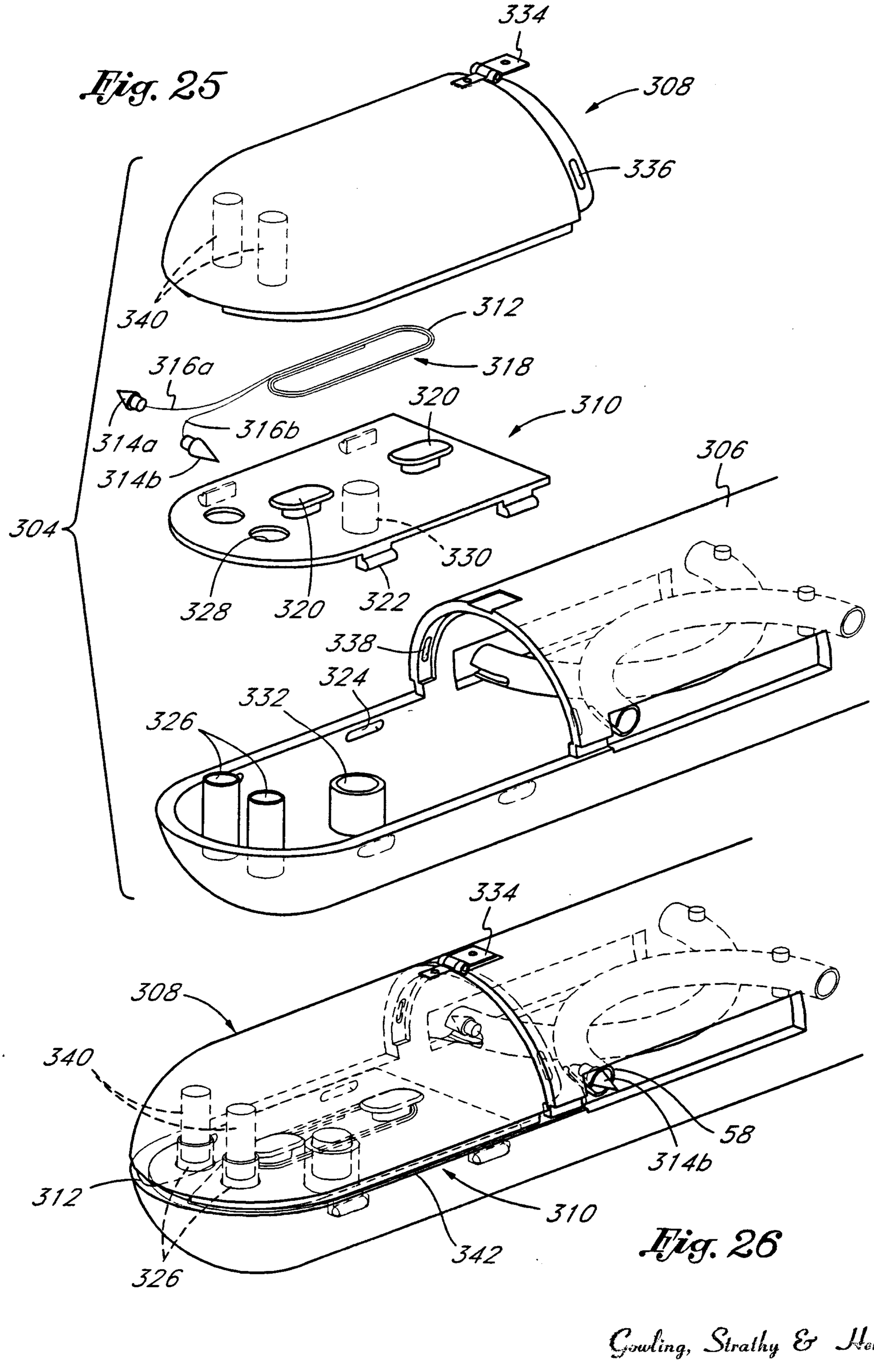
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Fig. 26

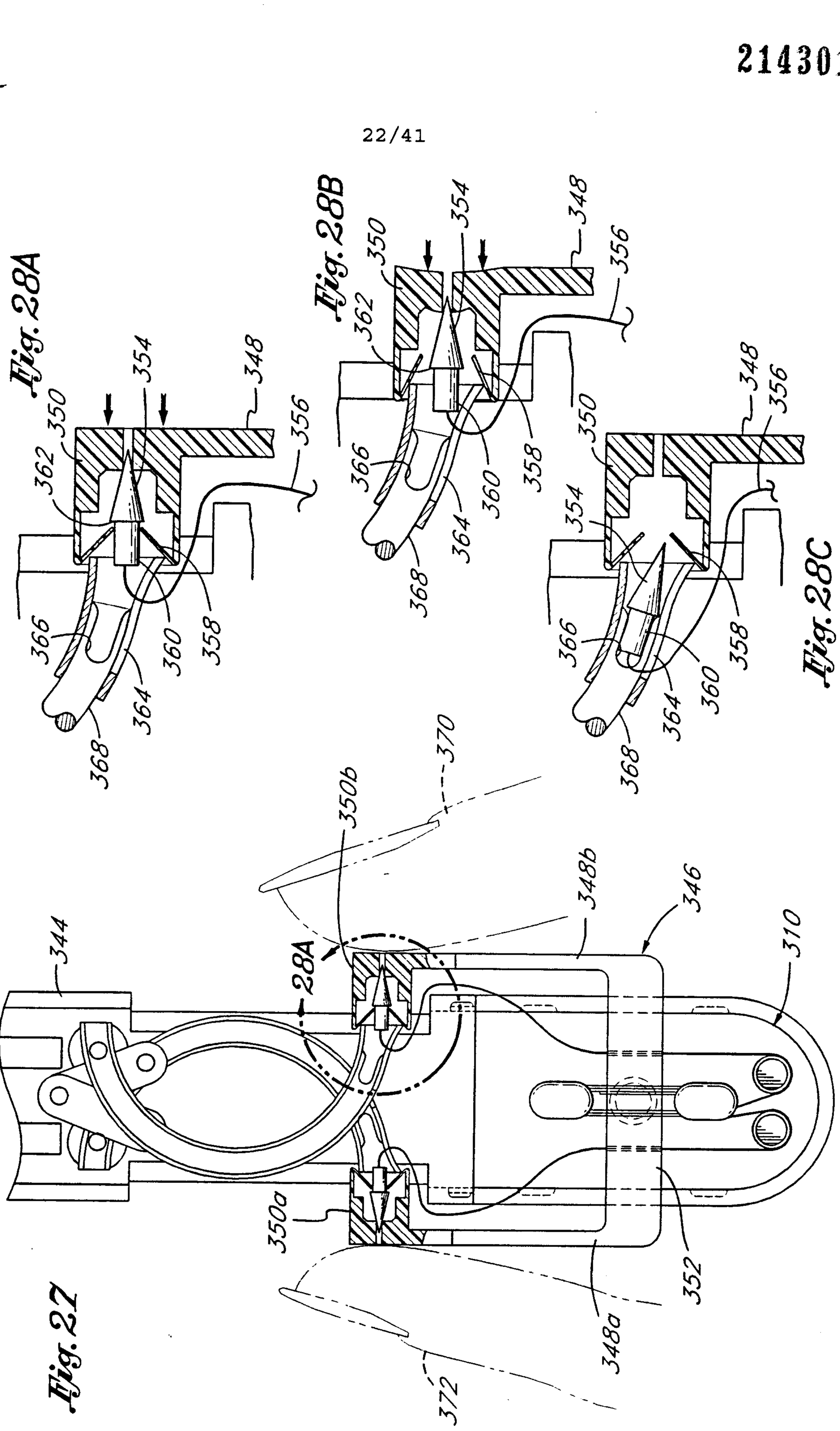


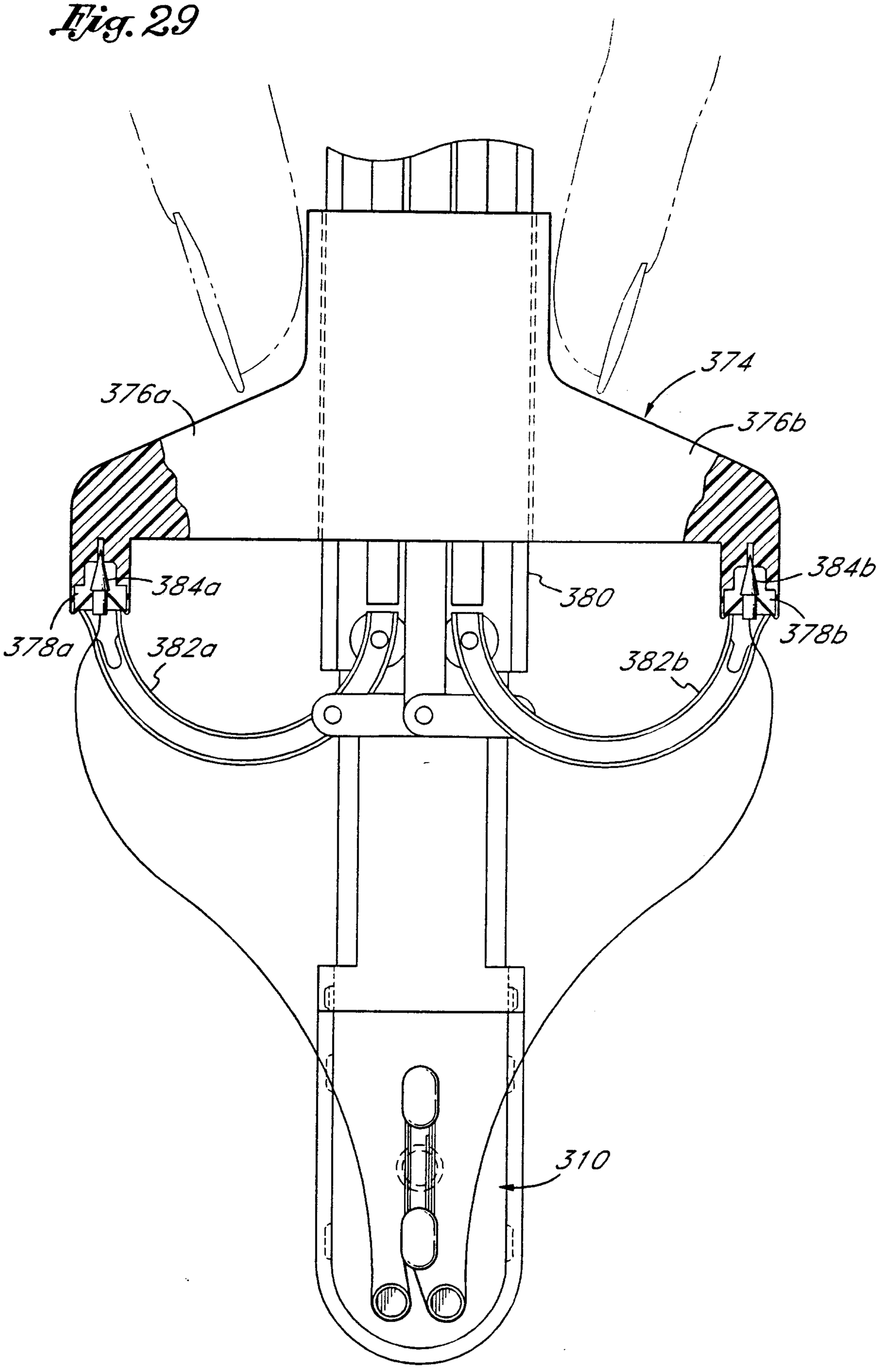
Fig. 27

Fig. 28A

Fig. 28B

Fig. 28C

Fig. 29



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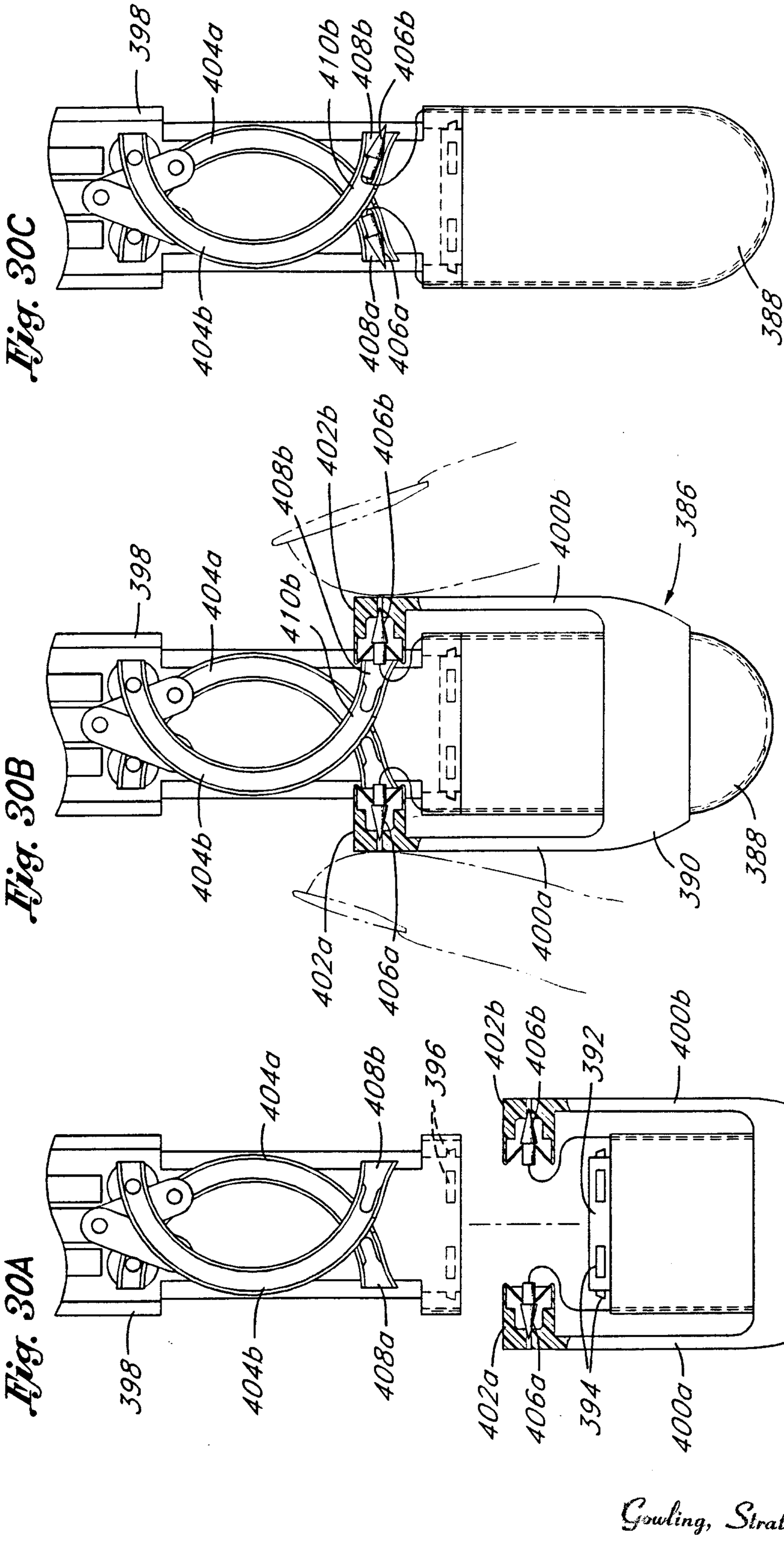

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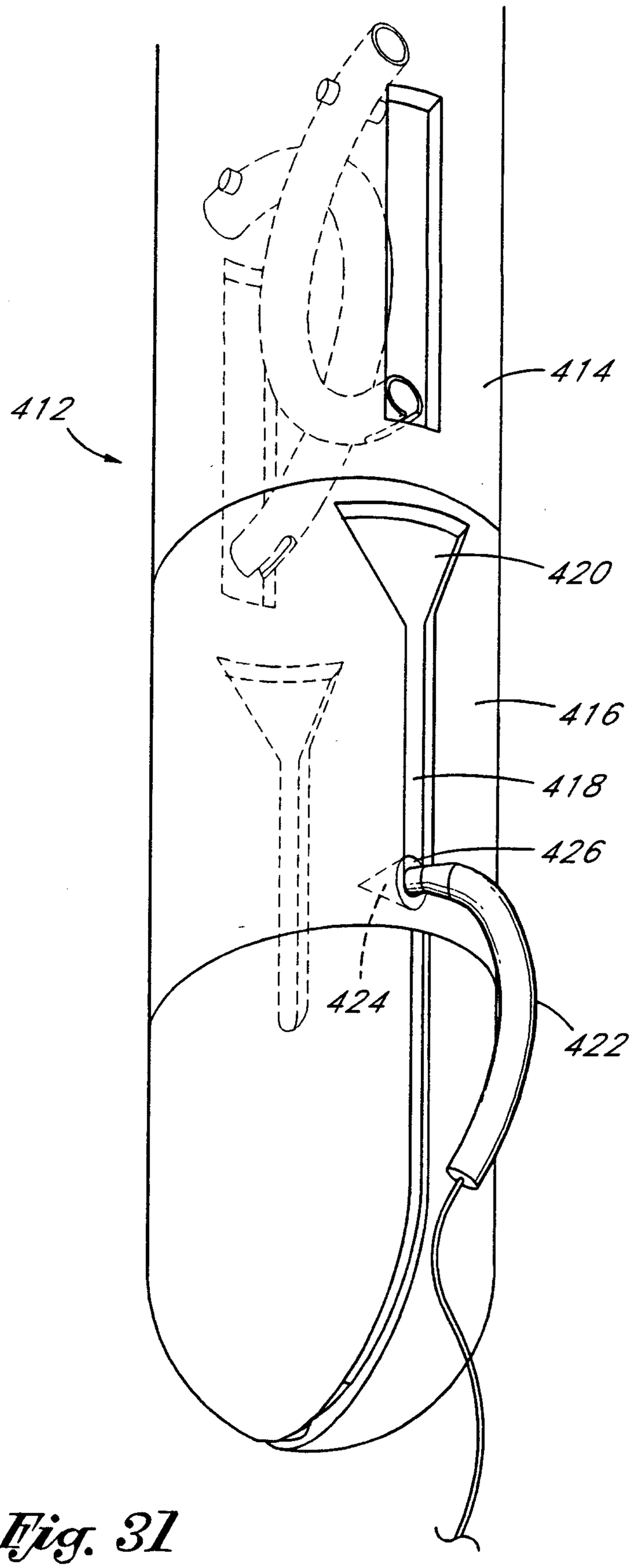

Fig. 31

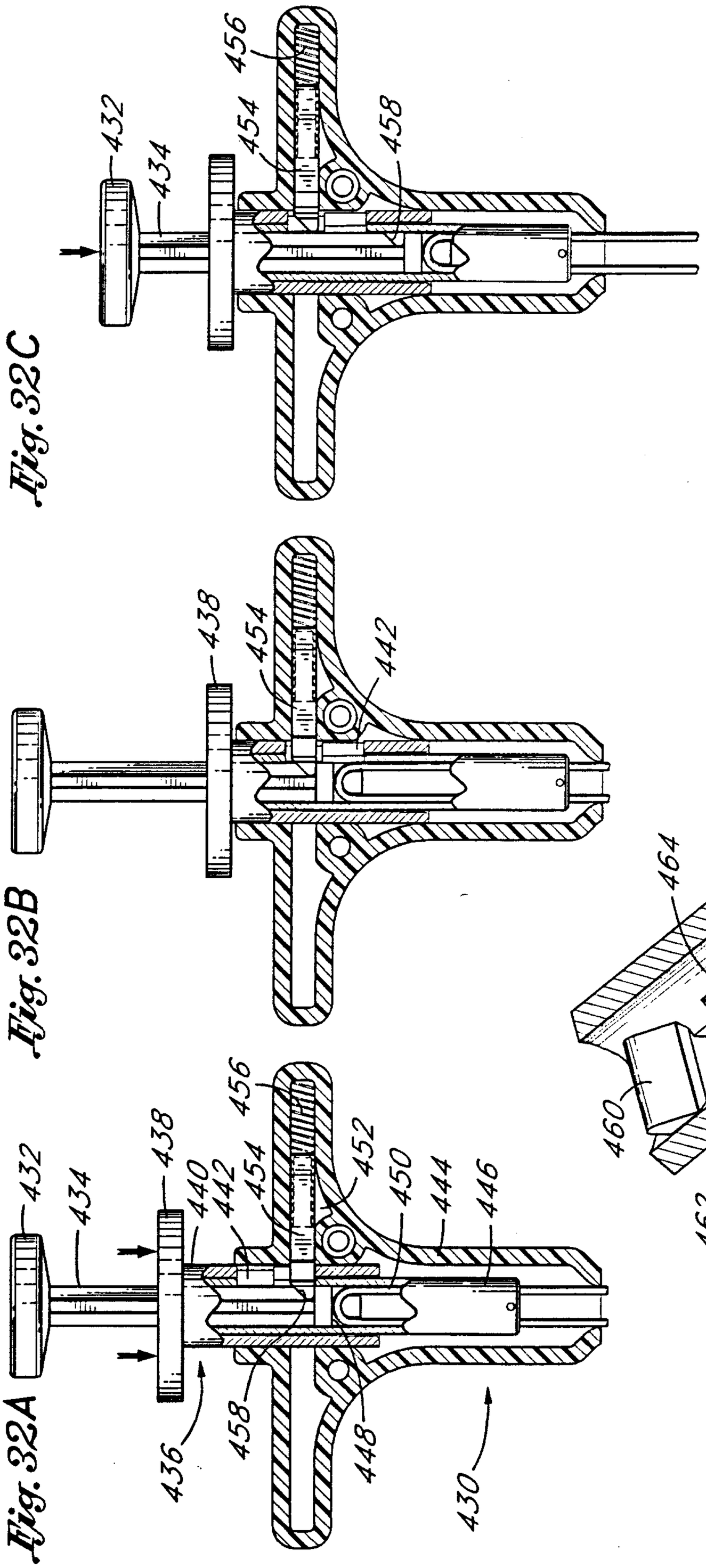

Fig. 32A

Fig. 32B

Fig. 32C

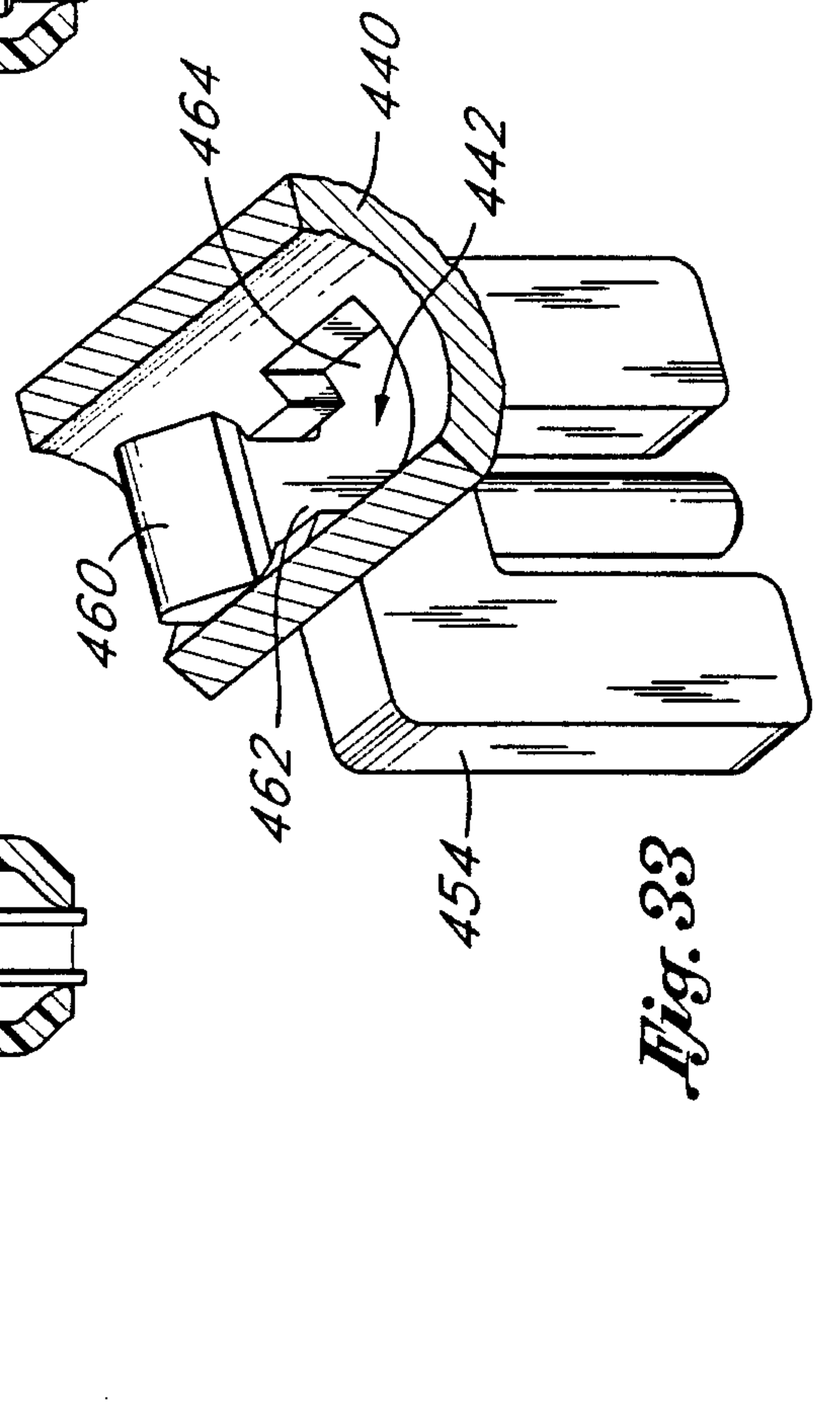

Fig. 33

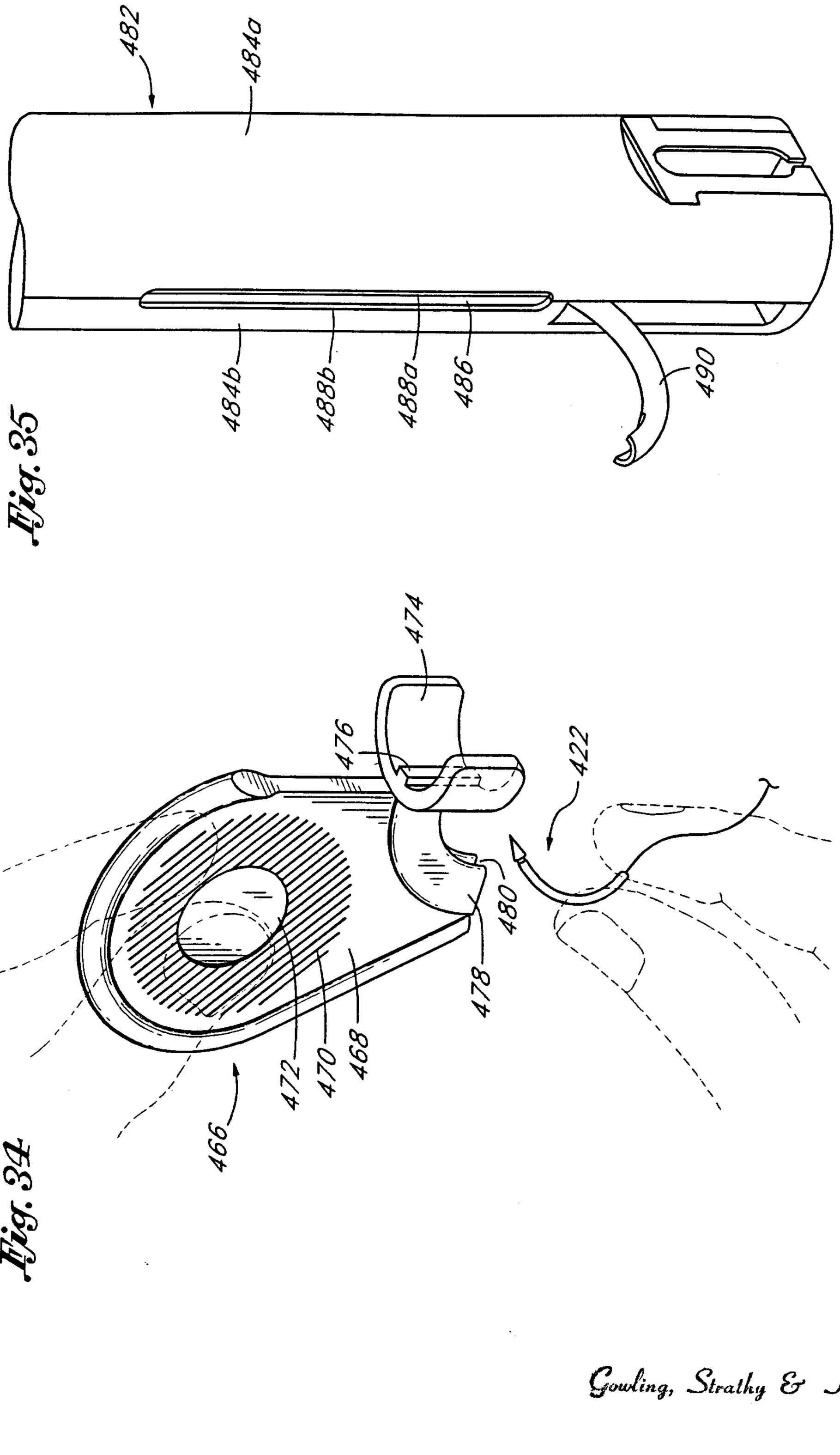
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Fig. 35

Fig. 34

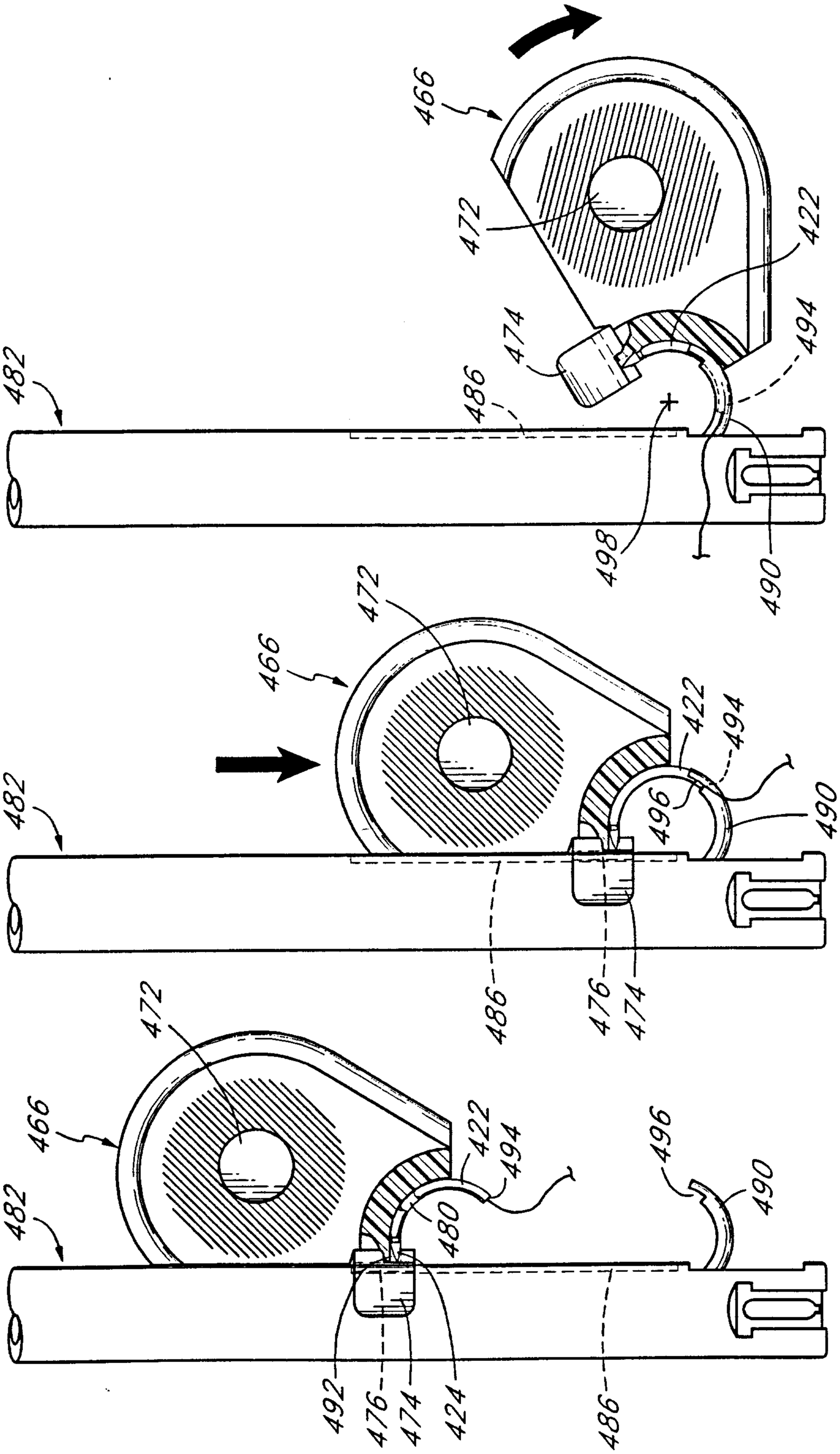

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Fig. 37

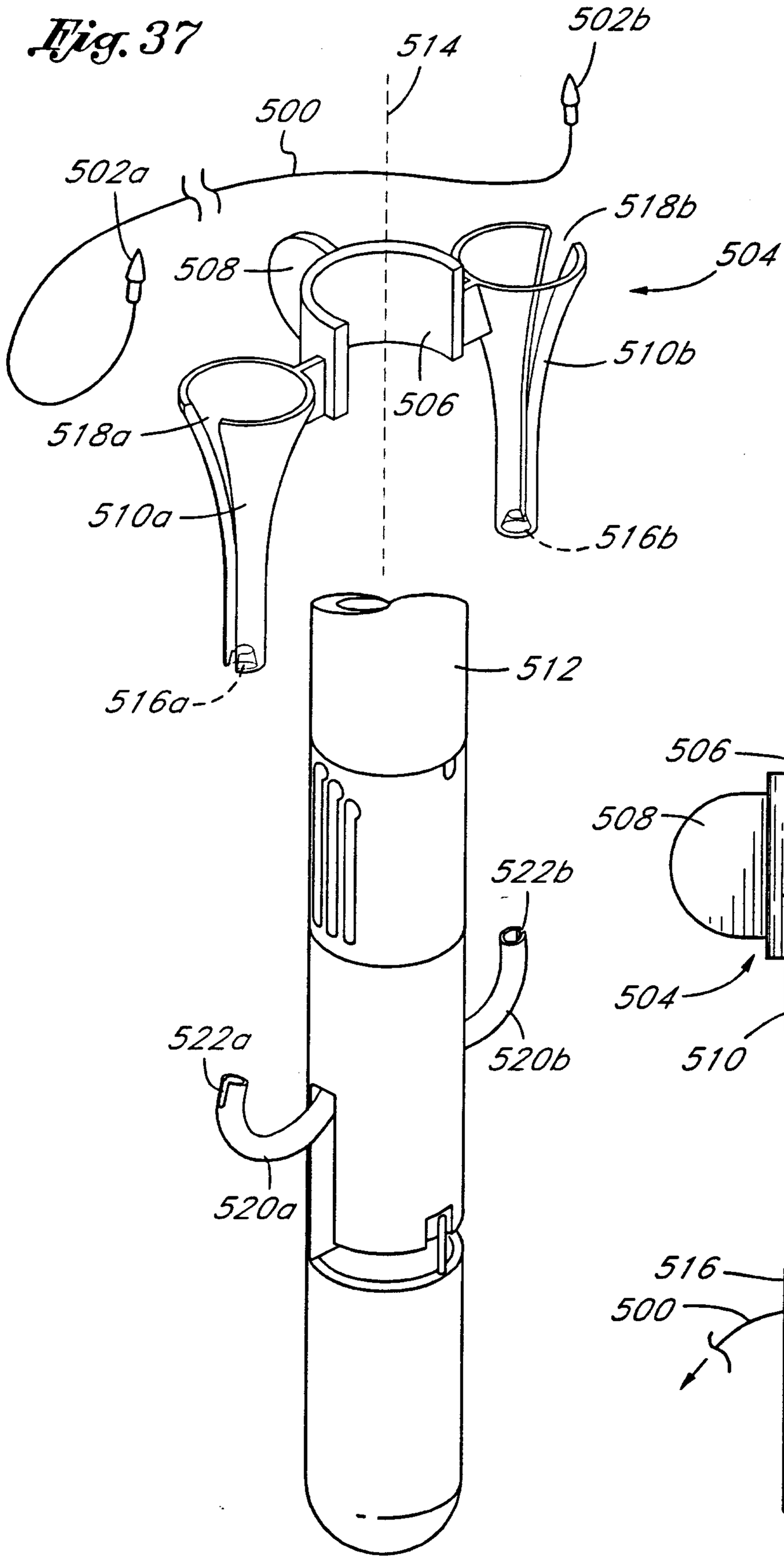

Fig. 38

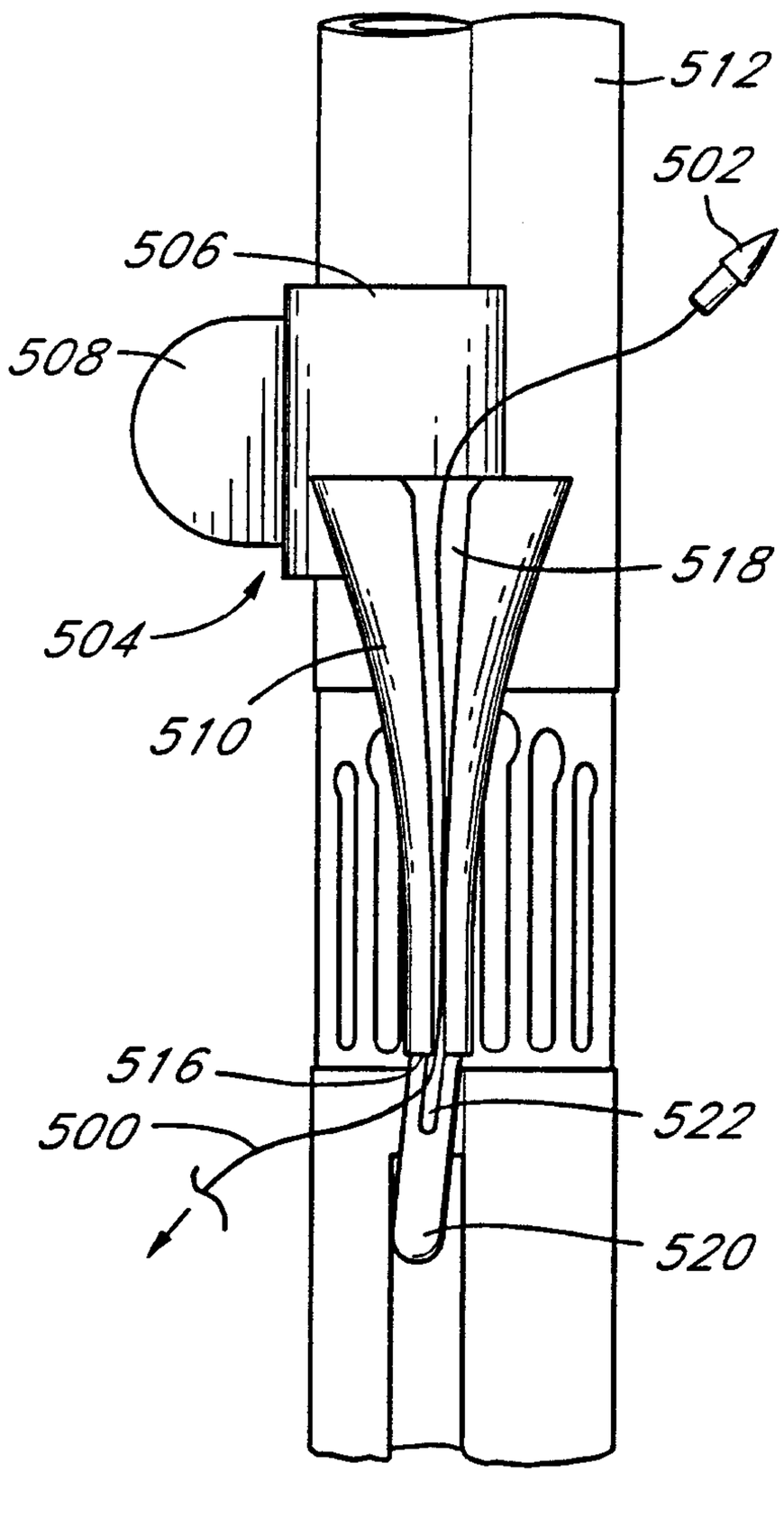

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Fig. 39

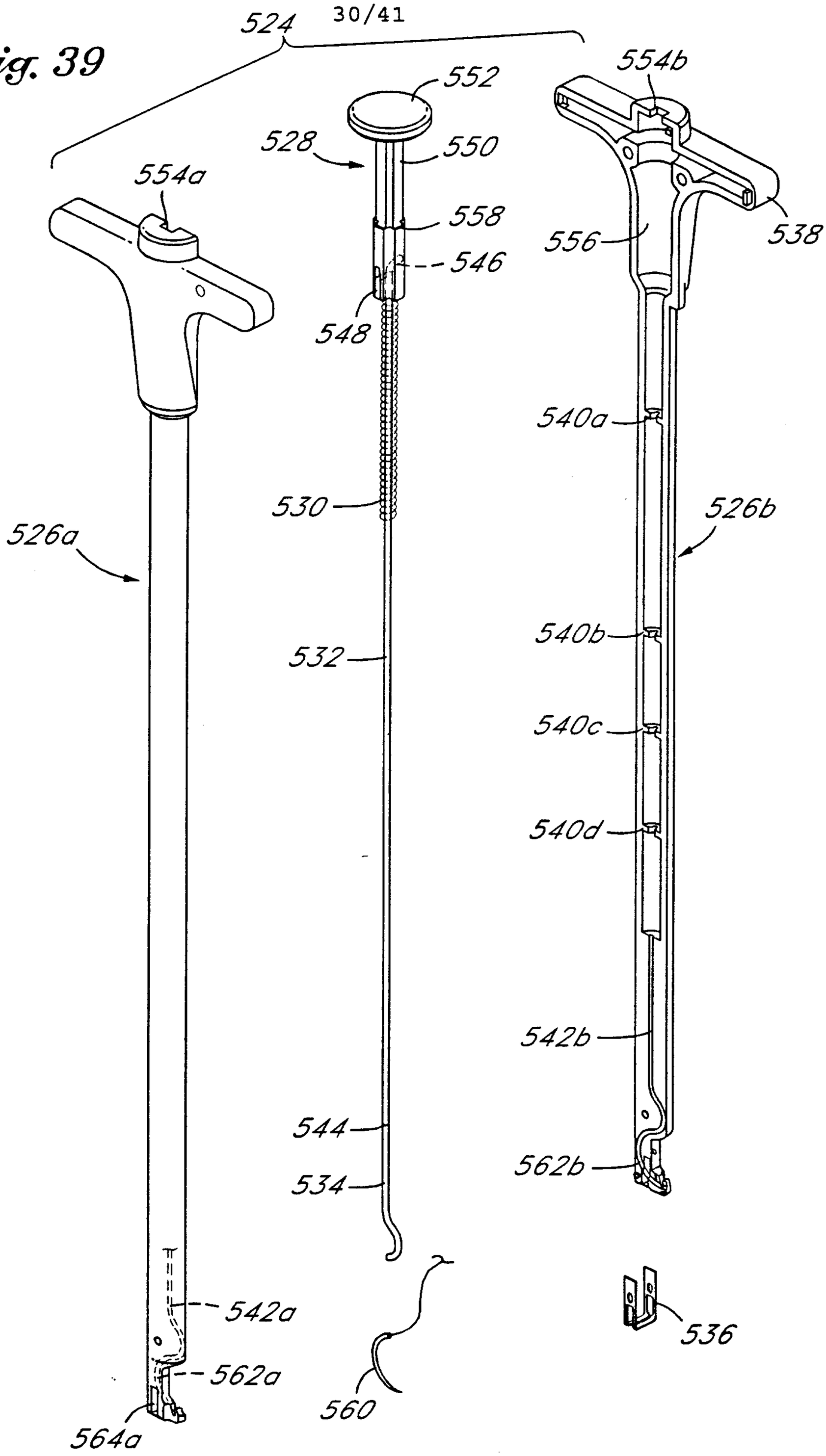

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Fig. 40A

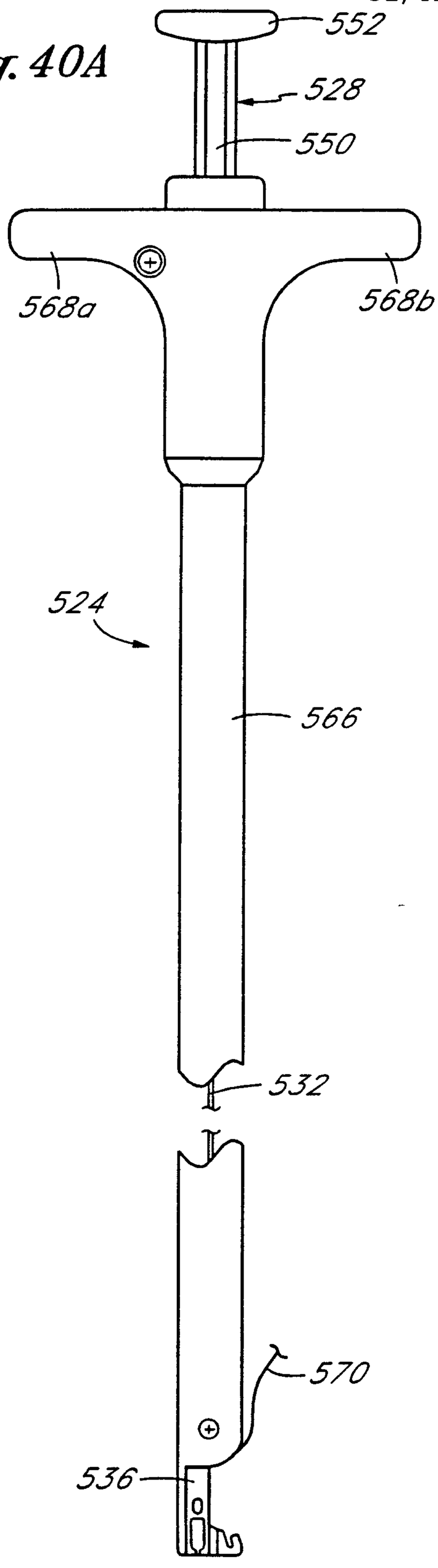

Fig. 40B

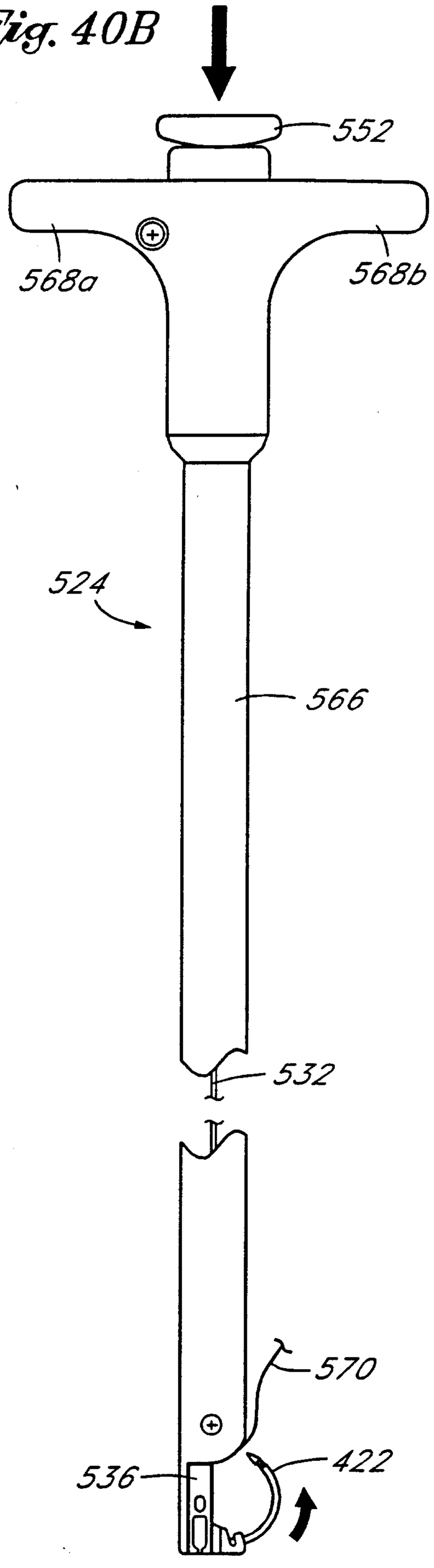

Fig. 41C

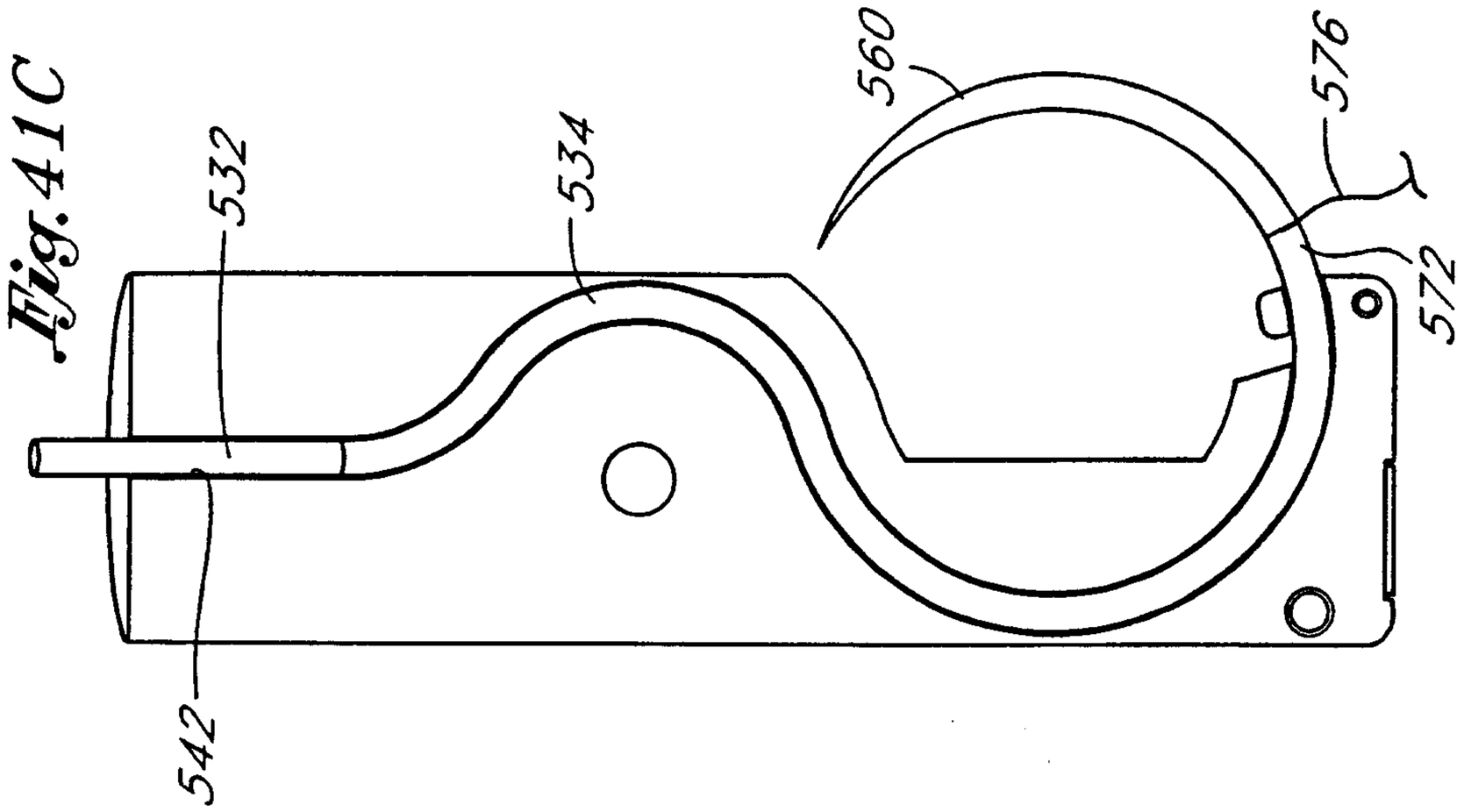

Fig. 41B

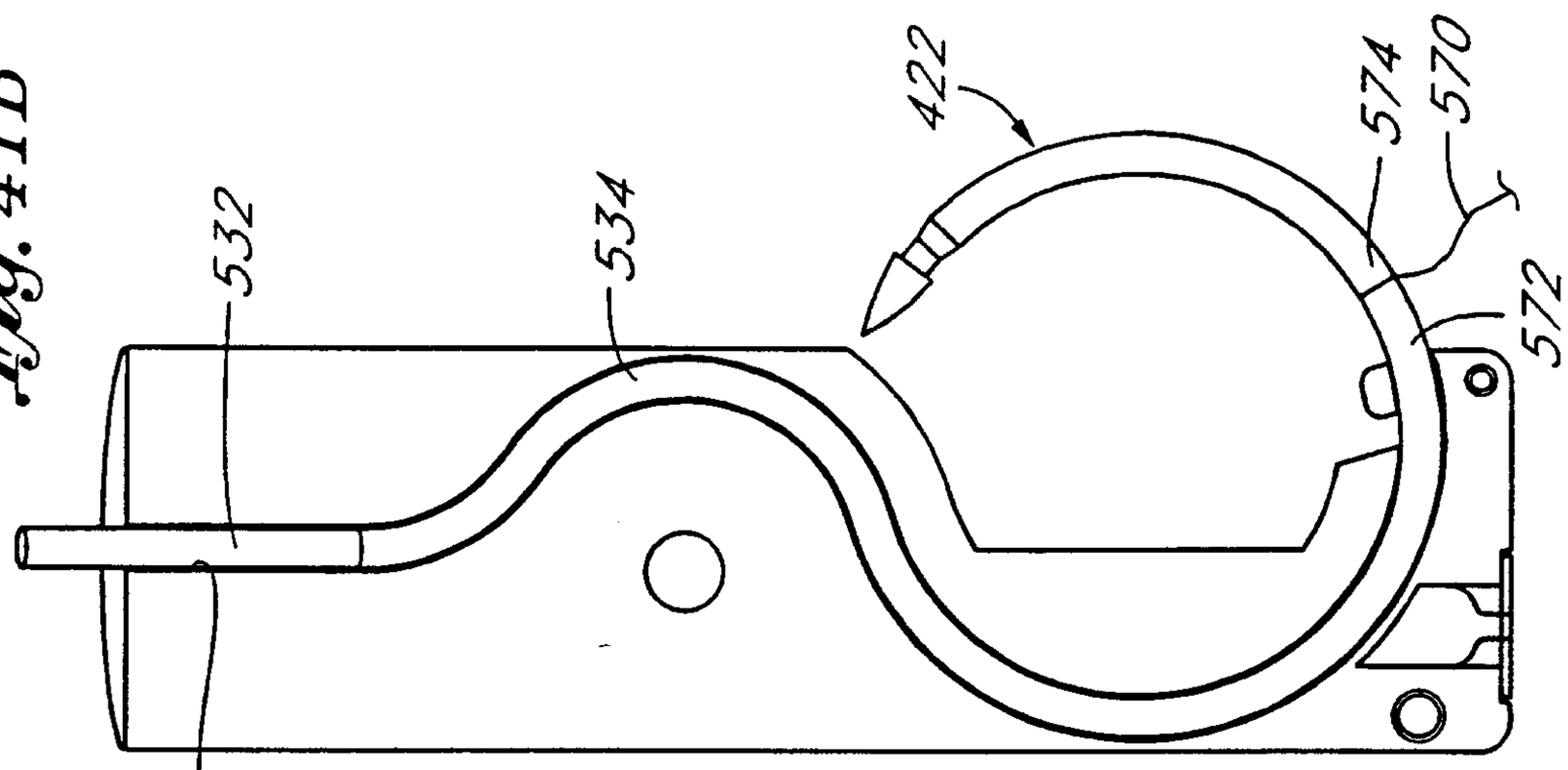

Fig. 41A

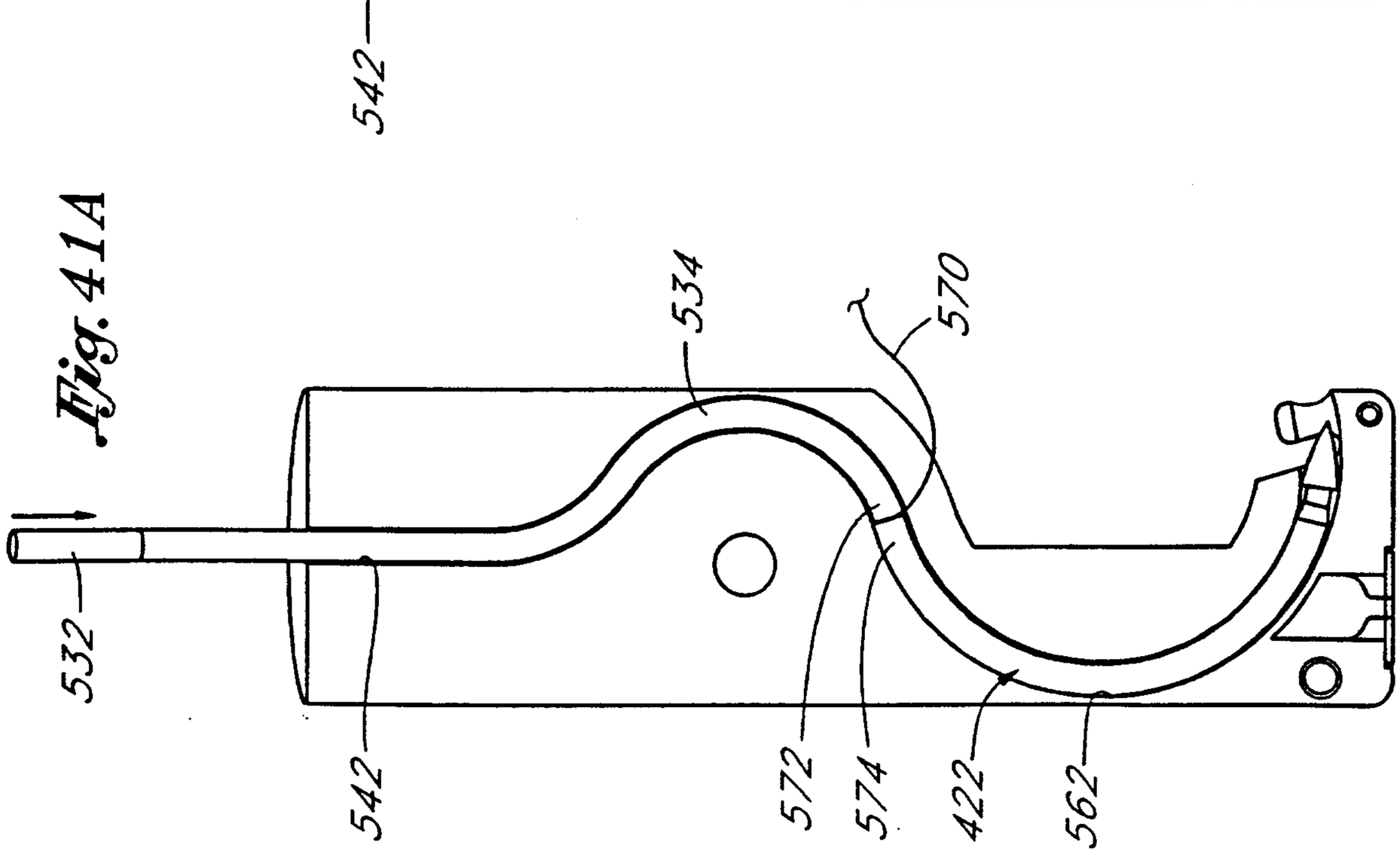

Fig. 42

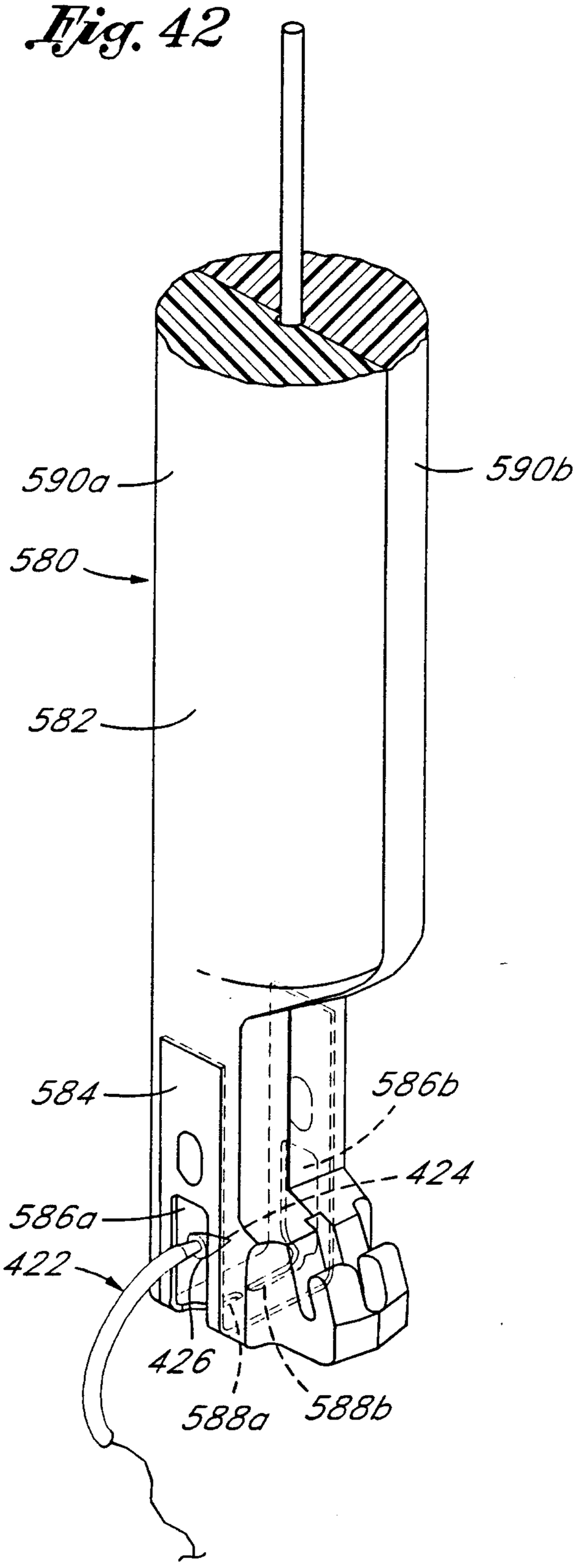
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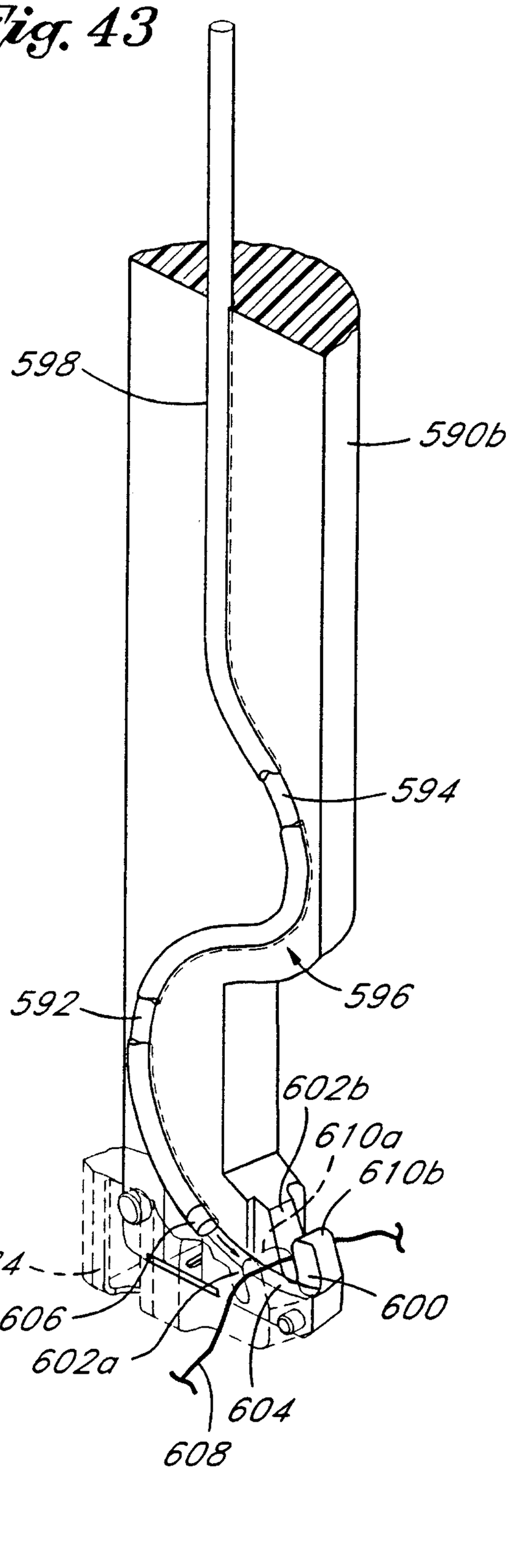
Fig. 43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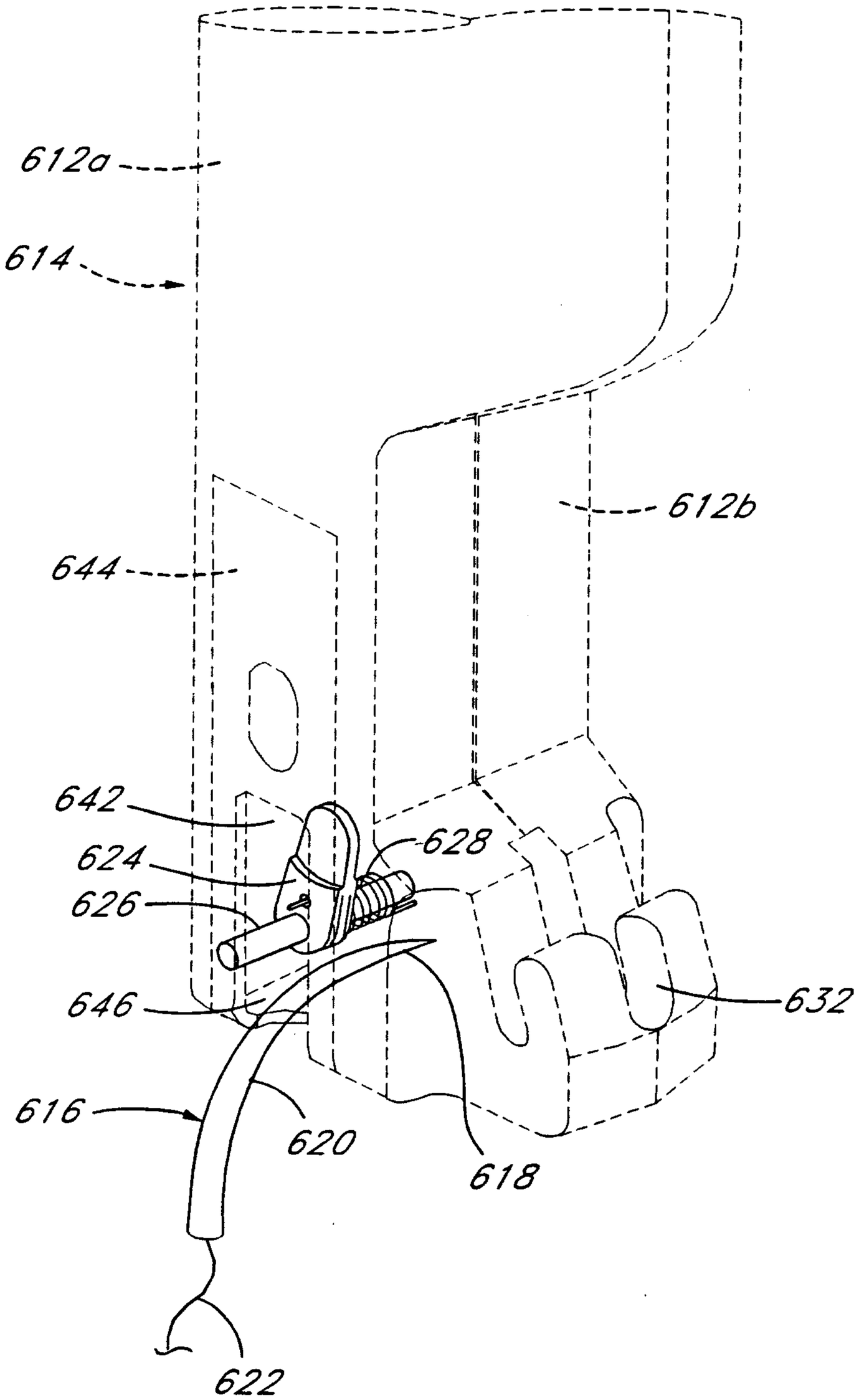

Fig. 44

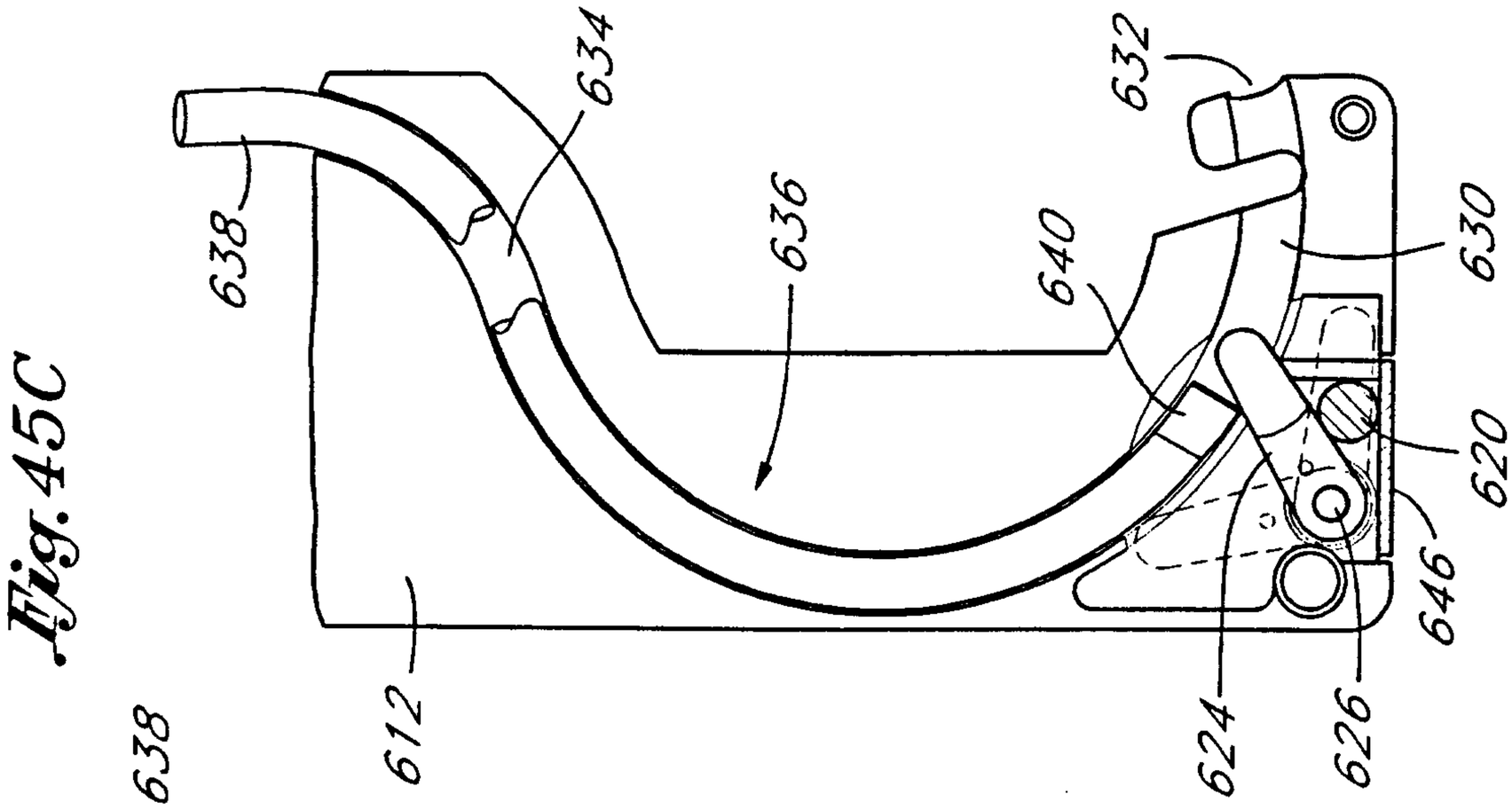

Fig. 45C

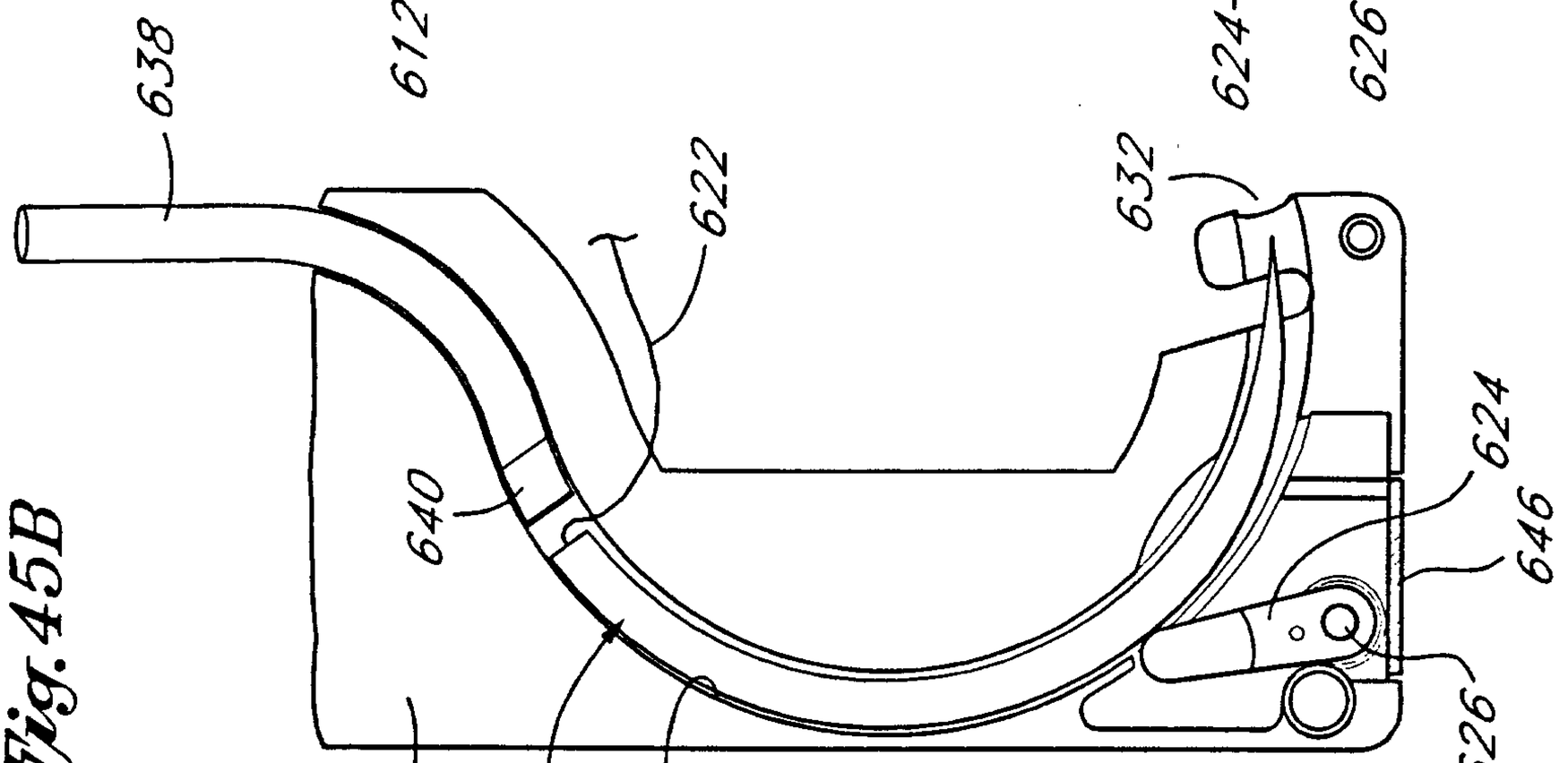

Fig. 45B

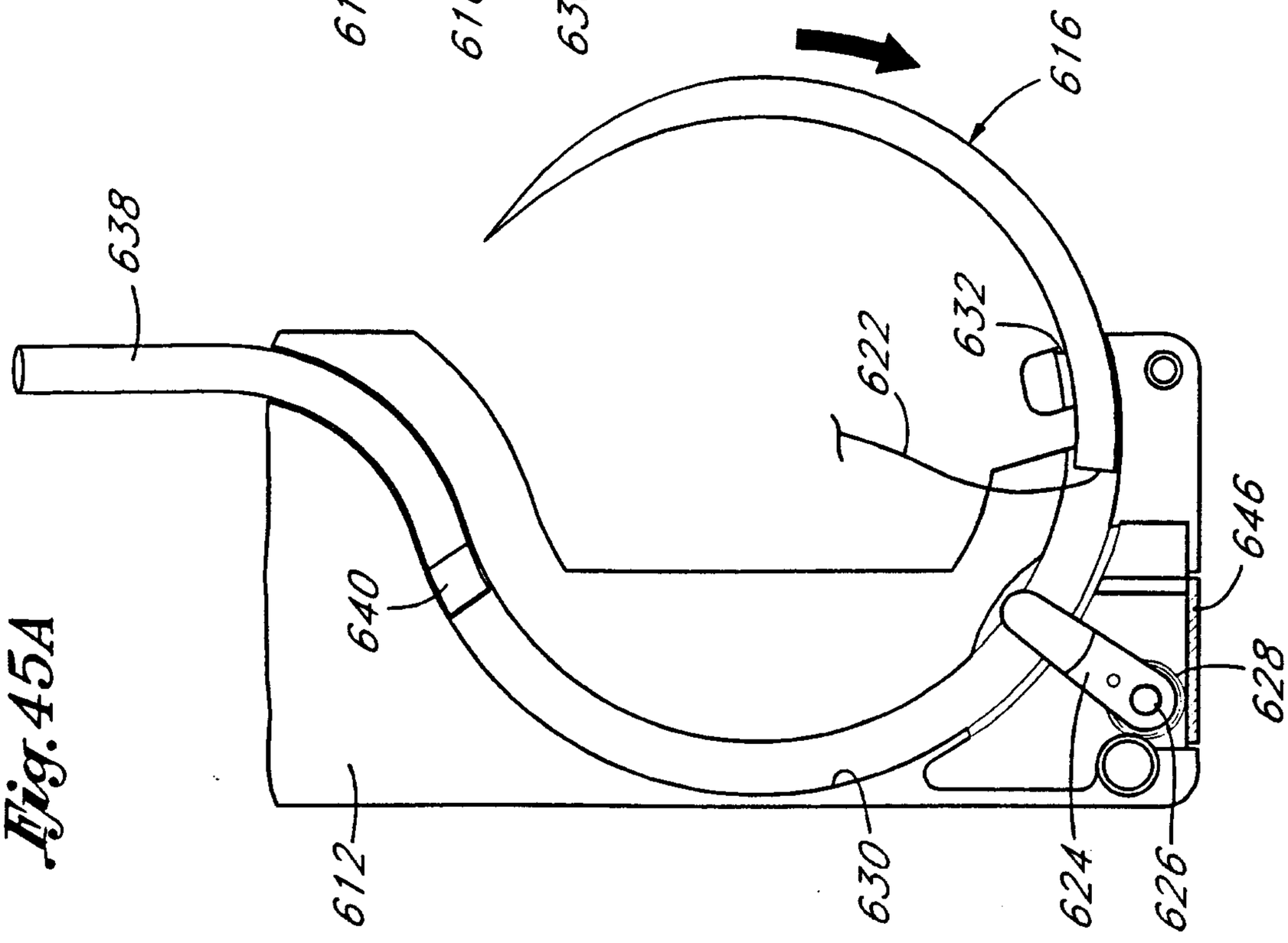

Fig. 45A

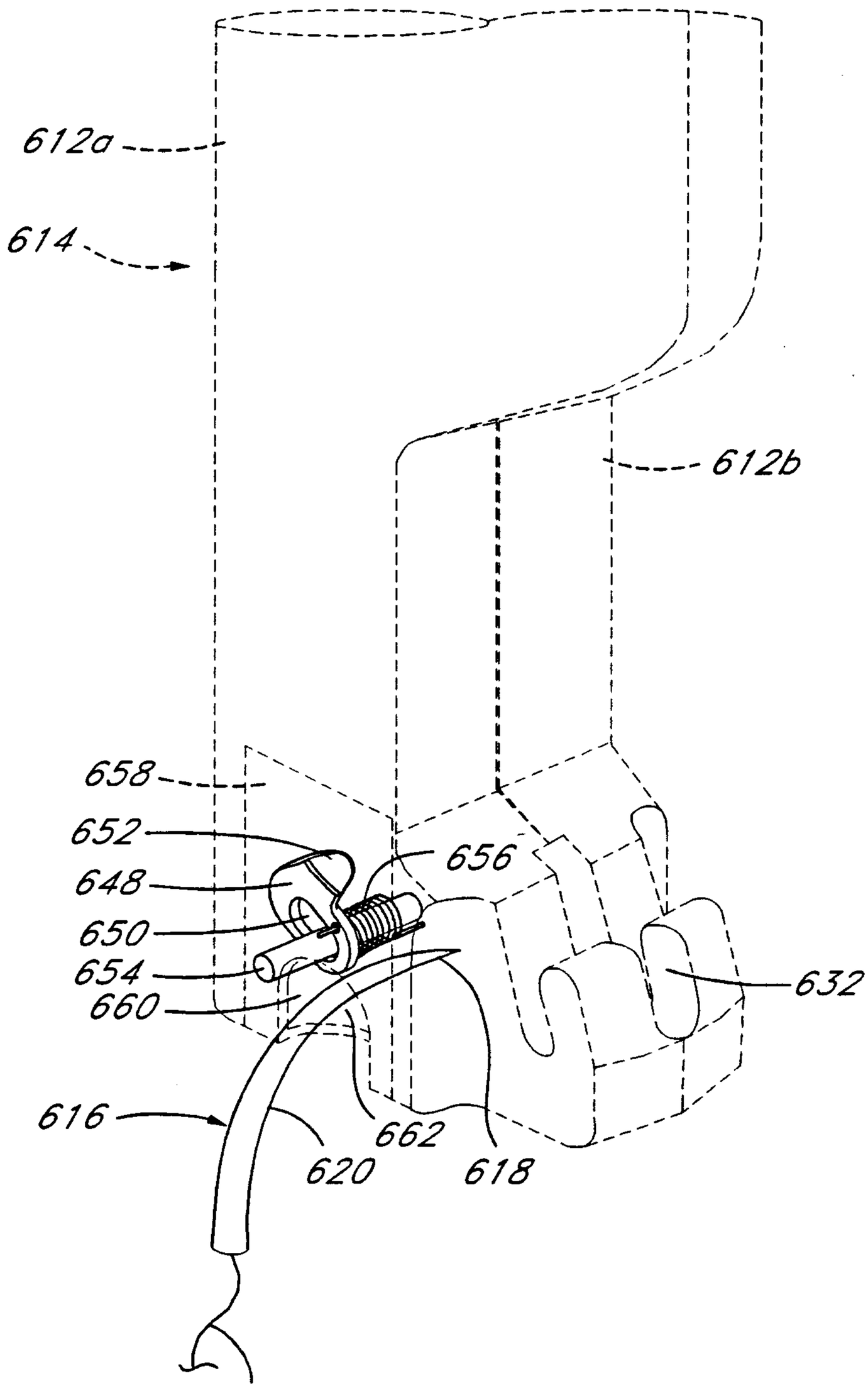
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Fig. 46

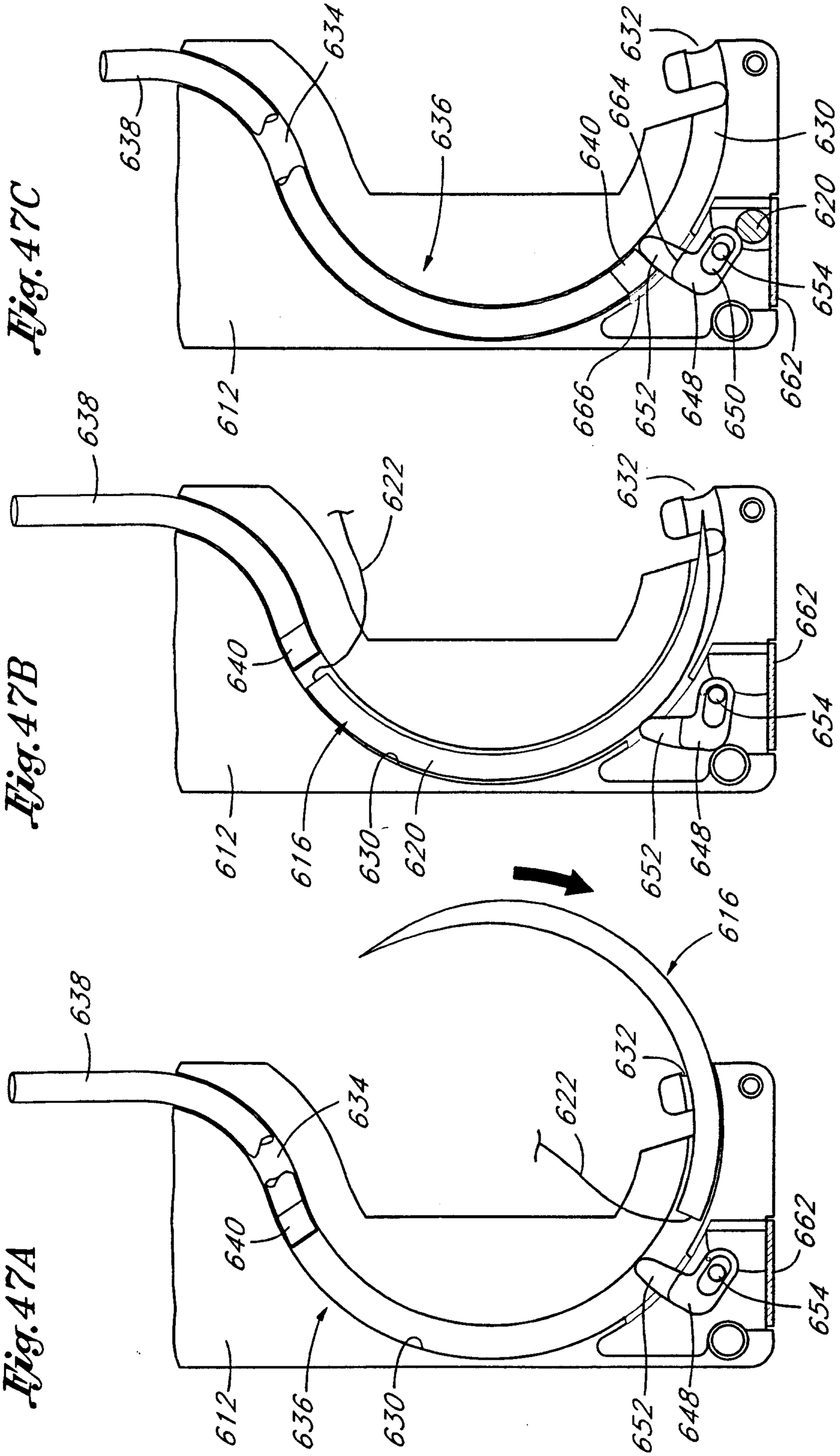

Fig. 47C

Fig. 47B

Fig. 47A

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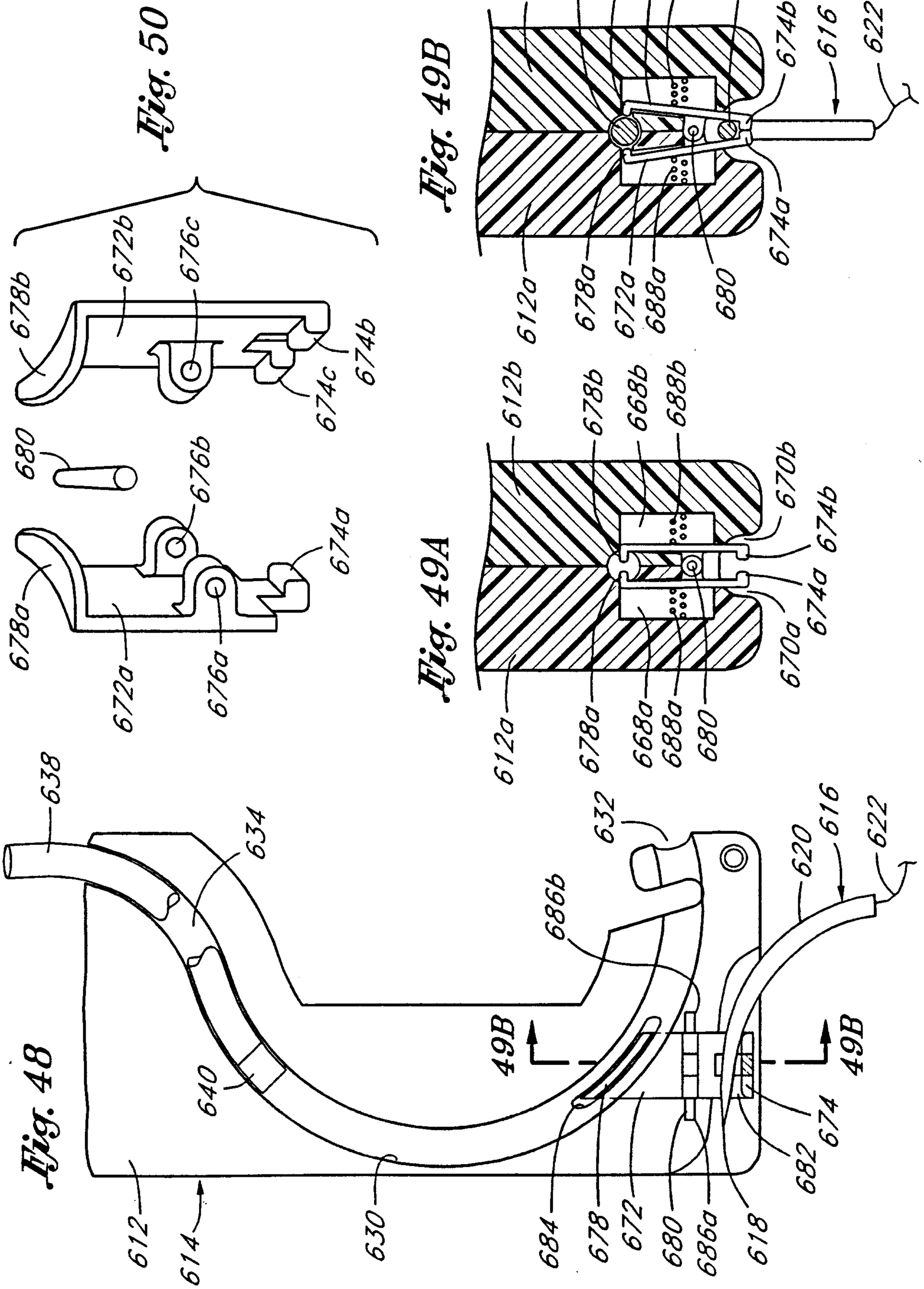

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Fig. 51

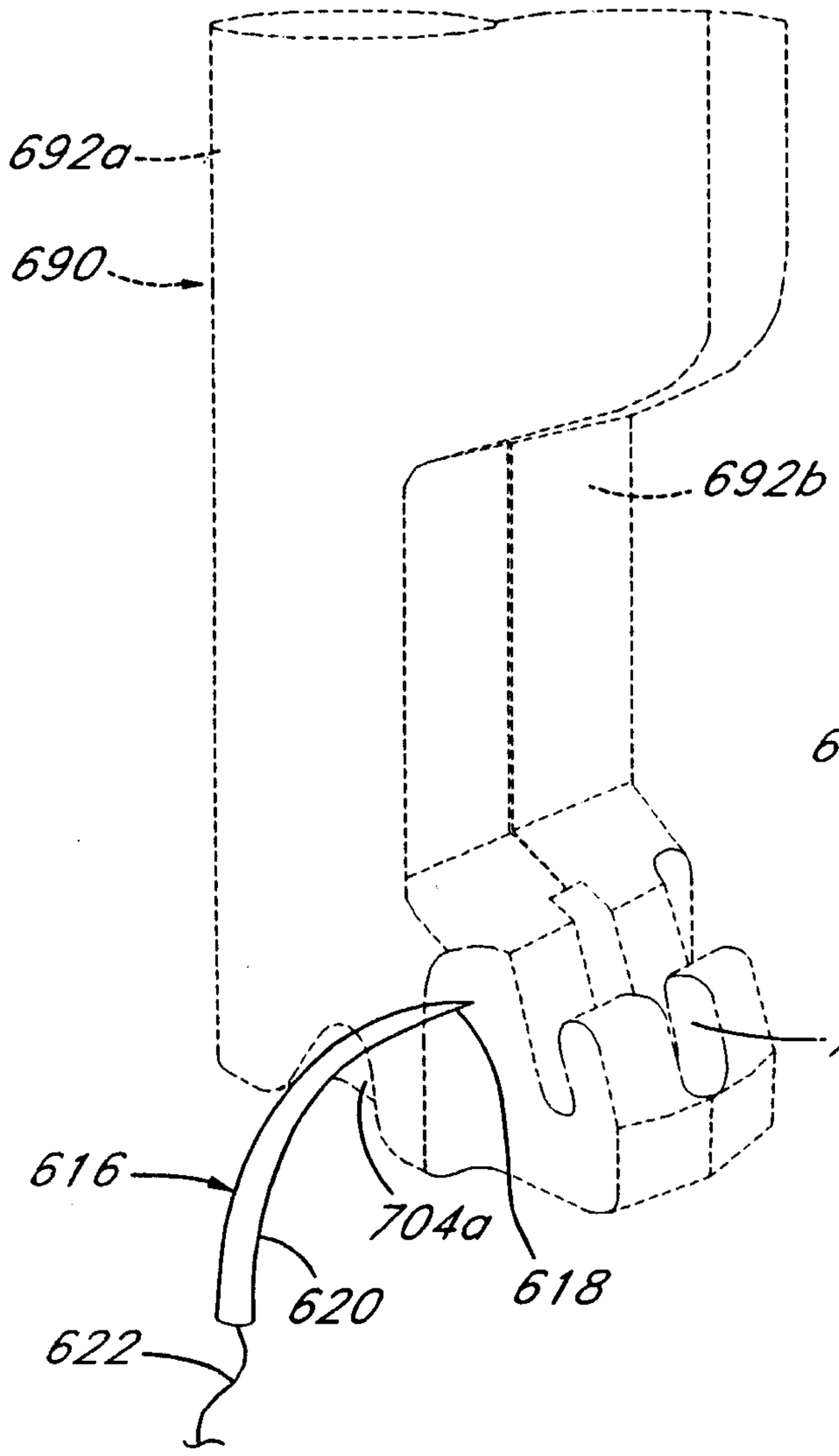


Fig. 53

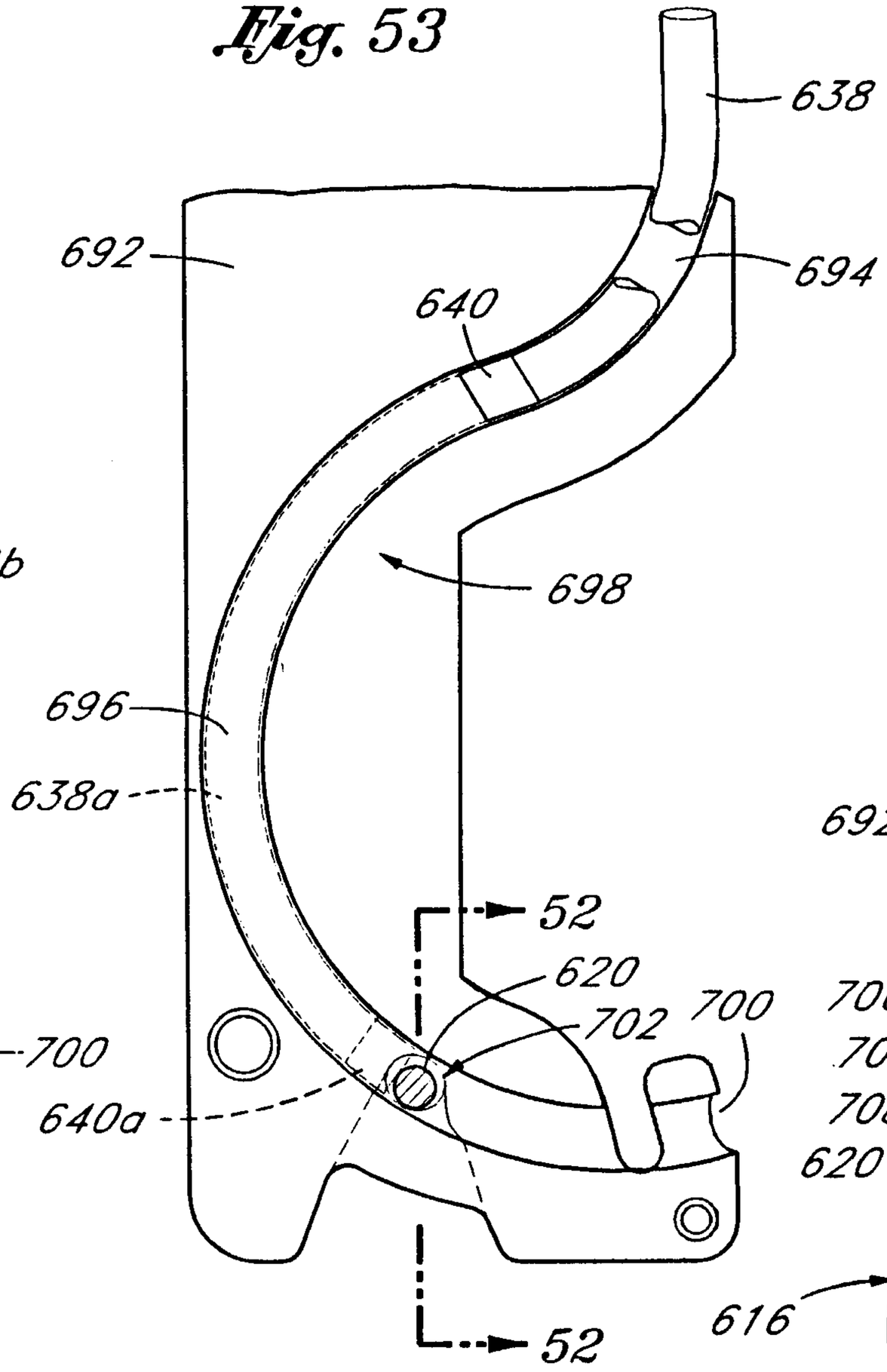


Fig. 52

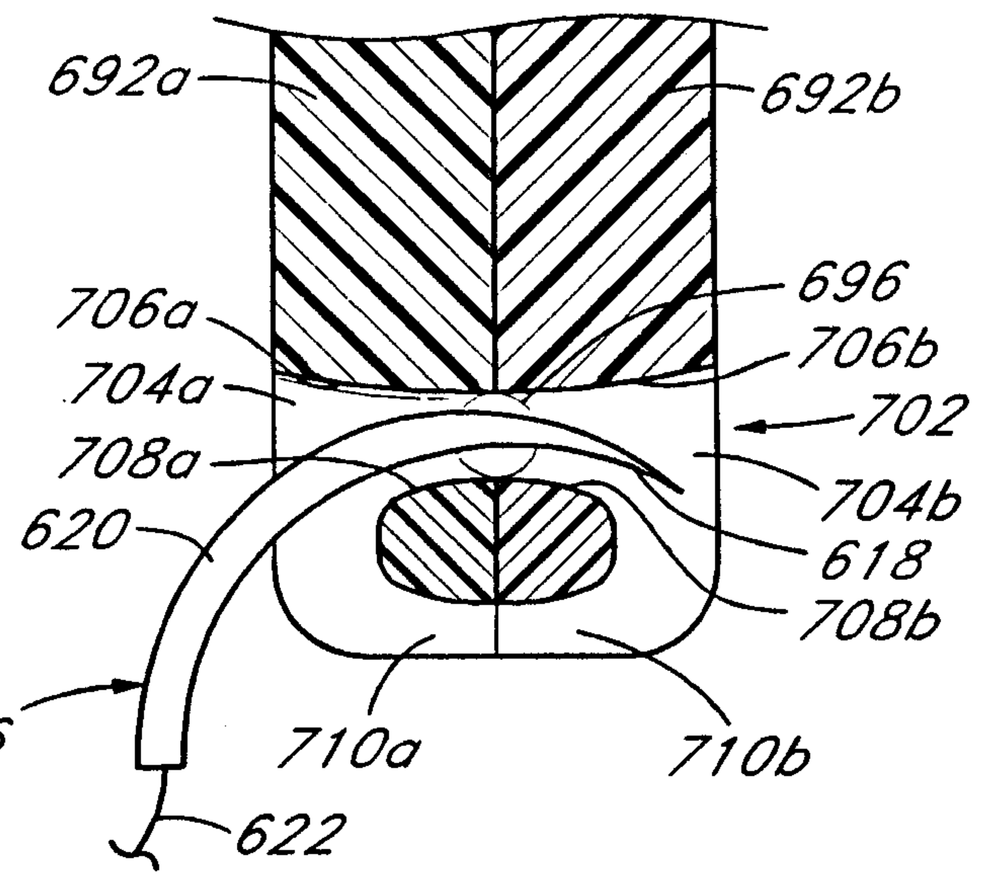


Fig. 54

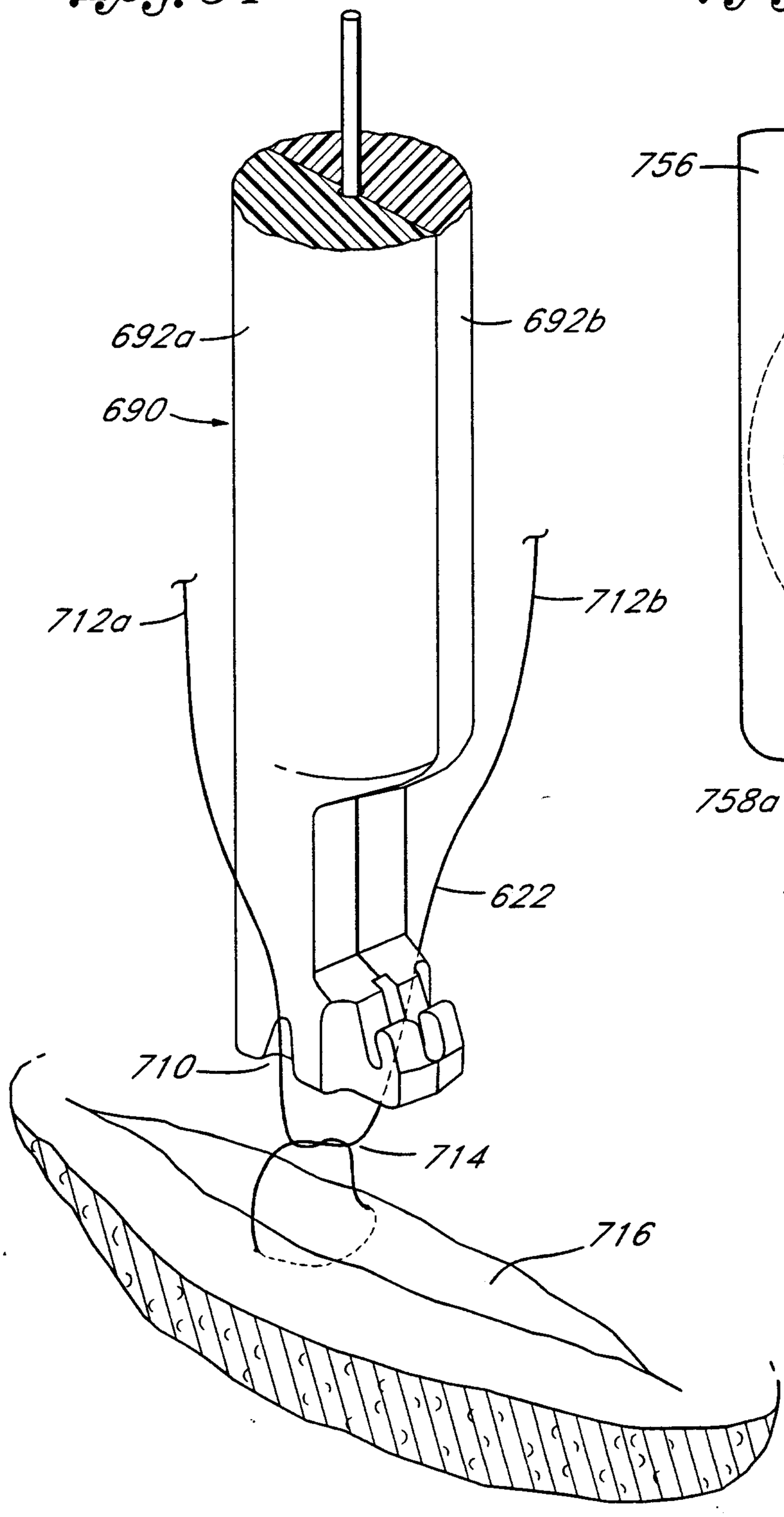
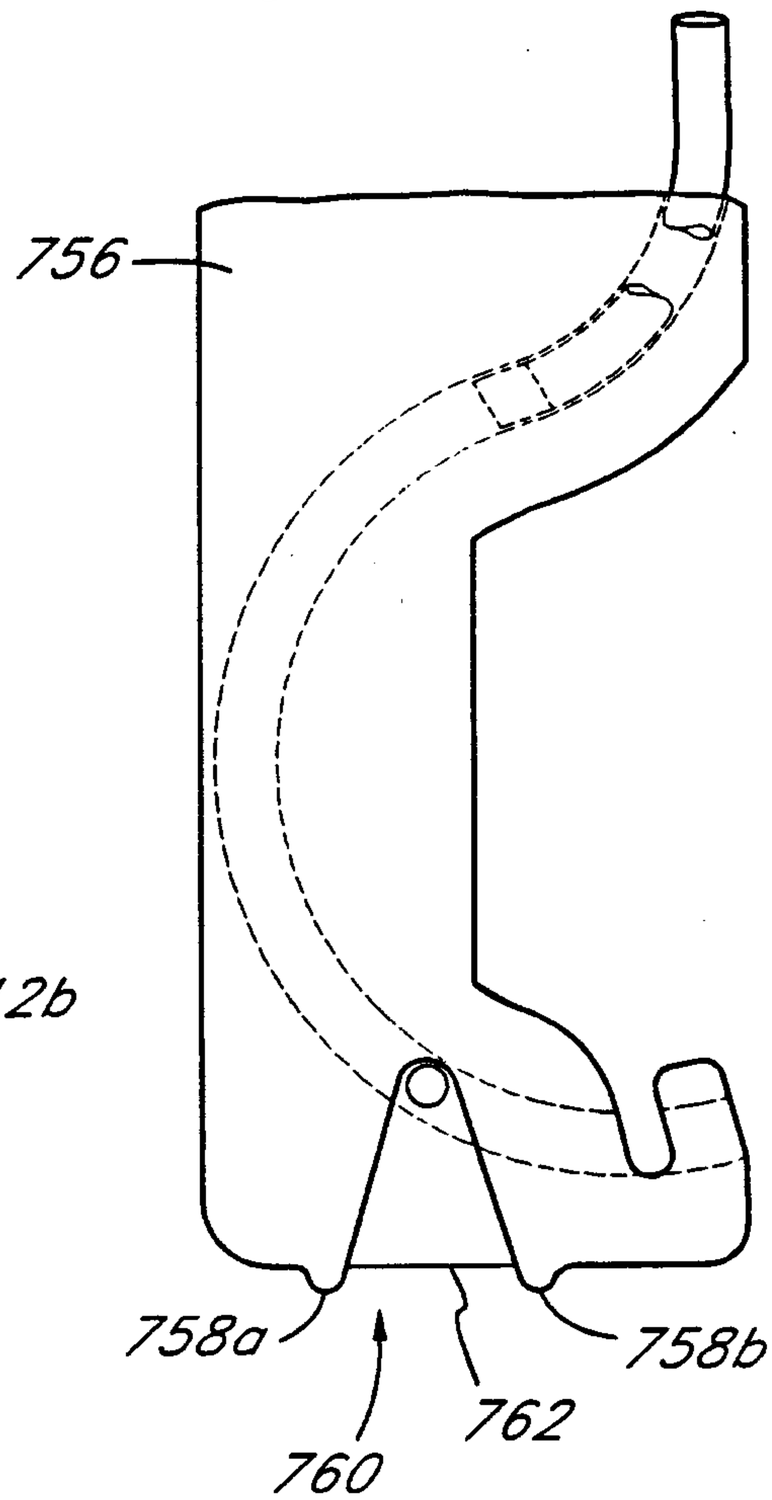


Fig. 54A



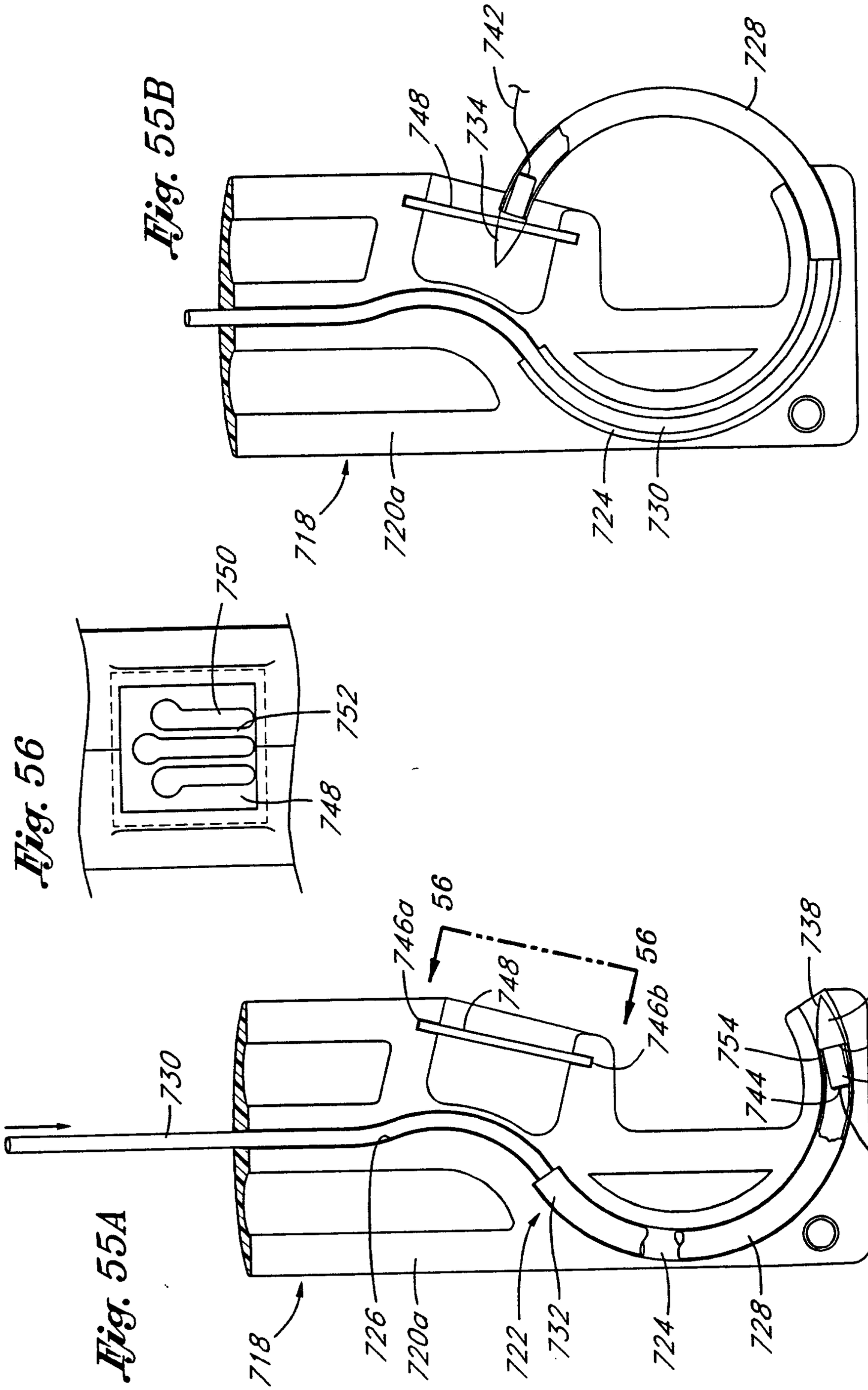
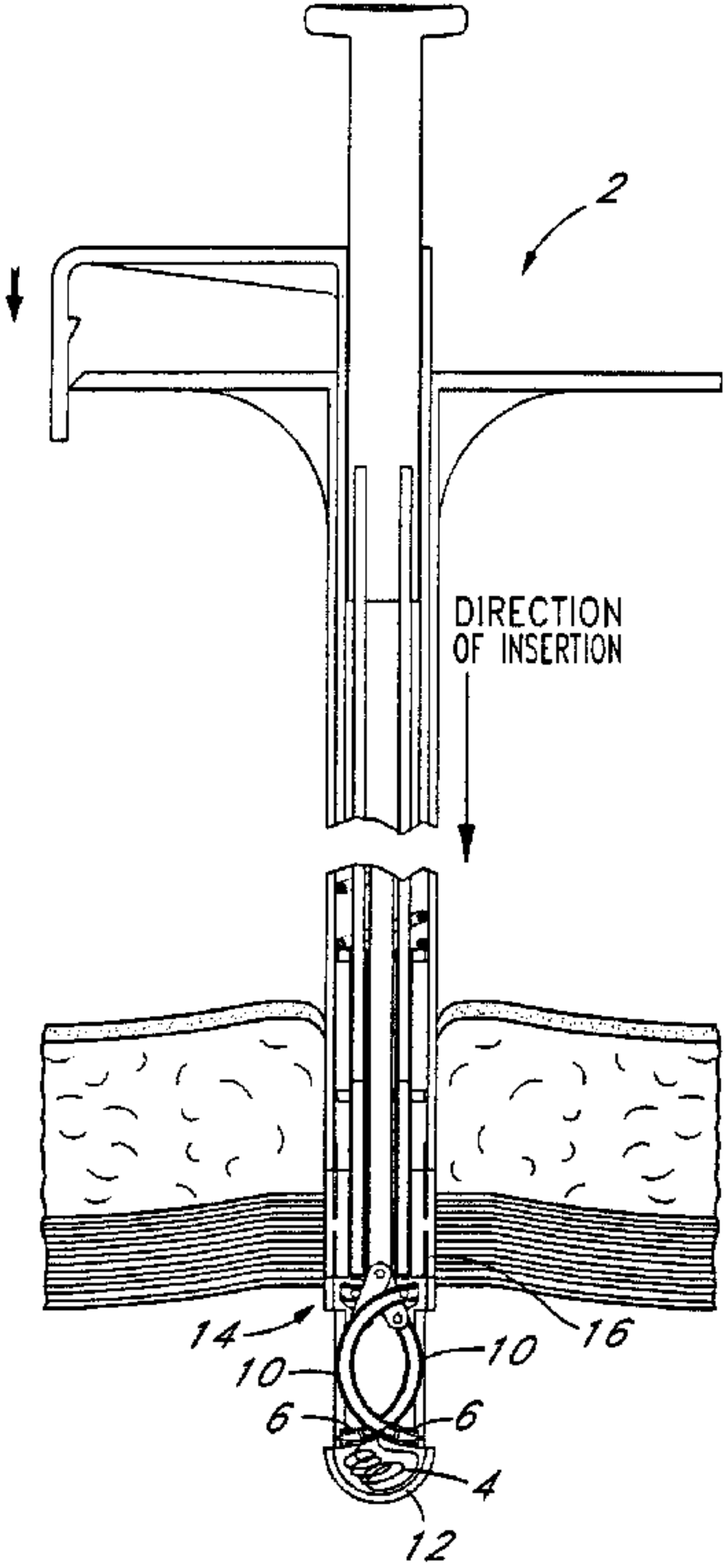


Fig. 55B

Fig. 56

Fig. 55A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