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(54) **INSULATING BOOT FOR ELECTROSURGICAL FORCEPS**

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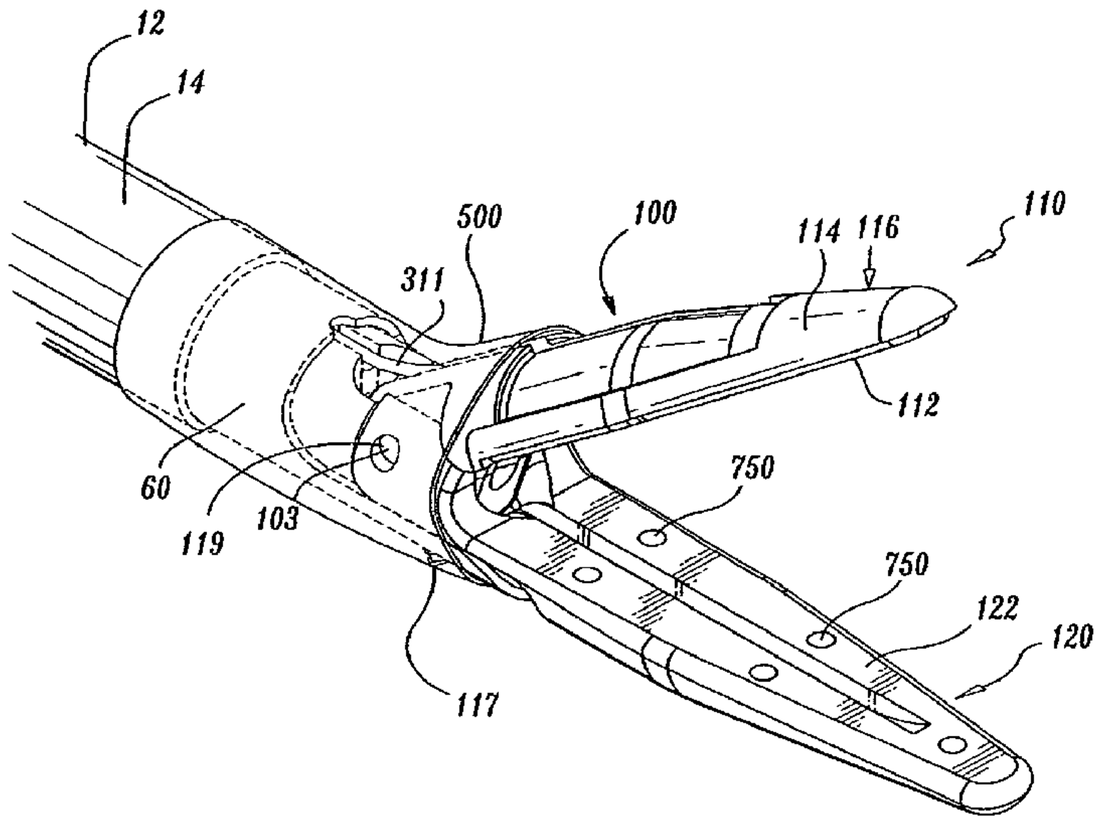
(57) **ABSTRACT**

Either an endoscopic or open bipolar forceps includes a flexible, generally tubular insulating boot for insulating patient tissue, while not impeding motion of the jaw members. The jaw members are movable from an open to a closed position and the jaw members are connected to a source of electrosurgical energy such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal. A knife assembly may be included that allows a user to selectively divide tissue upon actuation thereof. The insulating boot may be made from a viscoelastic, elastomeric or flexible material suitable for use with a sterilization process including ethylene oxide.

16 Claims, 28 Drawing Sheets



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Int'l Search Report EP 07 021646.0 dated Jul. 9, 2008.
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Int'l Search Report EP 08 006917.2 dated Jul. 3, 2008.
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Int'l Search Report EP 09 152267.2 Dated Jun. 15, 2009.
Int'l Search Report EP 09 152898.4 Dated Jun. 10, 2009.
Int'l Search Report PCT/US98/24281 dated Feb. 22, 1999.
Int'l Search Report PCT/US03/28534 dated Dec. 19, 2003.
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Int'l Search Report PCT/US07/021440 dated Apr. 8, 2008.
Int'l Search Report PCT/US08/61498 dated Sep. 22, 2008.
Int'l Search Report PCT/US09/032690 dated Jun. 16, 2009.

* cited by examiner

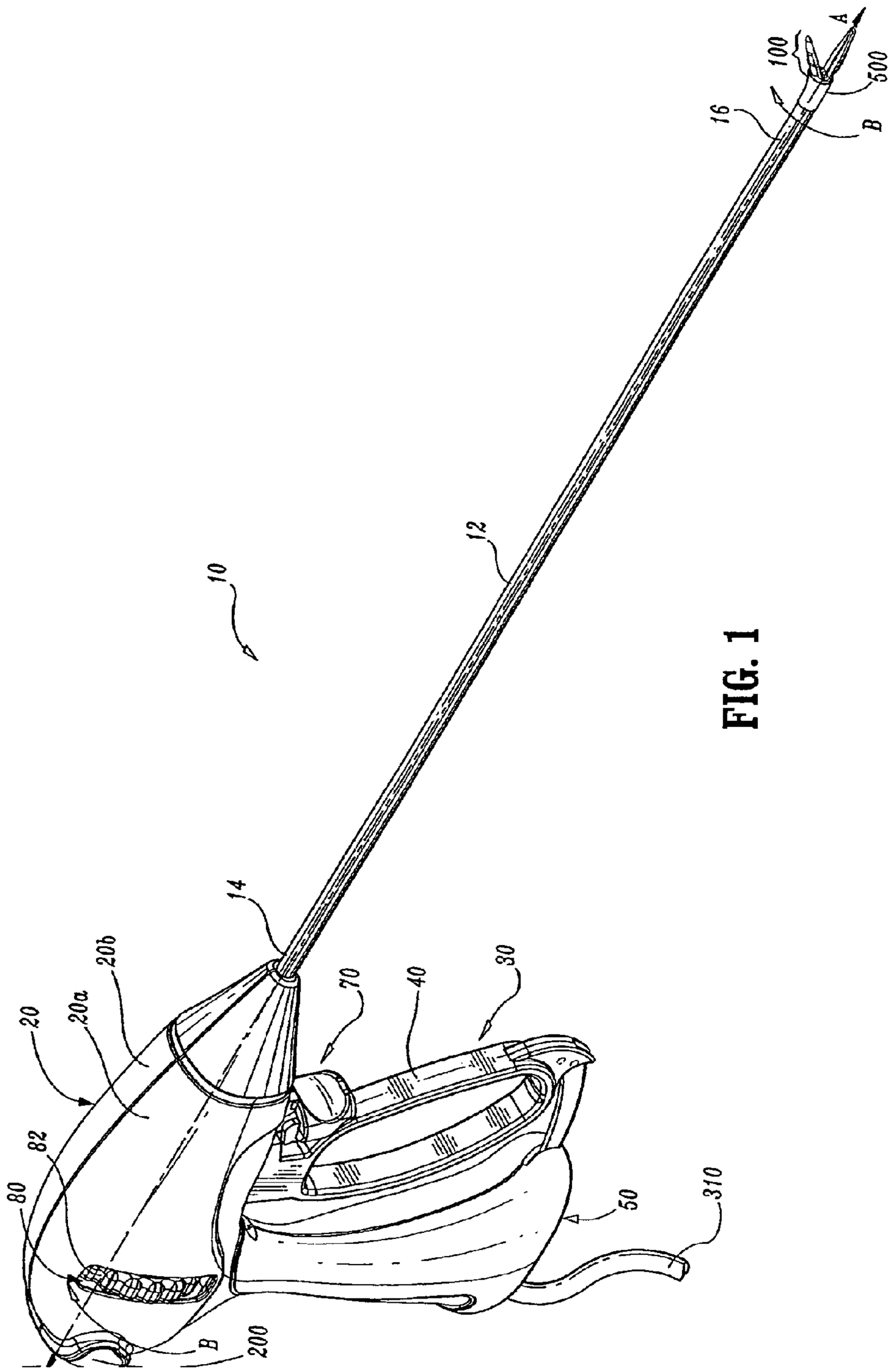
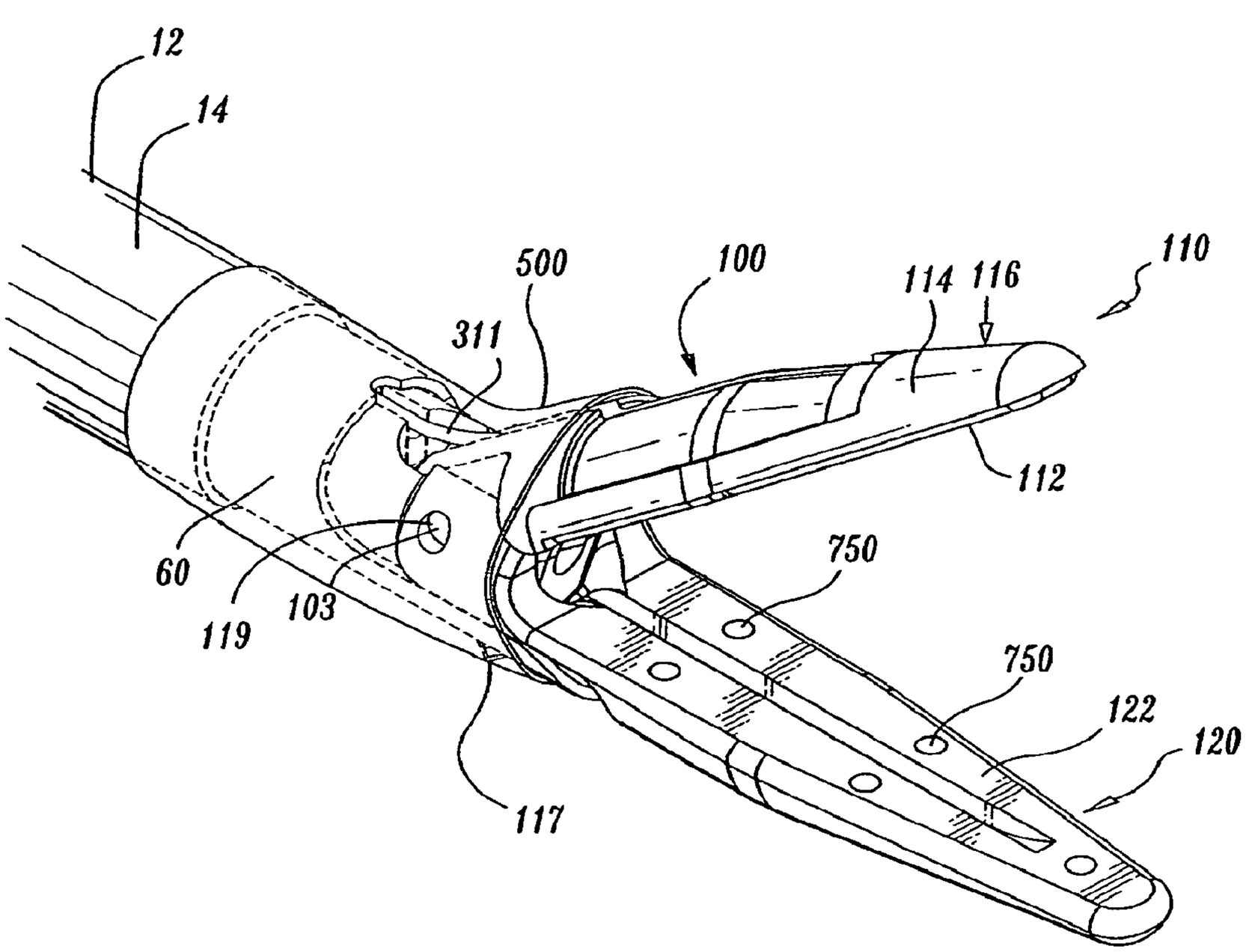


FIG. 1



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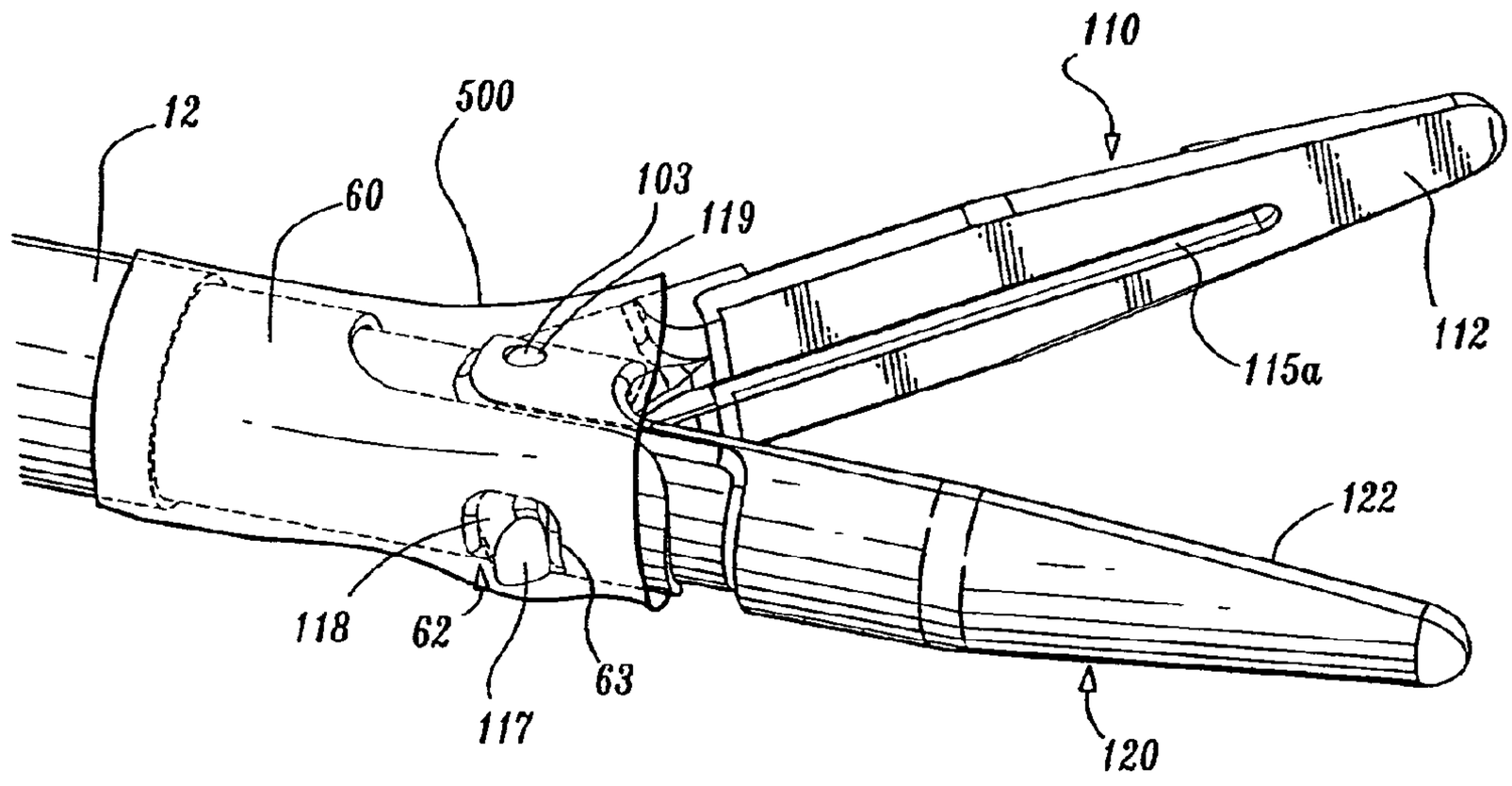

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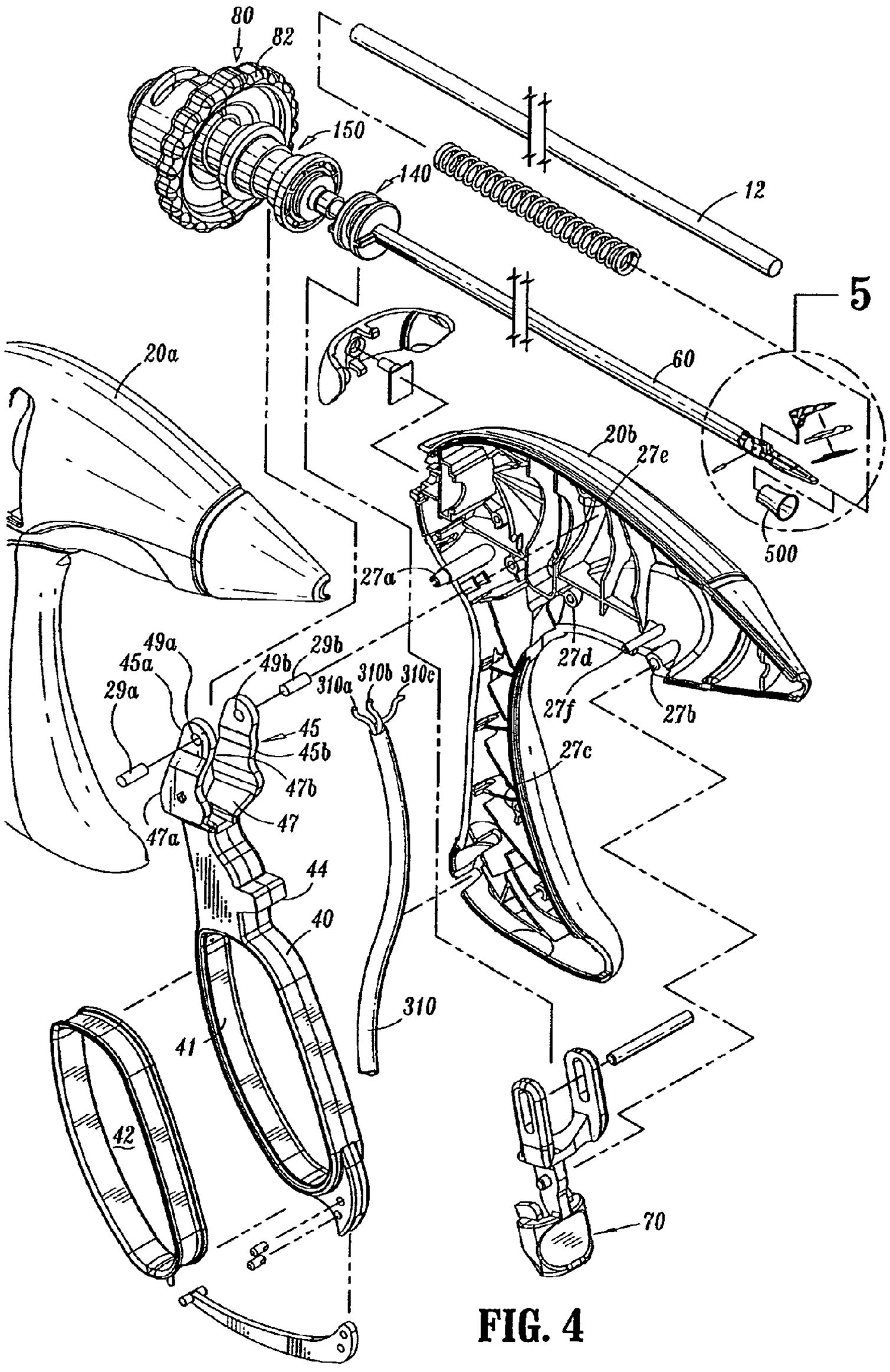
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45a
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29b
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310b
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47b
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42
310
27d
27f
27b
27c
70

FIG. 4

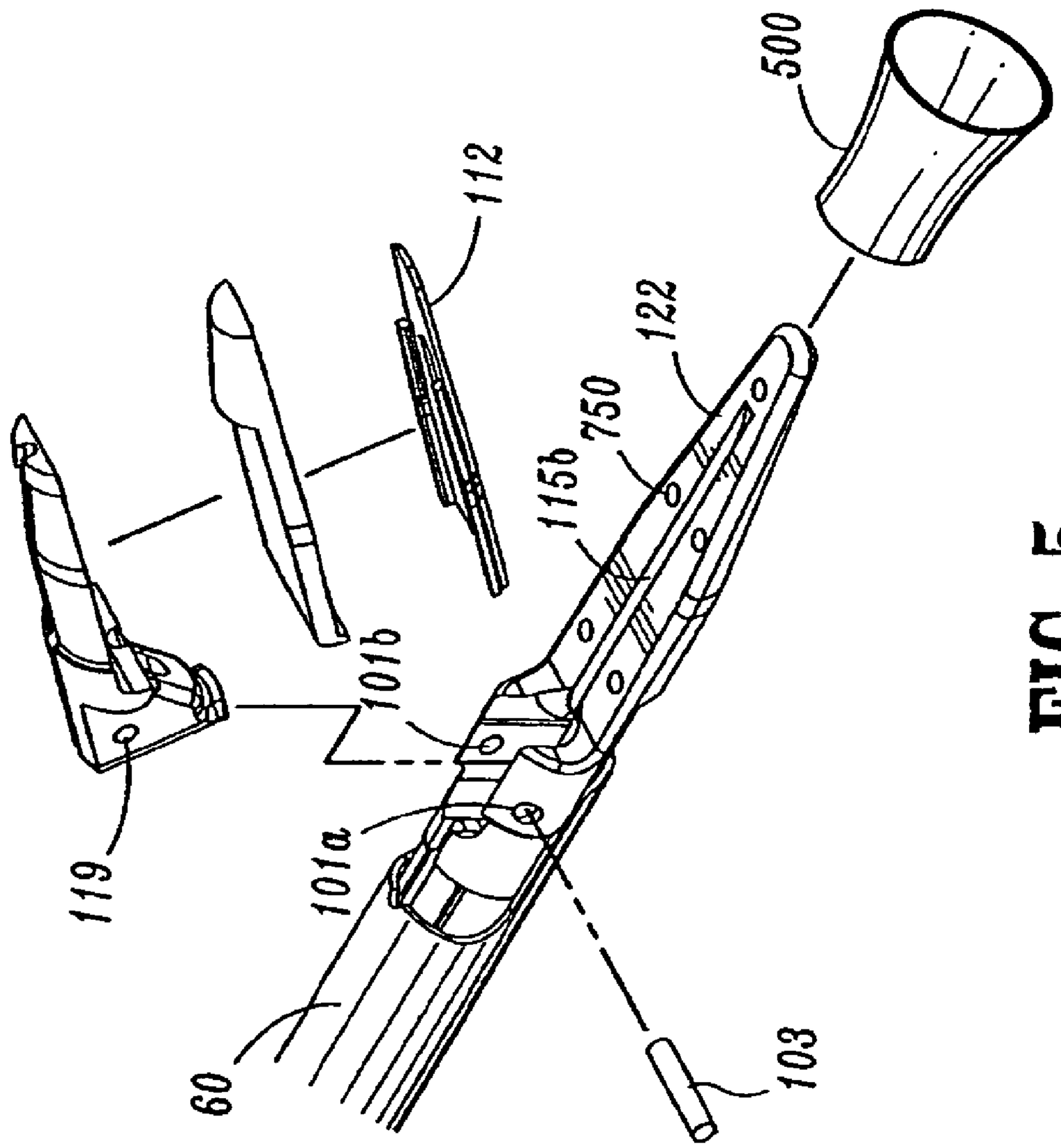


FIG. 5

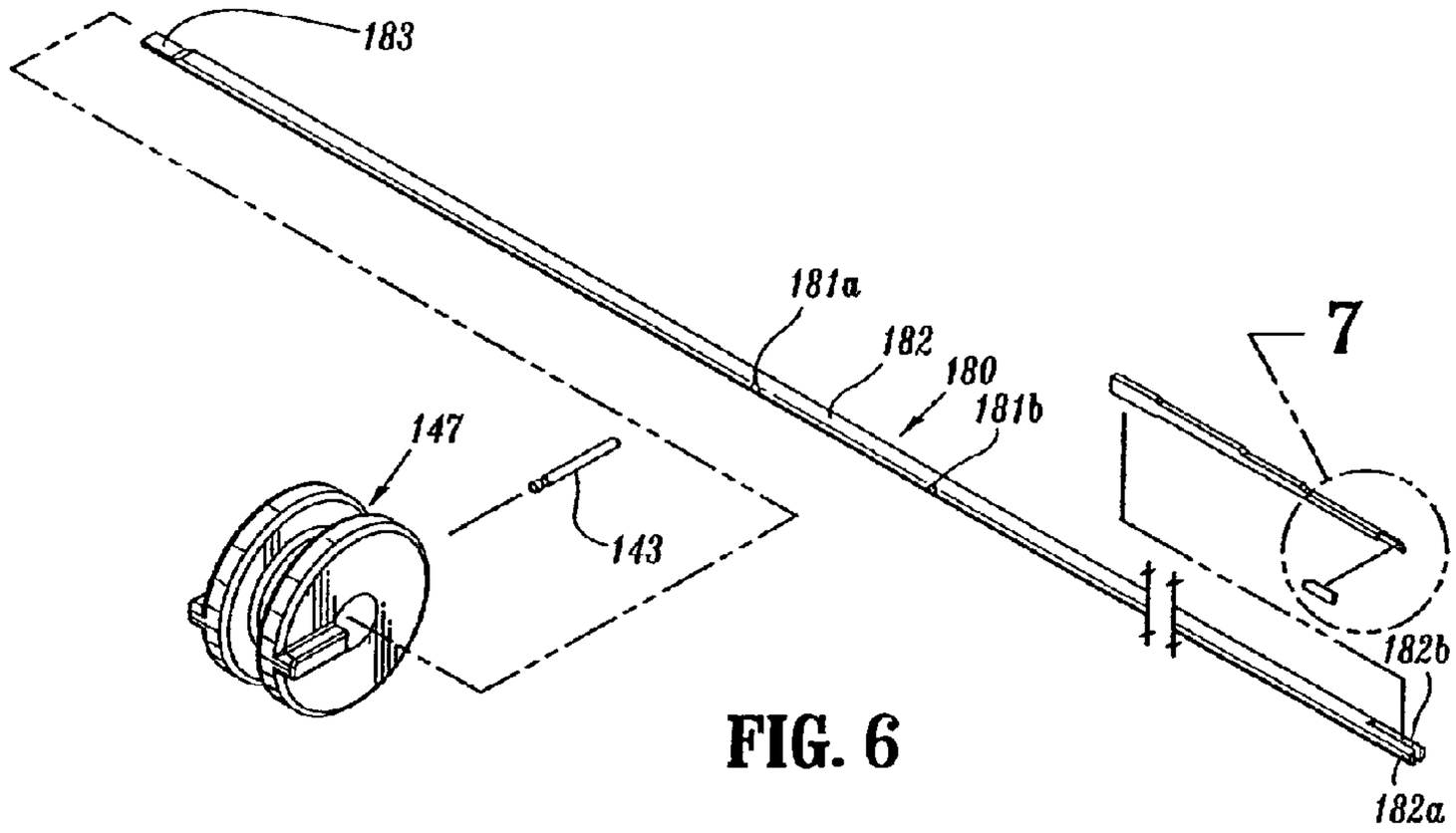


FIG. 6

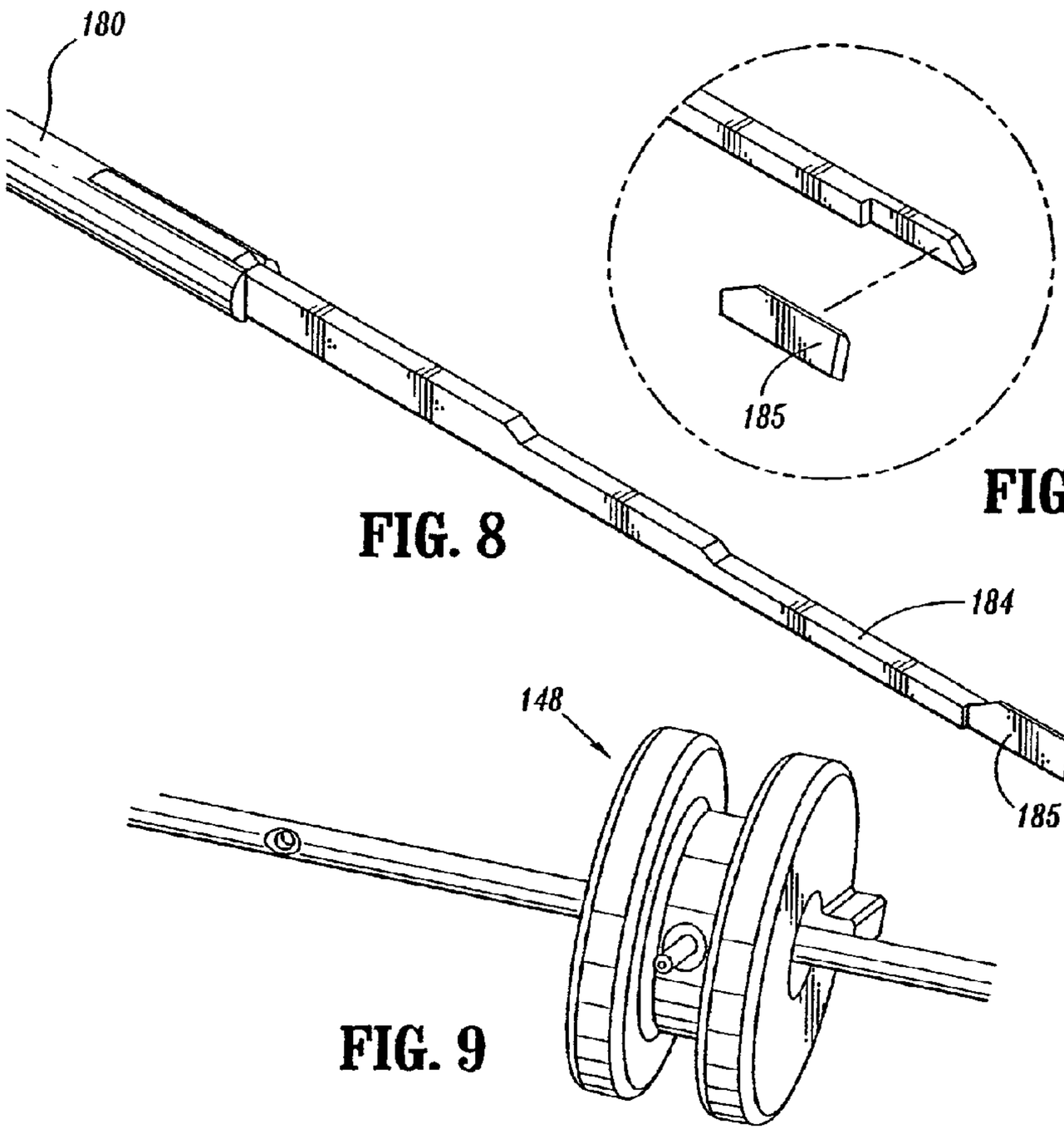
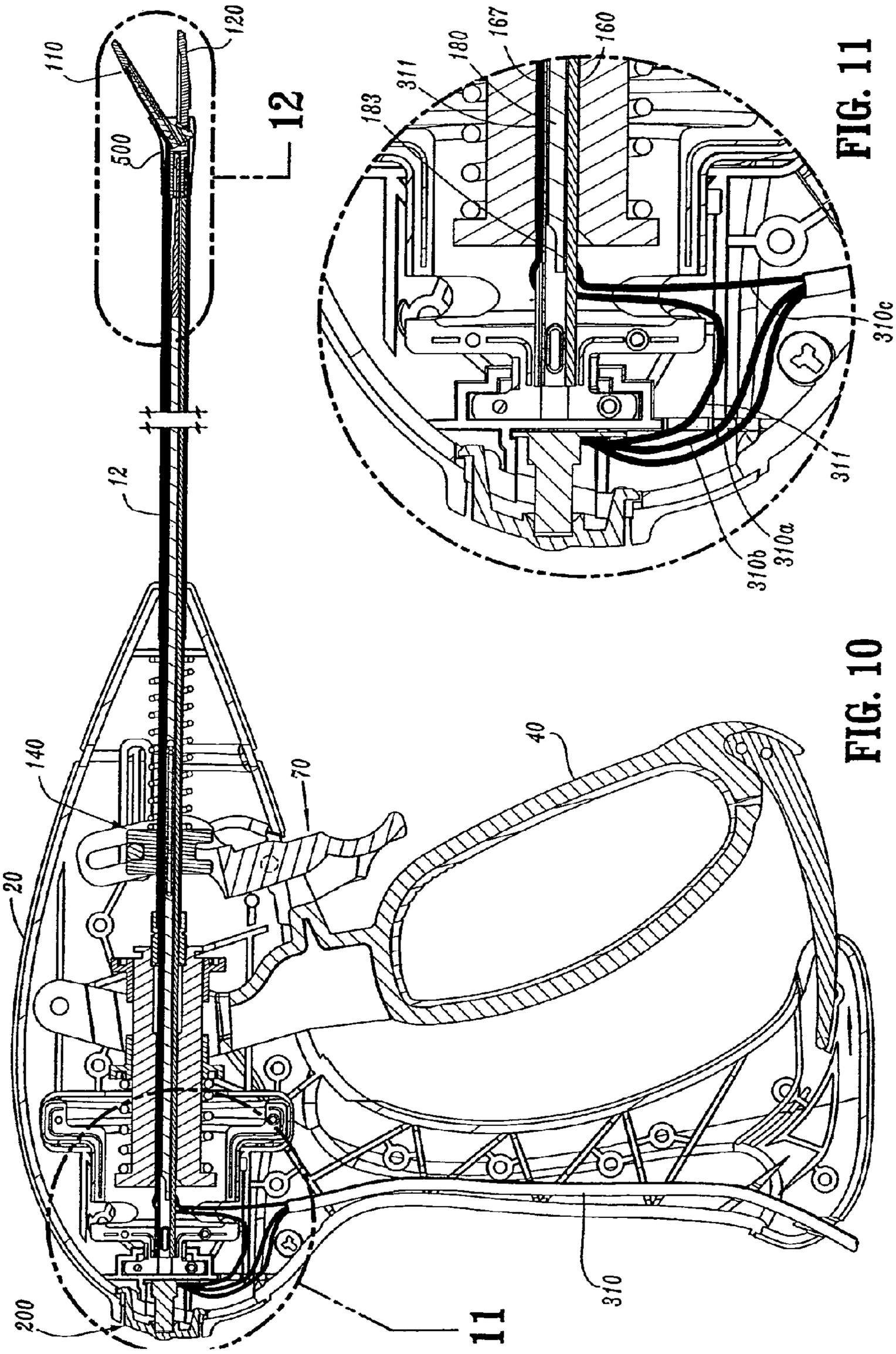


FIG. 8

FIG. 7

FIG. 9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160
310c
311
310b
310a
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40
20
200
310
11

FIG. 10

FIG. 11

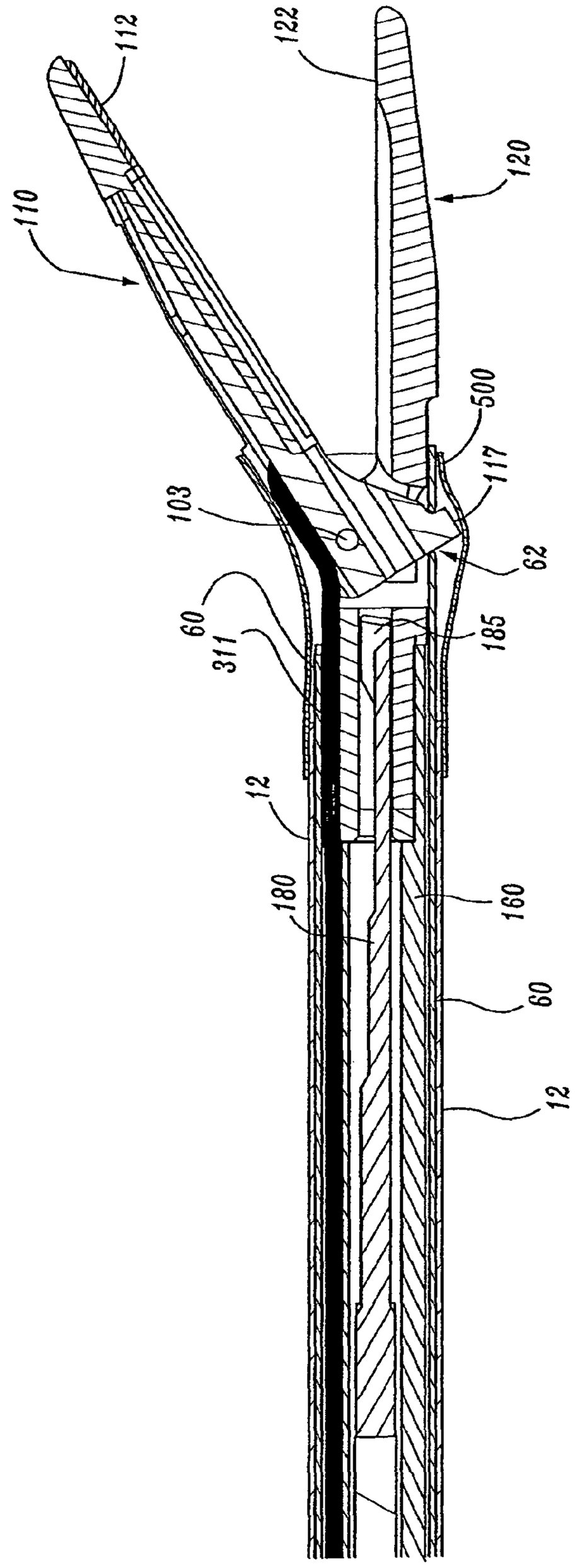


FIG. 12

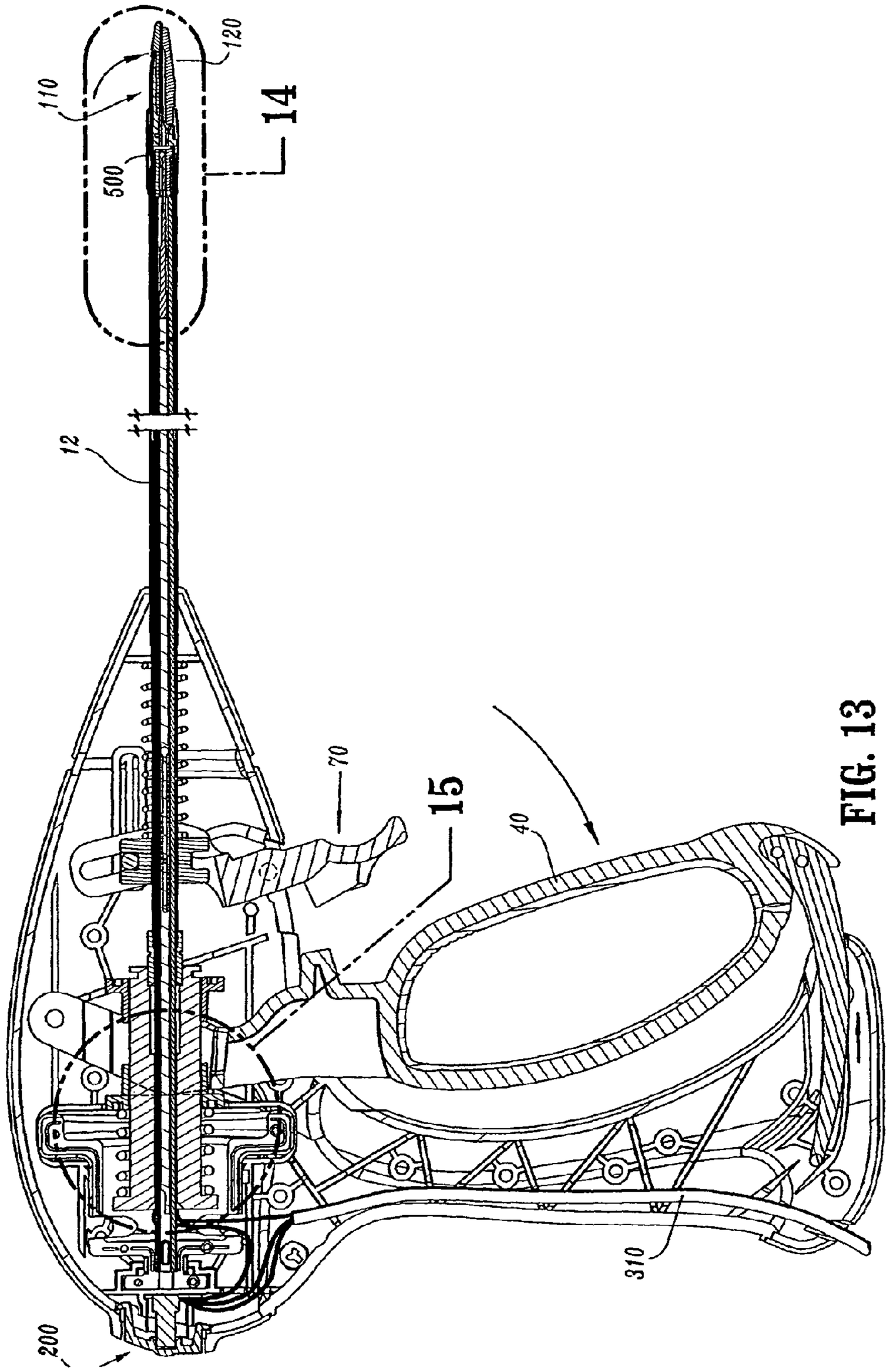
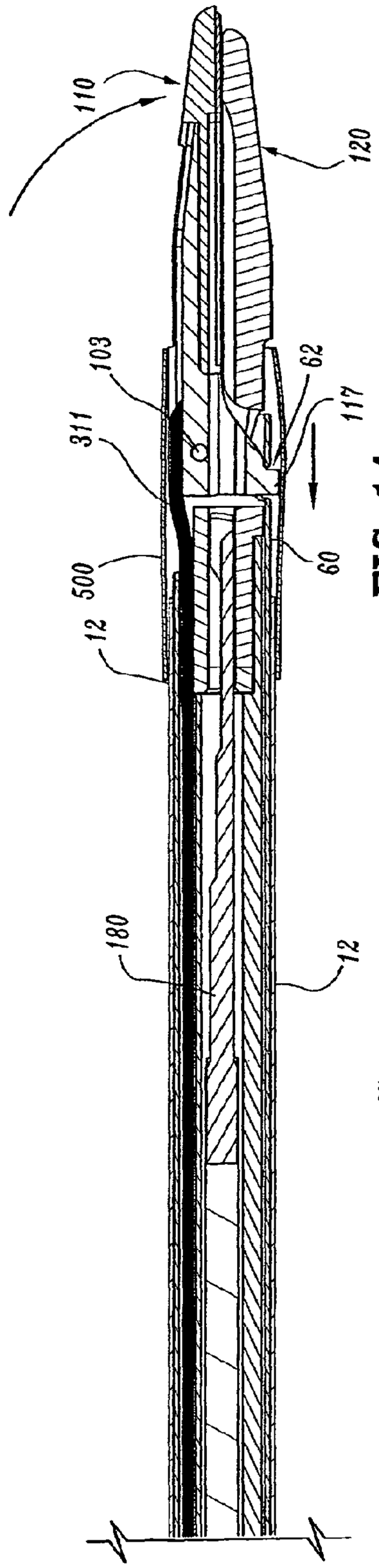


FIG. 13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117
500
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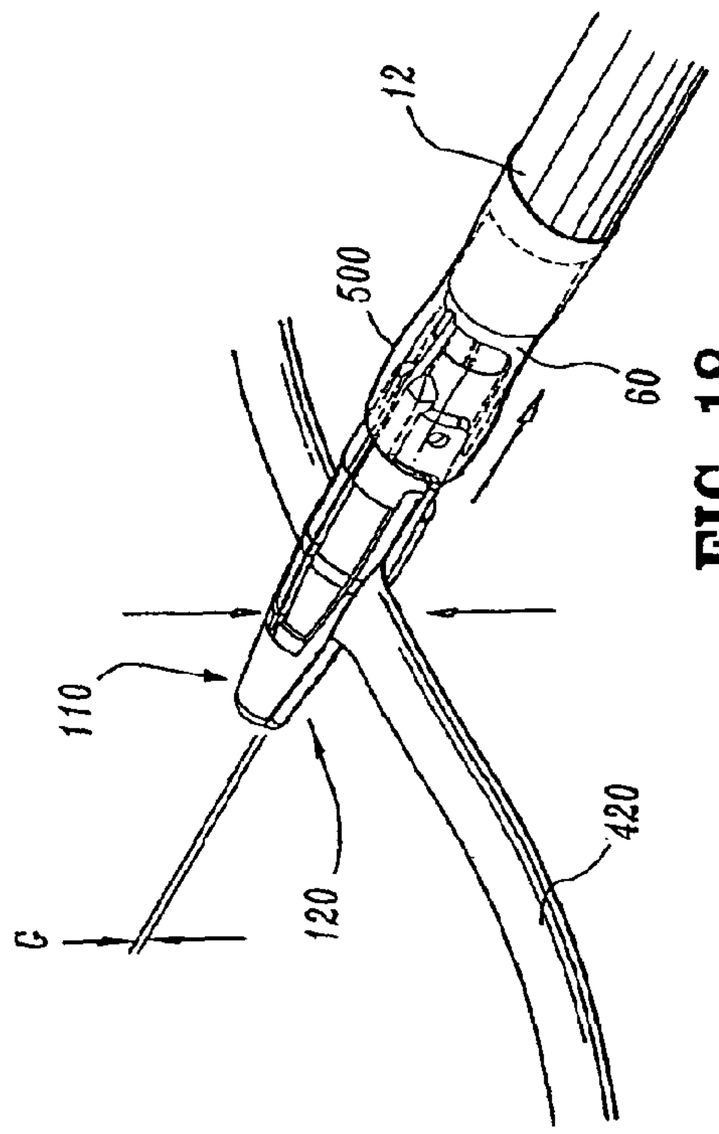
12
180
12

FIG. 14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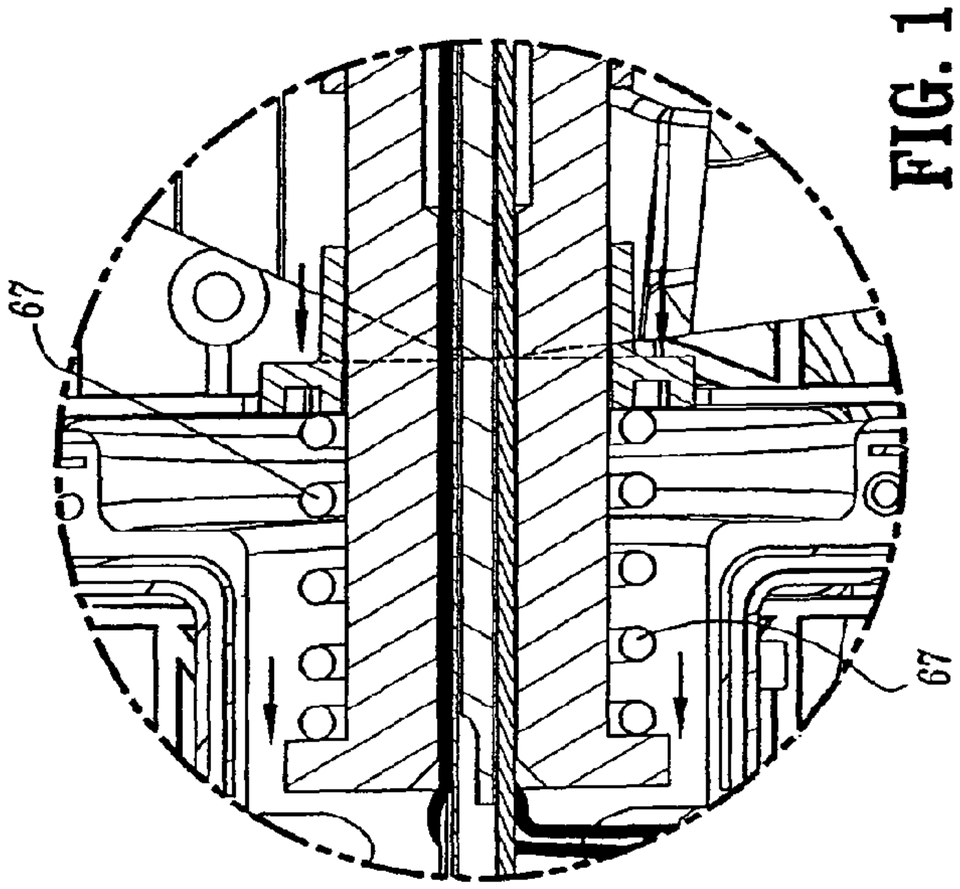
500
60
110
120
C
420

FIG. 15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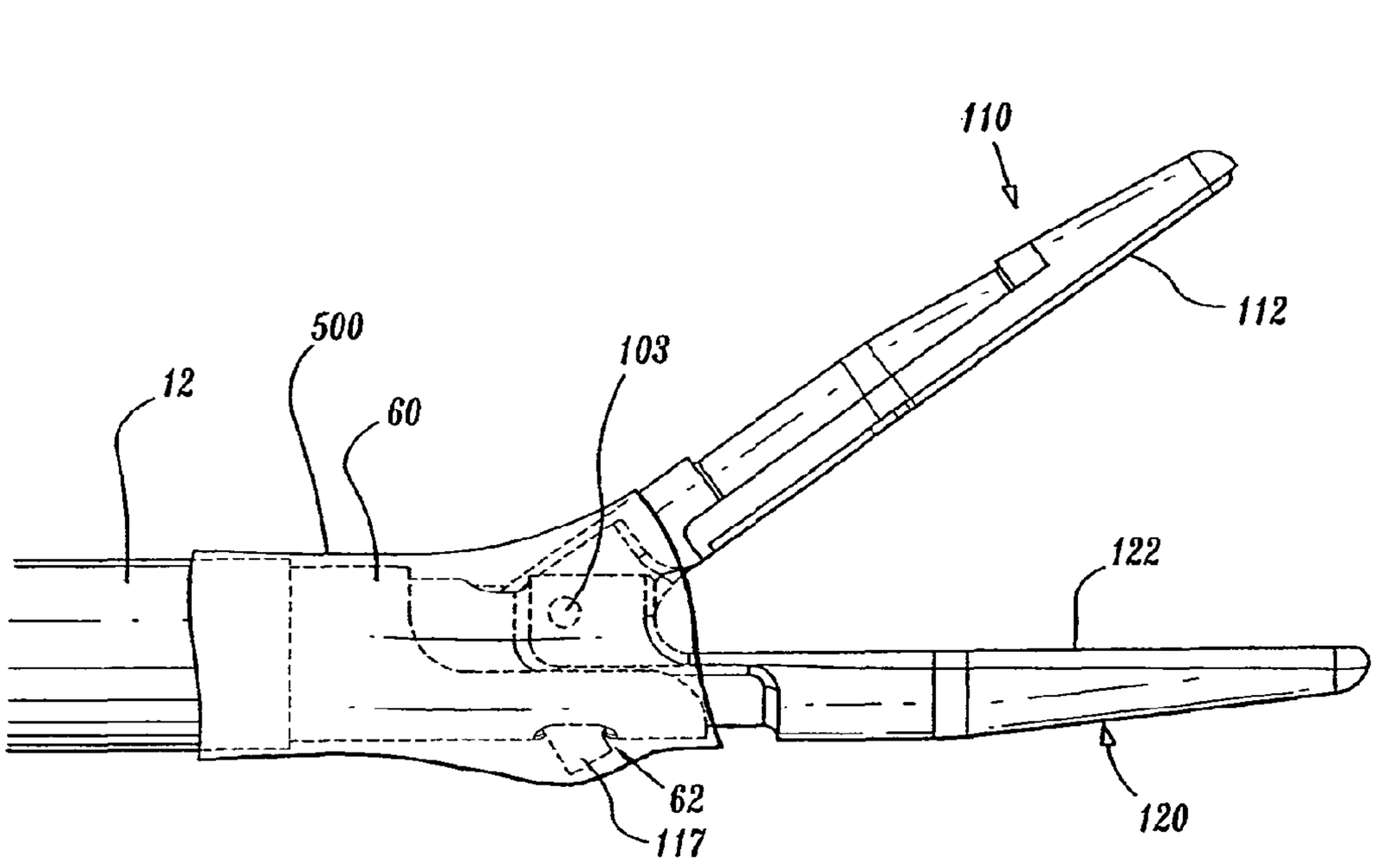


FIG. 16

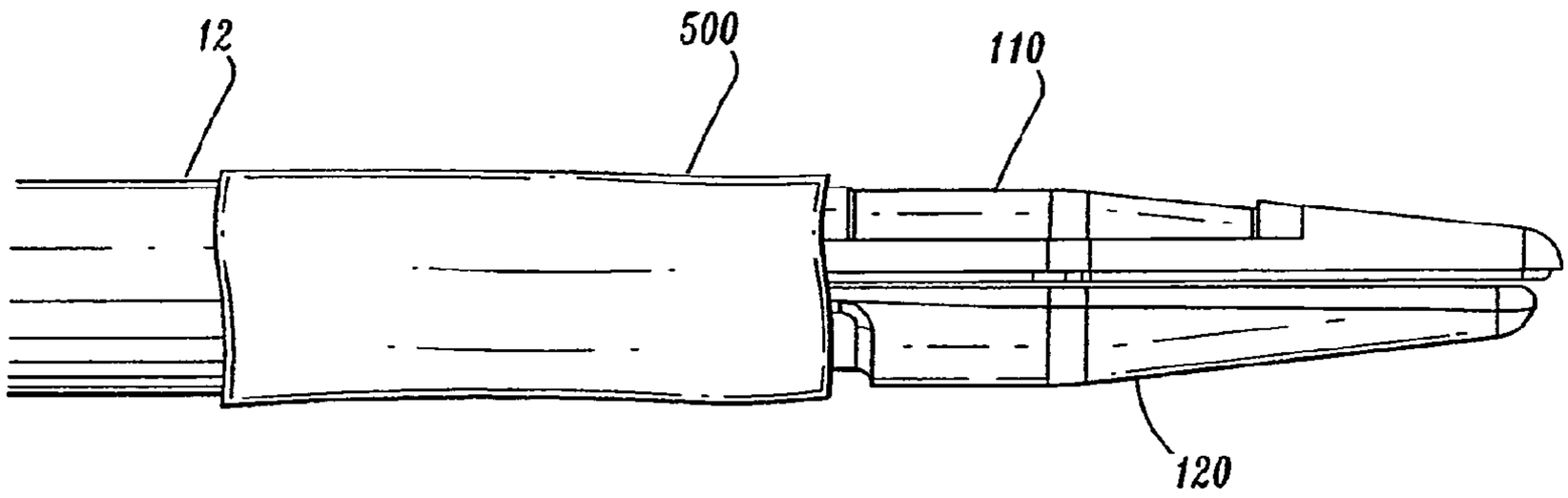


FIG. 17

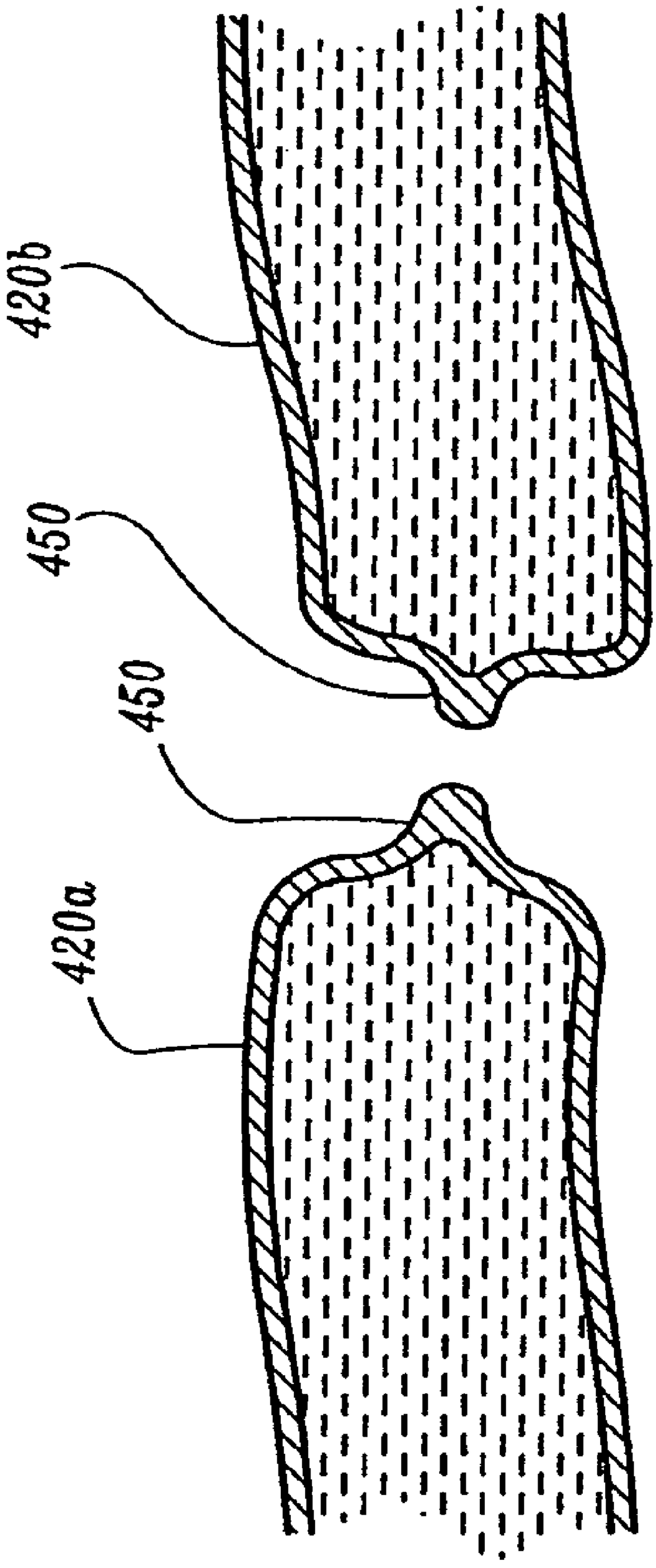
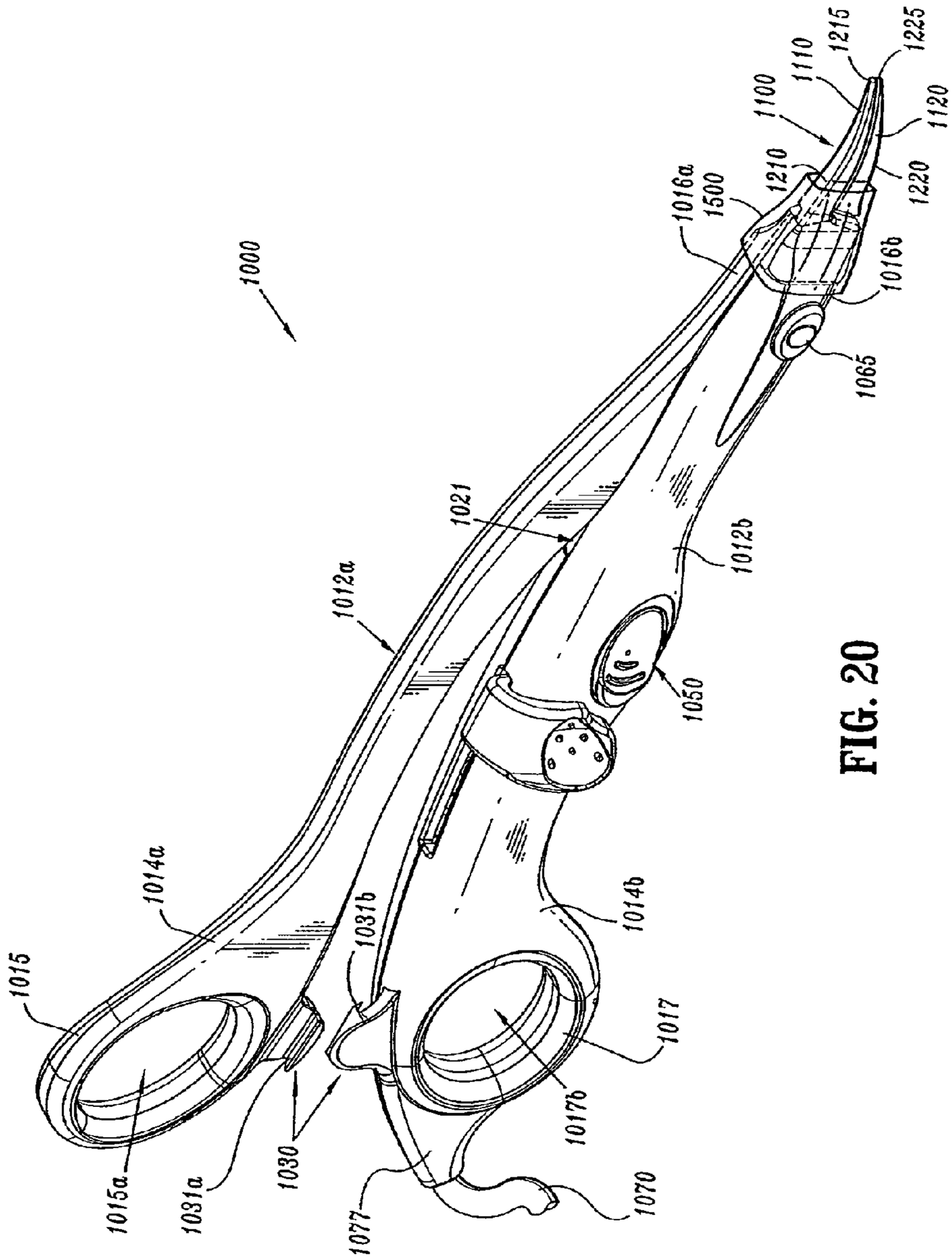


FIG. 19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1012a
1021
1012b
1014a
1014b
1015
1015a
1016a
1016b
1017
1017b
1030
1031a
1031b
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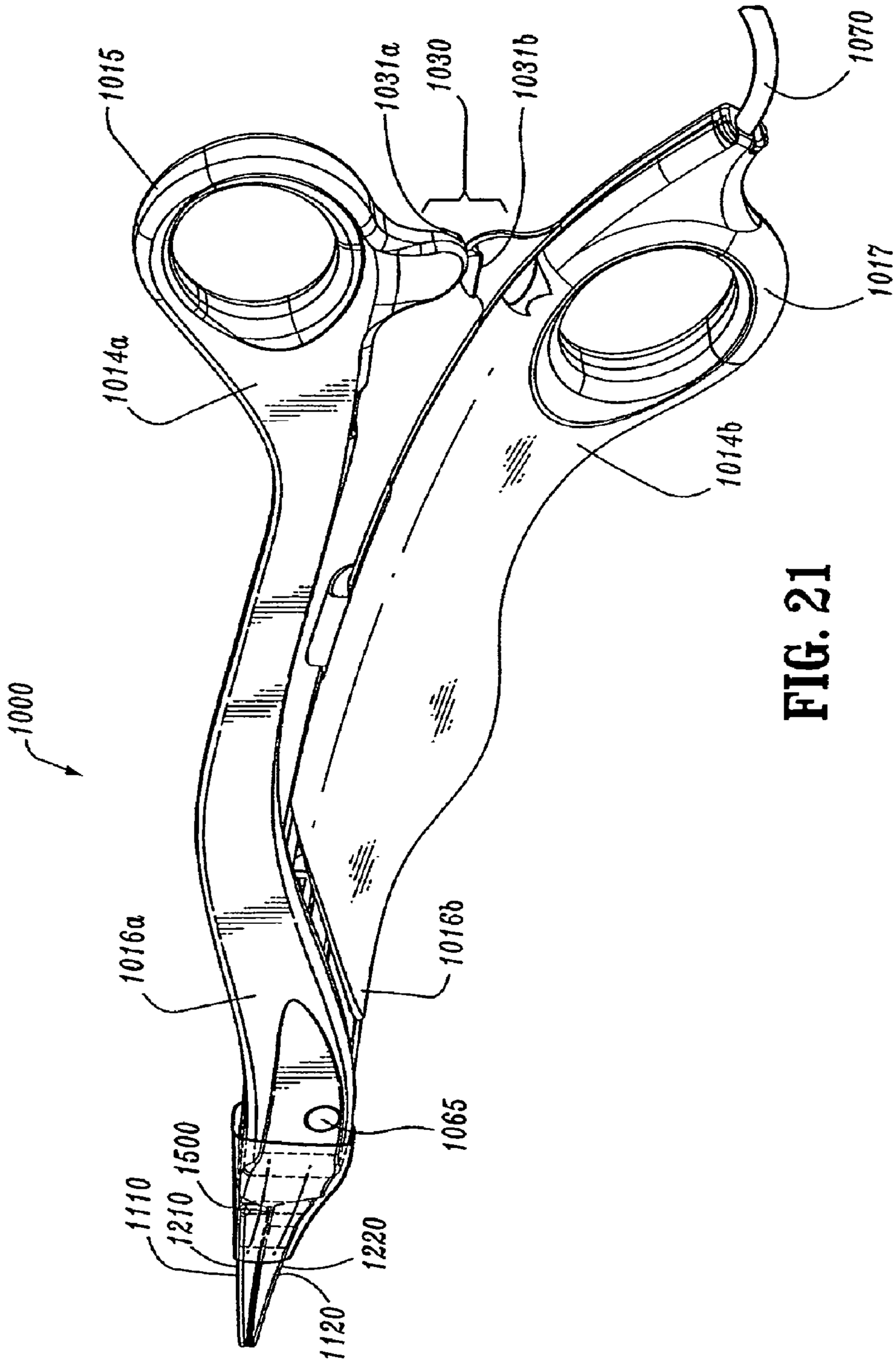
1120
1210
1215
1220
1225
1500

FIG. 20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1016a
1016b
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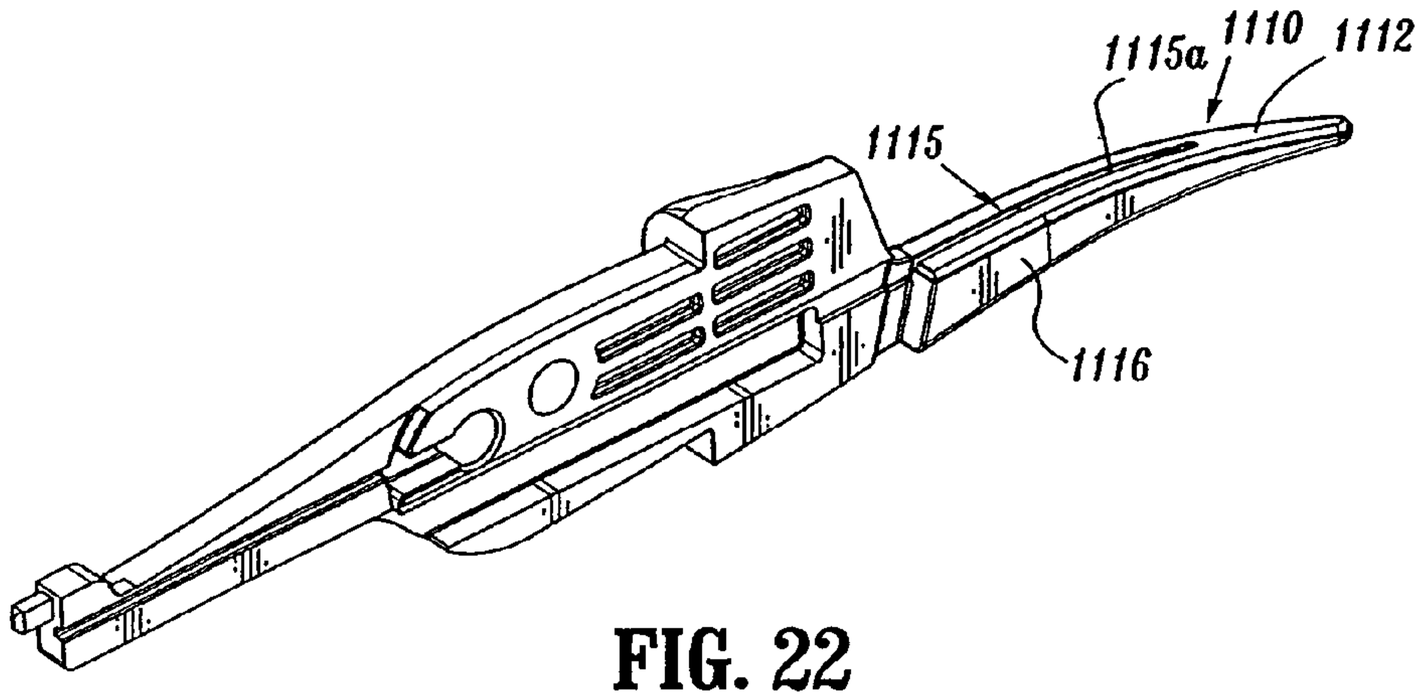
1110
1210
1500
1220
1120

FIG. 21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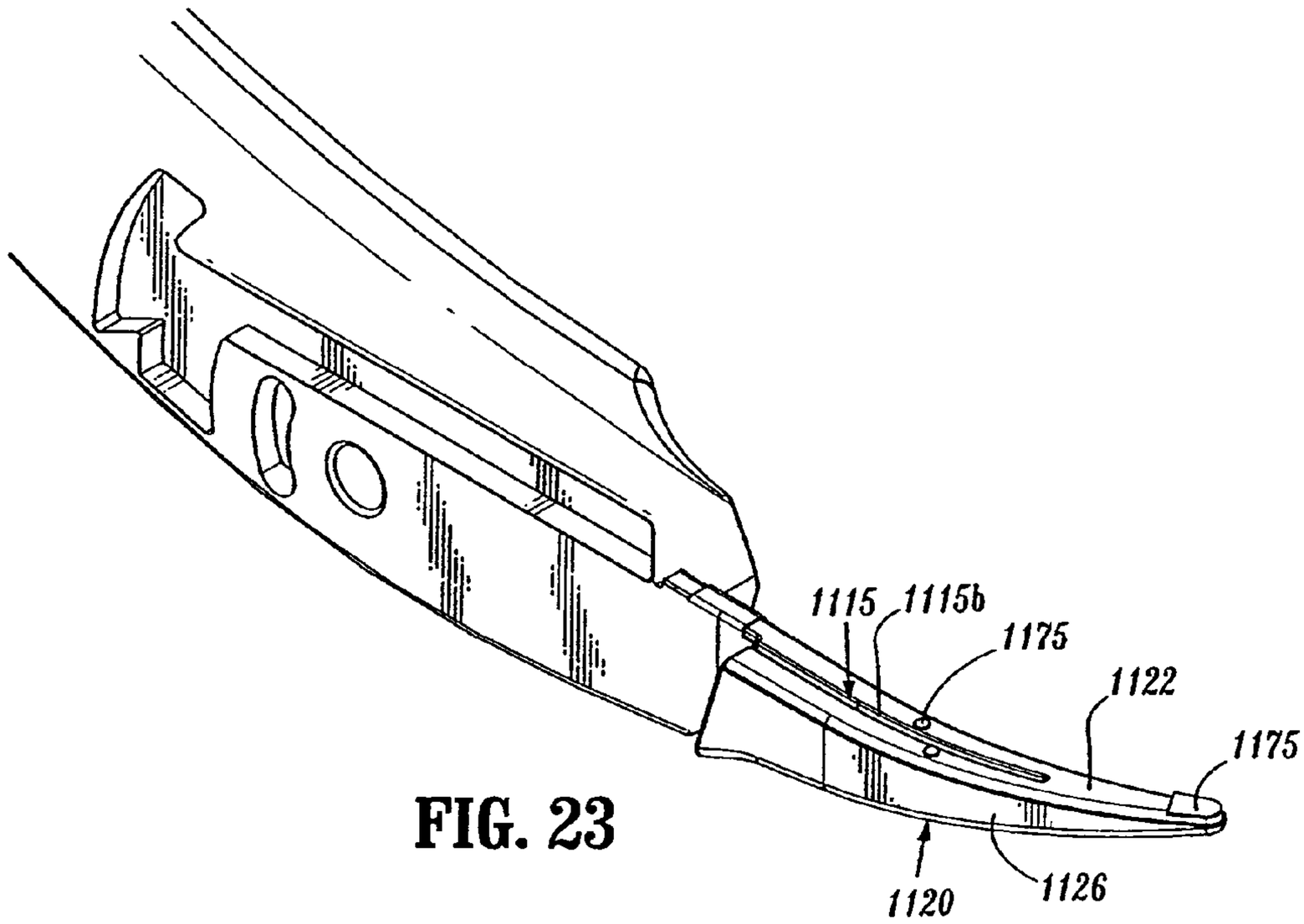
1115
1116

FIG. 22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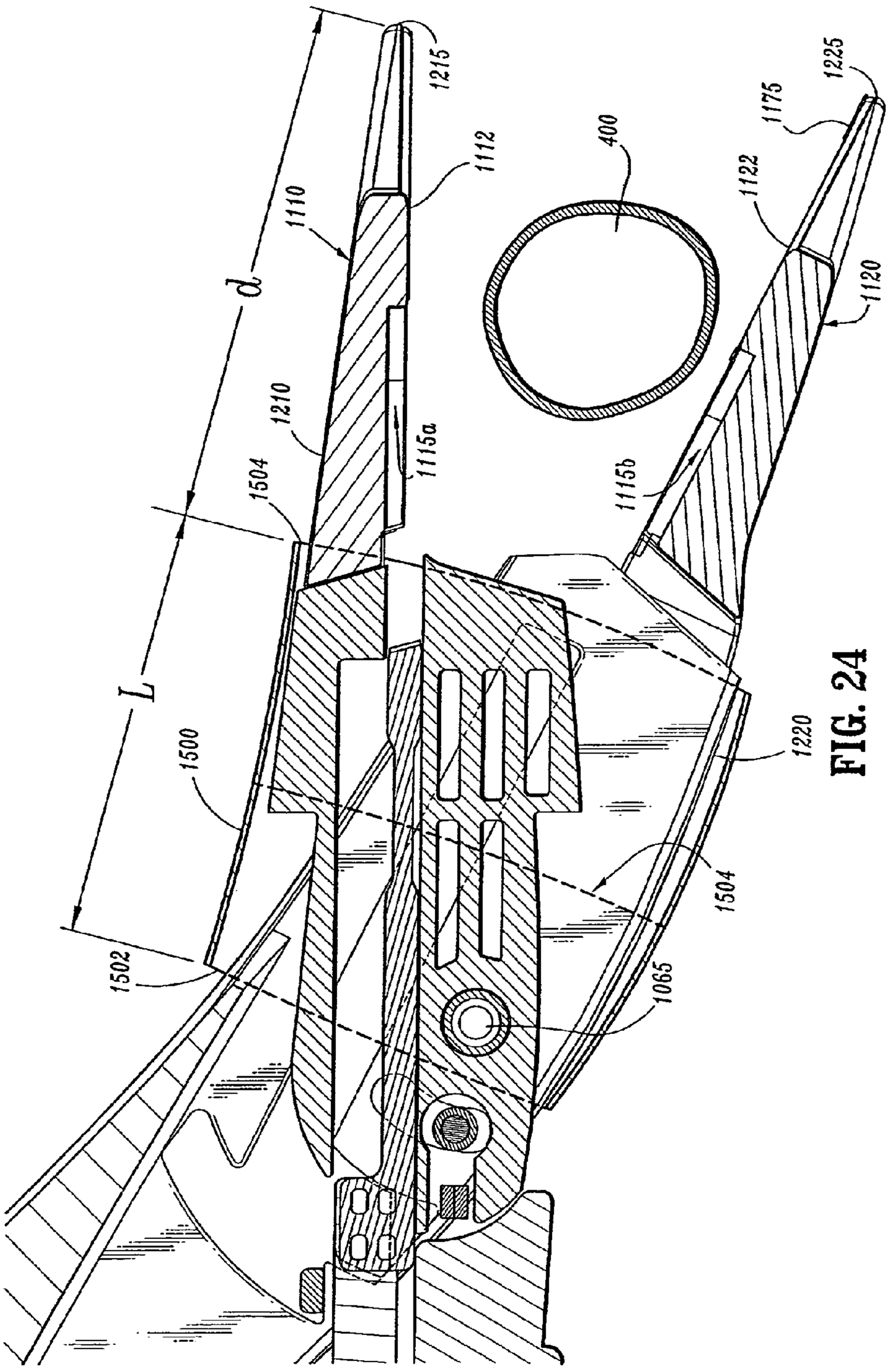
1175
1120
1126

FIG. 23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d
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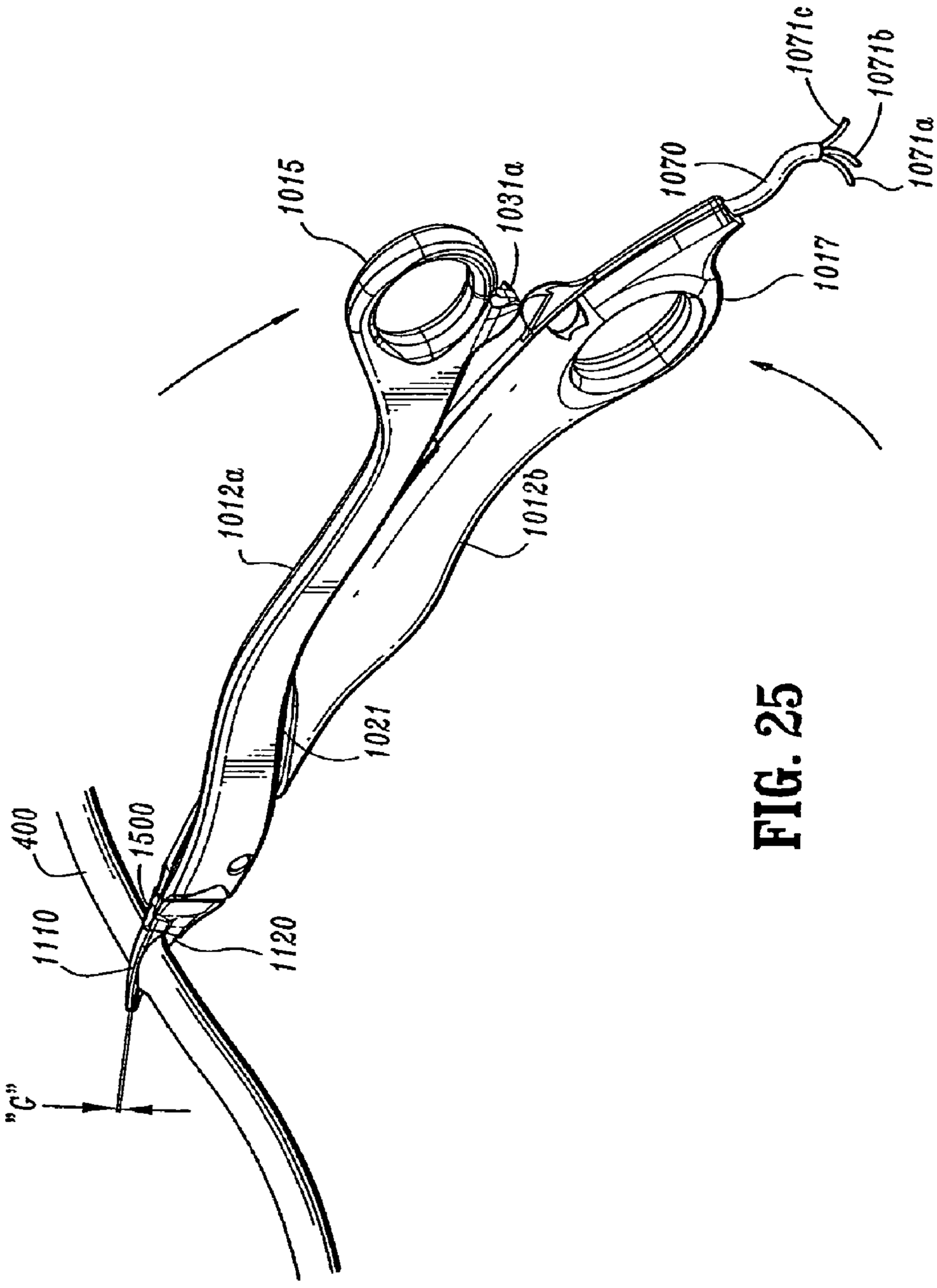
1210
1115a
1504
1115b
L
1500
1220
1504
1502
1065

FIG. 24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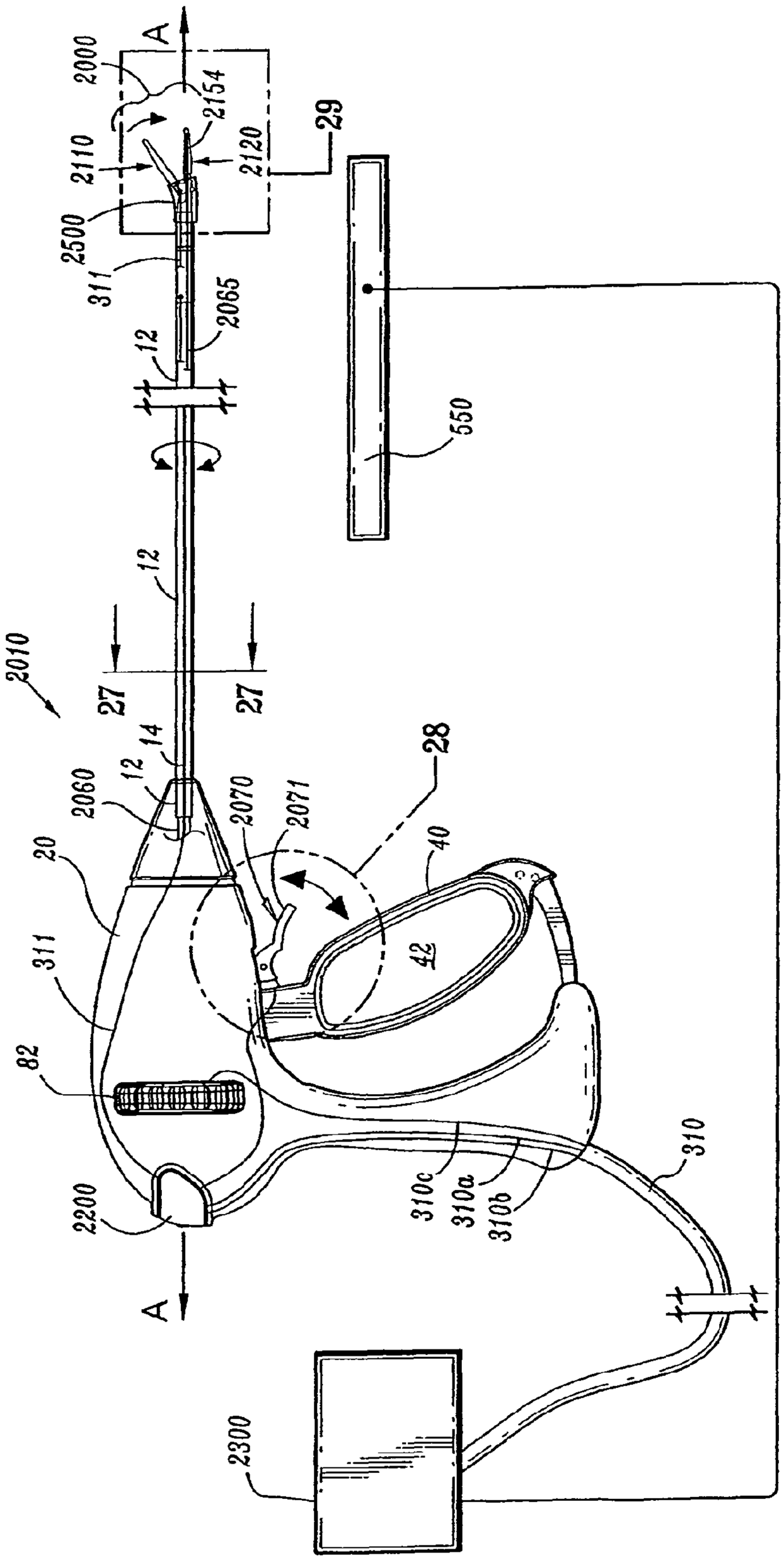
1120
"C"

FIG. 25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2110
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14
28
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310a
310b
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A
2300

FIG. 26

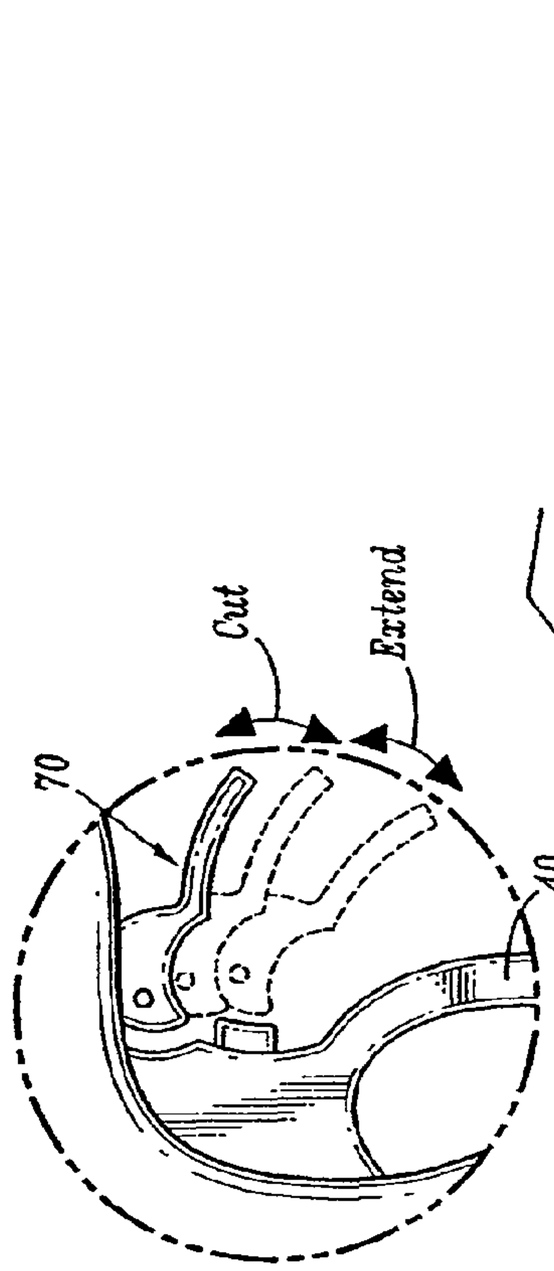


FIG. 28

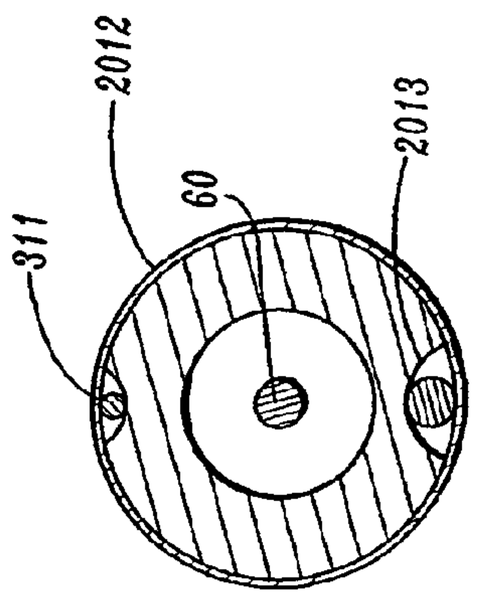


FIG. 27

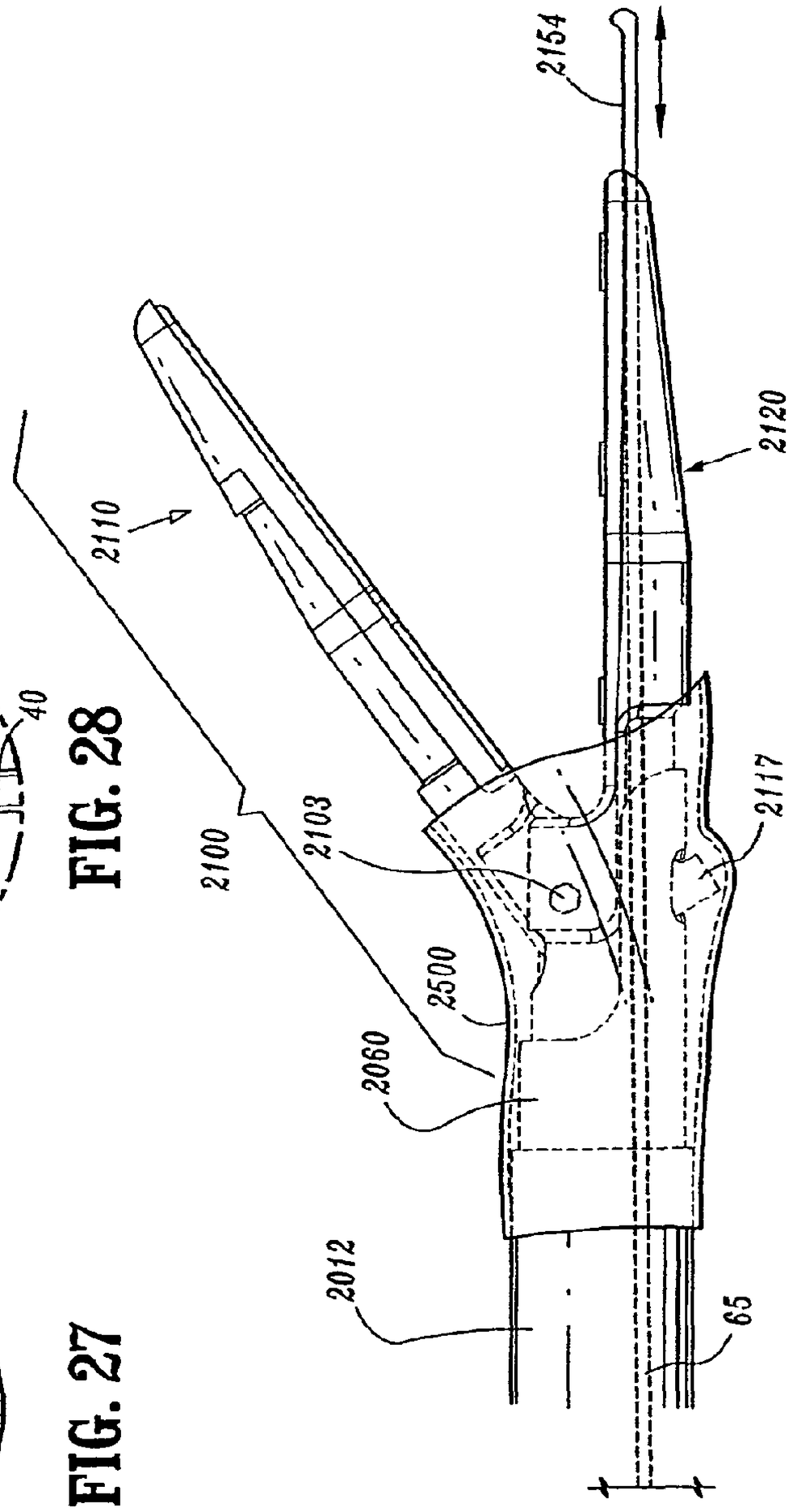


FIG. 29

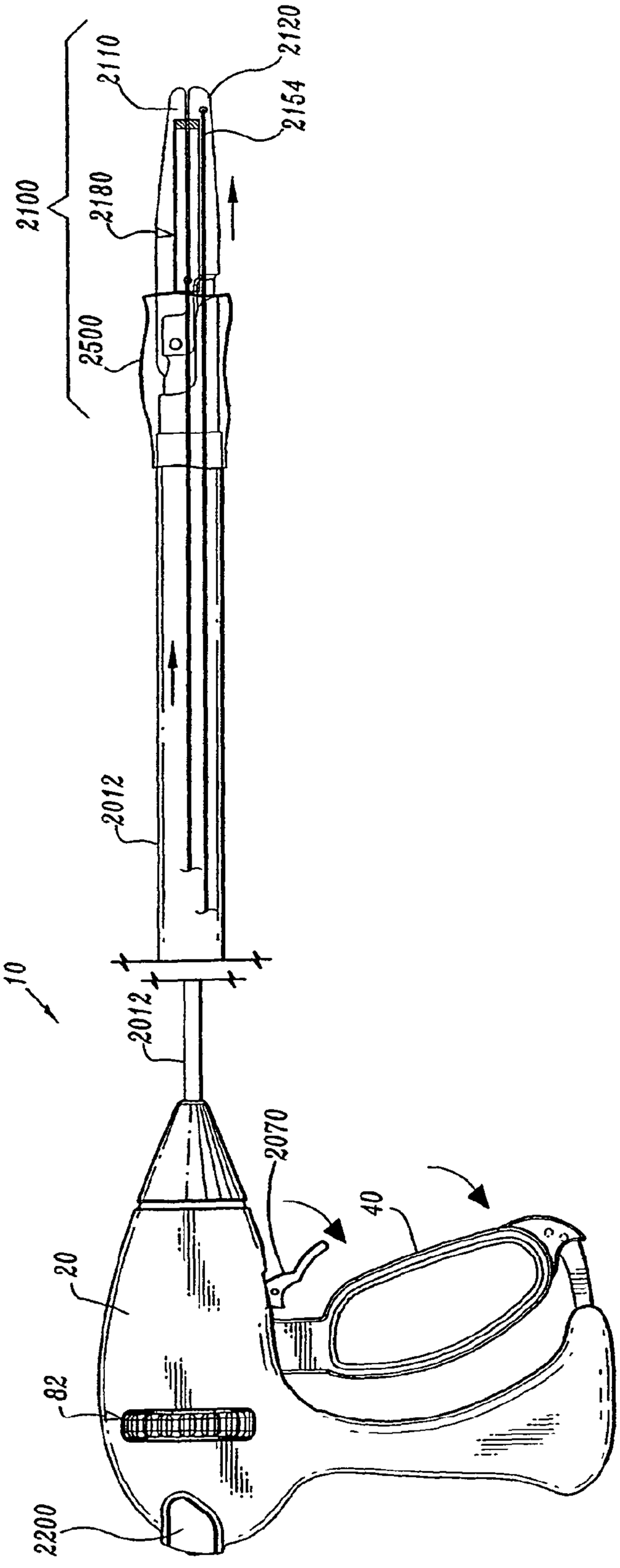


FIG. 30

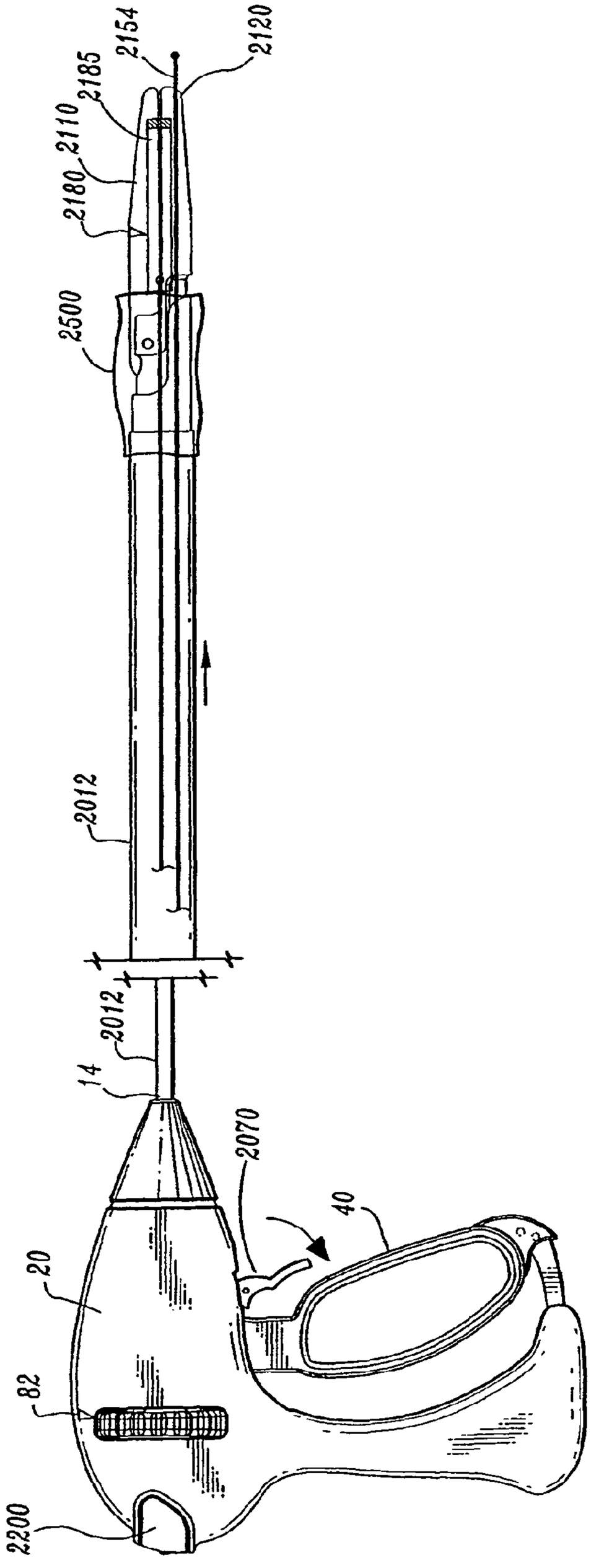
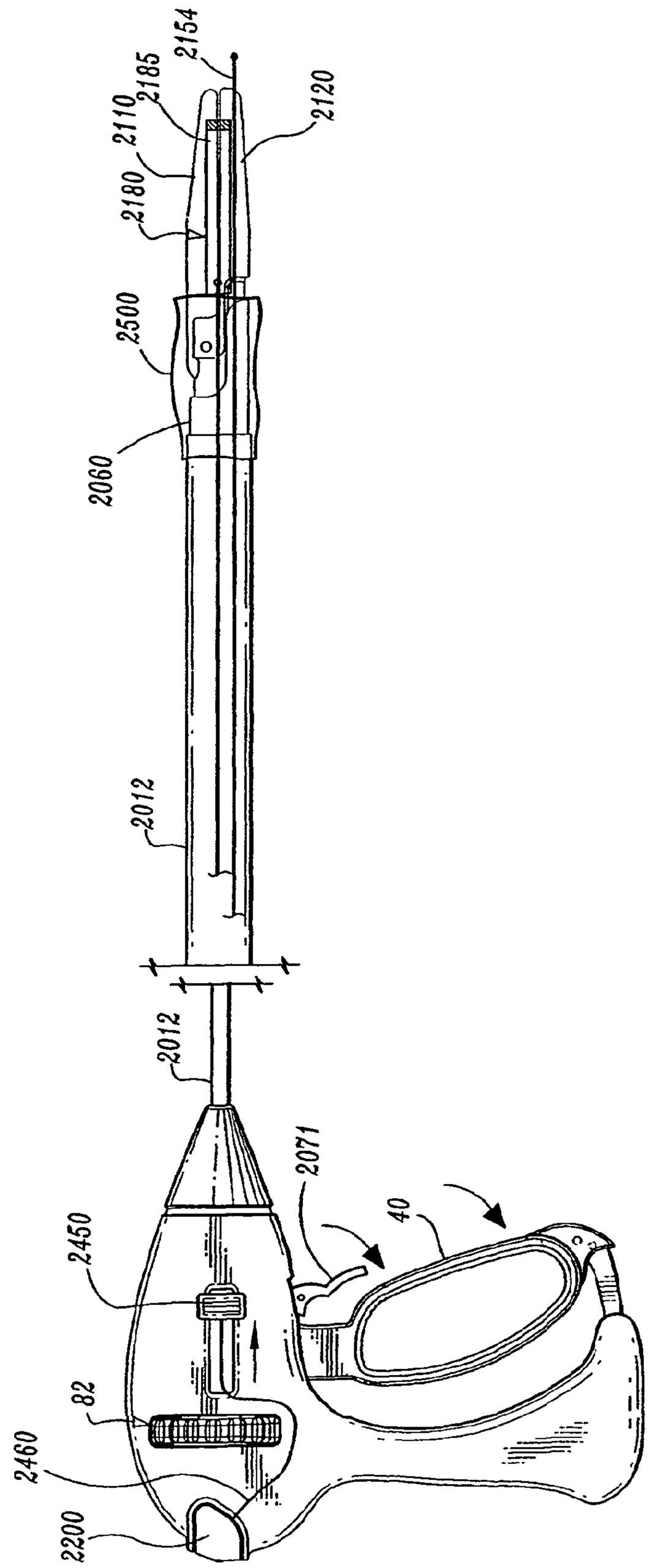


FIG. 31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2200

FIG. 32

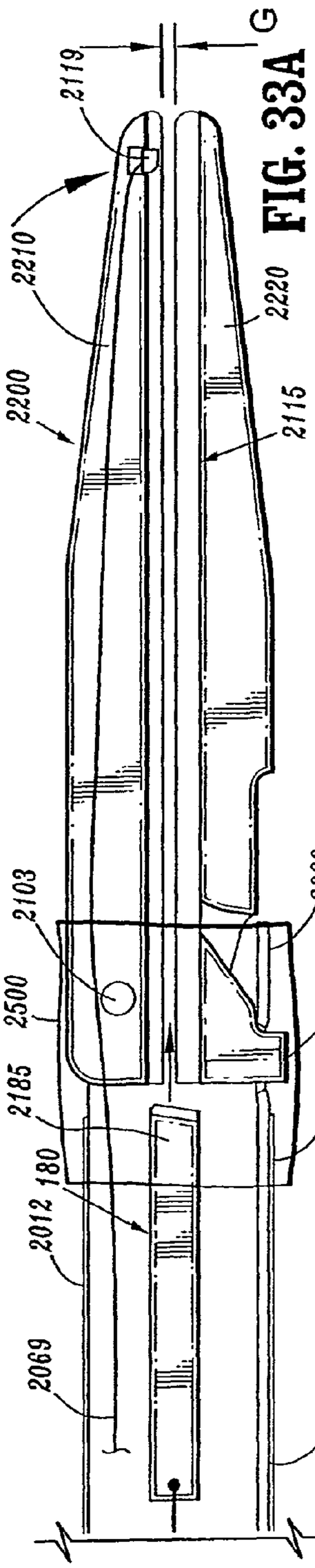

FIG. 33A

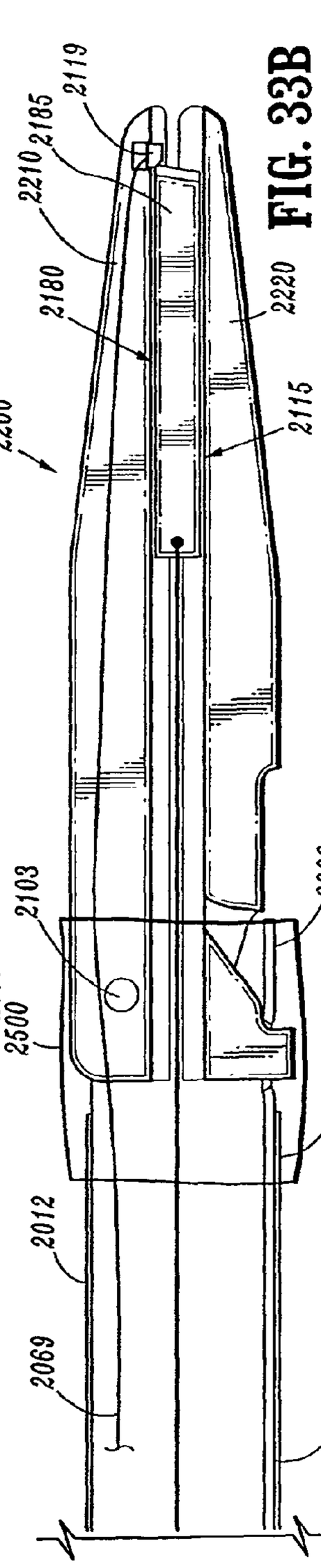

FIG. 33B

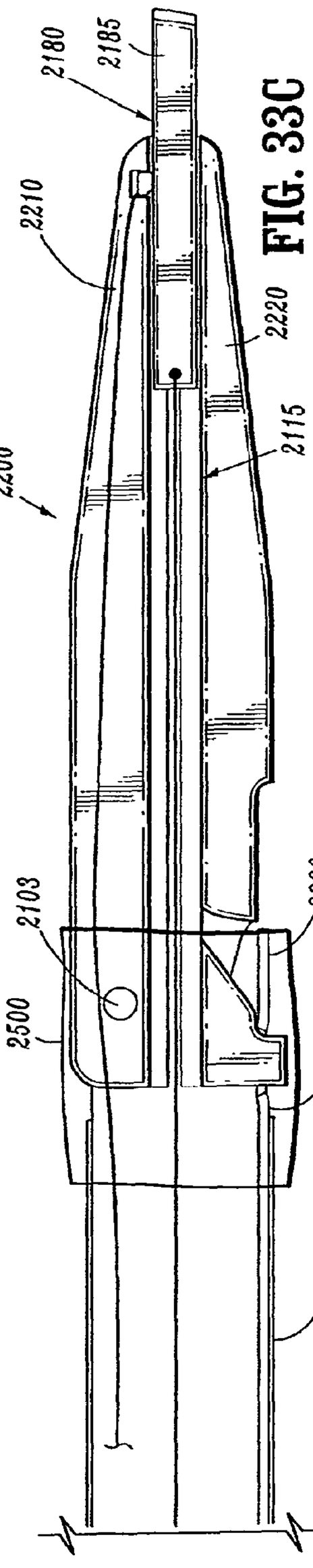

FIG. 33C

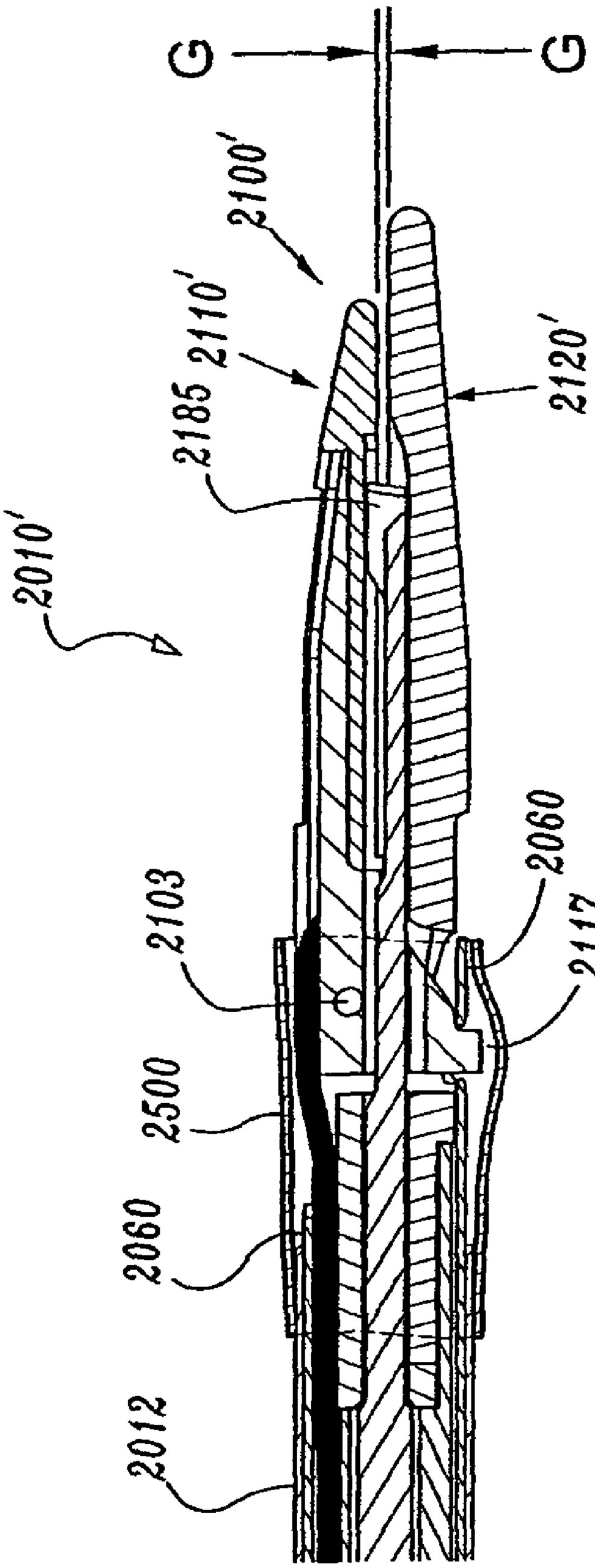

FIG. 34A

Mode	A	B	C
Off	Off	Off	Off
Bi Polar	Off	-	+
Mono Polar	-	+	+

FIG. 34C

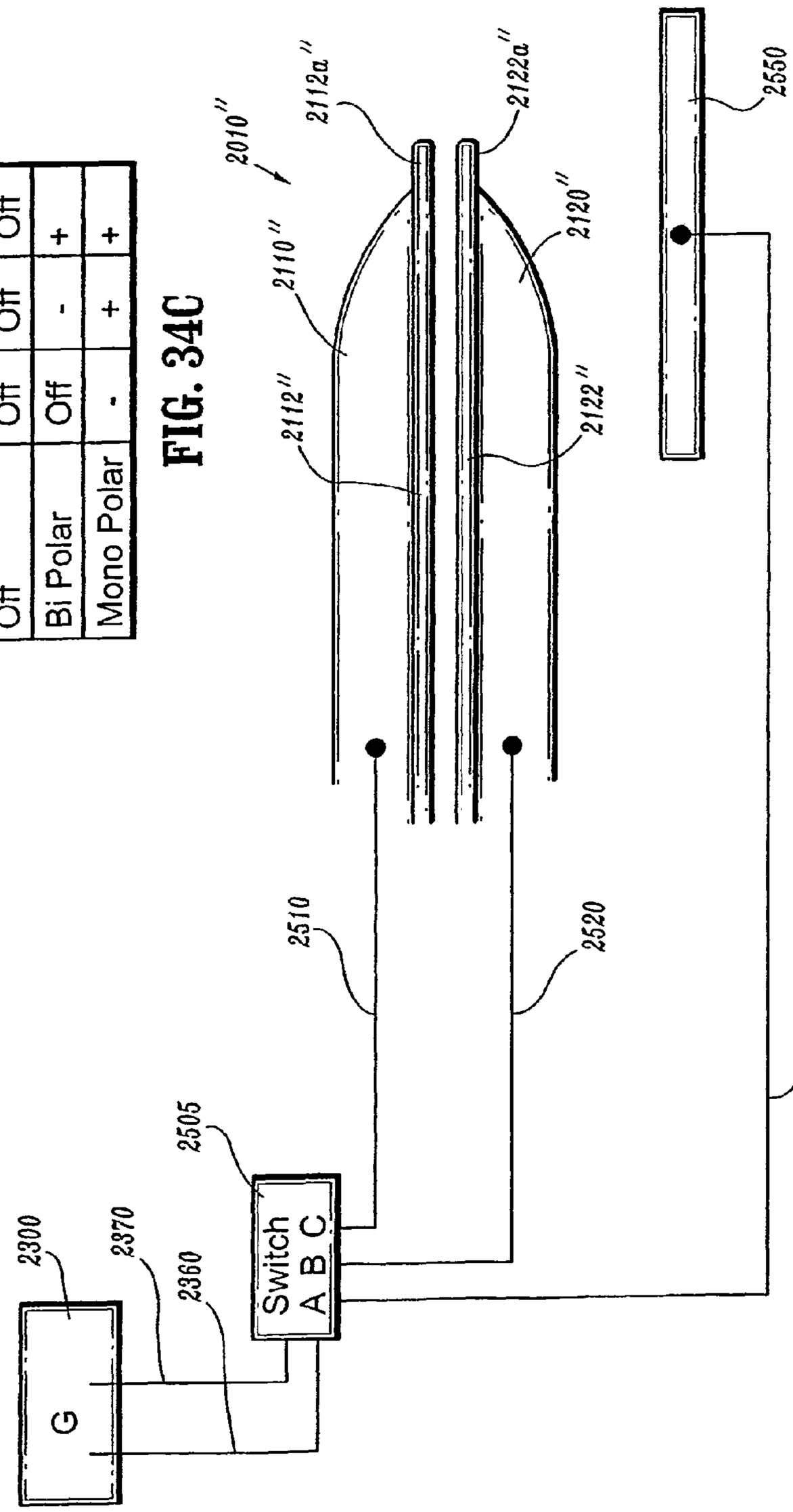

FIG. 34B

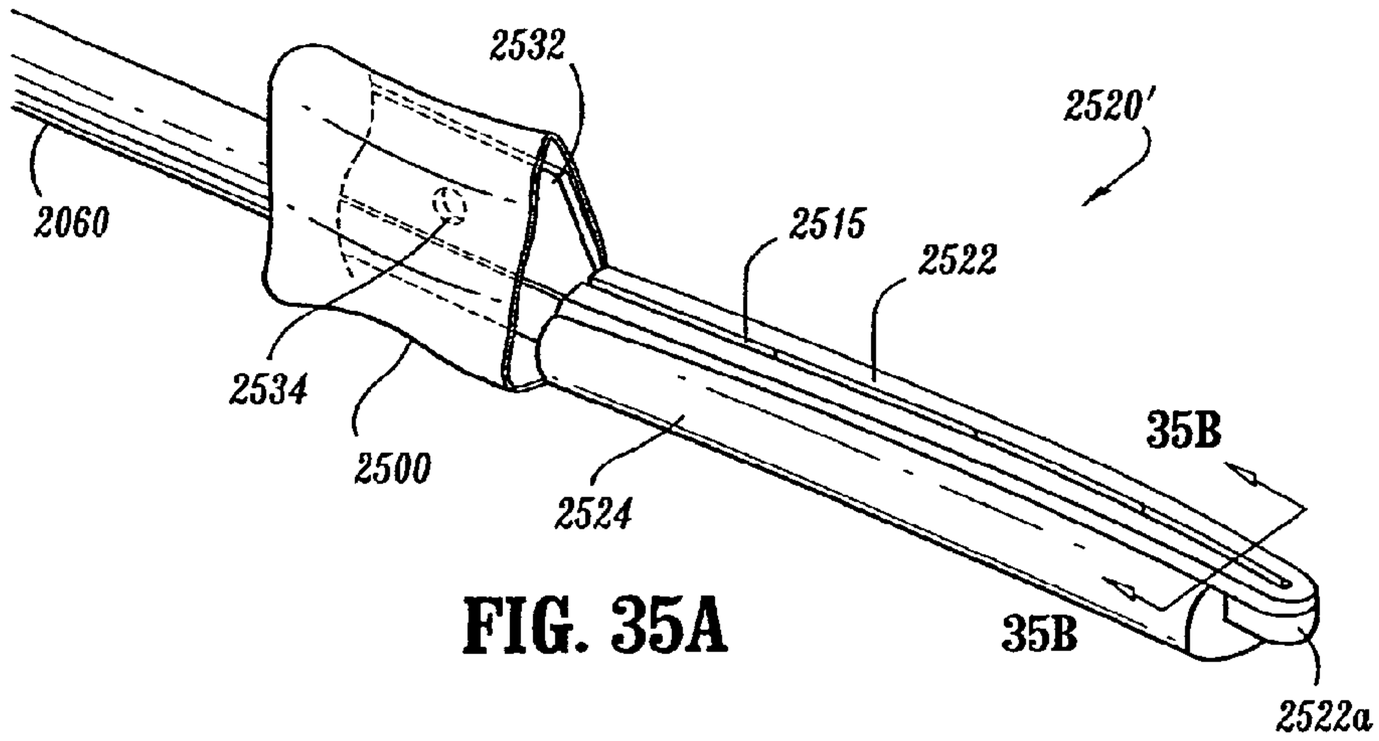

FIG. 35A

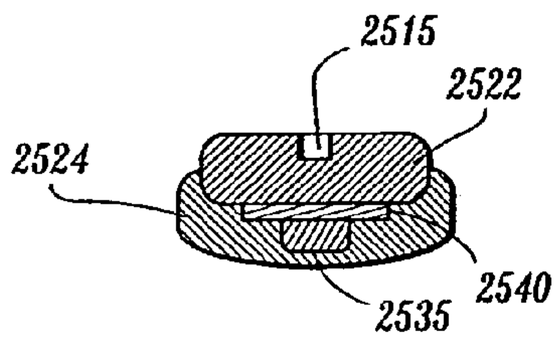

FIG. 35B

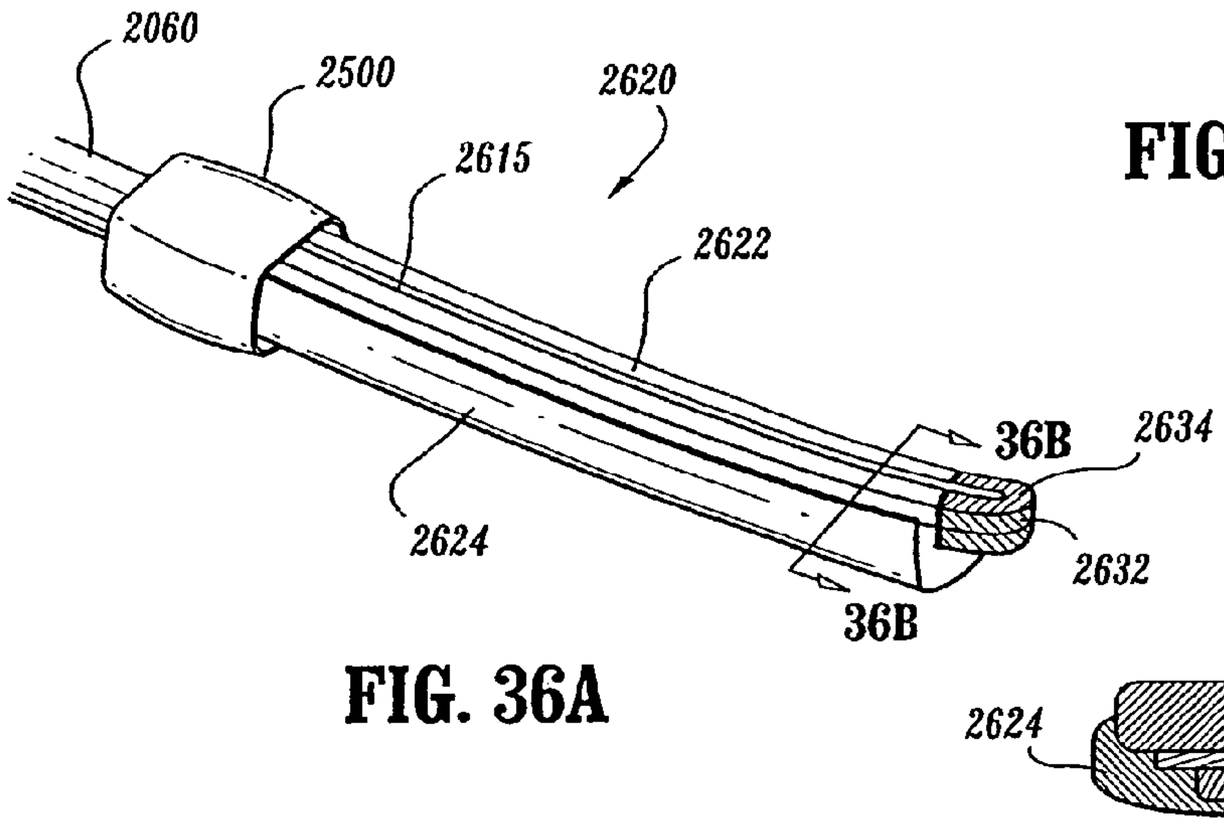

FIG. 36A

FIG. 36B

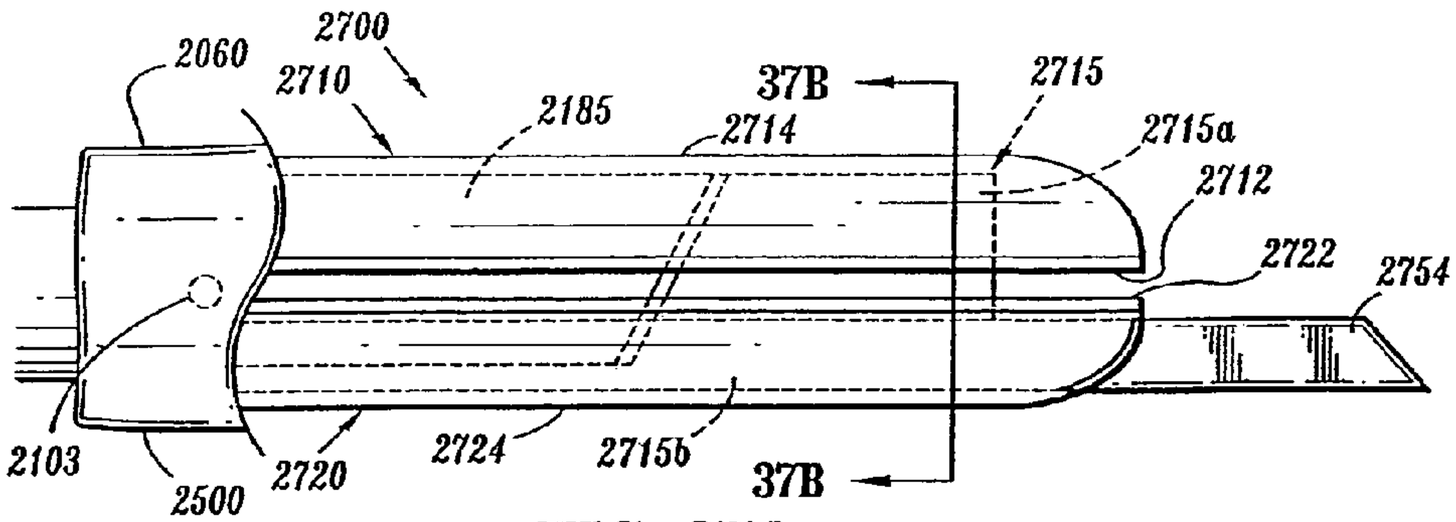

FIG. 37A

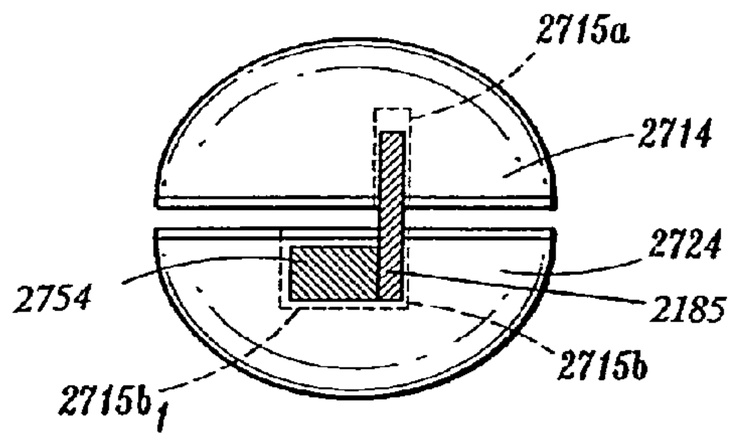

FIG. 37B

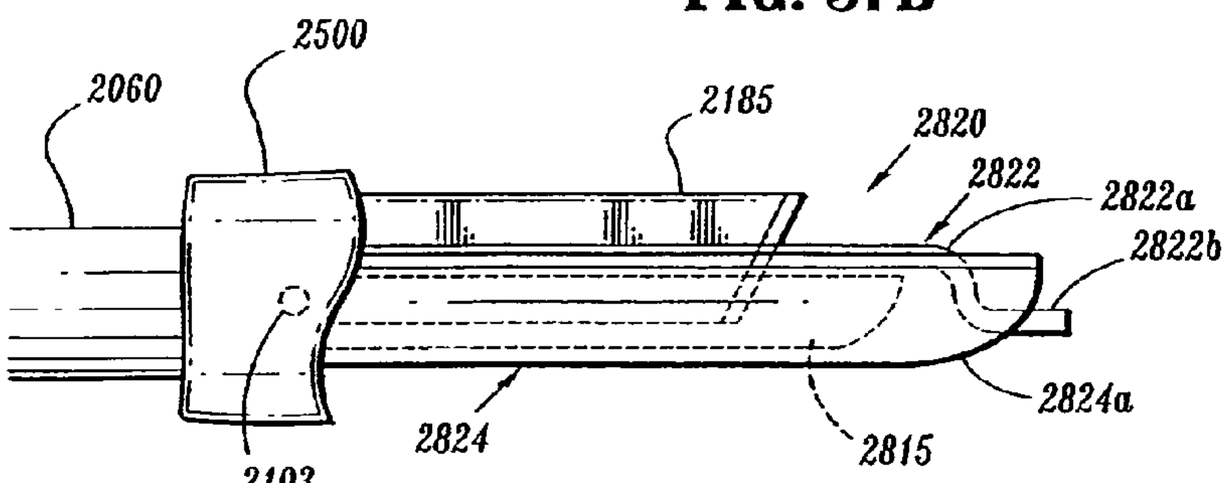

FIG. 38A

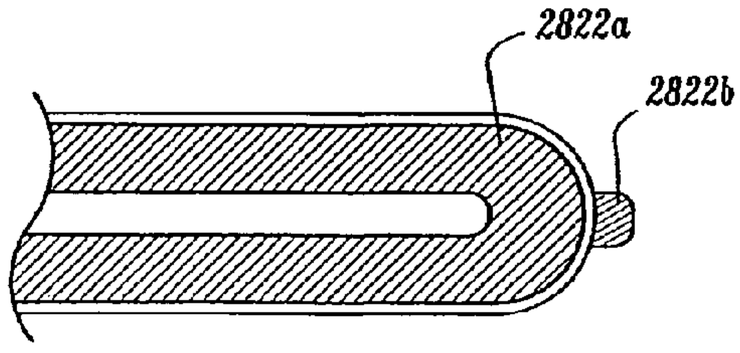

FIG. 38B

INSULATING BOOT FOR ELECTROSURGICAL FORCEPS

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority of U.S. Provisional Patent Application Ser. No. 60/722,213 by Scott DePierro et al., entitled "INSULATING BOOT FOR ELECTROSURGICAL FORCEPS" filed on Sep. 30, 2005, now U.S. patent application Ser. No. 11/529,798 published as U.S. Patent Application Publication No. US2007/0078458 A1, the entire contents of which is incorporated by reference herein. This application cross-references U.S. Provisional Patent Application Ser. No. 60/722,186 by Paul Guerra, entitled "METHOD FOR MANUFACTURING AN END EFFECTOR ASSEMBLY," filed on Sep. 30, 2005, now U.S. patent application Ser. No. 11/529,414 published as U.S. Patent Application Publication No. US2007/0074807 A1 and U.S. Provisional Patent Application Ser. No. 60/722,359 by Kristin Johnson et al, entitled "FLEXIBLE ENDOSCOPIC CATHETER WITH LIGASURE," [[both]] filed on Sep. 30, 2005, now U.S. patent application Ser. No. 11/540,779 published as U.S. Patent Application Publication No. US2007/0078559A1, the entire contents of both applications being incorporated by reference herein.

BACKGROUND

1. Technical Field

The present disclosure relates to an insulated electrosurgical forceps and more particularly, the present disclosure relates to an insulating boot for use with either an endoscopic or open bipolar and/or monopolar electrosurgical forceps for sealing, cutting, and/or coagulating tissue.

2. Background of Related Art

Electrosurgical forceps utilize both mechanical clamping action and electrical energy to effect hemostasis by heating the tissue and blood vessels to coagulate, cauterize and/or seal tissue. As an alternative to open forceps for use with open surgical procedures, many modern surgeons use endoscopes and endoscopic instruments for remotely accessing organs through smaller, puncture-like incisions. As a direct result thereof, patients tend to benefit from less scarring and reduced healing time.

Endoscopic instruments are inserted into the patient through a cannula, or port, which has been made with a trocar. Typical sizes for cannulas range from three millimeters to twelve millimeters. Smaller cannulas are usually preferred, which, as can be appreciated, ultimately presents a design challenge to instrument manufacturers who must find ways to make endoscopic instruments that fit through the smaller cannulas.

Many endoscopic surgical procedures require cutting or ligating blood vessels or vascular tissue. Due to the inherent spatial considerations of the surgical cavity, surgeons often have difficulty suturing vessels or performing other traditional methods of controlling bleeding, e.g., clamping and/or tying-off transected blood vessels. By utilizing an endoscopic electrosurgical forceps, a surgeon can either cauterize, coagulate/desiccate and/or simply reduce or slow bleeding simply

by controlling the intensity, frequency and duration of the electrosurgical energy applied through the jaw members to the tissue. Most small blood vessels, i.e., in the range below two millimeters in diameter, can often be closed using standard electrosurgical instruments and techniques. However, if a larger vessel is ligated, it may be necessary for the surgeon to convert the endoscopic procedure into an open-surgical procedure and thereby abandon the benefits of endoscopic surgery. Alternatively, the surgeon can seal the larger vessel or tissue.

It is thought that the process of coagulating vessels is fundamentally different than electrosurgical vessel sealing. For the purposes herein, "coagulation" is defined as a process of desiccating tissue wherein the tissue cells are ruptured and dried. "Vessel sealing" or "tissue sealing" is defined as the process of liquefying the collagen in the tissue so that it reforms into a fused mass. Coagulation of small vessels is sufficient to permanently close them, while larger vessels need to be sealed to assure permanent closure.

In order to effectively seal larger vessels (or tissue) two predominant mechanical parameters must be accurately controlled—the pressure applied to the vessel (tissue) and the gap distance between the electrodes—both of which are affected by the thickness of the sealed vessel. More particularly, accurate application of pressure is important to oppose the walls of the vessel; to reduce the tissue impedance to a low enough value that allows enough electrosurgical energy through the tissue; to overcome the forces of expansion during tissue heating; and to contribute to the end tissue thickness which is an indication of a good seal. It has been determined that a typical fused vessel wall is optimum between 0.001 and 0.006 inches (about 0.03 mm to about 0.15 mm). Below this range, the seal may shred or tear and above this range the lumens may not be properly or effectively sealed.

With respect to smaller vessels, the pressure applied to the tissue tends to become less relevant whereas the gap distance between the electrically conductive surfaces becomes more significant for effective sealing. In other words, the chances of the two electrically conductive surfaces touching during activation increases as vessels become smaller.

Many known instruments include blade members or shearing members which simply cut tissue in a mechanical and/or electromechanical manner and are relatively ineffective for vessel sealing purposes. Other instruments rely on clamping pressure alone to procure proper sealing thickness and are not designed to take into account gap tolerances and/or parallelism and flatness requirements which are parameters which, if properly controlled, can assure a consistent and effective tissue seal. For example, it is known that it is difficult to adequately control thickness of the resulting sealed tissue by controlling clamping pressure alone for either of two reasons: 1) if too much force is applied, there is a possibility that the two poles will touch and energy will not be transferred through the tissue resulting in an ineffective seal; or 2) if too low a force is applied the tissue may pre-maturely move prior to activation and sealing and/or a thicker, less reliable seal may be created.

As mentioned above, in order to properly and effectively seal larger vessels or tissue, a greater closure force between opposing jaw members is required. It is known that a large closure force between the jaws typically requires a large moment about the pivot for each jaw. This presents a design challenge because the jaw members are typically affixed with pins which are positioned to have small moment arms with respect to the pivot of each jaw member. A large force, coupled with a small moment arm, is undesirable because the large forces may shear the pins. As a result, designers must

compensate for these large closure forces by either designing instruments with metal pins and/or by designing instruments which at least partially offload these closure forces to reduce the chances of mechanical failure. As can be appreciated, if metal pivot pins are employed, the metal pins must be insulated to avoid the pin acting as an alternate current path between the jaw members which may prove detrimental to effective sealing.

Increasing the closure forces between electrodes may have other undesirable effects, e.g., it may cause the opposing electrodes to come into close contact with one another which may result in a short circuit and a small closure force may cause pre-mature movement of the tissue during compression and prior to activation. As a result thereof, providing an instrument which consistently provides the appropriate closure force between opposing electrode within a preferred pressure range will enhance the chances of a successful seal. As can be appreciated, relying on a surgeon to manually provide the appropriate closure force within the appropriate range on a consistent basis would be difficult and the resultant effectiveness and quality of the seal may vary. Moreover, the overall success of creating an effective tissue seal is greatly reliant upon the user's expertise, vision, dexterity, and experience in judging the appropriate closure force to uniformly, consistently and effectively seal the vessel. In other words, the success of the seal would greatly depend upon the ultimate skill of the surgeon rather than the efficiency of the instrument.

It has been found that the pressure range for assuring a consistent and effective seal is between about 3 kg/cm^2 to about 16 kg/cm^2 and, preferably, within a working range of 7 kg/cm^2 to 13 kg/cm^2. Manufacturing an instrument which is capable of providing a closure pressure within this working range has been shown to be effective for sealing arteries, tissues and other vascular bundles.

Various force-actuating assemblies have been developed in the past for providing the appropriate closure forces to effect vessel sealing. For example, one such actuating assembly has been developed by Valleylab Inc., a division of Tyco Healthcare LP, for use with Valleylab's vessel sealing and dividing instrument commonly sold under the trademark LIGASURE ATLAS®. This assembly includes a four-bar mechanical linkage, a spring and a drive assembly which cooperate to consistently provide and maintain tissue pressures within the above working ranges. The LIGASURE ATLAS® is presently designed to fit through a 10 mm cannula and includes a bi-lateral jaw closure mechanism which is activated by a foot switch. A trigger assembly extends a knife distally to separate the tissue along the tissue seal. A rotating mechanism is associated with distal end of the handle to allow a surgeon to selectively rotate the jaw members to facilitate grasping tissue. U.S. Pat. Nos. 7,101,371 and 7,083,618 and PCT Application Ser. Nos. PCT/US01/01890 PCT/US02/01890, now WO 2002/080799, and PCT/US01/11340, now WO 2002/080795, describe in detail the operating features of the LIGASURE ATLAS® and various methods relating thereto. Copending U.S. application Ser. No. 10/970,307, now U.S. Pat. No. 7,232,440, relates to another version of an endoscopic forceps sold under the trademark LIGASURE V® by Valleylab, Inc., a division of Tyco Healthcare, LP. In addition, commonly owned, U.S. patent application Ser. No. 10/873,860, filed on Jun. 22, 2004 and entitled "Open Vessel Sealing Instrument with Cutting Mechanism and Distal Lockout", now U.S. Pat. No. 7,252,667, and incorporated by reference in its entirety herein discloses an open forceps which is configured to seal and cut tissue which can be configured to include one or more of the presently disclosed embodiments described herein. The entire contents of all of these applications are hereby incorporated by reference herein.

For example, the commonly owned U.S. patent application Ser. No. 10/970,307 filed on Oct. 21, 2004 and entitled "Bipolar Forceps Having Monopolar Extension", now U.S. Pat. No. 7,232,440, discloses an electrosurgical forceps for coagulating, sealing, and/or cutting tissue having a selectively energizable and/or extendable monopolar extension for enhanced electrosurgical effect. The instrument includes a monopolar element which may be selectively extended and selectively activated to treat tissue. Various different designs are envisioned which allow a user to selectively energize tissue in a bipolar or monopolar mode to seal or coagulate tissue depending upon a particular purpose. Some of the various designs include: (1) a selectively extendable and energizable knife design which acts as a monopolar element; (2) a bottom jaw which is electrically and selectively configured to act as a monopolar element; (3) tapered jaw members having distal ends which are selectively energized with a single electrical potential to treat tissue in a monopolar fashion; and (4) other configurations of the end effector assembly and/or bottom or second jaw member which are configured to suit a particular purpose or to achieve a desired surgical result.

However, a general issue with existing electrosurgical forceps is that the jaw members rotate about a common pivot at the distal end of a metal or otherwise conductive shaft such that there is potential for both the jaws, a portion of the shaft, and the related mechanism components to conduct electrosurgical energy (either monopolar or as part of a bipolar path) to the patient tissue. Existing electrosurgical instruments with jaws either cover the pivot elements with an inflexible shrink-tube or do not cover the pivot elements and connection areas and leave these portions exposed.

SUMMARY

It would be desirous to provide electrosurgical instruments with a flexible insulating boot that both permits pivoting and other associated movements of the jaw members and also reduces the potential for stray or miscellaneous currents affecting surrounding tissue.

The present disclosure relates to an electrosurgical forceps having a shaft with jaw members at a distal end thereof. The jaw members are movable about a pivot by actuation of a drive assembly that moves the jaw members from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members are closer to one another for grasping and treating tissue. The forceps also includes a movable handle that actuates the drive assembly to move the jaw members relative to one another.

At least one jaw member is adapted to connect to a source of electrical energy such that at least one of the jaw members is capable of conducting energy to tissue held therebetween to treat tissue. A flexible insulating boot is disposed on at least a portion of an exterior surface of at least one jaw member. The insulating boot is configured and made from a material that insulates tissue from various exposed areas of the shaft and the jaw members.

In one particularly useful embodiment, one end of the insulating boot is disposed on at least a portion of an exterior surface of the shaft and another end of the insulating boot is disposed on at least a portion of an exterior surface of at least one jaw member proximate the pivot such that movement of the jaw members is substantially unimpeded. In another embodiment according to the present disclosure, the insulating boot is made of at least one of a viscoelastic, elastomeric,

and flexible material suitable for use with a sterilization process that does not substantially impair structural integrity of the boot. In particular, the sterilization process may include ethylene oxide.

The jaw members (or jaw member) may also include a series of stop members disposed thereon for regulating distance between the jaw members such that a gap is created between the jaw members during the sealing process.

The forceps may also include a knife that is selectively deployable to cut tissue disposed between the jaw members.

In one embodiment, the jaw members are configured to treat tissue in a monopolar fashion, while in another embodiment, the jaw members are configured to treat tissue in a bipolar fashion.

In one embodiment of the present disclosure, the present disclosure is directed to an electrosurgical forceps for sealing tissue having a pair of first and second shaft members each with a jaw member disposed at a distal end thereof. The jaw members are movable about a pivot from a first position in spaced relation relative to one another to at least one subsequent position wherein the jaw members cooperate to grasp tissue therebetween. At least one of the jaw members includes an electrically conductive sealing plate adapted to communicate electrosurgical energy to tissue held therebetween and a flexible insulating boot disposed on at least a portion of an exterior surface of at least one jaw member.

In yet another useful embodiment, the present disclosure relates to an electrosurgical forceps having a housing with a shaft affixed thereto. The shaft includes first and second jaw members attached to a distal end thereof. The forceps includes an actuator for moving jaw members relative to one another from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to grasp tissue therebetween. Each jaw member is adapted to connect to a source of electrosurgical energy such that the jaw members are selectively capable of conducting energy to tissue held therebetween to treat tissue.

The forceps also includes a knife that is selectively moveable within a knife channel defined within at least one of the jaw members to cut tissue disposed therebetween. A monopolar element is housed within at least one jaw member and is selectively movable from a first proximal position within the jaw members to a second distal position within the jaw member(s). The monopolar element may be connected to the source of electrosurgical energy and may be selectively activatable independently of the jaw members. The forceps includes a flexible insulating boot disposed on at least a portion of at least one jaw member.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the subject instrument are described herein with reference to the drawings wherein:

FIG. **1** is a left, perspective view of one version of the present disclosure that includes an endoscopic bipolar forceps showing a housing, a shaft and an end effector assembly having an insulating boot according to the present disclosure;

FIG. **2** is an enlarged, left perspective view of the end effector assembly with the jaw members shown in open configuration having the insulating boot according to the present disclosure;

FIG. **3** is a full perspective view of the end effector assembly of FIG. **1** having the insulating boot according to the present disclosure;

FIG. **4** is an exploded top, perspective view of the housing and internal working components thereof of the endoscopic bipolar forceps of FIG. **1** with parts separated;

FIG. **5** is an enlarged, top, perspective view of the end effector assembly having the insulating boot of the present disclosure with parts separated;

FIG. **6** is an enlarged, perspective view of the knife assembly with parts separated;

FIG. **7** is an enlarged view of the indicated area of detail of FIG. **6** showing a knife blade of the knife assembly;

FIG. **8** is a greatly-enlarged, perspective view of a distal end of the knife assembly;

FIG. **9** is a greatly-enlarged, perspective view of a knife drive of the knife assembly;

FIG. **10** is a cross-section of the housing with the end effector shown in open configuration having the insulating boot of the present disclosure and showing the internal, electrical routing of an electrosurgical cable and electrical leads;

FIG. **11** is a greatly-enlarged view of the indicated area of detail of FIG. **10**;

FIG. **12** is a side, cross section of the shaft and end effector assembly with the end effector assembly having the insulating boot of the present disclosure;

FIG. **13** is a side, cross section of the housing showing the moving components of the drive assembly during actuation and the end effector assembly;

FIG. **14** is a greatly-enlarged view of the indicated area of detail in FIG. **13**;

FIG. **15** is a greatly-enlarged view of the indicated area of detail in FIG. **13**;

FIG. **16** is an enlarged, side view of the end effector assembly shown in an open configuration and having the insulating boot of the present disclosure;

FIG. **17** is a side view of the end effector assembly shown in a closed configuration and having the insulating boot of the present disclosure with the jaw members in the closed position;

FIG. **18** is an enlarged, rear, perspective view of the end effectors shown grasping tissue;

FIG. **19** is a side, cross section of a tissue seal after separation by the knife assembly;

FIG. **20** is a left, front perspective view of an open forceps with a cutting mechanism having an insulating boot according to the present disclosure;

FIG. **21** is a right, rear perspective view of the forceps of FIG. **20**;

FIG. **22** is an enlarged, left perspective view of one of the jaw members of the forceps of FIG. **20**;

FIG. **23** is an enlarged, perspective view of the other jaw member of the forceps of FIG. **20**;

FIG. **24** is a side cross sectional view showing the forceps of FIG. **20** in open configuration for grasping tissue;

FIG. **25** is a rear, perspective view of the forceps of FIG. **20** shown grasping tissue with a ratchet mechanism shown prior to engagement;

FIG. **26** is a side view of an endoscopic forceps showing a housing, a shaft, an end effector assembly having an insulating boot according to the present disclosure and a trigger assembly in a first position;

FIG. **27** is an enlarged, cross section taken along line **27-27** of FIG. **26**;

FIG. **28** is an enlarged, side view of the trigger assembly of FIG. **26**;

FIG. **29** is an enlarged, side view of the embodiment of an end effector assembly of FIG. **26** having the insulating boot

according to the present disclosure and showing relative extension of a monopolar element from a distal end of the end effector assembly;

FIG. **30** is a side view of the trigger assembly in a second position for advancing a knife within the end effector assembly and having the insulating boot according to the present disclosure;

FIG. **31** is a side view of the trigger assembly in a third position for extending a monopolar element from a distal end of the end effector assembly;

FIG. **32** is a side view of an alternate embodiment of the present invention showing a second actuator advancing the monopolar element relative to the distal end of the end effector;

FIG. **33**A is an enlarged, side schematic view of one embodiment of an end effector assembly having the insulating boot according to the present disclosure and showing relative movement of a first jaw member relative to a second jaw member prior to advancement of the knife through the end effector assembly;

FIG. **33**B is an enlarged, side schematic view of the end effector assembly showing relative movement of the knife through the end effector assembly to divide tissue;

FIG. **33**C is an enlarged, side schematic view of the end effector assembly showing relative movement of the knife extending from the distal end of the end effector assembly;

FIG. **34**A is an enlarged, side schematic view of another embodiment of an end effector assembly having the insulating boot according to the present disclosure;

FIG. **34**B is schematic view of another embodiment of an end effector assembly capable of being configured with the insulating boot according to the present disclosure and showing a series of electrical connections to a control switch and a generator to enable both bipolar activation and monopolar activation;

FIG. **34**C is a table showing the various modes of operation of the forceps utilizing the end effector configuration of FIG. **34**B;

FIGS. **35**A and **35**B are enlarged views of an alternate embodiment of the second jaw member configured with an insulating boot according to the present disclosure;

FIGS. **36**A and **36**B are enlarged views of another alternate embodiment of the second jaw member configured with an insulating boot according to the present disclosure;

FIGS. **37**A and **37**B are enlarged views of another alternate embodiment of the end effector assembly configured with an insulating boot according to the present disclosure showing the monopolar element in an extended configuration; and

FIGS. **38**A and **38**B are enlarged views of yet another alternate embodiment of the second jaw member configured with an insulating boot according to the present disclosure.

DETAILED DESCRIPTION

Referring initially to FIGS. **1-3**, one particularly useful endoscopic forceps **10** is shown for use with various surgical procedures and generally includes a housing **20**, a handle assembly **30**, a rotating assembly **80**, a trigger assembly **70**, a knife assembly and an end effector assembly **100** that mutually cooperate to grasp, seal and divide tubular vessels and vascular tissue **420** (see FIGS. **18-19**). For the purposes herein, forceps **10** will be described generally. However, the various particular aspects of this particular forceps are detailed in commonly owned U.S. patent application Ser. No. 10/460,926, filed on Jun. 13, 2003, and entitled "VESSEL SEALER AND DIVIDER FOR USE WITH SMALL TROCARS AND CANNULAS," now U.S. Pat. No. 7,156,846, and previously mentioned U.S. patent application Ser. No. 10/970,307, now U.S. Pat. No. 7,232,440, the entire contents of each of which are incorporated by reference herein. Forceps **10** includes a shaft **12** that has a distal end **16** dimensioned to mechanically engage the end effector assembly **100** and a proximal end **14** that mechanically engages the housing **20**. As will be discussed in more detail below, the end effector assembly **100** includes a flexible insulating boot **500** configured to cover at least a portion of the exterior surfaces of the end effector assembly **100**.

Forceps **10** also includes an electrosurgical cable **310** that connects the forceps **10** to a source of electrosurgical energy, e.g., a generator (not shown). The generator includes various safety and performance features including isolated output, independent activation of accessories, and Instant Response™ technology (a proprietary technology of Valleylab, Inc., a division of Tyco Healthcare, LP) that provides an advanced feedback system to sense changes in tissue many times per second and adjust voltage and current to maintain appropriate power. Cable **310** is internally divided into cable lead **310**a, **310**b and **310**c that each transmit electrosurgical energy through their respective feed paths through the forceps **10** to the end effector assembly **100**. (See FIG. **11**).

Handle assembly **30** includes a fixed handle **50** and a movable handle **40**. Fixed handle **50** is integrally associated with housing **20** and handle **40** is movable relative to fixed handle **50**. Rotating assembly **80** is integrally associated with the housing **20** and is rotatable approximately 180 degrees in either direction about a longitudinal axis "A" (See FIG. **1**). Details of the rotating assembly **80** are described in more detail below.

As best seen in FIGS. **1** and **4**, housing **20** is formed from two (2) housing halves **20**a and **20**b that each include a plurality of interfaces **27**a-**27**f that are dimensioned to mechanically align and engage one another to form housing **20** and enclose the internal working components of forceps **10**. Fixed handle **50** that, as mentioned above, is integrally associated with housing **20**, takes shape upon the assembly of the housing halves **20**a and **20**b. Movable handle **40** and trigger assembly **70** are of unitary construction and are operatively connected to the housing **20** and the fixed handle **50** during the assembly process. Rotating assembly **80** includes two halves that, when assembled, form a knurled wheel **82** that, in turn, houses a drive assembly **150** and a knife assembly **140**.

As mentioned above, end effector assembly **100** is attached at the distal end **14** of shaft **12** and includes a pair of opposing jaw members **110** and **120**. Movable handle **40** of handle assembly **30** is ultimately connected to the drive assembly **150** that, together, mechanically cooperate to impart movement of the jaw members **110** and **120** from an open position wherein the jaw members **110** and **120** are disposed in spaced relation relative to one another, to a clamping or closed position wherein the jaw members **110** and **120** cooperate to grasp tissue therebetween. All of these components and features are best explained in detail in the above-identified commonly owned U.S. application Ser. No. 10/460,926, now U.S. Pat. No. 7,156,846.

Turning now to the more detailed features of the present disclosure as described with respect to FIGS. **1-4**, movable handle **40** includes a finger loop **41** that has an aperture **42** defined therethrough that enables a user to grasp and move the handle **40** relative to the fixed handle **50**. As best seen in FIG. **4**, movable handle **40** is selectively moveable about a pair of pivot pins **29**a and **29**b from a first position relative to fixed handle **50** to a second position in closer proximity to the fixed handle **50** that, as explained below, imparts movement of the jaw members **110** and **120** relative to one another. The mov-

able handle include a clevis **45** that forms a pair of upper flanges **45**a and **45**b each having an aperture **49**a and **49**b, respectively, at an upper end thereof for receiving the pivot pins **29**a and **29**b therethrough and mounting the upper end of the handle **40** to the housing **20**. In turn, each pin **29**a and **29**b mounts to a respective housing half **20**a and **20**b.

Each upper flange **45**a and **45**b also includes a force-actuating flange or drive flange **47**a and **47**b, respectively, each of which is aligned along longitudinal axis "A" and which abut the drive assembly **150** such that pivotal movement of the handle **40** forces actuating flange against the drive assembly **150** that, in turn, closes the jaw members **110** and **120**.

Movable handle **40** is designed to provide a distinct mechanical advantage over conventional handle assemblies due to the unique position of the pivot pins **29**a and **29**b (i.e., pivot point) relative to the longitudinal axis "A" of the shaft **12** and the disposition of the driving flange **47** along longitudinal axis "A". In other words, by positioning the pivot pins **29**a and **29**b above the driving flange **47**, the user gains lever-like mechanical advantage to actuate the jaw members **110** and **120** enabling the user to close the jaw members **110** and **120** with lesser force while still generating the required forces necessary to effect a proper and effective tissue seal.

In addition, the unilateral closure design of the end effector assembly **100** will also increase mechanical advantage. More particularly, as best shown in FIGS. **3** and **5**, the unilateral end effector assembly **100** includes one stationary or fixed jaw member **120** that is mounted in fixed relation to the shaft **12** and a pivoting jaw member **110** mounted about a pivot pin **103** attached to the stationary jaw member **120**. A reciprocating sleeve **60** is slidingly disposed within the shaft **12** and is remotely operable by the drive assembly **150** to move jaw member **110** relative to jaw member **120**. The pivoting jaw member **110** includes a detent or protrusion **117** that extends from jaw member **110** through an aperture **62** disposed within the reciprocating sleeve **60** (FIG. **3**). The pivoting jaw member **110** is actuated by sliding the sleeve **60** axially within the shaft **12** such that a distal end **63** of the aperture **62** abuts against the detent **117** on the pivoting jaw member **110** (See FIG. **3**). Pulling the sleeve **60** proximally closes the jaw members **110** and **120** about tissue grasped therebetween and pushing the sleeve **60** distally opens the jaw members **110** and **120** for grasping purposes.

As best illustrated in FIGS. **3-9** and **18**, a knife channel **115**a and **115**b runs through the center of the jaw members **110** and **120**, respectively, such that a blade **185** from the knife assembly **140** can cut the tissue **420** grasped between the jaw members **110** and **120** when the jaw members **110** and **120** are in a closed position. More particularly, the blade **185** can only be advanced through the tissue **420** when the jaw members **110** and **120** are closed, thus preventing accidental or premature activation of the blade **185** through the tissue **420**. The unilateral end effector assembly **100** is structured such that electrical energy can be routed through the sleeve **60** at the protrusion **117** contact point with the sleeve **60** or using a "brush" or lever (not shown) to contact the back of the moving jaw member **110** when the jaw member **110** closes. In this instance, the electrical energy would be routed through the protrusion **117** to the stationary jaw member **120**.

As best illustrated in FIG. **2**, jaw member **110** also includes a jaw housing **116** that has an insulative substrate or insulator **114** and an electrically conductive surface **112**. Details relating to the specific structure of the jaw members **110** and **120** are disclosed in previously mentioned commonly owned U.S. patent application Ser. No. 10/460,926.

As best shown in FIGS. **3** and **16**, jaw member **110** includes a pivot flange **118** that, in turn, includes protrusion **117** that extends from pivot flange **118** and has an arcuately-shaped inner surface **111** dimensioned to matingly engage the aperture **62** of sleeve **60** upon retraction thereof. Pivot flange **118** also includes a pin slot **119** that is dimensioned to engage pivot pin **103** to allow jaw member **110** to rotate relative to jaw member **120** upon retraction of the reciprocating sleeve **60**. As explained in more detail below, pivot pin **103** mounts to the stationary jaw member **120** through a pair of apertures **101**a and **101**b disposed within a proximal portion of the jaw member **120**. The pivot pin **103** serves as a common joint between the jaw members **110** and **120**.

Jaw member **120** is designed to be fixed to the end of a rotating tube **160** that is part of the rotating assembly **80** such that rotation of the tube **160** around axis "B" of FIG. **1** will impart rotation to the end effector assembly **100** (See FIGS. **1**, **2** and **15**). Details relating to the rotation of the jaw members **110** and **120** are described in the previously mentioned commonly owned U.S. patent application Ser. No. 10/460,926, now U.S. Pat. No. 7,156,846, that is incorporated by reference herein in its entirety.

Fixed jaw member **120** is connected to a second electrical potential through tube **160** that is connected at its proximal end to lead **310**c. More particularly, as best shown in FIGS. **2**, **4**, **10** and **11**, fixed jaw **120** is welded to the rotating tube **160** and includes a fuse clip, spring clip or other electro-mechanical connection that provides electrical continuity to the fixed jaw member **120** from lead **310**c. The rotating tube **160** includes an elongated guide slot **167** disposed in an upper portion thereof that is dimensioned to carry lead **311** therealong. Lead **311** carries a first electrical potential to movable jaw **110**. A second electrical connection from lead **310**c is conducted through the tube **160** to the fixed jaw member **120**. Details relating to the electrical connections are described in the aforementioned U.S. patent application Ser. No. 10/460,926, now U.S. Pat. No. 7,156,846.

A tubular insulating boot **500** is included that is configured to mount over the pivot **103** and at least a portion of the end effector assembly **100**. The tubular insulating boot **500** is flexible to permit opening and closing of the jaw members **110** and **120** about pivot **103**. The flexible insulating boot **500** is made typically of any type of visco-elastic, elastomeric or flexible material that is biocompatible. Such a visco-elastic, elastomeric or flexible material is preferably durable and is configured to minimally impede movement of the jaw members **110** and **120** from the open to the closed positions. The particularly selected material of the flexible insulating boot **500** has a dielectric strength sufficient to withstand the voltages encountered during electrosurgery, and is suitable for use with a sterilization process that does not substantially impair structural integrity of the boot, such as an ethylene oxide process that does not melt or otherwise impair the structural integrity of the insulating boot **500**. The insulating boot **500** is dimensioned to further reduce stray electrical potentials so as to reduce the possibility of subjecting the patient tissue to unintentional electrosurgical RF energy.

As best shown in FIGS. **2**, **3**, **12**, **16** and **17**, one end of the tubular insulating boot **500** is disposed on at least a portion of the exterior surface of shaft **12** while the other end of the tubular insulating boot **500** is disposed on at least a portion of the exterior surfaces of jaw members **110** and **120**. Operability of the jaw members **110** and **120** is substantially unimpeded and not affected significantly by the flexible insulating boot **500**. More particularly, the tubular insulating boot **500** is maintained on the shaft **12** such that boot **500** remains in a substantially stationary position axially with respect to reciprocating sleeve **60** and the jaw members **110** and **120**. The flexible insulating boot **500** expands and contracts both radi-

ally and axially to cover the pivot pin **103** and to accommodate motion of the protrusion **117** and the movable jaw member **110**.

Again, as previously mentioned, since one end of the tubular insulating boot **500** is disposed on at least a portion of the shaft **12** while the other end of the tubular insulating boot **500** is disposed on at least a portion of the exterior surfaces of fixed jaw member **120** and pivoting jaw member **110**, operability of the pivoting jaw member **110** and the fixed jaw member **120**, either with respect to reciprocation of the reciprocating sleeve **60** or rotation of the rotating tube **160**, is not significantly limited by or impeded by the flexible insulating boot **500**. The tubular insulating boot **500** does not interface with the shaft **12** but rather remains in a substantially stationary position axially with respect to reciprocating sleeve **60** and the jaw members **110** and **120**.

As best shown in FIGS. **1**, **4** and **10**, once actuated, handle moves in a generally arcuate fashion towards fixed handle **50** about the pivot pins **29**a and **29**b that forces driving flange **47** proximally against the drive assembly **150** that, in turn, pulls reciprocating sleeve **60** in a generally proximal direction to close jaw member **110** relative to jaw member **120**. Moreover, proximal rotation of the handle **40** causes the locking flange **44** to release, i.e., "unlock", the trigger assembly **70** for selective actuation.

The operating features and relative movements of the internal working components of the forceps **10** and the trigger assembly **70** are shown by phantom representation in the various figures and explained in more detail with respect to the aforementioned U.S. patent application Ser. No. 10/460,926, now U.S. Pat. No. 7,156,846, and also in U.S. patent application Ser. No. 10/970,307, now U.S. Pat. No. 7,232,440, the contents of both of which are incorporated herein in their entirety.

As can be appreciated, as illustrated in FIG. **15**, the utilization of an over-the-center pivoting mechanism will enable the user to selectively compress the coil spring **67** a specific distance that, in turn, imparts a specific pulling load on the reciprocating sleeve **60** that is converted to a rotational torque about the jaw pivot pin **103**. As a result, a specific closure force can be transmitted to the opposing jaw members **110** and **120**. The combination of the mechanical advantage of the over-the-center pivot along with the compressive force associated with the compression spring **67** facilitate and assure consistent, uniform and accurate closure pressure about tissue within a desired working pressure range of about 3 kg/cm^2 to about 16 kg/cm^2 and, preferably, about 7 kg/cm^2 to about 13 kg/cm^2. By controlling the intensity, frequency and duration of the electrosurgical energy applied to the tissue, the user can seal tissue.

As best shown in FIGS. **4**, **6-9** and **18**, the knife assembly **140** includes an elongated rod **182** having a bifurcated distal end comprising prongs **182**a and **182**b that cooperate to receive a knife bar **184** therein. The knife assembly **180** also includes a proximal end **183** that is keyed to facilitate insertion into tube **160** of the rotating assembly **80**. A knife wheel **148** is secured to the knife bar **182** by a pin **143**. More particularly, the elongated knife rod **182** includes apertures **181**a and **181**b that are dimensioned to receive and secure the knife wheel **148** to the knife rod **182** such that longitudinal reciprocation of the knife wheel **148**, in turn, moves the elongated knife rod **182** to sever tissue **420**. More details relating to the operational features of the knife assembly **180** are discussed in the previously mentioned U.S. patent application Ser. No. 10/460,926, *now U.S. Pat. No. 7,232,440,* which is incorporated herein by reference in its entirety.

As best shown in the exploded view of FIG. **4** and in FIGS. **14-15**, the electrical leads **310**a, **310**b, **310**c and **311** are fed through the housing **20** by electrosurgical cable **310**. More particularly, the electrosurgical cable **310** is fed into the bottom of the housing **20** through fixed handle **50**. Lead **310**c extends directly from cable **310** into the rotating assembly **80** and connects (via a fused clip or spring clip or the like) to tube **60** to conduct the second electrical potential to fixed jaw member **120**. Leads **310**a and **310**b extend from cable **310** and connect to the hand switch or joy-stick-like toggle switch **200**. Details relating to the switch **200** are disclosed in the aforementioned U.S. patent application Ser. Nos. 10/460,926 and 10/970,307, now U.S. Pat. Nos. 7,156,846 and 7,232,440, respectively.

The jaw members **110** and **120** are electrically isolated from one another such that electrosurgical energy can be effectively transferred through the tissue to form seal **450**, as shown in FIGS. **18** and **19**. The two electrical potentials are isolated from one another by virtue of the insulative sheathing surrounding cable lead **311**. At least one of the jaw members **110** and **120** is adapted to connect to a source of electrosurgical energy (a generator (not shown)) such that at least one of the jaw members **110** and **120** is capable of conducting electrosurgical energy to tissue held therebetween.

In addition, by virtue of the flexible insulating boot **500** of the present disclosure, desired motion of and force between the jaw members **110** and **120** is maintained and substantially unimpeded while at the same time insulating boot **500** further insulates the patient tissue from possible stray energy from the exterior surfaces of the jaw members **110** and **120** and the associated elements, e.g., pivot **103** (See FIG. **2**). Details relating to various forceps that may be utilized with an insulating boot include the commonly-owned aforementioned instrument described in U.S. patent application Ser. Nos. 10/460,926 and 10/970,307, now U.S. Pat. Nos. 7,156,846 and 7,232,440, respectively, and commonly-owned and concurrently filed U.S. Provisional Patent Application Ser. No. 60/722,177 entitled "INLINE VESSEL SEALER AND DIVIDER", filed on Sep. 30, 2005, filed as U.S. patent application Ser. No. 11/540,335, published as U.S. Patent Application Publication No. US2007/0078456 A1, *now U.S. Pat. No. 7,789,878,* the entire contents of which is incorporated by reference herein.

As mentioned above with respect to FIG. **3**, at least one jaw member, e.g., **120**, may include a stop member **750** that limits the movement of the two opposing jaw members **110** and **120** relative to one another. The stop member **750** extends from the sealing surface **122** a predetermined distance according to the specific material properties (e.g., compressive strength, thermal expansion, etc.) to yield a consistent and accurate gap distance "G" (preferably between about 0.001 inches to about 0.006 inches, i.e., between about 0.03 mm to about 0.15 mm) during sealing (FIG. **18**). The non-conductive stop members **750** are sprayed or otherwise deposited onto the jaw members **110** and **120** (e.g., overmolding, injection molding, etc.), stamped onto the jaw members **110** and **120** or deposited (e.g., deposition) onto the jaw members **110** and **120**. For example, one technique involves thermally spraying a ceramic material onto the surface of the jaw member **110** and **120** to form the stop members **750**.

As best shown in FIGS. **4**, **6-9**, and **18-19**, as energy is being selectively transferred to the end effector assembly **100**, across the jaw members **110** and **120** and through the tissue **420**, a tissue seal **450** forms isolating two tissue halves **420**a and **420**b. The knife assembly **140** is then activated via the trigger assembly **70**, to progressively and selectively divide the tissue **420** along an ideal tissue plane in precise manner to

effectively and reliably divide the tissue **420** into two sealed halves **420**a and **420**b (See FIGS. **18-19**) with a tissue gap **475** therebetween. The knife assembly **140** allows the user to quickly separate the tissue **420** immediately after sealing or, if desired, without sealing, without substituting a cutting instrument through a cannula or trocar port. As can be appreciated, accurate sealing and dividing of tissue **420** is accomplished with the same forceps **10**. Again, desired motion or movement of and force between the jaw members **110** and **120** is maintained and substantially unimpeded in the presence of the flexible insulating boot **500** of the present disclosure. For example, FIG. **16** is a side view of the end effector assembly **100** having the flexible insulating boot **500** of the present disclosure illustrating the jaw members **110** and **120** in the open position. FIG. **17** is a side view of the end effector assembly **100** having the flexible insulating boot **500** of the present disclosure illustrating the jaw members **110** and **120** in the closed position.

FIGS. **20** and **21** show an open forceps **1000** for use with an insulating boot **1500** of the present disclosure. Forceps **1000** includes elongated shaft portions **1012**a and **1012**b each having a proximal end **1014**a, **1014**b and a distal end **1016**a and **1016**b, respectively. The forceps **1000** includes an end effector assembly **1100** that attaches to the distal ends **1016**a and **1016**b of shafts **1012**a and **1012**b, respectively. The end effector assembly **1100** includes pair of opposing jaw members **1110** and **1120** that are pivotably connected about a pivot pin **1065** and that are movable relative to one another to grasp vessels and/or tissue.

Each shaft **1012**a and **1012**b includes a handle **1015** and **1017**, respectively, disposed at the proximal end **1014**a and **1014**b thereof that each define a finger hole **1015**a and **1017**b, respectively, therethrough for receiving a finger of the user. Finger holes **1015**a and **1017**b facilitate movement of the shafts **1012**a and **1012**b relative to one another that, in turn, pivot the jaw members **1110** and **1120** from an open position wherein the jaw members **1110** and **1120** are disposed in spaced relation relative to one another to a clamping or closed position wherein the jaw members **1110** and **1120** cooperate to grasp tissue or vessels therebetween.

Shaft **1012**a is secured about pivot **1065** and positioned within a cut-out or relief **1021** such that shaft **1012**a is movable relative to shaft **1012**b. More particularly, when the user moves the shaft **1012**a relative to shaft **1012**b to close or open the jaw members **1110** and **1120**, the distal portion of shaft **1012**a moves within cutout **1021**. One of the shafts, e.g., **1012**b, includes a proximal shaft connector **1077** that is designed to connect the forceps **1000** to a source of electrosurgical energy such as an electrosurgical generator (not shown).

The distal end of the cable **1070** connects to a handswitch **1050** to permit the user to selectively apply electrosurgical energy as needed to seal tissue or vessels grasped between jaw members **1110** and **1120** (See FIGS. **20**, **21** and **25**). As best shown in FIGS. **22-23**, jaw members **1110** and **1120** include outer insulative coatings or layers **1116** and **1126** that are dimensioned to surround the outer periphery of jaw member **1110** and **1120** and expose electrically conductive sealing surfaces **1112** and **1122**, respectively on an inner facing surface thereof. The electrically conducive sealing surfaces **1112** and **1122** conduct electrosurgical energy to the tissue upon activation of the handswitch **1050** such that the two opposing electrically conductive sealing surfaces **1112** and **1122** conduct bipolar energy to seal tissue disposed between the sealing surfaces **1112** and **1122** upon activation. At least one of the jaw members **1110** and **1120** is adapted to connect to the source of electrosurgical energy (not shown) such that at least one of the jaw members **1110** and **1120** is capable of conducting electrosurgical energy to tissue held therebetween.

As best shown in FIG. **24**, the upper jaw member **1110** includes an exterior surface or outer edge **1210** extending from a distal end or tip **1215** of the upper jaw member **1110**. Similarly, the lower jaw member **1120** includes an exterior surface or outer edge **1220** extending from a distal end or tip **1225** of the lower jaw member **1120**. In addition, in accordance with the present disclosure, generally tubular insulating boot **1500** having a length "L" may be positioned about at least a portion of the end effector assembly **1100**. The distal end **1504** of the insulating boot **1500** is disposed on the outer edge **1210** of the upper jaw member **1110** at a distance "d" retracted away from the tip **1215** and at a corresponding position on the outer edge **1220** of the lower jaw member **1120** retracted away from the tip **1225**.

In one embodiment, the length "L" of the insulating boot **1500** is such that the proximal end **1502** of the insulating boot **1500** is disposed on the outer edges **1210** and **1220** so that the pivot pin **1065** remains exposed. In an alternate embodiment shown in phantom in FIG. **24**, the length "L" of the insulating boot **1500** is such that the proximal end **1502** of the insulating boot **1500** is disposed on the outer edges **1210** and **1220** so that the pivot pin **1065** is covered by the insulating boot **1500**. Those skilled in the art recognize that the distance "d" and the length "L" of the insulating boot **1500** are chosen so as to maximize continued operability of the jaw members **1110** and **1120** to perform their intended functions.

In either embodiment, the insulating boot **1500** limits stray current dissipation to surrounding tissue upon activation and continued use of the forceps **1000**. As mentioned above, the insulating boot **1500** is made from any type of visco-elastic, elastomeric or flexible material that is biocompatible and that is configured to minimally impede movement of the jaw members **1110** and **1120** from the open to closed positions. Moreover, in one embodiment, the material is selected to have a dielectric strength sufficient to withstand the voltages encountered during electrosurgery, and is suitable for use with a sterilization process that does not substantially impair structural integrity of the boot, such as an ethylene oxide process. More particularly, the insulating boot **1500** further reduces stray electrical potential so as to reduce the possibility of subjecting the patient tissue to unintentional electrosurgical RF energy.

As best shown in FIG. **24**, the tubular insulating boot **1500** is disposed on at least a portion of the exterior surface **1210** of jaw members **1110** and **1120** such that operability of the jaw members **1110** and **1120** is substantially unimpeded and not affected significantly by the flexible insulating boot **1500**. More particularly, the tubular insulating boot **1500** remains in a substantially stationary position axially with respect to the jaw members **1110** and **1120**, i.e., the distance "d" remains substantially constant during motion of the upper jaw member **1110** with respect to the lower jaw member **1120**. However, the flexible insulating boot **1500** expands and contracts both radially and axially to accommodate motion of the movable jaw member **1110**, and to cover the pivot pin **1103** where applicable.

Details relating to the jaw members **1110** and **1120** and various elements associated therewith are discussed in commonly-owned U.S. application Ser. No. 10/962,116, filed on Oct. 8, 2004, and entitled "Open Vessel Sealing Instrument with Hourglass Cutting Mechanism and Over-Ratchet Safety", *published as U.S. patent Application Publication No. US 2005/0154387 A1, now U.S. Pat. No. 7,811,283,* the entire contents of which are hereby incorporated by reference herein.

As best illustrated in FIG. **23**, jaw member **1120** (or jaw member **1110**) includes one or more stop members **1175** disposed on the inner facing surface of the electrically conductive sealing surface **1122**. The stop members are designed to facilitate gripping and manipulation of tissue and to define a gap "G" between opposing sealing surfaces **1112** and **1122** during sealing (See FIGS. **24** and **25**). The separation distance during sealing or the gap distance "G" is within the range of about 0.001 inches (about 0.03 millimeters) to about 0.006 inches (about 0.016 millimeters) for optimizing the vessel sealing process.

As best seen in FIGS. **22** and **23**, the jaw members **1110** and **1120** include a knife channel **1115** disposed therebetween that is configured to allow distal translation of a cutting mechanism (not shown) therewithin to sever tissue disposed between the seal surfaces **1112** and **1122**. The complete knife channel **1115** is formed when two opposing channel halves **1115**a and **1115**b associated with respective jaw members **1110** and **1120** come together upon grasping of the tissue. Details relating to the cutting mechanism and associated actuating mechanism (not shown) are discussed in commonly-owned U.S. application Ser. No. 10/962,116, *now U.S. Pat. No. 7,811,283, as described above,* the entire contents of which are hereby incorporated by reference herein.

FIG. **21** shows the details of a ratchet **1030** for selectively locking the jaw members **1110** and **1120** relative to one another during pivoting. A first ratchet interface **1031**a extends from the proximal end **1014**a of shaft member **1012**a towards a second ratchet interface **1031**b on the proximal end **1014**b of shaft **1012**b in general vertical registration therewith such that the inner facing surfaces of each ratchet **1031**a and **1031**b abut one another upon closure of the jaw members **1110** and **1120** about the tissue **400**. The position associated with the cooperating ratchet interfaces **1031**a and **1031**b holds a specific, i.e., constant, strain energy in the shaft members **1012**a and **1012**b that, in turn, transmits a specific closing force to the jaw members **1110** and **1120** within a specified working range of about 3 kg/cm^2 to about 16 kg/cm^2 when the jaw members **1110** and **1120** are ratcheted.

In operation, the surgeon utilizes the two opposing handle members **1015** and **1017** to grasp tissue between jaw members **1110** and **1120**. The surgeon then activates the handswitch **1050** to provide electrosurgical energy to each jaw member **1110** and **1120** to communicate energy through the tissue held therebetween to effect a tissue seal. Once sealed, the surgeon activates the actuating mechanism to advance the cutting blade through the tissue to sever the tissue **400** along the tissue seal.

The jaw members **1110** and **1120** are electrically isolated from one another such that electrosurgical energy can be effectively transferred through the tissue to form a tissue seal. Each jaw member, e.g., **1110**, includes a uniquely-designed electrosurgical cable path disposed therethrough that transmits electrosurgical energy to the electrically conductive sealing surface **1112**. The two electrical potentials are isolated from one another by virtue of the insulative sheathing surrounding each cable lead **1071**a, **1071**b and **1071**c. In addition, to further enhance safety, as noted previously, insulating boot **1500** may be positioned about at least a portion of the end effector assembly **1000**, and optionally the pivot **1065**, to limit stray current dissipation to surrounding tissue upon activation and continued use of the forceps **1010**. As mentioned above, the insulating boot **1500** is made from any type of visco-elastic, elastomeric or flexible material that is biocompatible and that is configured to minimally impede movement of the jaw members **1110** and **1120** from the open to closed positions.

The presently disclosed insulating boot may also be utilized with a forceps **2010** designed for both bipolar electrosurgical treatment of tissue (either by vessel sealing as described above or coagulation or cauterization with other similar instruments) and monopolar treatment of tissue. For example, FIGS. **26-32** show one embodiment of a forceps **2010** that includes a monopolar element, e.g., element **2154** that may be selectively extended and selectively activated to treat tissue. FIGS. **33**A-**33**B show alternate embodiments of the present disclosure that show that the knife **2185** may be extended from the distal end of the end effector assembly **2100** and selectively energized to treat tissue in a monopolar fashion. FIG. **34**A shows another embodiment of a forceps **2010'** wherein the bottom jaw member **2120'** extends distally from the top jaw member **2110'** to allow the surgeon to selectively energize the bottom jaw member **2120'** and treat tissue in a monopolar fashion. FIG. **34**B shows yet another embodiment of a forceps **2010"** wherein the jaw members **2110"** and **2120"** include tapered distal ends that are selectively energized with a single electrical potential to treat tissue in a monopolar fashion. FIGS. **35**A-**38**B show other configurations of the end effector assembly and/or bottom or second jaw member that are configured to suit a particular purpose or to achieve a desired surgical result. An insulating boot **2500** may be configured to cover the various uninsulated elements of the end effector assembly **1100** of the above mentioned and below further described elements including but not limited to portions of one or both of the jaw members **2110** and **2120**, the pivot **2103** and the knife assembly **2180** etc. The insulating boot **2500** is contemplated to be particularly useful with forceps capable of monopolar activation since the boot prevents the various uninsulated elements from acting as alternative or unintended current sources or paths during activation that may result in unintended or undesirable tissue effects during a particular surgical procedure.

More particularly, FIGS. **26-31** show one embodiment wherein a monopolar element **2154** is housed for selective extension within one jaw member, e.g., jaw member **2120**, of the end effector assembly **2100**. Monopolar element **2154** is designed to move independently from knife assembly **2180** and may be extended by further proximal movement of the trigger assembly **2070** (FIGS. **26**, **30** and **31**) or by a separate actuator **2450** (FIG. **32**).

The monopolar element **2154** may be connected to a reciprocating rod **2065** that extends through an elongated notch **2013** in the outer periphery of the shaft **2012** as best seen in FIG. **27**. Drive rod **2060** that actuates the knife **2185** extends through the inner periphery of shaft **2012**. In order to extend the monopolar element **2154**, the jaw members **2110** and **2120** are initially closed and the knife **2185** is advanced distally utilizing the trigger assembly **2070** (See FIG. **30**). As best shown in FIG. **28**, the trigger **2071** is initially advanced to translate the knife **2185** distally to cut through tissue, i.e., the "cut" stage (shown in phantom). Thereafter and as shown in FIGS. **28** and **31**, the trigger **2071** may be further actuated in a proximal direction to extend the monopolar element **2154**, i.e., the "extend" stage (shown in phantom).

As best shown in FIG. **29**, a tubular insulating boot **2500** is included that is configured to mount over the pivot **2103**, connecting the upper, pivoting jaw member **2110** with the lower, fixed jaw member **2120**, and over at least a portion of the end effector assembly **2100**. The tubular insulating boot **2500** is flexible to permit opening and closing of the jaw members **2110** and **2120** about the pivot **2103**. The flexible insulating boot **2500** is made typically of any type of viscoelastic, elastomeric or flexible material that is biocompatible. More particularly, the insulating boot **2500** is configured

to reduce stray electrical potential so as to reduce the possibility of subjecting the patient tissue to unintentional electrosurgical RF energy.

As best shown in FIG. **29**, one end of the tubular insulating boot **2500** is disposed on at least a portion of the exterior surface of shaft **2012** while the other end of the tubular insulating boot **2500** is disposed on at least a portion of the exterior surfaces of fixed jaw member **2120** and pivoting jaw member **2110** such that operability of the jaw members **2110** and **2120** is substantially unimpeded and not affected significantly by the flexible insulating boot **2500**. More particularly, the tubular insulating boot **2500** is maintained on the shaft **2012** such that boot **2500** remains in a substantially stationary position axially with respect to reciprocating sleeve **2060** and the jaw members **2110** and **2120**. The flexible insulating boot **2500** expands and contracts both radially and axially to cover the pivot pin **2103** and to accommodate motion of protrusion **2117** and the movable jaw member **2110**.

Details relating to this particular embodiment of a monopolar forceps is disclosed in aforementioned commonly-owned U.S. application Ser. No. 10/970,307, the entire contents of which are hereby incorporated by reference herein.

FIG. **32** shows another embodiment of the present disclosure wherein the monopolar element **2154** is selectively extendible utilizing a second actuator **2450**. As described above, the knife **2185** is advanced by actuating the trigger **2071** in a generally proximal direction. The monopolar element **2154** is selectively advanceable independently of the knife **2185** and may be extended when the jaw members **2110** and **2120** are disposed in either the open configuration or closed configuration. The actuator **2450** may be electrically configured to activate the monopolar element **2154** automatically once extended or manually by activation switch **2200** or perhaps another switch (not shown). As mentioned above, a safety circuit **2460** may be employed to deactivate jaw members **2110** and **2120** when the monopolar element **2154** is extended such that activation of the switch **2200** energizes the monopolar element **2154**. In the case of a separate activation switch for the monopolar element, the safety circuit would deactivate the switch **2200**.

In a similar manner as discussed previously with respect to FIG. **29**, and as shown in FIG. **32**, the tubular insulating boot **2500** is included that is configured to mount over the pivot **2103** and at least a portion of the end effector assembly **2100**. The tubular insulating boot **2500** is flexible to permit opening and closing of the jaw members **2110** and **2120** about pivot **2103**.

Those skilled in the art recognize that the material properties of the insulating boot **2500** and operability considerations from disposition of the insulating boot **2500** are in all respects either similar to or in some cases identical to those described in the preceding discussion with respect to FIGS. **26-31**.

FIGS. **33**A-**33**C show another alternate embodiment of the present disclosure of a forceps **2200** wherein the knife **2185** can be extended distally beyond the jaw members **2210** and **2220**, respectively, and separately energized to treat tissue. In this instance, when the knife is extended beyond the jaw members **2210** and **2220**, respectively, the knife **2185** becomes the monopolar element.

As illustrated in FIGS. **33**A-**33**C and partially in FIG. **34**B, once the knife **2185** extends beyond the jaw members **2110** and **2120**, a safety or switch deactivates energizing circuitry to the jaw members **2110** and **2120** and activates the energizing circuitry to the knife **285** such that activation of the switch **2200** energizes the knife **2185** and the jaw members remain neutral. For example, the stop **2119** may act as a safety switch such that upon being forced by the knife **2185** out of or away from the knife channel **2115**, the stop **2119** deactivates circuitry to the jaw members **2210** and **2220** and activates circuitry to the monopolar knife **2185** and the return electrode **2550**. A separate lead **2069** may be used to electrically communicate with the generator **2300** (See FIG. **34**B). As can be appreciated, the knife **2185** may now be used in a monopolar fashion to treat tissue.

Upon release of a trigger such as trigger **2070** (See FIG. **26**), the knife **2185** automatically retracts into the knife channel **2115** and back to the pre-actuated position as shown in FIG. **33**A. At the same time, the stop **2119** reverts to its original position to temporarily block the knife channel **2115** for subsequent actuation.

Again, in a similar manner as discussed previously with respect to FIG. **29**, the tubular insulating boot **2500** is included that is configured to mount over the pivot **2103** and at least a portion of the end effector assembly **2200**. The tubular insulating boot **2500** is flexible to permit opening and closing of the jaw members **2210** and **2220** about pivot **2103**.

Again, those skilled in the art recognize that the material properties of the insulating boot **2500** and operability considerations from disposition of the insulating boot **2500** are similar to those described in the preceding discussions.

As shown in FIG. **34**A and partially in the schematic FIG. **34**B, another embodiment of a forceps **2010'** according to the present disclosure wherein the lower jaw member **2120'** is designed to extend beyond the distal end of jaw member **2110'**. In order to switch from a bipolar mode of the operation to a monopolar mode, the surgeon activates a switch or control that energizes jaw member **2120'** to a first potential and activates a return pad **2550** to a second potential. Energy is transferred from jaw member **2120**, through tissue, and to the return pad **2550** to treat tissue. The distal end of jaw member **2120'** acts as the monopolar element for treating the tissue and may be shaped accordingly to enhance electrosurgical effect.

FIG. **34**B shows yet another schematic embodiment of a forceps **2010"** according to the present disclosure wherein the distal ends of both jaw members **2110"** and **2120"** are shaped to treat tissue when disposed in a monopolar mode. More particularly, the distal tips **2112**a" and **2122**a" are preferably elongated or tapered to enhance energy delivery when the forceps **2010"** is disposed in the monopolar mode. When disposed in the bipolar mode, the tapered ends **2112**a" and **2122**a" do not effect treating tissue between electrically conductive plates **2112"** and **2122"**.

A control switch **2505** is preferably included that regulates the transition between bipolar mode and monopolar mode. Control switch **2505** is connected to generator **2300** via cables **2360** and **2370**. A series of leads **2510**, **2520** and **2530** are connected to the jaw members **2110"**, **2120"** and the return electrode **2550**, respectively. As best shown in the table depicted in FIG. **34**B, each lead **2510**, **220**, and **2530** is provided with an electrical potential or remains neutral depending upon the particular "mode" of the forceps **2010"**. For example, in the bipolar mode, lead **2510** (and, in turn, jaw member **2110"**) is energized with a first electrical potential and lead **2520** (and, in turn, jaw member **2120"**) is energized with second electrical potential. As a result thereof, electrosurgical energy is transferred from jaw member **2110"** through the tissue and to jaw member **2120"**. The return electrode **2550** remains off or neutral.

In a monopolar mode, jaw member **2110"** and **2120"** are both energized with the same electrical potential and the return pad **2550** is energized with a second electrical potential forcing the electrical current to travel from the jaw members **2110"** and **2120"**, through the tissue and to the return elec-

trode **2550**. This enables the jaw members **2110"** and **2120"** to treat tissue in a monopolar fashion that, as mentioned above, advantageously treats a vascular tissue structures and/or allows quick dissection of narrow tissue planes. As can be appreciated, all of the leads **2510**, **2520** and **2530** may be deactivated when the forceps **2010"** is turned off or idle.

Yet again, as discussed previously with respect to FIG. **29**, the tubular insulating boot **2500** is included that is configured to mount over the pivot **2103** and at least a portion of the end effector assembly **2100'**.

FIGS. **35**A and **35**B show an alternate embodiment of the forceps **2010** according to the present disclosure that includes a second or bottom jaw member **2520'** that is manufactured such that the distal end **2522**a of the tissue sealing surface **2522** extends beyond the bottom jaw housing **2524**. More particularly, in this particular embodiment, the tissue sealing surface **2522** is made from a stamped sheet metal that is formed atop a stamped sheet metal skeleton **2532**. The proximal end of the sheet metal skeleton **2532** may be configured with various pivot points (or apertures **2534**), cam slots or grooves depending upon the particular type of pivot action associated with the forceps **2010**. As can be appreciated, the sealing surface **2522** may be supported atop a hem or spine **2535** that extends along the skeleton **2532** by many ways known in the art.

An insulating layer **2540** is disposed between the skeleton **2532** and the tissue sealing surface **2522** to isolate the electrically conductive sealing surface **2522'** from hem **2535** during activation. The stamped tissue sealing surface **2522'** is formed of a double layer of sheet metal material separated by a slot or knife channel **2515** that allows selective reciprocation of a knife, such as knife **2185** disclosed in FIGS. **33**A-**33**C, therein. The distal end **2522**a of the tissue sealing surface **2522** may be bent 180° to provide a larger conductive surface area that extends beyond the jaw housing **2524**.

It is envisioned that the tissue sealing surface **2522** may be curved or straight depending upon a particular surgical purpose. The jaw housing **2524** may be overmolded to encapsulate the hem **2535** of the skeleton **2532** and sealing plate **2522** that serves to insulate surrounding tissue from the conductive surfaces of the sealing plate **2522** as well as to give the jaw member **2520'** a desired shape at assembly.

In a similar manner as discussed previously with respect to FIG. **29**, and as shown in FIG. **32**, the tubular insulating boot **2500** is included of which one end is configured to mount over the sheet metal skeleton **2532** and pivot pin aperture **2534** and another end of the insulating boot **2500** configured to mount over at least a portion of an exterior surface of reciprocating sleeve **2060**. The tubular insulating boot **2500** is flexible to permit opening and closing of the jaw members **2110** and **2520'** about pivot **2103**.

Details relating to the forceps **2010'**, which is manufactured such that the distal end **2522**a' of the tissue sealing surface **2522** extends beyond the bottom jaw housing **2524**, are disclosed in previously mentioned commonly owned U.S. patent application Ser. No. 10/970,307 that is incorporated by reference herein.

FIGS. **36**A and **36**B show another embodiment of the bottom or second jaw member **2620** that includes both an electrically conductive sealing surface **2622** for sealing purposes as well as an electrically conductive surface **2632** that is designed for monopolar activation. More particularly, the bottom jaw member **2620** includes a jaw housing **2624** that supports (or encapsulates) a tissue sealing surface **2622**. A knife channel **2615** is disposed along the length of the tissue sealing surface **2622** and allows reciprocation of a knife therein. An insulating layer **2634** is positioned at or proximal to the distal end of the tissue sealing surface **2622** distal to the knife channel **2615**. A second conductive material **2632** (that may or may not be the same material as tissue sealing surface **2622**) is disposed on the opposite side of the insulating layer **2634**.

It is envisioned that the insulating material **2634** will isolate the monopolar portion **2632** during electrical activation of tissue surface **2622** and isolate the tissue surface **2622** during electrical activation of monopolar element **2632**. As can be appreciated, the two different electrically conductive elements **2622** and **2632** are connected to electrical generator **2300** by different electrical connections and may be selectively activated by the user. Various switches or electrical control elements or the like (not shown) may be employed to accomplish this purpose.

Still yet again, to further enhance safety, as discussed previously with respect to FIG. **29**, the tubular insulating boot **2500** is included that is configured to mount over the pivot (not shown) and at least a portion of the end effector assembly. The tubular insulating boot **2500** is flexible to permit opening and closing of the jaw members **2110** and **2620**.

Bottom or second jaw member **2620** includes both an electrically conductive sealing surface **2622** for sealing purposes as well as an electrically conductive surface **2632** that is designed for monopolar activation are disclosed in previously mentioned commonly owned U.S. patent application Ser. No. 10/970,307 which is incorporated by reference herein.

FIGS. **37**A and **37**B show another embodiment of an end effector assembly **2700** according to the present disclosure that includes top and bottom jaw members **2710** and **2720**, respectively each including similar jaw elements as described above, i.e., tissue sealing surfaces **2712** and **2722**, respectively and insulative housings **2714** and **2724**, respectively. In a similar manner as mentioned above with respect to tissue sealing surface **2622** and knife channel **2615**, the tissue sealing surfaces **2712** and **2722** of jaw members **2710** and **2720** mutually cooperate to form a knife channel **2715** that allows knife **2185** to be selectively reciprocated therethrough. More particularly, jaw member **2710** includes a first part of knife channel **2715**a and jaw member **2720** includes a second part of the knife channel **2715**b that align to form knife channel **2715**.

As best shown in FIG. **37**B, knife channels **2715**a and **2715**b are aligned in vertical registration along one side of the jaw members **2710** and **2720** to allow reciprocation of knife **2185** therethrough. Knife channel **2715**b of jaw member **2720** is wider (i.e., as measured transversally across the length of the jaw member **2720**) and includes a separate channel **2715b1** that is dimensioned to slidingly receive a monopolar element **2754** therethrough. A trigger **70** (or the like) may be utilized as described above with respect to FIGS. **26-31** to extend the monopolar element **2754** for treatment of tissue. In addition, the monopolar element **2754** and the knife **2185** may be made of separate components, as shown, or the monopolar element **2754** and the knife **2185** may be integral with one another.

As can be appreciated various switching algorithms may be employed to activate both the bipolar mode for vessel sealing and the monopolar mode for additional tissue treatments (e.g., dissection). Also, a safety or lockout may be employed either electrically, mechanically or electromechanically to "lock out" one electrical mode during activation of the other electrical mode. In addition, a toggle switch (or the like) may be employed to activate one mode at a time for safety reasons. The monopolar element **2754** may also include a safety (either mechanical, electrical or electro-mechanical—not shown) that only allows electrical activation of the monopolar

element **2754** when the monopolar element **2754** is extended from the distal end of jaw member **2720**. Insulating boot **2500** is included that is configured to mount over the pivot **2103** and at least a portion of the end effector assembly **2100**.

FIGS. **38**A and **38**B show yet another embodiment of bottom jaw member **2820** that may be utilized for both bipolar vessel sealing and monopolar tissue dissection or other monopolar tissue treatments. More particularly, jaw member **2820** includes an outer jaw housing **2824** that is overmolded to encapsulate a tissue sealing plate **2822** therein. Tissue sealing plate **2822** includes a knife channel **2815** for reciprocating a knife as described in detail above. Tissue sealing plate **2822** also includes a sealing surface **2822**a that is disposed in opposing relation to a corresponding sealing surface (not shown) on the opposite upper jaw member (not shown).

Tissue sealing surface **2822** also includes a sealing surface extension **2822**b that extends through a distal end **824**a of the overmolded jaw housing **2824**. As can be appreciated, sealing surface extension **2822**b is designed for monopolar tissue dissection, enterotomies or other surgical functions and may be separately electrically energized by the user by a hand switch, footswitch or at the generator **2300** in a similar manner as described above (See FIG. **34**B). As can be appreciated, the extension **2822**b also serves to further anchor the sealing plate **2822** in the jaw housing **2824** during the overmolding process. Insulating boot **2500** is included that is configured to mount over the pivot **2103** and at least a portion of the end effector assembly.

From the foregoing and with reference to the various figure drawings, those skilled in the art will appreciate that certain modifications can also be made to the present disclosure without departing from the scope of the same. For example and although the general operating components and interco-operating relationships among these components have been generally described with respect to a vessel sealing forceps, other instruments may also be utilized that can be configured to allow a surgeon to selectively treat tissue in both a bipolar and monopolar fashion. Such instruments include, for example, bipolar grasping and coagulating instruments, cauterizing instruments, bipolar scissors, etc.

Furthermore, those skilled in the art recognize that while the insulating boots **500**, **1500**, or **2500** are disclosed as having a generally tubular configuration, the cross-section of the generally tubular configuration can assume substantially any shape such as, but not limited to, an oval, a circle, a square, or a rectangle, and also include irregular shapes necessary to cover at least a portion of the jaw members and the associated elements such as the pivot pins and jaw protrusions, etc.

In addition, while several of the disclosed embodiments show endoscopic forceps that are designed to close in a unilateral fashion, forceps that close in a bilateral fashion may also be utilized with the insulating boot described herein. The presently disclosed insulating boot may be configured to fit atop or encapsulate pivot or hinge members of other known devices such as jawed monopolar devices, standard laparoscopic "Maryland" dissectors and/or bipolar scissors.

While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed is:

1. An electrosurgical forceps, comprising:

a shaft having a pair of jaw members at a distal end thereof, the jaw members being movable about a pivot from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members are closer to one another for grasping tissue, the shaft defining a longitudinal axis therethrough;

a movable handle that actuates a drive assembly to move the jaw members relative to one another;

at least one of the jaw members including a tissue-engaging surface adapted to connect to a source of electrical energy such that the at least one jaw member is capable of conducting energy to tissue held therebetween; and

a flexible insulating boot mounted over the pivot, the flexible insulating boot having a proximal portion disposed on a portion of the shaft and a distal portion disposed on a portion of an exterior surface of the pair of jaw members proximal to the tissue-engaging surface of the at least one jaw member, the proximal portion and the distal portion of the flexible insulating boot disposed such that the flexible insulating boot remains in a substantially stationary position relative to the longitudinal axis and with respect to a reciprocating sleeve of the drive assembly and the jaw members when the drive assembly mechanically advances the reciprocating sleeve to apply a predetermined closure force between the jaw members.

2. An electrosurgical forceps according to claim **1**, wherein at least one of the jaw members includes a series of stop members disposed thereon for regulating distance between the jaw members such that a gap is created between the jaw members during the sealing process.

3. An electrosurgical forceps according to claim **1**, wherein the forceps includes a knife that is selectively deployable to cut tissue disposed between the jaw members.

4. An electrosurgical forceps according to claim **1**, wherein the insulating boot is made of at least one of a viscoelastic, elastomeric, and flexible material suitable for use with a sterilization process that does not substantially impair structural integrity of the boot.

5. An electrosurgical forceps according to claim **4**, wherein the sterilization process includes ethylene oxide.

6. An electrosurgical forceps according to claim **1**, wherein the flexible insulating boot has a generally tubular configuration.

7. An electrosurgical forceps according to claim **1**, wherein two jaw members are adapted to connect to the source of electrical energy such that the jaw members are capable of treating tissue in a bipolar manner upon selective activation of the forceps.

8. An electrosurgical forceps according to claim **1**, wherein at least one jaw member is adapted to connect to the source of electrical energy such that the at least one jaw members is capable of treating tissue in a monopolar manner upon selective actuation of the forceps.

9. An electrosurgical forceps, comprising:

a shaft having a pair of jaw members at a distal end thereof, the jaw members being movable about a pivot from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members are closer to one another for grasping tissue, the shaft defining a longitudinal axis therethrough;

a drive assembly that includes a reciprocating sleeve and a movable handle that actuates the reciprocating sleeve and the drive assembly to move the jaw members relative to one another;

at least one of the jaw members including a tissue-engaging surface adapted to connect to a source of electrical energy such that the at least one jaw member is capable of conducting energy to tissue held therebetween; and

a flexible insulating boot defining an internal surface, the flexible insulating boot mounted over the pivot such that at least a portion of the internal surface is in direct contact with the pivot, the flexible insulating boot having a proximal portion disposed on a portion of the shaft and a distal portion disposed on a portion of an exterior surface of the pair of jaw members proximal to the tissue-engaging surface of the at least one jaw member such that at least a portion of the internal surface defined by the flexible insulating boot is in direct contact with the portion of the exterior surface of the pair of jaw members proximal to the tissue-engaging surface of the at least one jaw member, the proximal portion and the distal portion of the flexible insulating boot disposed such that the flexible insulating boot remains in a substantially stationary position relative to the longitudinal axis and with respect to the reciprocating sleeve and the jaw members when the drive assembly mechanically advances the reciprocating sleeve of the drive assembly to apply a predetermined closure force between the jaw members.

10. An electrosurgical forceps according to claim 9, wherein at least one of the jaw members includes a series of stop members disposed thereon for regulating distance between the jaw members such that a gap is created between the jaw members during the sealing process.

11. An electrosurgical forceps according to claim 9, wherein the forceps includes a knife that is selectively deployable to cut tissue disposed between the jaw members.

12. An electrosurgical forceps according to claim 9, wherein the insulating boot is made of at least one of a viscoelastic, elastomeric, and flexible material suitable for use with a sterilization process that does not substantially impair structural integrity of the boot.

13. An electrosurgical forceps according to claim 12, wherein the sterilization process includes ethylene oxide.

14. An electrosurgical forceps according to claim 9, wherein the flexible insulating boot has a generally tubular configuration.

15. An electrosurgical forceps according to claim 9, wherein two jaw members are adapted to connect to the source of electrical energy such that the jaw members are capable of treating tissue in a bipolar manner upon selective activation of the forceps.

16. An electrosurgical forceps according to claim 9, wherein at least one jaw member is adapted to connect to the source of electrical energy such that the at least one jaw members is capable of treating tissue in a monopolar manner upon selective actuation of the forceps.

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