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OPEN VESSEL SEALING INSTRUMENT WITH CUTTING MECHANISM

Abstract

An open electromechanical forceps (10) for sealing tissue includes a pair of first and second shaft members (12, 20) each having a jaw member (62, 64) disposed at a distal end thereof. The jaw members (62, 64) are movable from a first position in spaced relation relative to one another to a subsequent position wherein the jaw members (62, 64) cooperate to grasp tissue therebetween. Each of the jaw members (62, 64) includes an electrically conductive sealing plate (67, 68) for communicating electrosurgical energy through tissue held therebetween. At least one of the jaw members (62, 64) includes a cutting slot defined along a length thereof which is dimensioned to reciprocate a cutting instrument (90) therealong for cutting tissue disposed between jaw members (62, 64). An actuator (40) advances the cutting instrument (90) from a first position wherein the cutting instrument (90) is disposed proximal to tissue held between the jaw members (62, 64) to at least one subsequent position wherein the cutting instrument (90) is disposed distal to tissue held between the jaw members (62, 64).

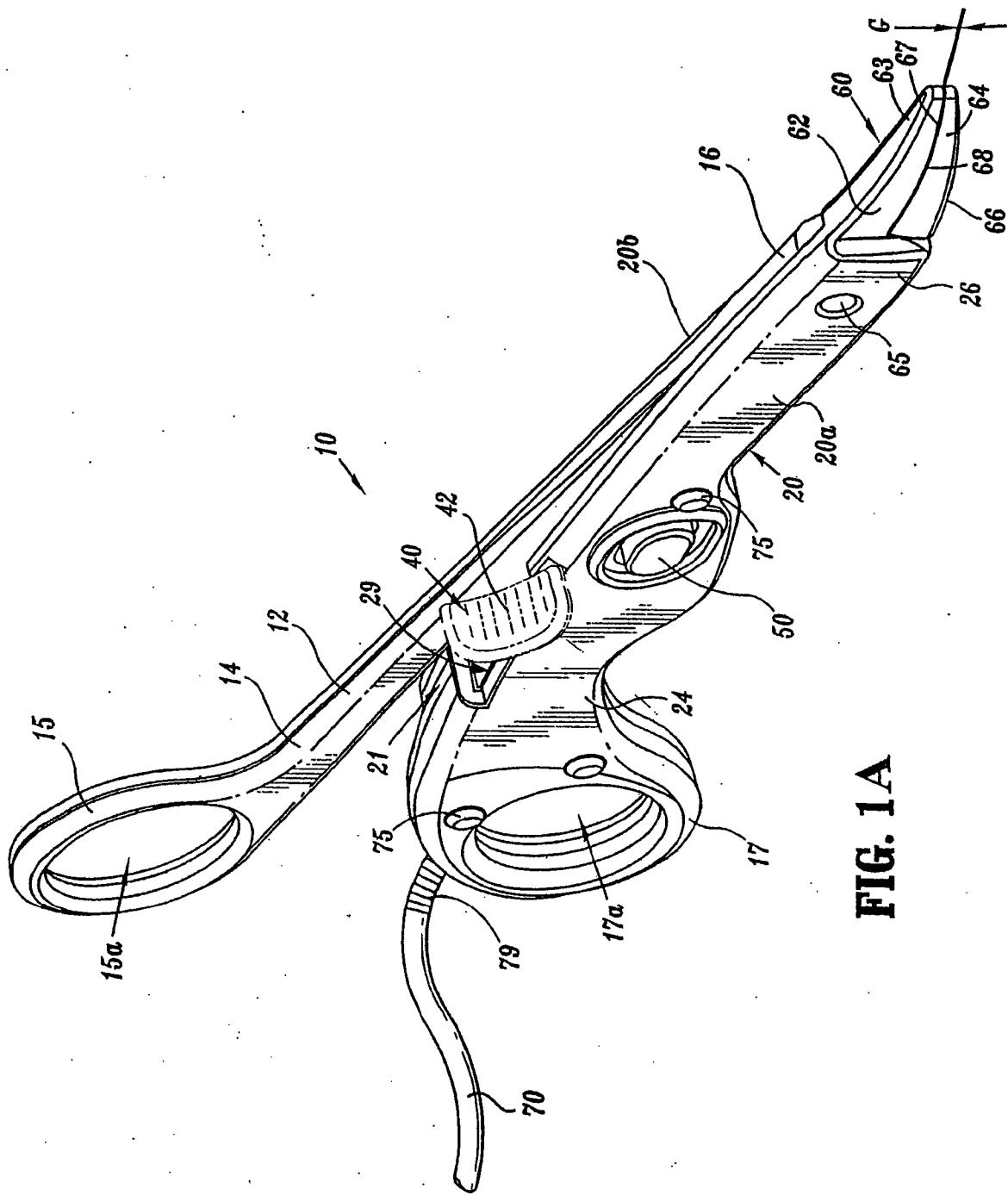


FIG. 1A

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Invention Title: Open vessel sealing instrument with cutting mechanism

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

OPEN VESSEL SEALING INSTRUMENT WITH CUTTING MECHANISM

FIELD OF THE INVENTION

The present disclosure relates to forceps used for open surgical procedures.
5 More particularly, the present disclosure relates to an open forceps which applies a combination of mechanical clamping pressure and electrosurgical energy to seal tissue and a knife which is selectively activateable to sever tissue.

BACKGROUND OF THE INVENTION

A forceps is a plier-like instrument which relies on mechanical action between 10 its jaws to grasp, clamp and constrict vessels or tissue. So-called "open forceps" are commonly used in open surgical procedures whereas "endoscopic forceps" or "laparoscopic forceps" are, as the name implies, used for less invasive endoscopic surgical procedures. Electrosurgical

forceps (open or endoscopic) utilize both mechanical clamping action and electrical energy to effect hemostasis by heating tissue and blood vessels to coagulate and/or cauterize tissue.

Certain surgical procedures require more than simply cauterizing 5 tissue and rely on the unique combination of clamping pressure, precise electrosurgical energy control and gap distance (i.e., distance between opposing jaw members when closed about tissue) to "seal" tissue, vessels and certain vascular bundles.

Vessel sealing or tissue sealing is a recently-developed 10 technology which utilizes a unique combination of radiofrequency energy, pressure and gap control to effectively seal or fuse tissue between two opposing jaw members or sealing plates. Vessel or tissue sealing is more than "cauterization" which is defined as the use of heat to destroy tissue (also called "diathermy" or "electrodiathermy") and vessel sealing is more than 15 "coagulation" which is defined as a process of desiccating tissue wherein the tissue cells are ruptured and dried. "Vessel sealing" is defined as the process of liquefying the collagen, elastin and ground substances in the tissue so that it reforms into a fused mass with significantly-reduced demarcation between the opposing tissue structures.

20 In order to effectively "seal" tissue or vessels, two predominant mechanical parameters must be accurately controlled: 1) the pressure applied

to the vessel or tissue; and 2) the gap distance between the conductive tissue contacting surfaces (electrodes). As can be appreciated, both of these parameters are affected by the thickness of the tissue being sealed. Accurate application of pressure is important for several reasons: to reduce the tissue 5 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 good seal for certain tissues is optimum between 0.001 inches and 0.006 inches.

10 With respect to smaller vessels or tissue, the pressure applied becomes less relevant and 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 the tissue thickness and the vessels become smaller.

15 Commonly owned, U.S. Patent No. 6,511,480, PCT Patent Application Nos. PCT/US01/11420 and PCT/US01/11218, U.S. Patent Applications Serial Nos. 10/116824, 10/284562 and 10/299650 all describe various open surgical forceps which seal tissue and vessels. All of these references are hereby incorporated by reference herein. In addition, several 20 journal articles have disclosed methods for sealing small blood vessels using electrosurgery. An article entitled Studies on Coagulation and the Development of an Automatic Computerized Bipolar Coagulator, J.

Neurosurg., Volume 75, July 1991, describes a bipolar coagulator which is used to seal small blood vessels. The article states that it is not possible to safely coagulate arteries with a diameter larger than 2 to 2.5 mm. A second article is entitled Automatically Controlled Bipolar Electrocoagulation – "COA-COMP", Neurosurg. Rev. (1984), pp. 187-190, describes a method for terminating electrosurgical power to the vessel so that charring of the vessel walls can be avoided.

Typically and particularly with respect to open electrosurgical procedures, once a vessel is sealed, the surgeon has to remove the sealing instrument from the operative site, substitute a new instrument and accurately sever the vessel along the newly formed tissue seal. As can be appreciated, this additional step may be both time consuming (particularly when sealing a significant number of vessels) and may contribute to imprecise separation of the tissue along the sealing line due to the misalignment or misplacement of the severing instrument along the center of the tissue sealing line.

Many endoscopic vessel sealing instruments have been designed which incorporate a knife or blade member which effectively severs the tissue after forming a tissue seal. For example, commonly-owned U.S. Application Serial Nos. 10/116,944 and 10/179,863 describe one such endoscopic instrument which effectively seals and cuts tissue along the tissue seal. Other 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.

There exists a need to develop an open electrosurgical forceps which is simple, reliable and inexpensive to manufacture and which effectively seals tissue and vessels and
5 which allows a surgeon to utilize the same instrument to effectively sever the tissue along the newly formed tissue seal.

OBJECT OF THE INVENTION

It is an object of the present invention to overcome or ameliorate some of the disadvantages of the prior art, or at least to provide a useful alternative.

10

SUMMARY OF THE INVENTION

The present disclosure preferably relates to an open electrosurgical forceps for sealing tissue and includes a pair of first and second shaft members each having a jaw member disposed at a distal end thereof. The jaw members preferably are moveable 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. Each of the
15 jaw members preferably includes an electrically conductive sealing plate or sealing surface on an inner facing surface which communicates electrosurgical energy through tissue held therebetween. Preferably, one of the jaw members includes a cutting slot defined along a longitudinal length thereof which is dimensioned to reciprocate a cutting instrument therealong to sever tissue held between the jaw members. An actuator is
20 preferably included for selectively advancing the cutting instrument from a first position wherein the cutting instrument is disposed proximal to tissue held

between the jaw members to at least one subsequent position wherein the cutting instrument is disposed distal to tissue held between the jaw members.

In one embodiment, the actuator includes a trigger assembly which cooperates with a pulley and cable system to advance the cutting instrument from the first to second positions through tissue held therebetween. The trigger assembly of the actuator may be moved proximally, distally or laterally to distally advance the cutting instrument through the cutting slot.

Preferably, the forceps includes a safety mechanism or lockout to prevent reciprocation of the cutting instrument when the jaws are disposed in the first position. The lock out may form part of the trigger assembly and/or part of one or both of the jaw assemblies.

In one embodiment, each of the shafts includes a handle and at least one of the handle defines a track therethrough for reciprocating a cable of the pulley and cable system. The cable is mechanically engaged with the cutting instrument such that movement of the cable imparts movement of the cutting instrument between the first and subsequent positions. Preferably, the cable is manufactured from a plastic or braided flexible material and may include one or more stiffeners to prevent the cable from buckling within the track.

In another embodiment, the forceps includes one or more springs which automatically bias the cutting instrument in the first position such that after the cutting instrument severs the tissue held between the jaw members, the cutting instrument automatically returns to the first position. Preferably, the 5 trigger assembly includes at least one spring for automatically returning the cutting instrument back to the first position.

In another embodiment, the actuator includes a trigger assembly which cooperates with a rack and pinion system to advance the cutting instrument from the first to second positions through tissue held therebetween. 10 Preferably, the rack and pinion system is engaged with one of the first and second shaft members. The trigger assembly of the actuator may be moved proximally, distally or laterally to distally advance the cutting instrument through the cutting slot.

BRIEF DESCRIPTION OF THE DRAWINGS

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

Fig. 1A is a left, perspective view of an open forceps according to the present disclosure;

Fig. 1B is a left, side view of the forceps of Fig. 1A;

Fig. 1C is an internal view of the forceps of Fig. 1A showing a rack and pinion actuating mechanism for advancing a cutting knife;

Fig. 1D is an internal, perspective view of an alternate embodiment of the open forceps according to the present disclosure having a
5 rack and pinion actuating mechanism for advancing the cutting knife;

Fig. 1E is an enlarged, perspective view showing the distal end of the actuating mechanism which attaches to the cutting knife;

Fig. 2A is a left, perspective view of an alternate embodiment of an open forceps according to the present disclosure;

10 Fig. 2B is a left, side view of the forceps of Fig. 2A;

Fig. 2C is an internal view of the forceps of Fig. 2A showing a flexible linkage actuating mechanism for advancing the cutting knife;

Fig. 2D is an internal view of the forceps of Fig. 2A showing a flexible wire actuating mechanism for advancing the cutting knife;

15 Fig. 2E is a side, internal view of the trigger for advancing and retracting the flexible wire of Fig. 2D;

Fig. 3 is a perspective view of an alternate embodiment of the open forceps according to the present disclosure having a forwardly activateable actuating mechanism for advancing the cutting knife;

5 Fig. 4 is a perspective view of an alternate embodiment of the open forceps according to the present disclosure having a lever arm which advances the cutting knife;

Fig. 5A is an internal, side view of a forceps according to the present disclosure showing an electrosurgical cable and the various internal electrical connections therein;

10 Fig. 5B is a cross section of the electrosurgical cable taken along line 5B-5B of Fig. 5A;

Fig. 5C is a side view of the electrosurgical cable with part of the outer insulative sheathing removed;

15 Fig. 6A is an enlarged view of a safety mechanism according to the present disclosure shown in a disengaged position;

Fig. 6B is a greatly-enlarged view of the safety mechanism of Fig. 6A;

Fig. 6C is a greatly-enlarged view of the safety mechanism of Fig. 6A shown being activated;

Fig. 6D is a greatly-enlarged view of the safety mechanism of Fig. 6A in an activated position to allow reciprocation of the actuating mechanism;

5 Fig. 6E is a greatly-enlarged view of another embodiment of a safety mechanism or lockout which may be utilized with any of the above embodiments of the open forceps described above;

10 Fig. 6F is a greatly-enlarged view of a knife carrier for use with the safety mechanism of Fig. 6E; and

Fig. 7 is an enlarged, top view showing a cutting knife which is generally disposed off-axis relative to the distal end of the forceps to facilitate tissue cutting around a curved jaw member.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

15 Referring now to Figs. 1A-1E, a forceps 10 for use with open surgical procedures includes elongated shaft portions 12 and 20 each having a proximal end 14 and 24, respectively, and a distal end 16 and 26, respectively.

In the drawings and in the descriptions which follow, the term "proximal", as is traditional, will refer to the end of the forceps 10 which is closer to the user, while the term "distal" will refer to the end which is further from the user.

The forceps 10 includes an end effector assembly 60 which
5 attaches to the distal ends 16 and 26 of shafts 12 and 20, respectively. As explained in more detail below, the end effector assembly 60 includes pair of opposing jaw members 62 and 64 which are pivotably connected about a pivot pin 65 and which are movable relative to one another to grasp tissue.

Preferably, each shaft 12 and 20 includes a handle 15 and 17,
10 disposed at the proximal end 14 and 24 thereof which each define a finger hole 15a and 17a, respectively, therethrough for receiving a finger of the user. As can be appreciated, finger holes 15a and 17a facilitate movement of the shafts 12 and 20 relative to one another which, in turn, pivot the jaw members 62 and 64 from an open position wherein the jaw members 62 and 64 are
15 disposed in spaced relation relative to one another to a clamping or closed position wherein the jaw members 62 and 64 cooperate to grasp tissue therebetween.

As best seen in Fig. 1A, shaft 20 is bifurcated to define an elongated channel 21 therealong which is dimensioned to receive shaft 12
20 therein. More particularly, shaft 20 is made from two halves 20a and 20b which are matingly engaged during assembly to form shaft 20 and to define

the elongated channel 21. It is envisioned that the two halves 20a and 20b may be sonic-welded together at a plurality of different weld points 75 or the housing halves may be mechanically engaged in any other known fashion, snap-fit, glued, screwed, etc. Upon assembly, shaft 12 is positioned within 5 shaft 20 and secured about pivot 65 which allows the two shafts 12 and 20 to pivot with respect to one another. When the user moves the shaft 12 relative to shaft 20 to close the jaw members 62 and 64, shaft 12 is received within the elongated channel 21 of shaft 20. It is envisioned that configuring the two shafts 12 and 20 in the fashion facilitates gripping and reduces the overall size 10 of the forceps 10 which is especially advantageous during surgeries in small cavities.

As best illustrated in Fig. 1A, one of the shafts, e.g., 20, includes a proximal shaft connector 79 which is designed to connect the forceps 10 to a source of electrosurgical energy such as an electrosurgical generator (not 15 shown). The proximal shaft connector 79 electromechanically engages an electrosurgical cable 70 such that the user may selectively apply electrosurgical energy as needed. Alternatively, the cable 70 may be feed directly into shaft 20 as best seen in Fig. 5A.

As explained in more detail below, the distal end of the cable 70 20 connects to a handswitch 50 to permit the user to selectively apply electrosurgical energy as need to seal tissue grasped between jaw members 62 and 64. More particularly, the interior of cable 70 houses leads 70a, 70b

and 70c which upon activation of the handswitch 50 conduct the different electrical potentials from the electrosurgical generator to the jaw members 62 and 64. As can be appreciated, positioning the switch 50 on the forceps 10 gives the user more visual and tactile control over the application of 5 electrosurgical energy. These aspects are explained below with respect to Figs. 5A-5C and the discussion of the handswitch 50 and the electrical connections associated therewith.

As best seen in Figs. 1A and 1B, the two opposing jaw members 62 and 64 of the end effector assembly 60 are pivotable about pin 65 from the 10 open position to the closed position for grasping tissue therebetween. Jaw members 62 and 64 are generally symmetrical and include similar component features which cooperate to permit facile rotation about pivot pin 65 to effect the grasping and sealing of tissue. As a result and unless otherwise noted, jaw member 62 and the operative features associated therewith are initially 15 described herein in detail and the similar component features with respect to jaw member 64 will be briefly summarized thereafter. Moreover, many of the features of the jaw members 62 and 64 are described in detail in commonly-owned U.S. Patent Application Serial Nos. 10/284,562, 10/116,824, 09/425,696, 09/178,027 and PCT Application Serial No. PCT/US01/11420 the 20 contents of which are all hereby incorporated by reference in their entirety herein.

Jaw member 62 includes an insulated outer housing 63 which is dimensioned to mechanically engage an electrically conductive sealing surface 67. The outer insulative housing 63 extends along the entire length of jaw member 62 to reduce alternate or stray current paths during sealing and/or incidental burning of tissue. The electrically conductive surface 67 conducts electrosurgical energy of a first potential to the tissue upon activation of the handswitch 50. Insulated outer housing 63 is dimensioned to securely engage the electrically conductive sealing surface 67. It is envisioned that this may be accomplished by stamping, by overmolding, by overmolding a stamped electrically conductive sealing plate and/or by overmolding a metal injection molded seal plate. Other methods of affixing the seal surface 67 to the outer housing 63 are described in detail in one or more of the above-identified references.

It is also envisioned that the electrically conductive sealing surface 67 may include a pinch trim (not shown) which facilitates secure engagement of the electrically conductive surface 67 to the insulated outer housing 63 and also simplifies the overall manufacturing process. It is also contemplated that the electrically conductive sealing surface 67 may include an outer peripheral edge which has a radius and the insulated outer housing 63 meets the electrically conductive sealing surface 67 along an adjoining edge which is generally tangential to the radius and/or meets along the radius. Preferably, at the interface, the electrically conductive surface 67 is raised relative to the insulated outer housing 63. These and other envisioned

embodiments are discussed in commonly-owned, co-pending PCT Application Serial No. PCT/US01/11412 and commonly owned, co-pending PCT Application Serial No. PCT/US01/11411, the contents of both of these applications being incorporated by reference herein in their entirety.

5 Preferably, the insulated outer housing 63 and the electrically conductive sealing surface 67 are dimensioned to limit and/or reduce many of the known undesirable effects related to tissue sealing, e.g., flashover, thermal spread and stray current dissipation. All of the aforementioned and cross referenced manufacturing techniques produce an electrode having an 10 electrically conductive surface 67 which is substantially surrounded by an insulated outer housing 63.

15 Likewise, jaw member 64 includes similar elements which include: an outer housing 66 which engages an electrically conductive sealing surface 68. The electrically conductive sealing surface 68 conducts electrosurgical energy of a second potential to the tissue upon activation of the handswitch 50.

20 It is envisioned that one of the jaw members, e.g., 62, includes at least one stop member (not shown) disposed on the inner facing surface of the electrically conductive sealing surface 67 (and/or 68). Alternatively or in addition, the stop member may be positioned adjacent to the electrically conductive sealing surfaces 67, 68 or proximate the pivot pin 65. The stop

member(s) is preferably designed to facilitate gripping and manipulation of tissue and to define a gap "G" (Fig. 1A) between opposing jaw members 62 and 64 during sealing. Preferably the separation distance during sealing or the gap distance "G" is within the range of about 0.001 inches (~0.03 millimeters) to about 0.006 inches (~0.016 millimeters).

A detailed discussion of these and other envisioned stop members as well as various manufacturing and assembling processes for attaching, disposing, depositing and/or affixing the stop members to the electrically conductive sealing surfaces 67, 68 are described in commonly-assigned, co-pending PCT Application Serial No. PCT/US01/11222 which is hereby incorporated by reference in its entirety herein.

As mentioned above, two mechanical factors play an important role in determining the resulting thickness of the sealed tissue and effectiveness of the seal, i.e., the pressure applied between opposing jaw members 62 and 64 and the gap "G" between the opposing jaw members 62 and 64 (or opposing seal surface 67 and 68 during activation). It is known that the thickness of the resulting tissue seal cannot be adequately controlled by force alone. In other words, too much force and the two jaw members 62 and 64 would touch and possibly short resulting in little energy traveling through the tissue thus resulting in a bad seal. Too little force and the seal would be too thick. Applying the correct force is also important for other reasons: to oppose the walls of the vessel; to reduce the tissue impedance to a low enough value

that allows enough current through the tissue; and to overcome the forces of expansion during tissue heating in addition to contributing towards creating the required end tissue thickness which is an indication of a good seal.

Preferably, the seal surfaces 67 and 68 are relatively flat to avoid current concentrations at sharp edges and to avoid arcing between high points. In addition and due to the reaction force of the tissue when engaged, jaw members 62 and 64 are preferably manufactured to resist bending, i.e., tapered along their length which provides a constant pressure for a constant tissue thickness at parallel and the thicker proximal portion of the jaw members 62 and 64 will resist bending due to the reaction force of the tissue.

As best seen in Figs. 1C and 1D, the jaw members 62 and 64 include a knife channel 69 disposed therebetween which is configured to allow reciprocation of a cutting mechanism 90 therewithin. One example of a knife channel is disclosed in commonly-owned U.S. Patent Application Serial No. 10/284,562 the entire contents of which are hereby incorporated by reference herein. Preferably, the complete knife channel 69 is formed when two opposing channel halves 69a and 69b come together upon grasping of the tissue. It is envisioned that the knife channel 69 may be tapered or some other configuration which facilitates or enhances cutting of the tissue during reciprocation of the cutting mechanism 90 in the distal direction. Moreover, the knife channel 69 may be formed with one or more safety features which prevent the cutting mechanism 90 from advancing through the tissue until the

jaw members 62 and 64 are closed about the tissue.

Fig. 1B shows a lockout mechanism 47 associated with the actuating assembly 40 to prevent advancement of the cutting mechanism until the jaw members are positioned about tissue. Other lockout mechanisms and 5 features are described in commonly-owned U.S. Application Serial Nos. 10/460,926, 10/461,550 and 10/462,121 which are all incorporated by reference herein in their entirety. Figs. 6A-6D show another example of a safety / lockout mechanism.

As best shown in Figs. 1A - 1D, the arrangement of shaft 12 is 10 slightly different from shaft 20. More particularly, shaft 20 is hollow to define a chamber 28 therethrough which is dimensioned to house both the handswitch 50 (and the electrical components associated therewith as explained in more detail below) and the actuating mechanism 40. As best seen in Figs. 1C and 1D, the actuating mechanism 40 includes a finger tab 42 which is operatively 15 associated with a first gear rack 44 such that movement of the finger tab 42 moves the first rack 44 in a corresponding direction. The actuating mechanism 40 also includes a second gear rack 46 which is operatively associated with a drive rod 48 which advances the cutting mechanism 90 as will be explained in more detail below. Drive rod 48 includes a distal end 49 20 which is configured to mechanically support the cutting mechanism 90 (See Fig. 1E).

Distal end 49 may include one or more guide mechanisms (not shown) to control or guide the cutting mechanism 90 through the knife channel 69 between opposing jaw members 62 and 64. Preferably, the drive rod 48 is made from a flexible wire or plastic sheath which does not buckle 5 upon forward movement thereof. It is also contemplated that the drive rod may include a groove or notch 43 which prevents movement thereof when the jaw members are opened relative to one another. Likewise, pivot 65 (or some other part of forceps 10) may include a corresponding detent or protrusion 69 which engages the notch 43 to prevent accidental firing of the cutting mechanism 90 when the forceps 10 is disposed in the open position. 10

Interdisposed between the first and second gear racks 44 and 46, respectively, is a pinion gear 45 which mechanically meshes with both gear racks 44 and 46 and converts proximal motion of the finger tab 42 into distal translation of the drive rod 48 and vice versa. More particularly, when the user 15 pulls the finger tab 42 in a proximal direction within a predisposed channel 29 in the chamber 28 as represented by arrow "A", the first rack 44 is translated proximally which, in turn, rotates the pinion gear 45 in a clockwise direction. Rotation of the pinion gear 45 in a clockwise direction forces the second rack 46 to translate the drive rod 48 distally (See arrow "B") which advances the 20 cutting mechanism 90 through tissue grasped between jaw members 62 and 64. As mentioned above, the cutting mechanism 90, e.g., knife, blade, wire, etc., is advanced through channel 69 upon distal translation of the drive rod 48.

It is envisioned that multiple gears or gears with different gear ratios may be employed to reduce surgical fatigue which may be associated with advancing the cutting mechanism 90. In addition, it is contemplated the tracks 44 and 46 may be of different length to provide additional mechanical advantage for advancing the jaw members through tissue. As best shown in Fig. 1C, the rack and pinion arrangement may be curved for spatial purposes and to facilitate handling and/or to enhance the overall ergonomics of the forceps 10.

A spring 85 may be employed within chamber 28 to bias the first rack 44 upon proximal movement thereof such that upon release of the finger tab 42, the force of the spring 85 automatically returns the first rack 44 to its distal most position within channel 29. Obviously, spring 85 may be operatively connected to bias the second rack 46 to achieve the same purpose.

Preferably, the finger tab 42 includes one or more ergonomically friendly features which enhance the tactile feel and grip for the user to facilitate actuation of the finger tab 42. Such features may include, raised protuberances, rubber inserts, scallops and gripping surfaces and the like.

Fig. 1D shows another embodiment of the present disclosure similar to the embodiment of Fig. 1C which includes a ratchet 74 for selectively

locking the jaw members 62 and 64 relative to one another at various positions during pivoting. A first ratchet interface 76 extends from the proximal end 14 of shaft member 12 towards a second ratchet interface 78 on the proximal end 24 of shaft 20 in a generally vertically aligned manner such that the inner 5 facing surfaces of each ratchet 76 and 78 abut one another upon closure about the tissue. Preferably, each ratchet interface 76 and 78 includes a plurality of flanges 77a and 77b, respectively, which project from the inner facing surface of each ratchet interface 76 and 78 such that the ratchet interfaces 77a and 77b interlock in at least one position. In the embodiment 10 shown in Fig. 1D, the ratchet interfaces 77a and 77b interlock at several different positions.

Preferably, each position associated with the cooperating ratchet interfaces 77a and 77b holds a specific, i.e., constant, strain energy in the shaft members 12 and 20 which, in turn, transmits a specific closing force to 15 the jaw members 62 and 64. It is envisioned that the ratchet 74 may include graduations or other visual markings which enable the user to easily and quickly ascertain and control the amount of closure force desired between the jaw members.

Fig. 1D also shows a lockout mechanism 99 which is designed to 20 prevent firing of the cutting mechanism until the jaw members 62 and 64 are moved into closed position about tissue. As can be appreciated, the lockout 99 acts as a safety mechanism to prevent accidental severing of tissue prior to

formation of a tissue seal. It is also envisioned that the lockout could cooperate with one or more electrical or electromechanical sensors (not shown) which prevent the cutting mechanism 90 from advancing through tissue until a tissue seal has been created. For example, the lockout 99 could

5 include a sensor which upon completion of a tissue seal activates a switch or release (not shown) which unlocks the cutting mechanism 90 for advancement through tissue.

It is envisioned that by making the forceps 10 disposable, the forceps 10 is less likely to become damaged since it is only intended for a single use and, therefore, does not require cleaning or sterilization. As a result, the functionality and consistency of the vital sealing components, e.g., the conductive surfaces 112 and 122, the stop member(s) 150, and the insulative housings 124 and 114 will assure a uniform and quality seal.

Figs. 2A-2E show another embodiment of the presently disclosed forceps 100 which includes an alternative actuating mechanism 140 which selectively advances the cutting mechanism 190 to separate the tissue once sealed. More particularly, forceps 140 includes shafts 112 and 120 which cooperate to move jaw members 162 and 164 from a first position wherein the jaw members 162 and 164 are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to grasp tissue therebetween. Much like the forceps 10 of Figs. 1A-1C, shaft 112 and shaft 120 are dimensioned to allow reciprocation of shaft 112 within the

elongated channel 121 of shaft 120. In addition, jaw members 162 and 164 are similar to the jaw members 62 and 64 of Figs. 1A-1C and include similar elements and features, e.g., sealing surfaces 167 and 168, outer insulative housings 163 and 166 and pivot 165. Forceps 100 also includes ring handles 5 115 and 117 which each define a corresponding finger hole 115a and 117a, respectively, therein to enable the user to manipulate and grasp tissue with the jaw members 162 and 164.

Ring handle 117 includes an elongated drive path 119 defined therethrough which extends from the chamber 129, around the ring handle 117 10 and through the shaft 120 to the distal end of the forceps 100. As best seen in Figs. 2B and 2C the finger tab 142 is slideable within channel 129 in a proximal direction (represented by arrow "A") which advances the cutting mechanism 90 through tissue held between jaw members 162 and 164. More particularly, the finger tab 142 is connected to a sled-like carrier 144 which is 15 operatively connected to a flexible element 148 such that movement of the carrier 144 moves the element 148. Element 148, in turn, is reciprocated within the drive path 119 and extends around the handle 117 to the distal end 116 where the distal end 149 mechanically engages the cutting mechanism 90. As can be appreciated, proximal movement of the finger tab 142 moves 20 the flexible element 148 within the drive path 119 around the handle 117 which distally advances the cutting mechanism 90 through tissue. It is envisioned that designing the forceps 100 to have the driving flexible element 148 advance around the ring handle 117 provides maximum spatial benefit and

facilitates handling of the forceps 100. A spring 185 may be employed to bias the finger tab 142 in a distal-most position and automatically return the finger tab 142 after deployment.

It is envisioned that the actuating mechanism 140 could be 5 configured utilizing one or more pulleys 225 (See Fig. 2E) to facilitate translation of the flexible element 148 through the tissue. In addition, it is contemplated that the actuating mechanism 140 can be configured such that distal movement of the finger tab 142 advances the flexible element 148 in a distal direction to cut tissue utilizing one or more pulleys (See Fig. 2E).

10 Fig. 2C preferably utilizes a flexible plastic sheath or flexible linkage as the flexible element 148 to advance the cutting mechanism 90. It is envisioned that the flexible linkage prevents buckling during activation. However and as best seen in Fig. 2D, a flexible wire may be utilized in lieu of the flexible plastic sheath. Wire 248 operates in a similar fashion as the plastic 15 flexible sheath 148 of Fig. 2C such that upon movement of the finger tab 142 the flexible wire 248 advances the cutting mechanism 90 through tissue held between jaw members 162 and 164.

20 Figs. 5A-5C show the electrical details relating to the switch 50. More particularly and as mentioned above, cable 70 includes three electrical leads 70a, 70b and 70c which are fed through shaft 20. The electrosurgical cable 70 is fed into the bottom of shaft 20 and is held securely therein by one

or more mechanical interfaces (not shown). Lead 70c extends directly from cable 70 and connects to jaw member 64 to conduct the second electrical potential thereto. Leads 70a and 70b extend from cable 70 and connect to the hand switch or joy-stick-like toggle switch 50 (or 150 in Fig. 2A).

5 Several different types of handswitches 50 are envisioned, for example, switch 50 is a regular push-button style switch while switch 150 of Fig. 2A is more like a toggle switch. It is envisioned that a toggle switch 150 permits the user to selectively activate the forceps 10 in a variety of different orientations, i.e., multi-oriented activation, which simplifies activation. One 10 particular type of handswitch is disclosed in commonly-owned, co-pending U.S. Patent Application Serial No. 10/460,926 the contents of which are hereby incorporated by reference herein.

15 The electrical leads 70a and 70b are electrically connected to the switch 50 (or 150). When the switch 50 is depressed, a trigger lead 71 carries the first electrical potential from the switch 50 to jaw member 62. As mentioned above, the second electrical potential is carried by lead 70c directly from the generator (not shown) to jaw member 64. It is envisioned that a safety switch or circuit (not shown) may be employed such that the switch 50 cannot fire unless the jaw members 62 and 64 are closed and/or unless the 20 jaw members 62 and 64 have tissue 420 held therebetween. In the latter instance, a sensor (not shown) may be employed to determine if tissue is held therebetween. In addition, other sensor mechanisms may be employed which

determine pre-surgical, concurrent surgical (i.e., during surgery) and/or post surgical conditions. The sensor mechanisms may also be utilized with a closed-loop feedback system coupled to the electrosurgical generator to regulate the electrosurgical energy based upon one or more pre-surgical, 5 concurrent surgical or post surgical conditions. Various sensor mechanisms and feedback systems are described in commonly-owned, co-pending U.S. Patent Application Serial No. 10/427,832 the entire contents of which are hereby incorporated by reference herein.

Preferably, the jaw members 62 and 64 are electrically isolated 10 from one another such that electrosurgical energy can be effectively transferred through the tissue to form a tissue seal. Preferably, each jaw member, e.g., 62, includes a uniquely-designed electrosurgical cable path disposed therethrough which transmits electrosurgical energy to the electrically conductive sealing surface 67. It is envisioned that jaw member 62 may 15 include one or more cable guides or crimp-like electrical connectors to direct cable lead 71 towards electrically conductive sealing surface 67. Preferably, cable lead 71 is held loosely but securely along the cable path to permit pivoting of the jaw member 62 about pivot 65.

As best shown in Figs. 5B and 5C, the cable leads 70a, 70b and 20 70c are protected by two insulative layers, an outer protective sheath 76 which surrounds all three leads 70a, 70b and 70c and a secondary protective sheath 75a, 75b and 75c which surrounds each individual cable lead, 70a, 70b and

70c, respectively. The two electrical potentials are isolated from one another by virtue of the insulative sheathing surrounding each cable lead 70a, 70b and 70c.

Fig. 3 shows yet another embodiment of the forceps 300 according to the present disclosure wherein the actuating mechanism 340 includes a slide switch 342 which advances the cutting mechanism 90 (not shown in this figure) through tissue grasped between opposing jaw members 362 and 364. More particularly, the slide switch 342 is pushed distally within channel 329 disposed in the shaft 320 by the surgeon to selectively sever tissue once sealed. The switch 342 may include a bias member or spring 343 which automatically returns the cutting mechanism once advanced in a distal direction, i.e., automatic return. Other biasing members are also contemplated which are known in the art, e.g., elastomeric bands, pulleys, etc.

Alternatively, the actuating mechanism 340 may be spring-loaded and advanced automatically when switch 342 is depressed by the surgeon. After deployment, the surgeon manually retracts the switch 342 to reset the switch 342 and cutting mechanism 90 for subsequent deployment.

Fig. 4 shows yet another embodiment of the presently disclosed forceps 400 which includes a lever-like actuator 440 which is designed to advance the cutting mechanism 90 through tissue grasped between jaw members 462 and 464. More particularly, actuating mechanism 440 includes

a finger tab 442 which is positioned for actuation by the user and which is connected to a proximal end of a first link 444. Link 444 is, in turn, connected at a distal end thereof to one end of a pivot lever 445. Pivot lever 445, in turn, is connected at the opposite end thereof to a second link 446 which connects 5 to the cutting mechanism 90.

Pivot lever 445 is rotatably connected about a pivot pin 447 to shaft 420 such that movement of the finger tab 442 and link 444 in a proximal direction distally advances link 446 in a distal direction to move the cutting mechanism 90 through tissue. A spring (not shown) may be included to 10 automatically return the finger tab 442 to its distal-most position after cutting. Alternatively, a third ring handle (not shown) may be employed in lieu of the finger tab 442 to advance link 444 to actuate the pivot lever 445.

As mentioned above, the knife channel 69 may be formed with a lockout or one or more other safety features which prevent the knife 90 from 15 advancing through the tissue until the jaw members 62 and 64 are closed about the tissue. As best seen in Figs. 6A-6D, one possible lockout or safety mechanism 505 is envisioned which both prevents actuation of the cutting blade 90 when the jaw members 62 and 64 are disposed in an open configuration and also prevents opening of the jaw members 62 and 64 when 20 the actuating mechanism 40 is being deployed to advance the cutting blade 90.

More particularly, the shaft 520 and respective handle 517 may be configured to include an elongated channel 529 disposed therethrough which allows reciprocation of a safety bar 527 therein. Although shown as generally an elongated channel, it is envisioned that the channel 529 may be circular or curved to accomplish the same purpose. Channel 529 is composed of two channel halves 529a and 529b disposed in horizontal registry with one another and which are separated by an opening 537 therebetween.

5 A leaf spring 525 (or the like) is disposed within a chamber 523 defined in the handle 517 and is moveable within the chamber 523 from a first 10 position wherein the spring 525 is biased to block opening 537 to a second position wherein the spring 525 is forced out of opening 537 to allow reciprocation of the safety bar 527. Handle 515 includes a flange 513 which extends upwardly towards handle 517 and which includes an aperture 519 defined therein which is dimensioned to receive the safety bar 527 15 therethrough. The flange 513 is designed to be in vertical registration with opening 537.

20 In use, as the jaw members 62 and 64 grasp tissue (move from the first to second positions), the flange 513 is forced into opening 537 to dislodge the spring 525 out of the opening 537 and into chamber 523. When the spring 525 is at least substantially incorporated into chamber 523, the aperture 519 will align with the elongated channels 529a and 529b (See Fig. 6C). As mentioned above, a ratchet may be employed to hold the two handles

515 and 517 together with the appropriate closure force for sealing tissue. At this point, the user is free to activate the actuating mechanism 40 to advance the cutting blade 90 which as best seen in Fig. 6D translates the safety bar 527 proximally and through aperture 513 and into elongated channel 529b.

5 As can be appreciated, the user is prevented from advancing the cutting blade 90 until the jaw members 62 and 64 are closed about tissue. Moreover, when the actuating mechanism 40 is activated, the handles 515 and 517 are locked and cannot be opened until the actuating mechanism 40 is released.

Figs. 6E and 6F show another version of a safety or lockout mechanism 700 which acts to prevent the cutting blade 90 from being distally activated when the forceps is disposed in an open configuration, i.e., the jaw members 62 and 64 are spaced relative to one another. More particularly, lockout mechanism 700 is designed of two components which mechanically cooperate to prevent accidental blade advancement, namely, a cutting blade carrier 749 and a blade lockout slot 715. Cutting blade carrier 749 is configured to mechanically support the cutting blade 90 for advancement through tissue held between the jaw members 62 and 64 and preferably includes a detent or protrusion 720 which extends from at least one side thereof. The lockout slot 715 is preferably disposed in a proximal portion of 15 jaw member 64 near the jaw pivot 165.

When the jaw members 62 and 64 are closed about tissue, the detent 720 is freely extendible within a blade slot 730 disposed within at least

one of the jaw members, e.g., jaw member 64, to cut tissue. Preferably, a return spring (not shown) automatically returns the cutting blade 90 once the user releases the actuator 40. When the jaw members 62 and 64 are disposed in an open configuration, the detent 720 rotates into lockout slot 715 5 thus preventing distal reciprocation of the cutting blade 90 when the actuator 40 is actuated. A guide notch 725 may be positioned within slot 730 to facilitate entry of the detent 720 into lockout slot 715.

Fig. 7 shows an alternate embodiment of the cutting mechanism 690 which is distally advanceable to cut tissue disposed between the jaw 10 members 662 and 664. More particularly, cutting mechanism 640 is designed to include a cutting blade 695 which is distally advance above by a drive rod 648 through a curved knife slot 669 disposed between jaw members 662 and 664. The drive rod 648 and the cutting blade 695 are positioned slightly off-axis to allow for blade 695 to easily move within curved slot 669. In other 15 words, the distal end of the instrument includes a longitudinal axis "AA" defined therethrough and the drive rod 648 is positioned at an angle α relative to the longitudinal axis "AA". As can be appreciated, positioning the drive rod "off-axis" enables the cutting blade 695 to move more easily move through the knife channel 669 to cut tissue disposed between the jaw members 662 and 20 664. It is envisioned that the jaw members 662 and 664 and/or the drive rod 648 may include a safety which prevents the blade 695 from reciprocating in the knife channel 669 when the jaw members 662 and 664 are disposed in an open configuration about pivot 665.

In operation, the surgeon simply utilizes the two opposing handle members 15 and 17 to approximate and grasp tissue between jaw members 62 and 64. The surgeon then activated the handswitch (or footswitch if applicable) to provide electrosurgical energy to each jaw members to 5 communicate energy through the tissue held therebetween. Once sealed the surgeon activates the actuating mechanism 40 to advance the cutting blade 90 through the tissue to sever the tissue along the tissue seal.

From the foregoing and with reference to the various figure drawings, those skilled in the art will appreciate that certain modifications can 10 also be made to the present disclosure without departing from the scope of the same. For example, although the electrical connections are preferably incorporated within one shaft 20 and the forceps is intended for right-handed use, it is contemplated the electrical connections may be incorporated within 15 the other shaft 12 depending upon a particular purpose and/or to facilitate manipulation by a left-handed user.

It is also contemplated that the forceps 10 (and/or the electrosurgical generator used in connection with the forceps 10) may include a sensor or feedback mechanism (not shown) which automatically selects the appropriate amount of electrosurgical energy to effectively seal the particularly-sized tissue grasped between the jaw members 62 and 64. The sensor or 20 feedback mechanism may also measure the impedance across the tissue

1 during sealing and provide an indicator (visual and/or audible) that an effective
2 seal has been created between the jaw members 62 and 64. Commonly-
3 owned U.S. Patent Application Serial No. 10/427,832 discloses several
4 different types of sensory feedback mechanisms and algorithms which may be
5 utilized for this purpose. The contents of this application are hereby
incorporated by reference herein.

10 Experimental results suggest that the magnitude of pressure
exerted on the tissue by the sealing surfaces of the jaw members 62 and 64
are important in assuring a proper surgical outcome. Tissue pressures within a
working range of about 3 kg/cm^2 to about 16 kg/cm^2 and, preferably, within a
11 working range of 7 kg/cm^2 to 13 kg/cm^2 have been shown to be effective for
sealing arteries and vascular bundles. Tissue pressures within the range of
about 4 kg/cm^2 to about 6.5 kg/cm^2 have proven to be particularly effective in
12 sealing arteries and tissue bundles.

15 In one embodiment, the shaft 12 and 20 are manufactured such
that the spring constant of the shaft portions 12a and 12b, in conjunction with
the placement of the ratchet interfaces 32a and 32b, will yield pressures within
the above working range. In addition, the successive positions of the ratchet
interfaces increase the pressure between opposing sealing surfaces
20 incrementally within the above working range.

It is also envisioned that the drive rod 48 may be connected to the same or alternate source of electrosurgical energy and may be selectively energizable by the surgeon during cutting. As can be appreciated, this would enable the surgeon to electrosurgically cut the tissue along the tissue seal. As 5 a result thereof, a substantially dull blade may be employed to electrosurgically cut the tissue.

It is also envisioned that a substantially dull blade may be utilized with a spring loaded cutting mechanism which, due to the clamping pressure between the opposing jaw members 62 and 64 and due to the force at which the spring-loaded cutting mechanism advances the cutting blade, the tissue 10 will sever along the tissue seal.

In one embodiment, a sealing and cutting mechanism is utilized which is selectively attachable to a conventional forceps. In other words, the sealing and cutting mechanism is disposable and the shaft members 12 and 15 20 are reposable. The disposable sealing and cutting mechanism along with their respective electrosurgical elements simply mount atop one or both shafts of a conventional forceps to enable the surgeon to seal and cut tissue. Once the surgeon is finished with the operation, the sealing and cutting mechanism is simply detached and discarded.

20 In one embodiment, a flexible blade may be used with a one or more of the above cutting mechanisms to advance through a curved knife

channel. For example, upon distal advancement of the cutting mechanism, the cutting blade will simply flex and ride around the knife channel through the tissue held between jaw members. Alternatively, a curved blade may be utilized which has a similar radius of curvature as the knife channel such that 5 the blade will travel through the knife slot without contacting the surfaces of the knife channel.

It is also contemplated that the blade 90 and blade slot 730 (See Fig. 6E) may be positioned in offset relation to the pivot 165 to facilitate manufacturing and assembly of the forceps 10. In other words, the pivot 165 10 is radially or laterally offset from the longitudinal axis "A" disposed through the forceps 10. In this embodiment, the offset configuration of the pivot 165 enables the blade 90 to be manufactured in a generally straight configuration which does not interfere with the pivot 165 during distal activation thereof. Likewise, the blade slot 730 may be configured generally straight as well.

15 It is also contemplated that the forceps may include a safety blade return mechanism (not shown). For example and as mentioned above, the cutting blade 90 may include one or more springs which automatically return the cutting blade after actuation of the actuator. In addition, a manual return may be included which allows the user to manually return the blade 90 if 20 the automatic blade return (e.g., spring) should fail due to sticking, skewing, or some other unforeseen surgical condition. For example, a second pulley (not shown) may be employed opposite the actuating mechanism 40 which allows

the user to manually retract the blade 90 should an automatic return (spring) fail. As can be appreciated, this second pulley (or series of pulleys if needed) would be connected to the cutting blade 90 and would operate to facilitate manual retraction as needed during the operation.

5 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 10 embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

The claims defining the invention are as follows:

1. An open electrosurgical forceps for sealing tissue, comprising:
 - a pair of first and second shaft members each having a jaw member disposed at a distal end thereof, said jaw members being movable 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;
 - each of said jaw members including an electrically conductive sealing plate for communicating electrosurgical energy through tissue held therebetween;
 - at least one of said jaw members including a cutting slot defined along a length thereof, said cutting slot being dimensioned to reciprocate a cutting instrument therealong;
 - an actuator for selectively advancing the cutting instrument from a first position wherein said cutting instrument is disposed proximal to tissue held between said jaw members to at least one subsequent position wherein said cutting instrument is disposed distal to tissue held between said jaw members, said actuator including a trigger assembly which cooperates with a pulley and cable system to advance said cutting instrument from the first to second positions through tissue held therebetween; and
 - each of said shafts including a handle, at least one of said handles defines a generally arcuate track therearound configured to reciprocate a plastic cable of said pulley and cable system, said plastic cable configured to mechanically engage said cutting instrument such that movement of said plastic cable imparts movement of said cutting instrument between the first and subsequent positions.

2. An open electrosurgical forceps for sealing tissue according to
claim 1 wherein said trigger assembly of said actuator is pulled proximally to
distally advance said cutting instrument through said cutting slot.

5 3. An open electrosurgical forceps for sealing tissue according to
claim 1 wherein said trigger assembly of said actuator is pushed distally to
distally advance said cutting instrument through said cutting slot.

4. An open electrosurgical forceps for sealing tissue according to
claim 1 wherein said trigger assembly of said actuator is moved laterally to
distally advance said cutting instrument through said cutting slot.

10 5. An open electrosurgical forceps for sealing tissue according to
claim 1 further comprising a lockout to prevent reciprocation of said cutting
instrument when said jaws are disposed in the first position.

6. An open electrosurgical forceps for sealing tissue according to
claim 5 wherein said lockout forms part of the trigger assembly.

15 7. An open electrosurgical forceps for sealing tissue according to
claim 5 wherein said lockout forms part of at least one of said jaw members.

8. An open electrosurgical forceps for sealing tissue according to
claim 7 wherein said lockout forms part of said cutting instrument.

9. An open electrosurgical forceps for sealing tissue according to claim 5, wherein said lockout forms part of at least one of said first and second shafts.

10. An open electrosurgical forceps for sealing tissue according to claim 1, wherein said cable includes at least one stiffener to prevent buckling of the cable within
5 said track.

11. An open electrosurgical forceps for sealing tissue according to claim 1, wherein said cable is a braided flexible cable.

12. An open electrosurgical forceps for sealing tissue according to claim 1, further comprising at least one spring for automatically biasing said cutting instrument in
10 said first position.

13. An open electrosurgical forceps for sealing tissue according to claim 12, wherein said trigger assembly includes said at least one spring for automatically returning said cutting instrument back to said first position.

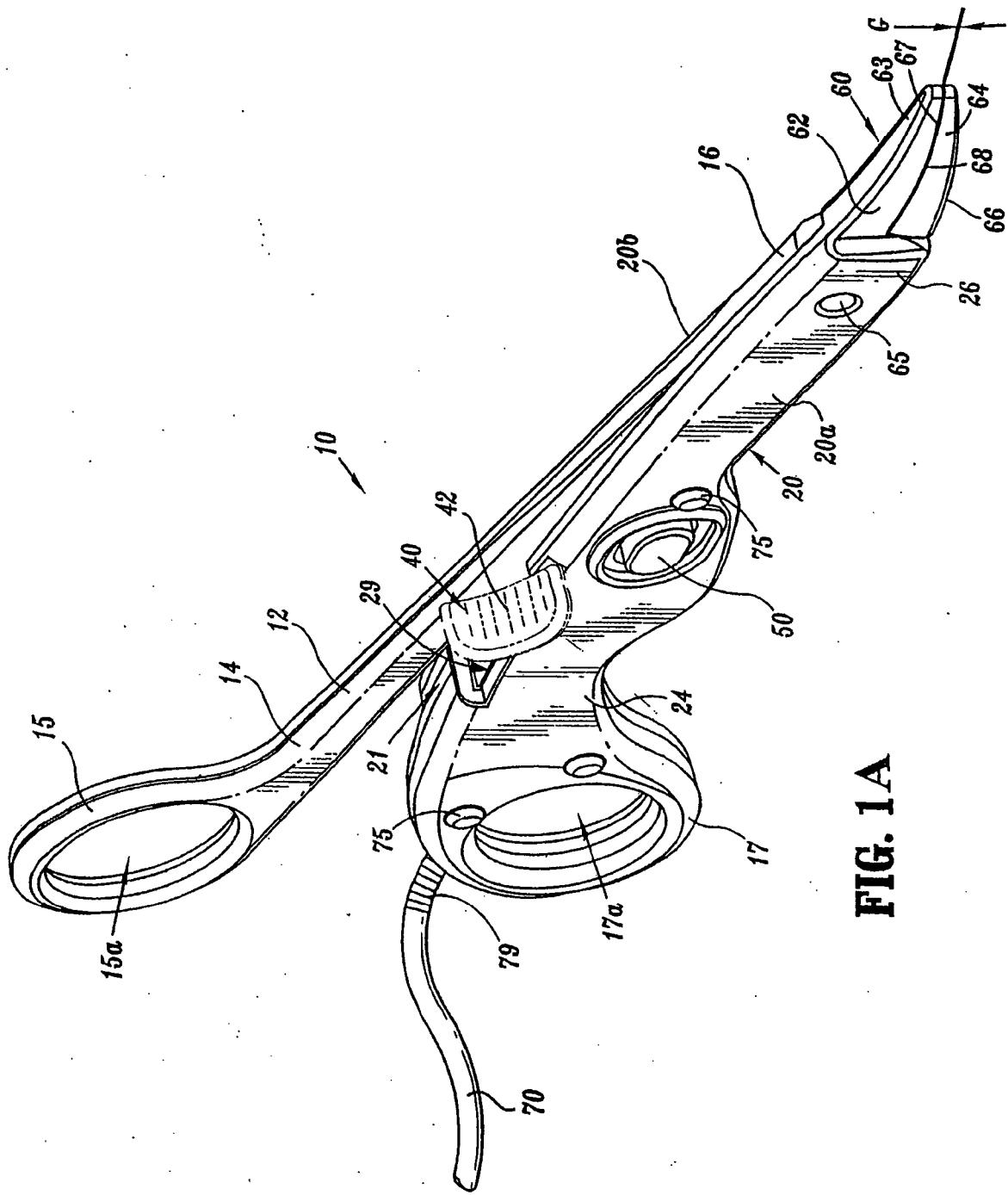
14. An open electrosurgical forceps, substantially as herein described with
15 reference to Figures 1A to 1E, 2A to 2E, 3, 4, 5A to 5C, 6A to 6F and 7.

Dated 14 May, 2010

Covidien AG

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON



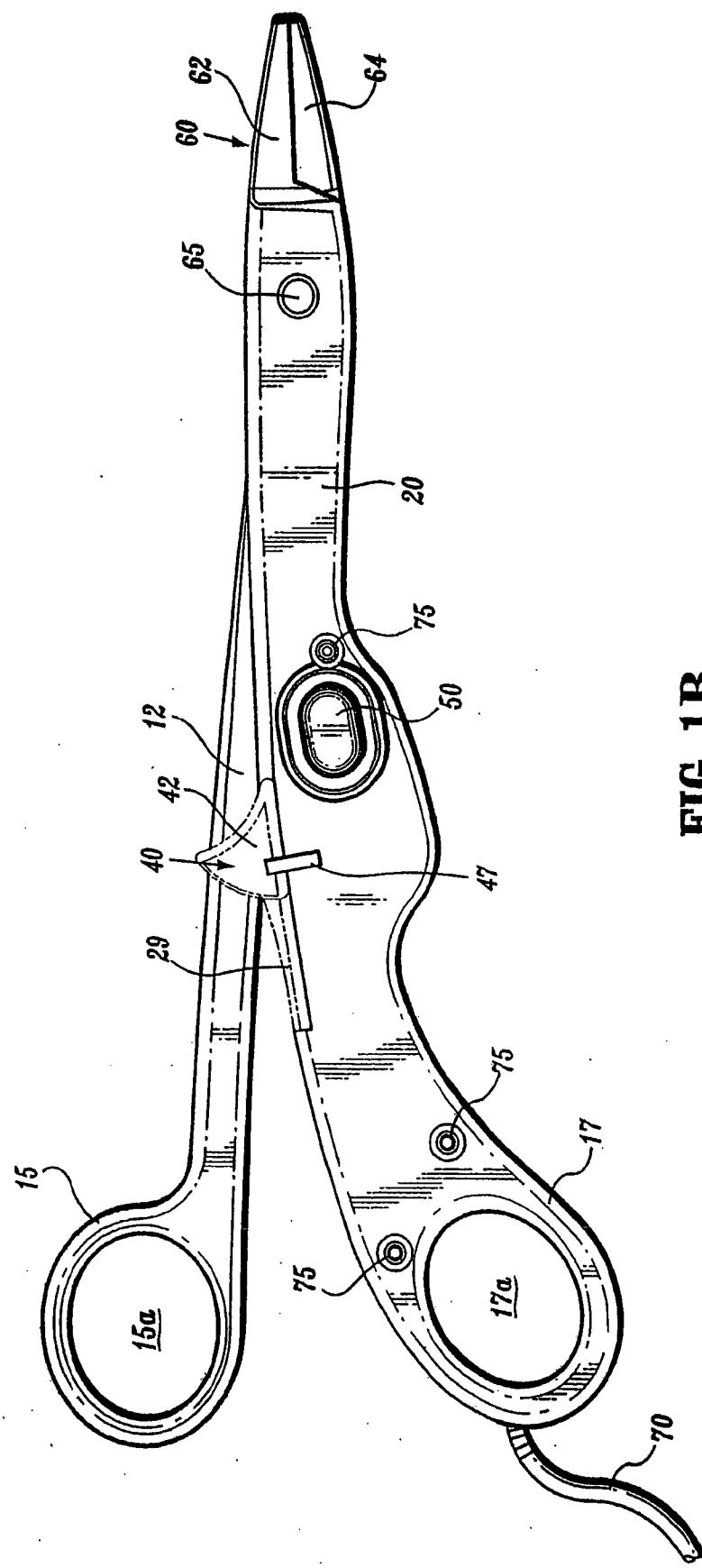
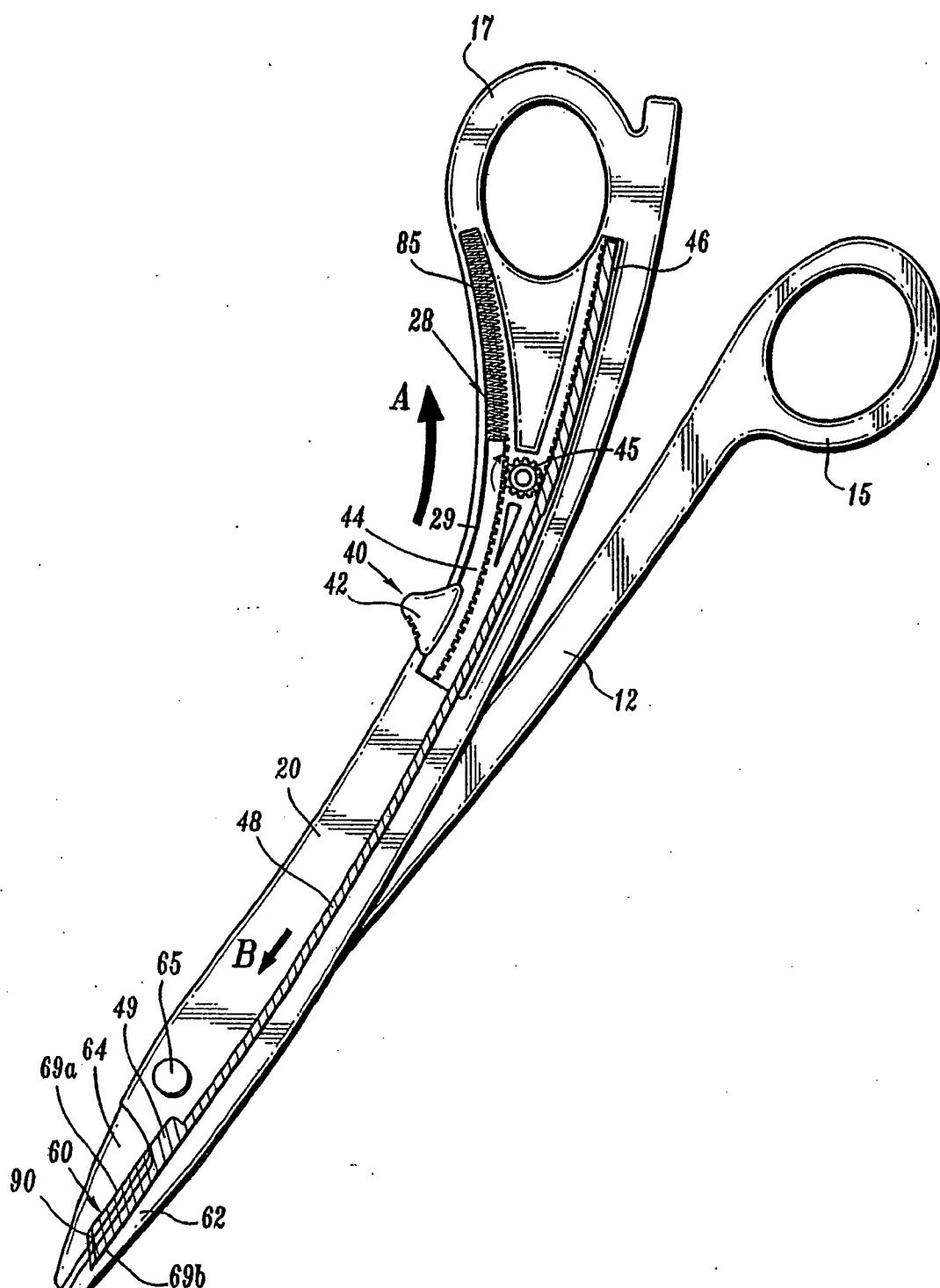


FIG. 1B



Rack & Pinion

FIG. 1C

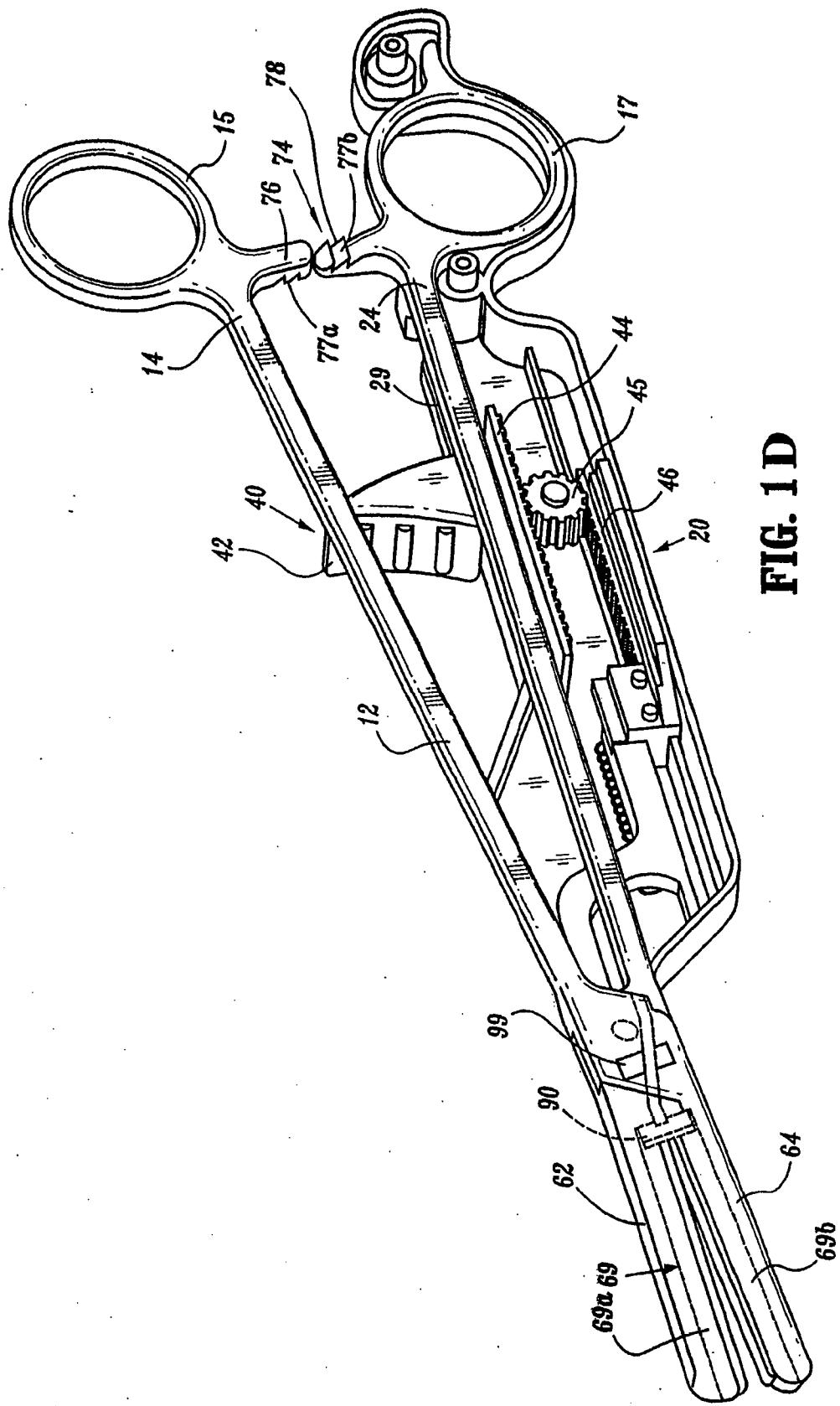


FIG. 1D

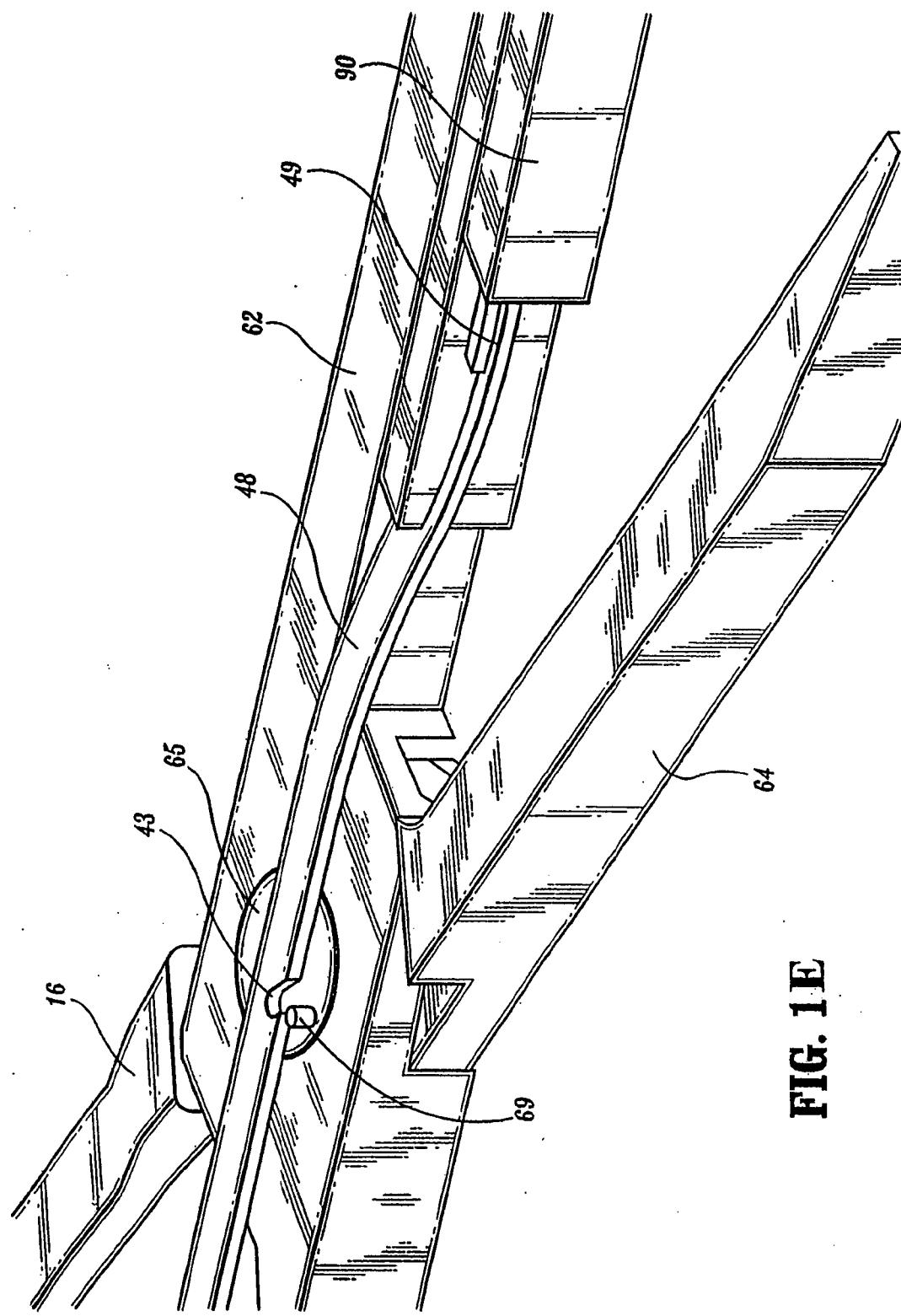


FIG. 1E

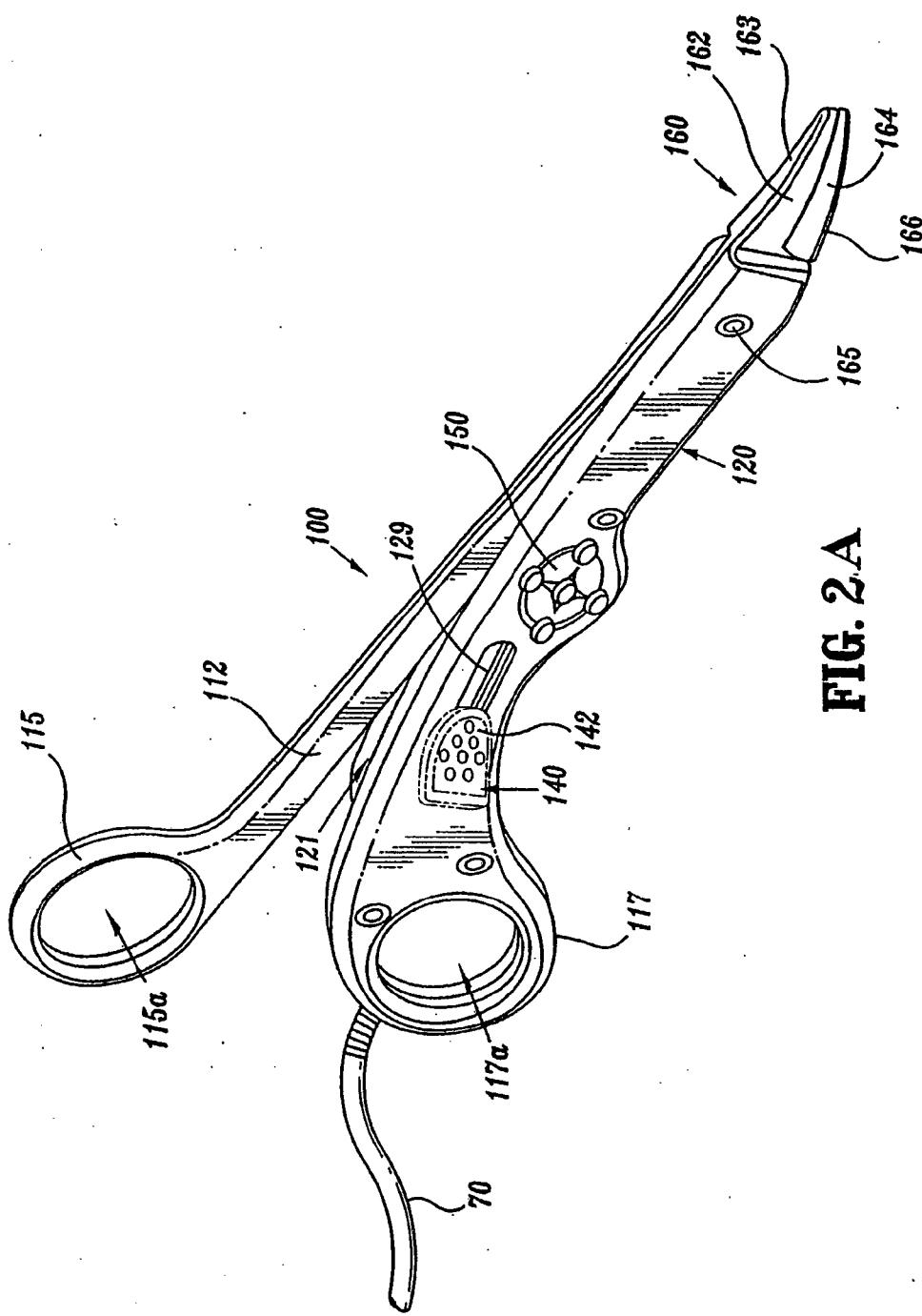


FIG. 2A

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7/20

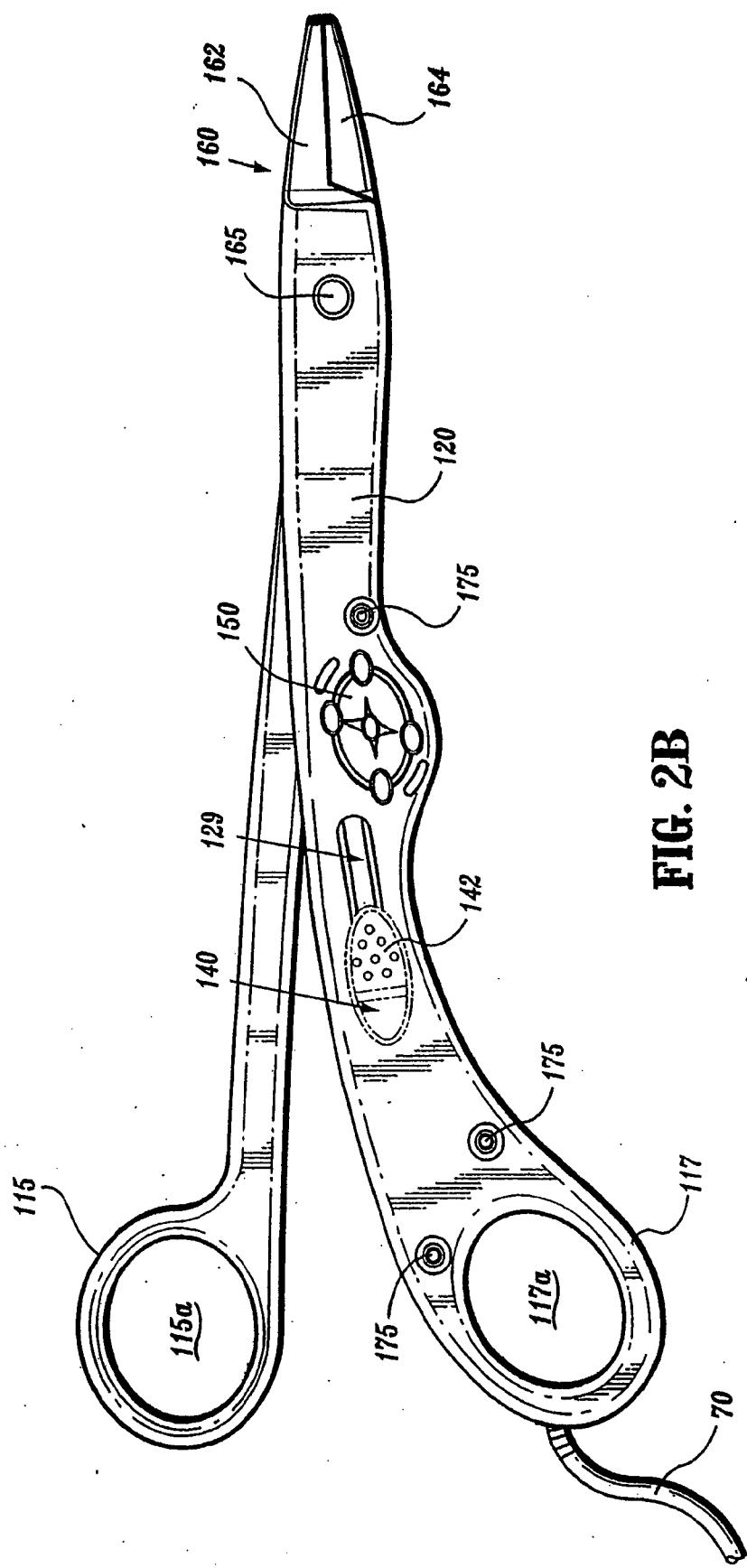
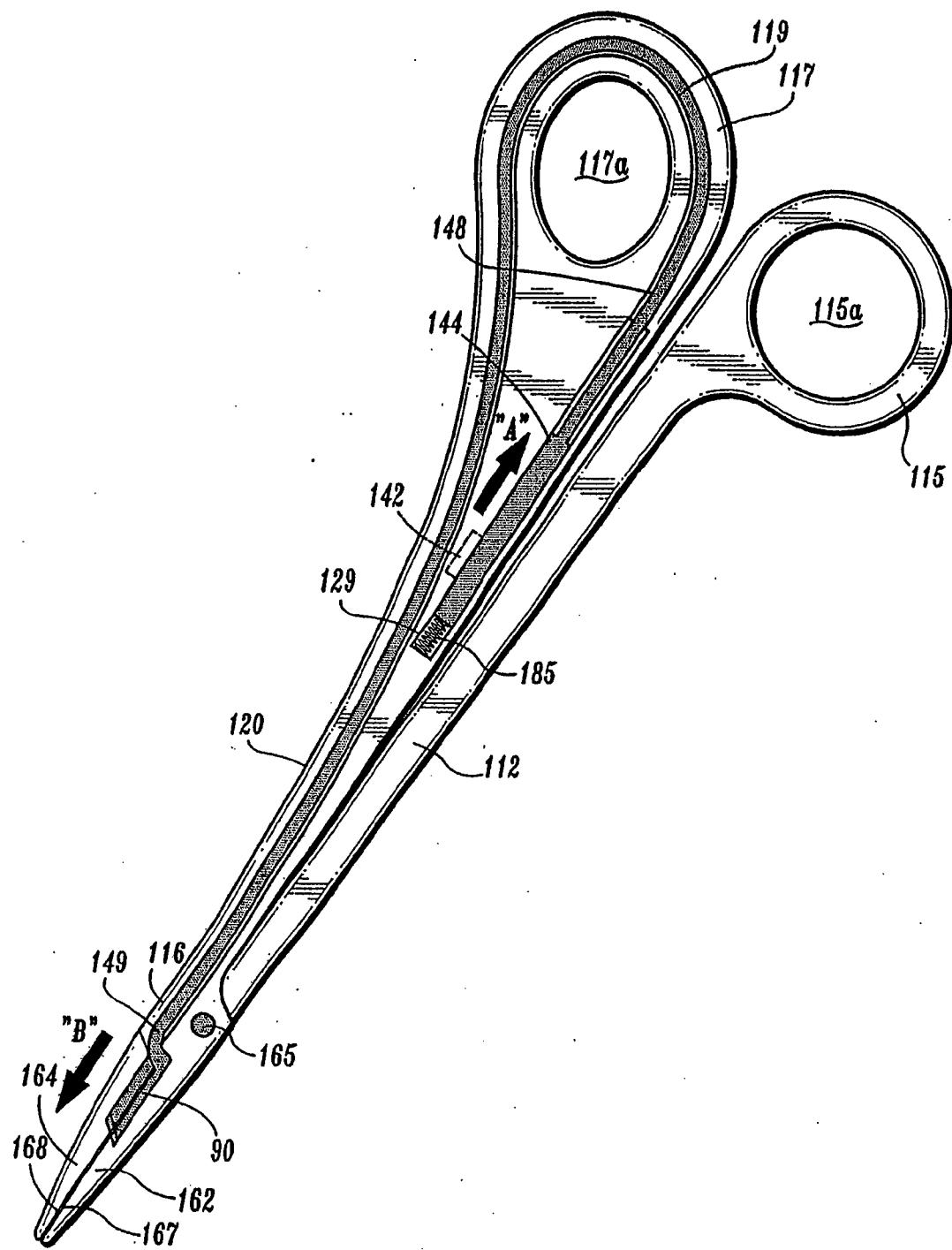
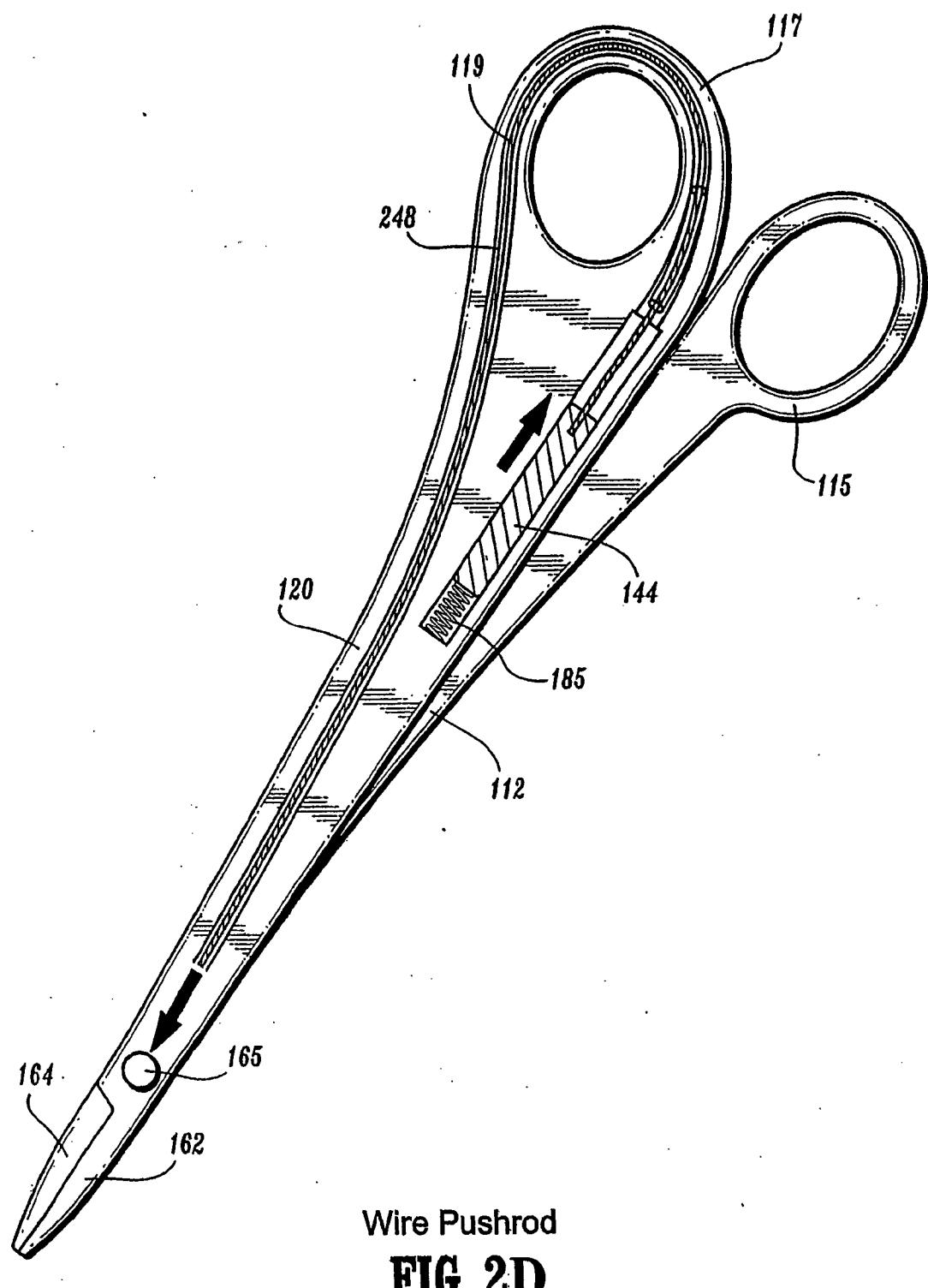


FIG. 2B



Flexible Linkage

FIG. 2C



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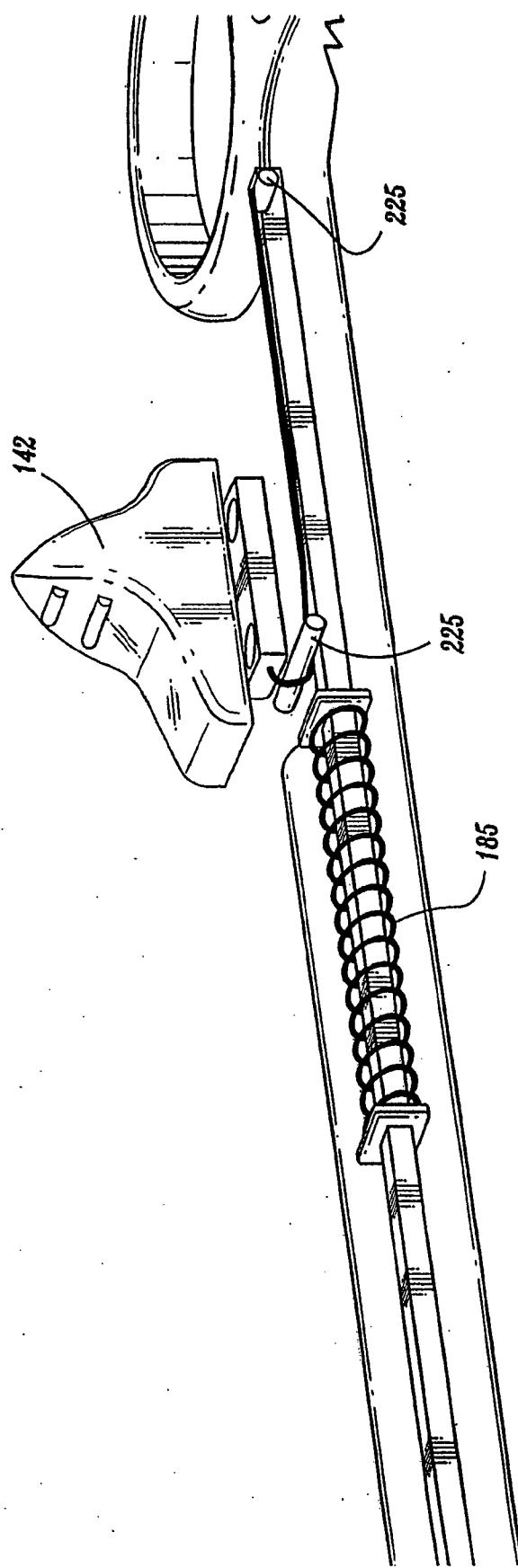


FIG. 2E

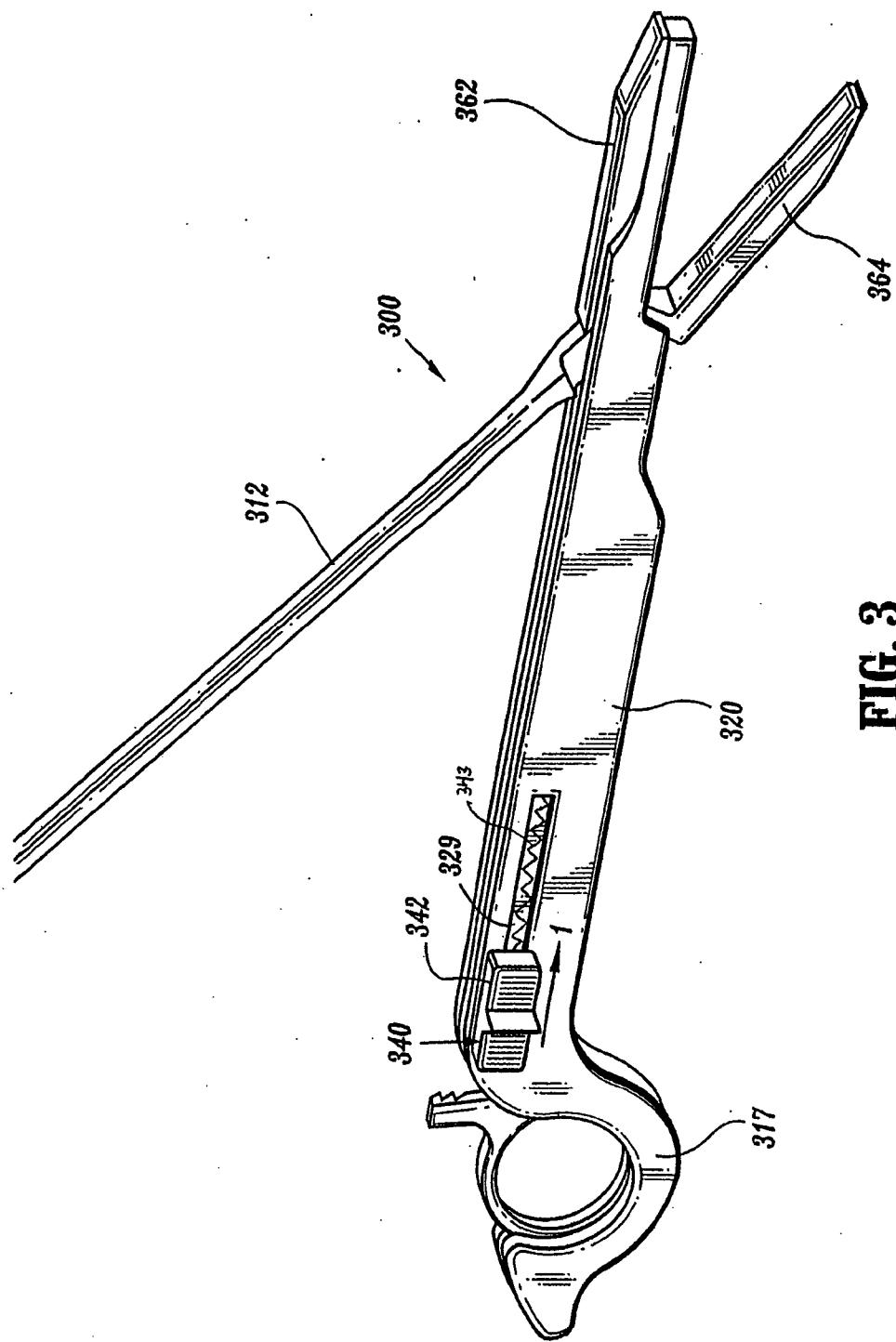


FIG. 3

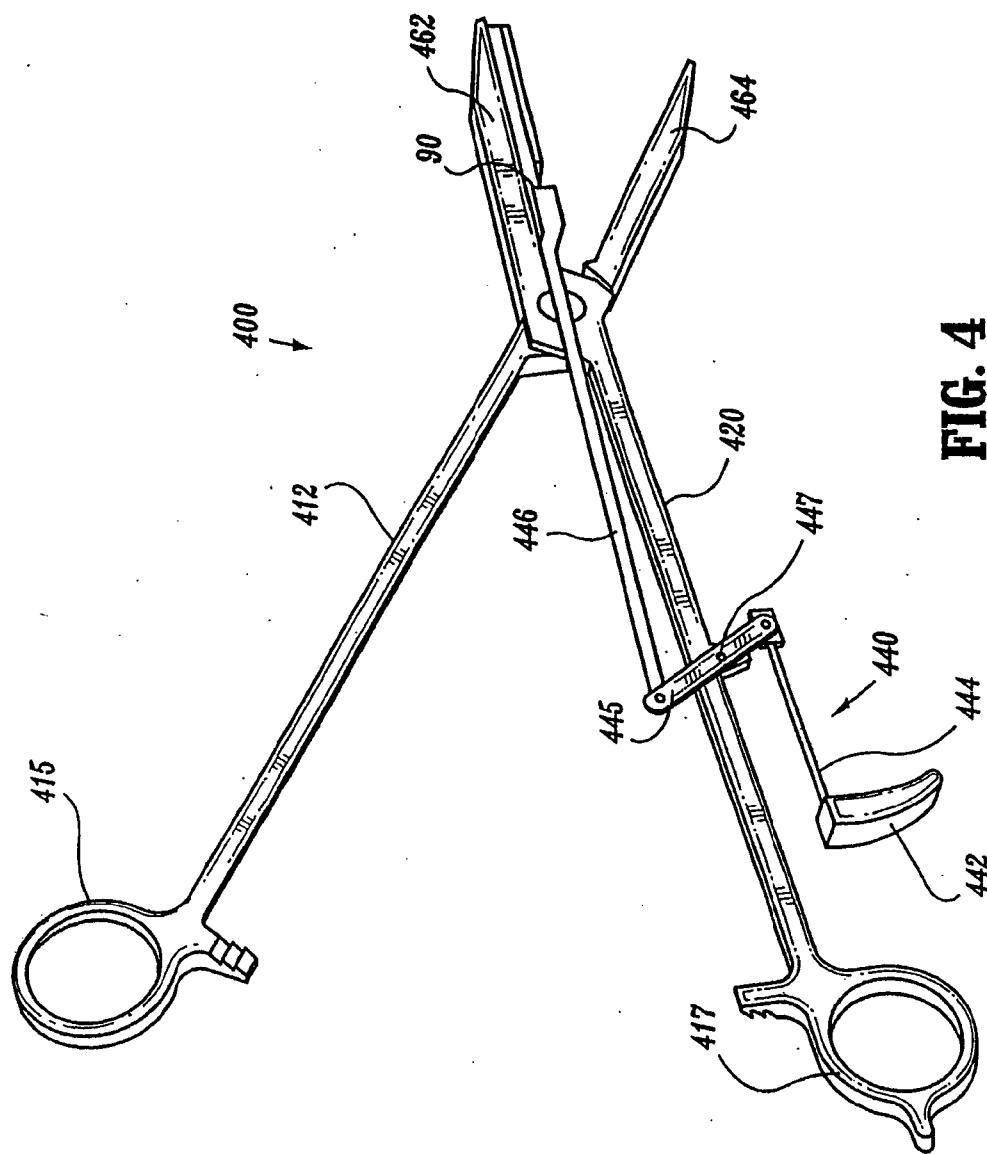


FIG. 4

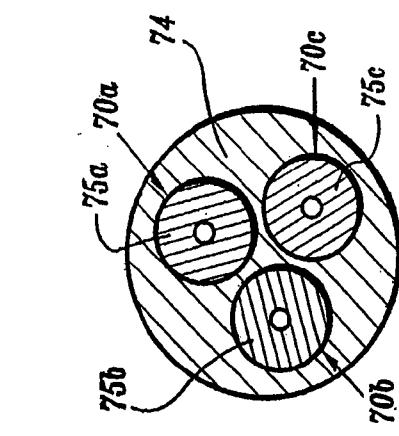


FIG. 5B

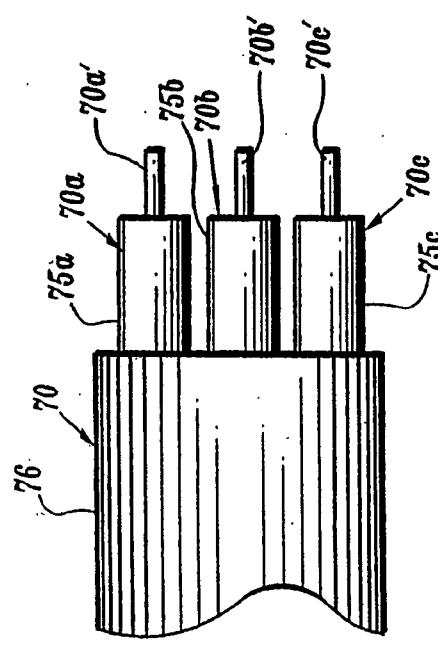


FIG. 5C

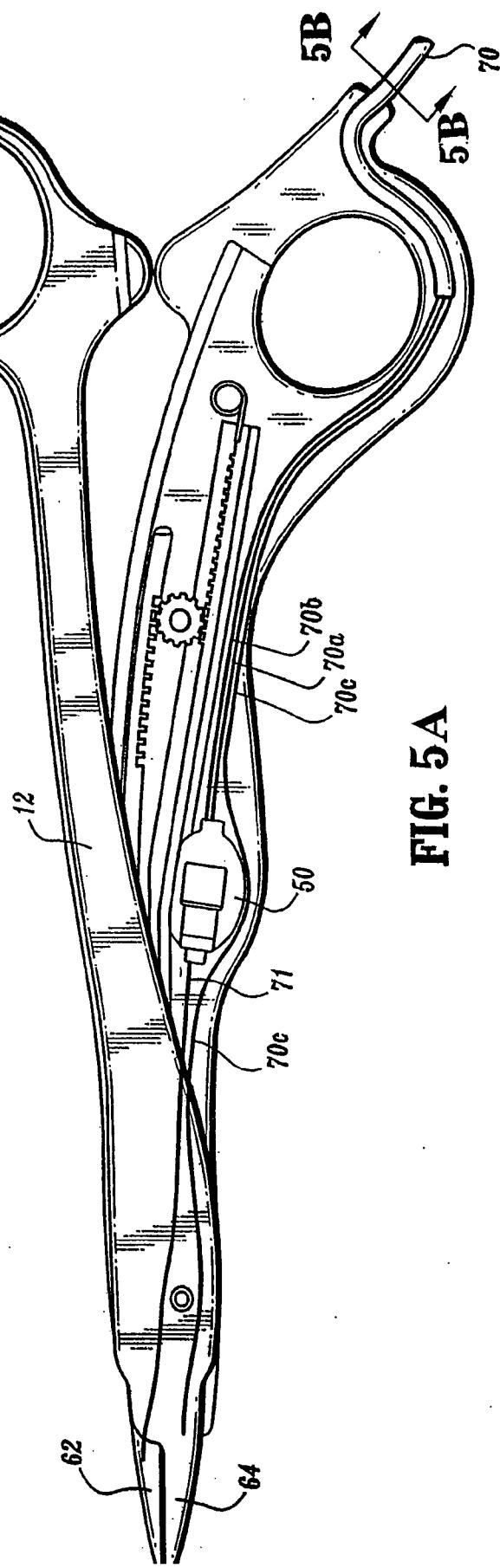
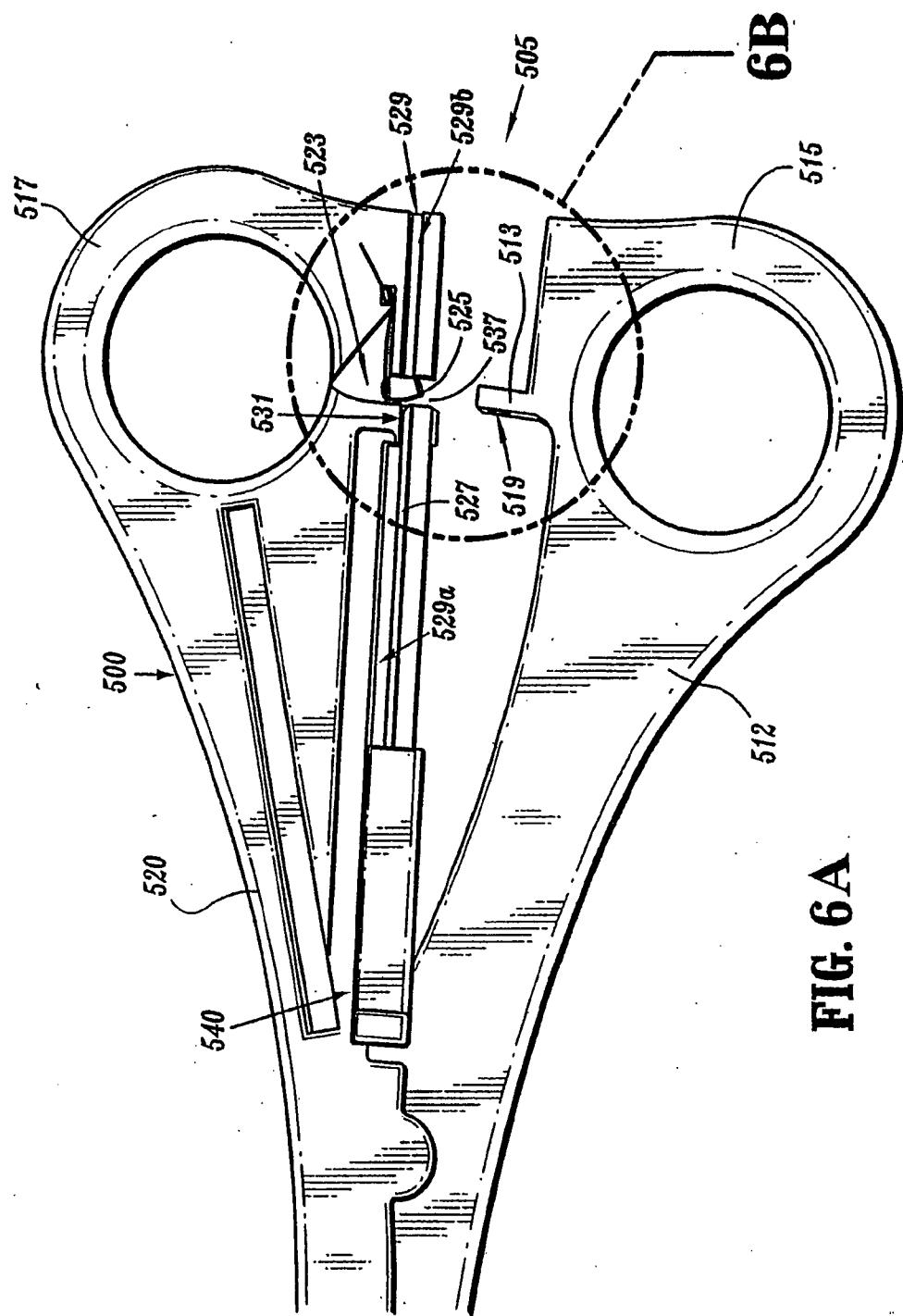


FIG. 5A



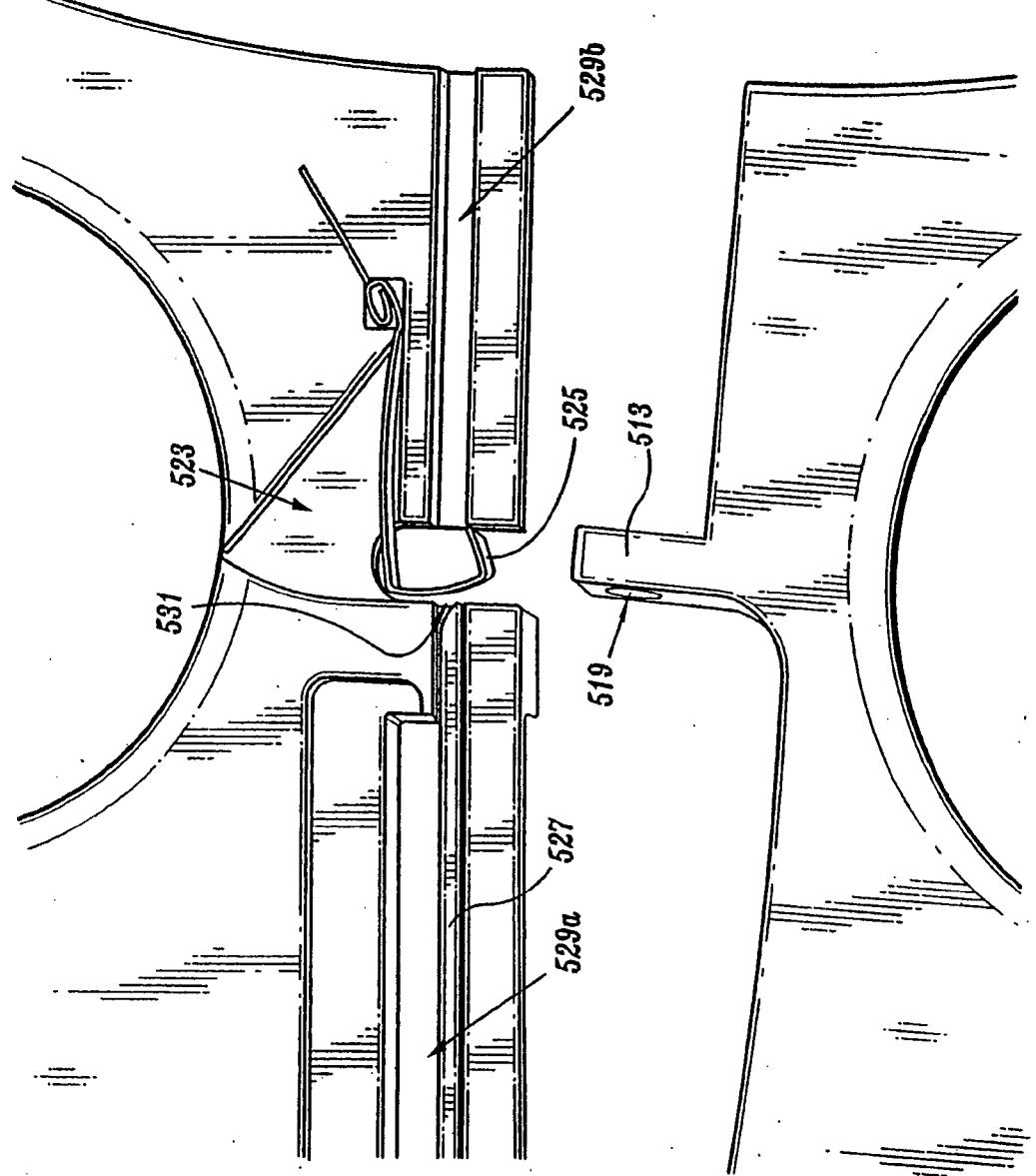


FIG. 6B

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16/20

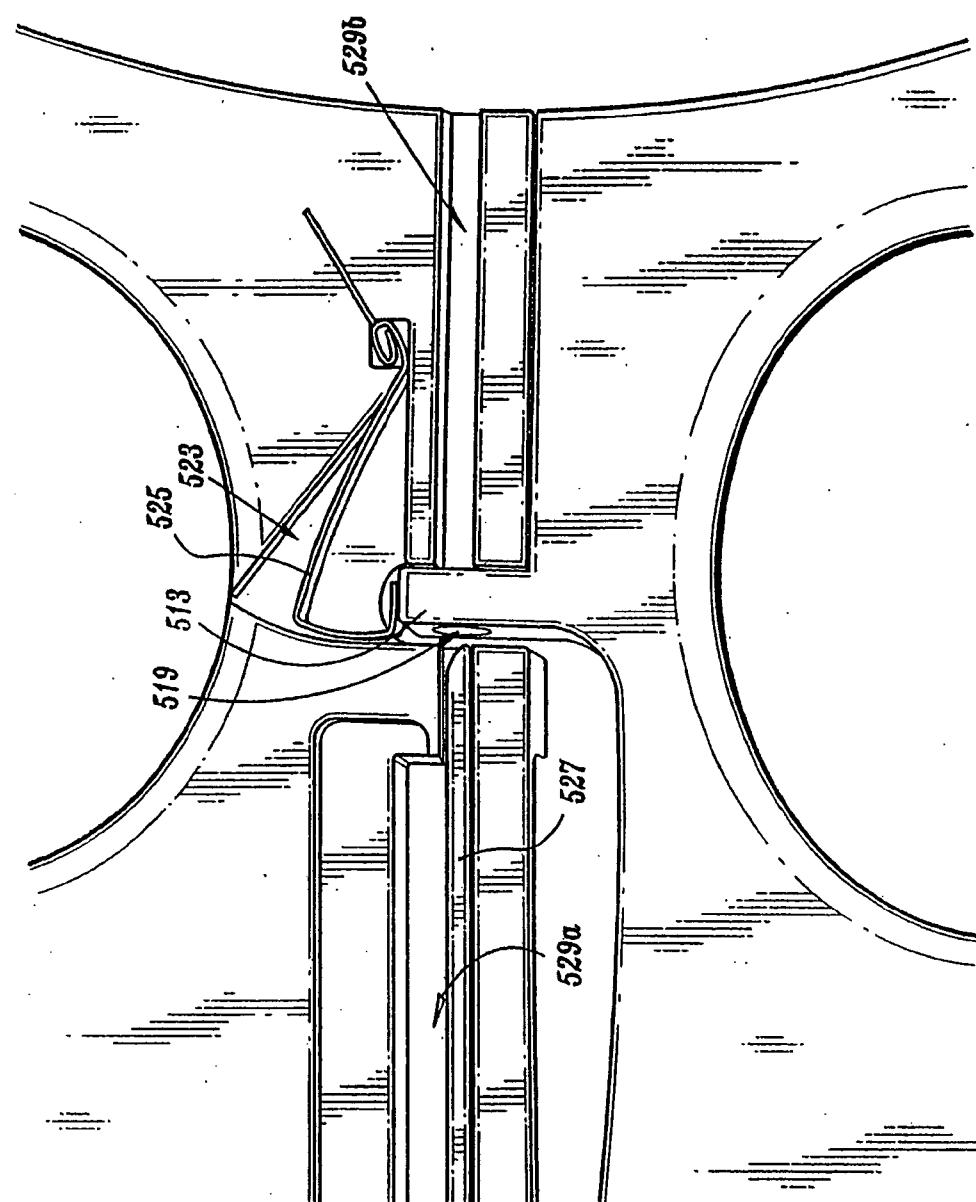


FIG. 6C

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17/20

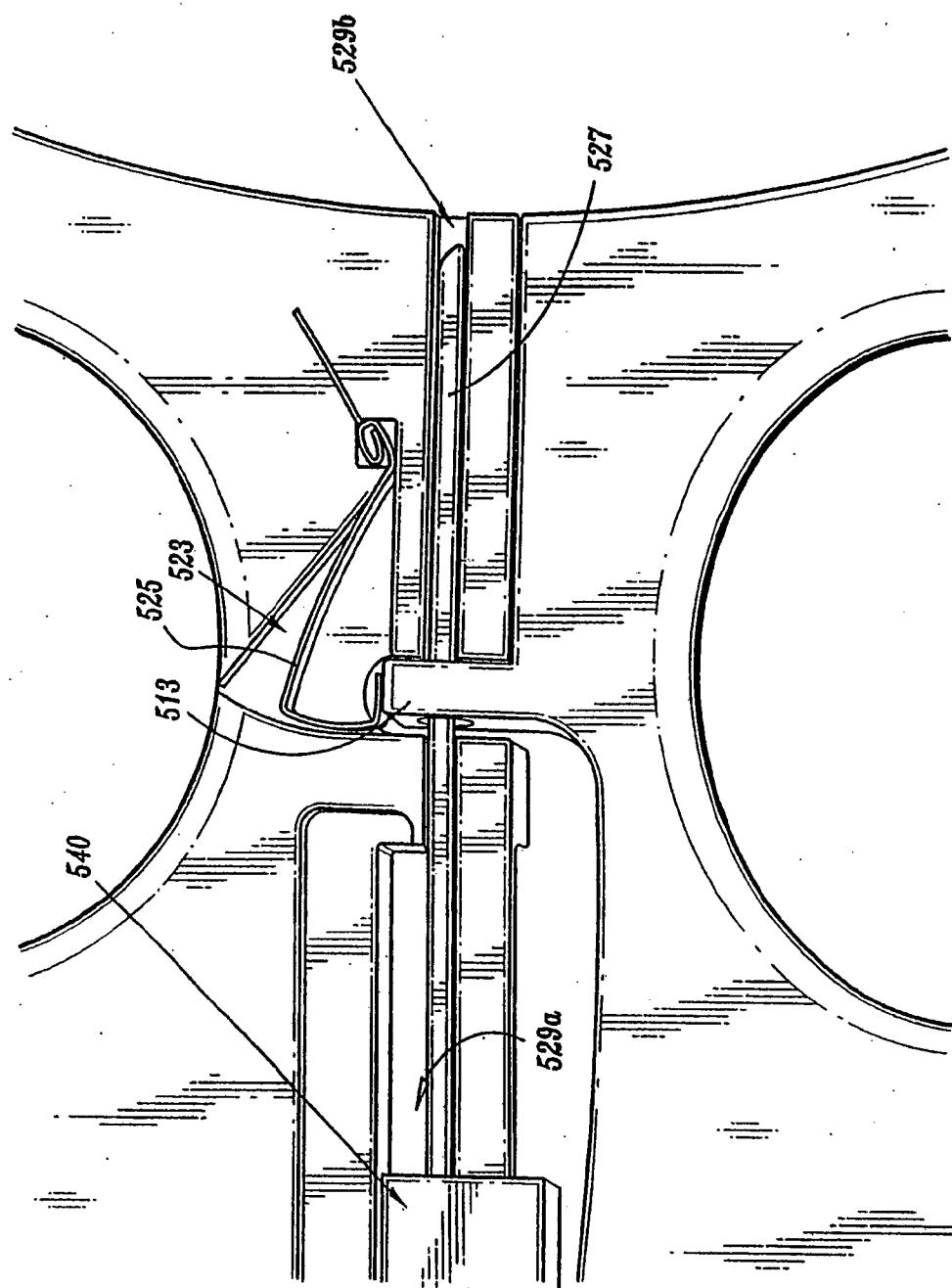
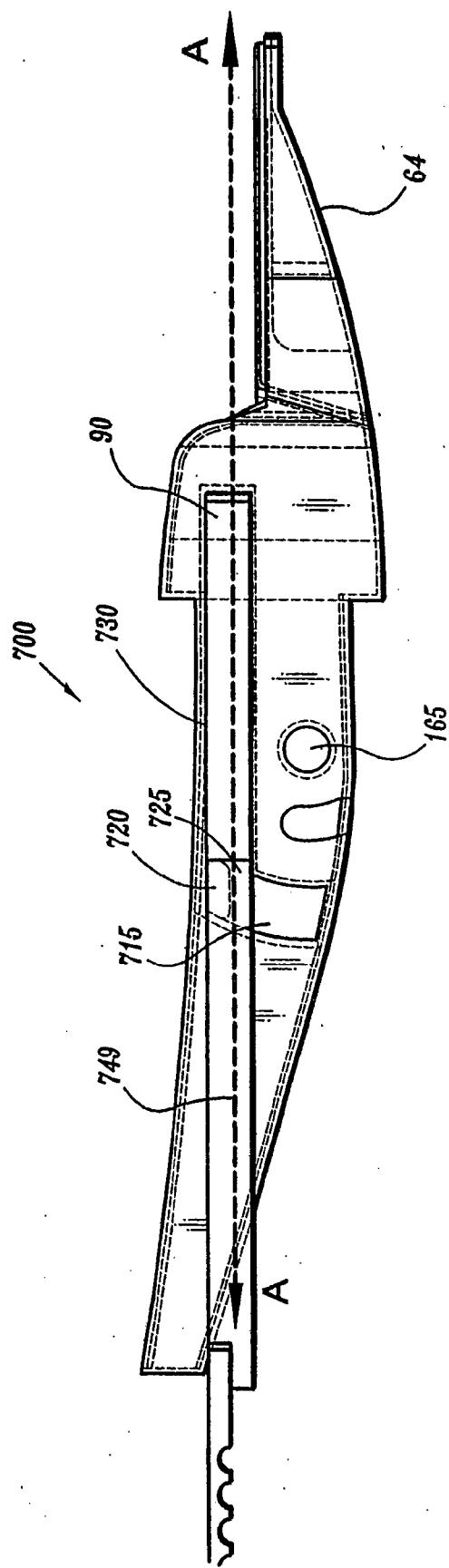
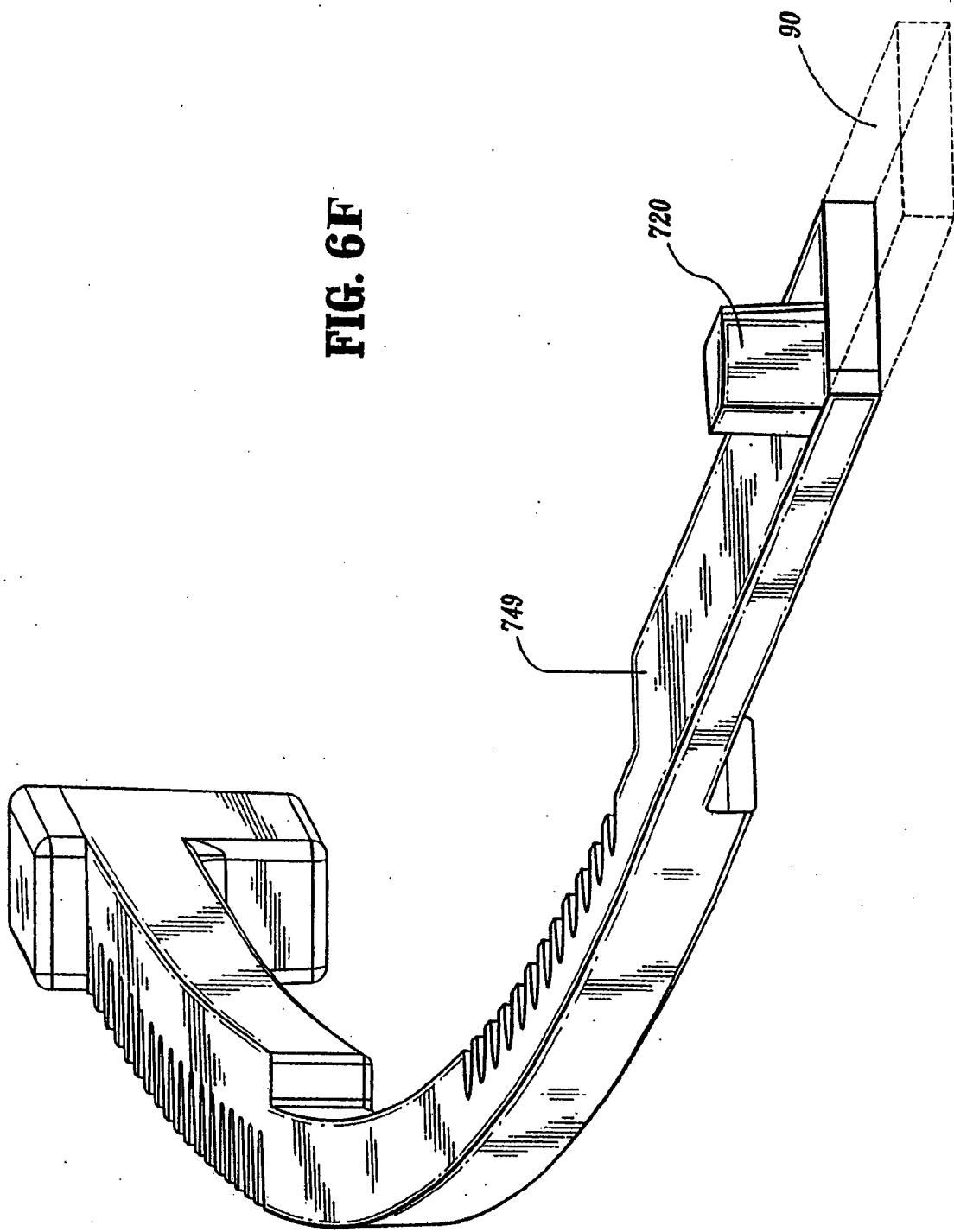


FIG. 6D



Lockout Mechanism
FIG. 6E

FIG. 6F



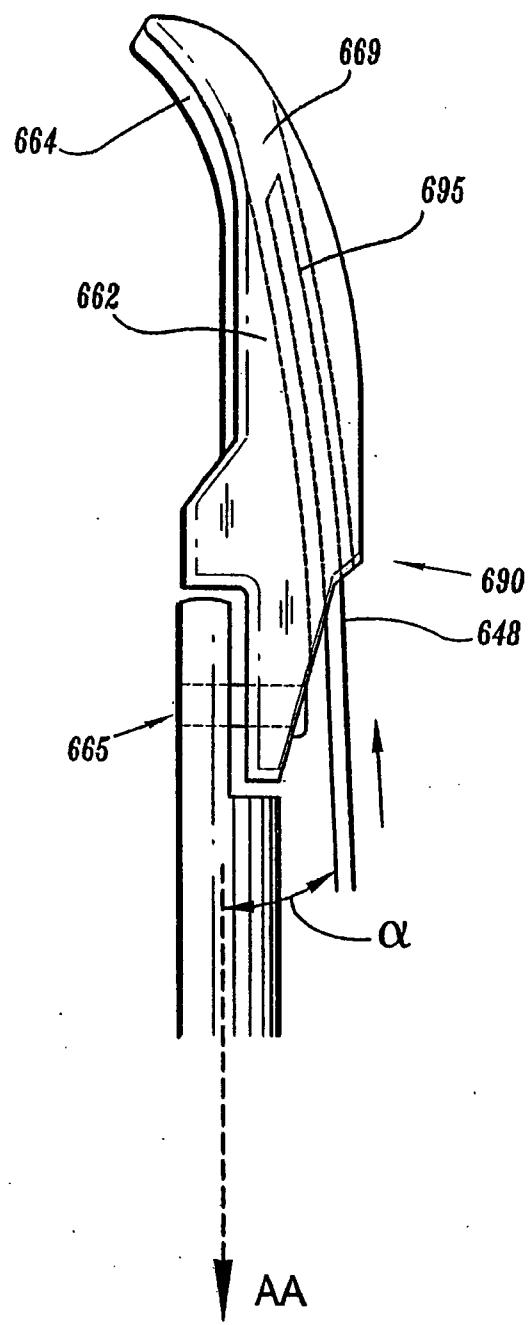


FIG. 7