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(54) DISPOSABLE LAPAROSCOPIC INSTRUMENT

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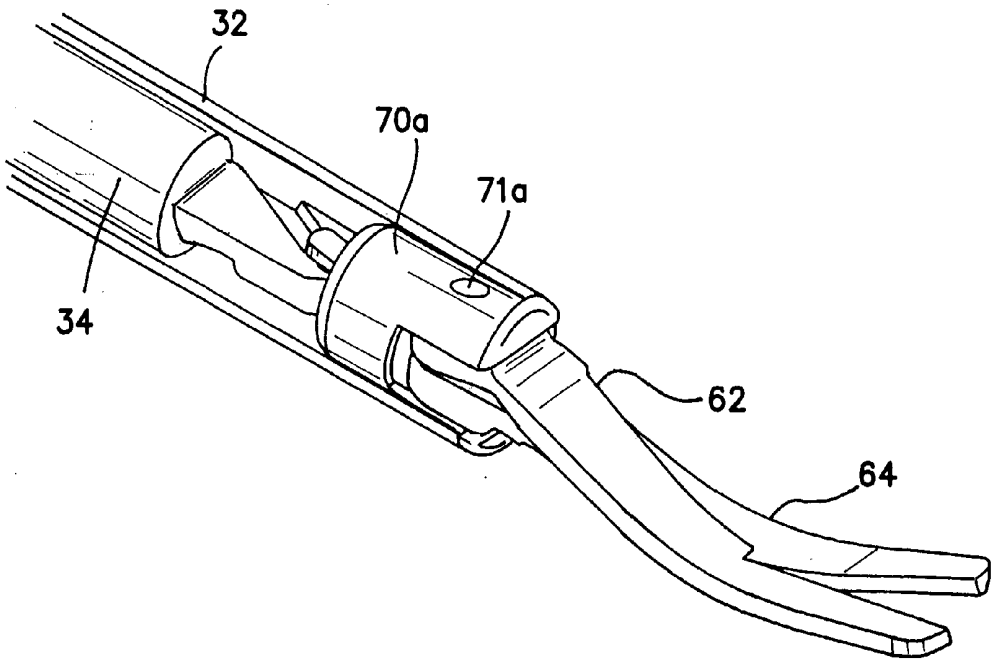
(57) **ABSTRACT**

The invention is directed to a surgical instrument including a handle assembly and a shaft assembly. The handle assembly further includes a fixed handle and a pivoting handle. The shaft assembly extends from the handle assembly and further includes an outer tube and an inner actuation rod that slides coaxially with the outer tube. The shaft assembly includes a rotatable knob to provide 360° rotation. The actuation rod has a proximal end and a distal end; the proximal end has a ball end that couples with the pivoting handle to form a rotatable ball-and-socket joint. The outer tube is formed of plastic and fits over the actuation rod to function as an electrical insulator.



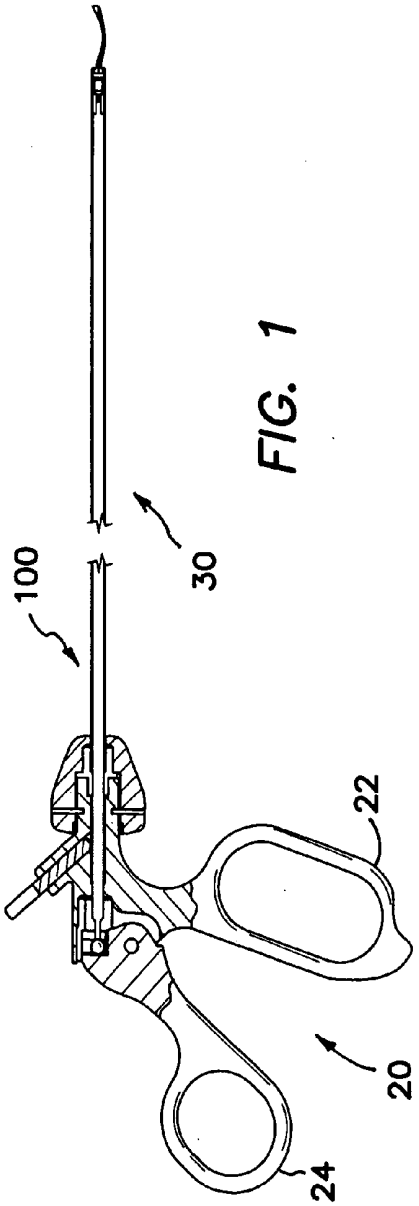


FIG. 1

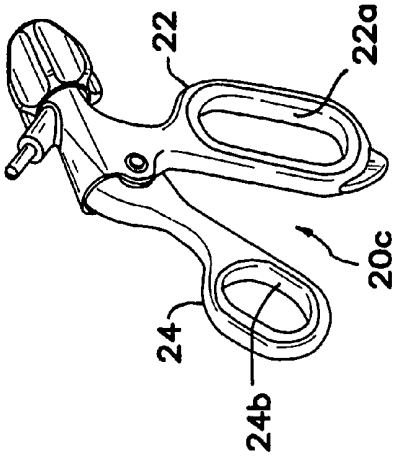


FIG. 8C

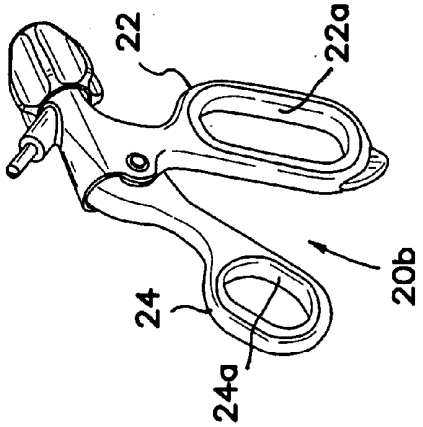


FIG. 8B

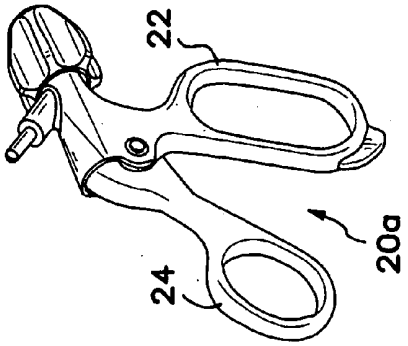


FIG. 8A

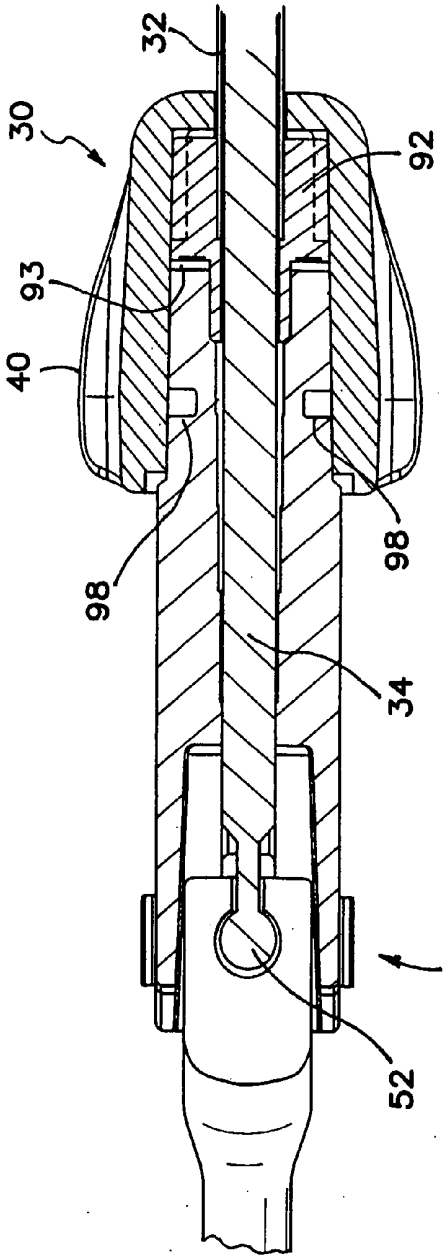


FIG. 2A

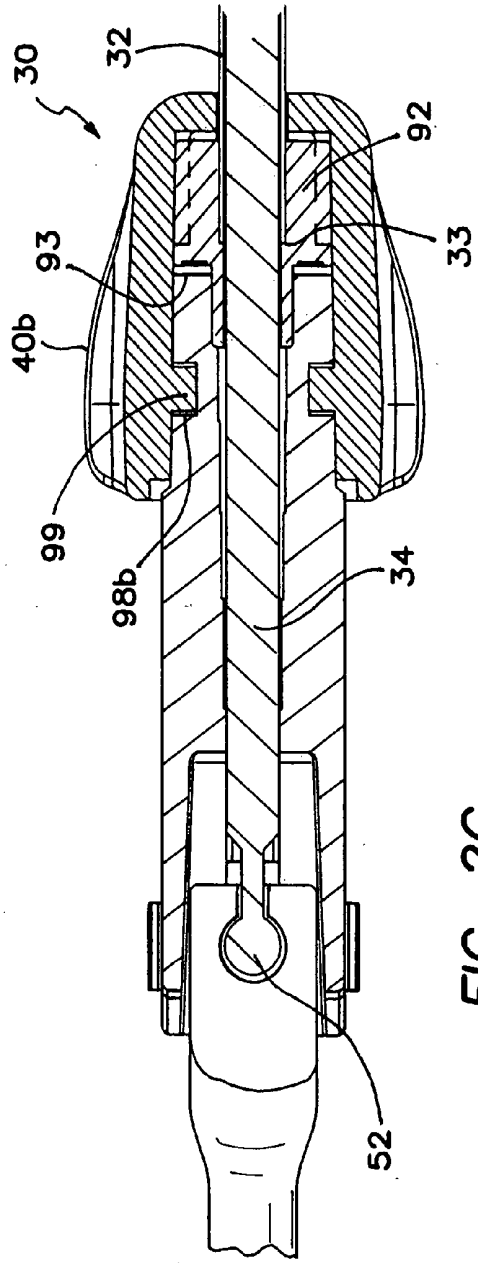


FIG. 2C

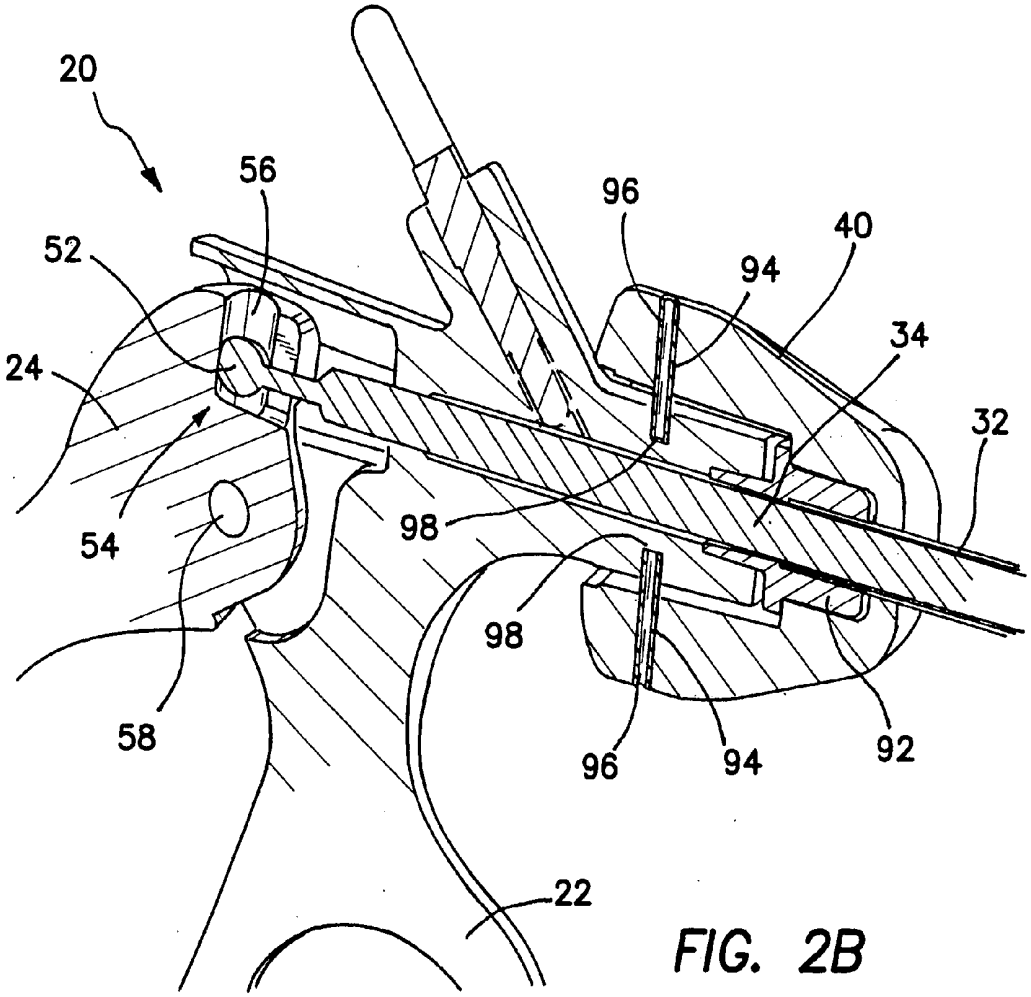


FIG. 2B

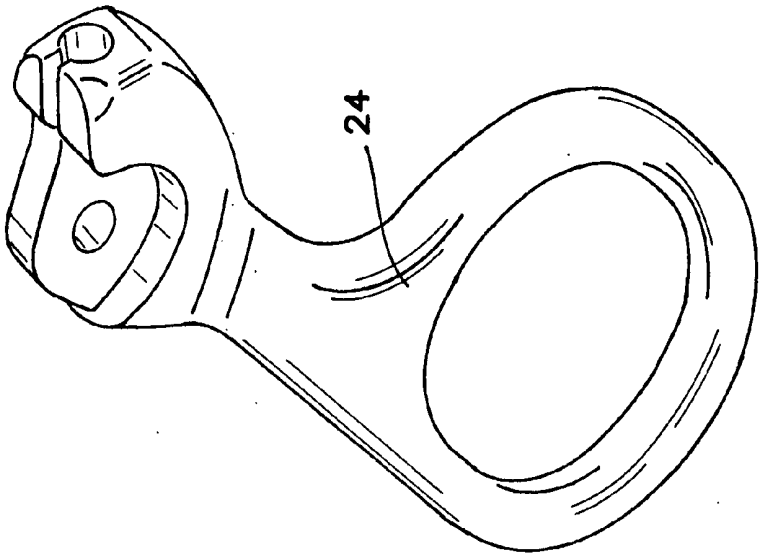


FIG. 3C

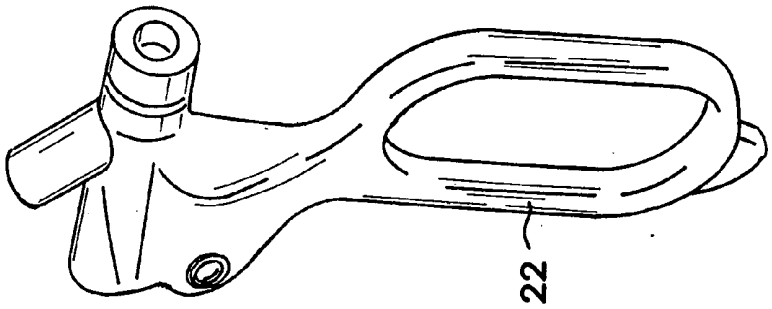


FIG. 3B

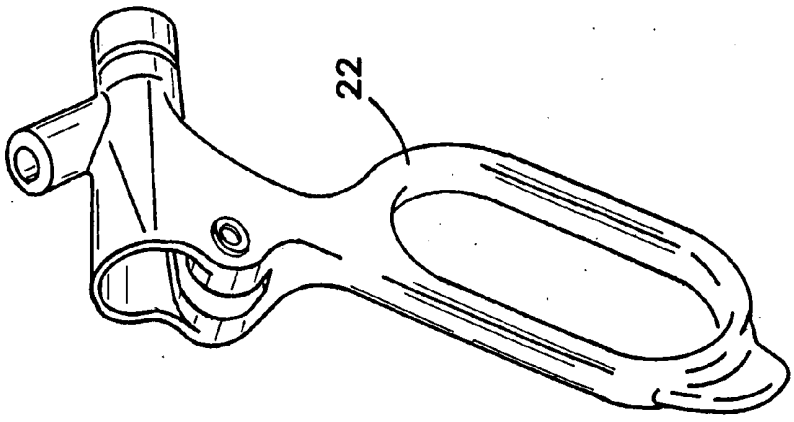


FIG. 3A

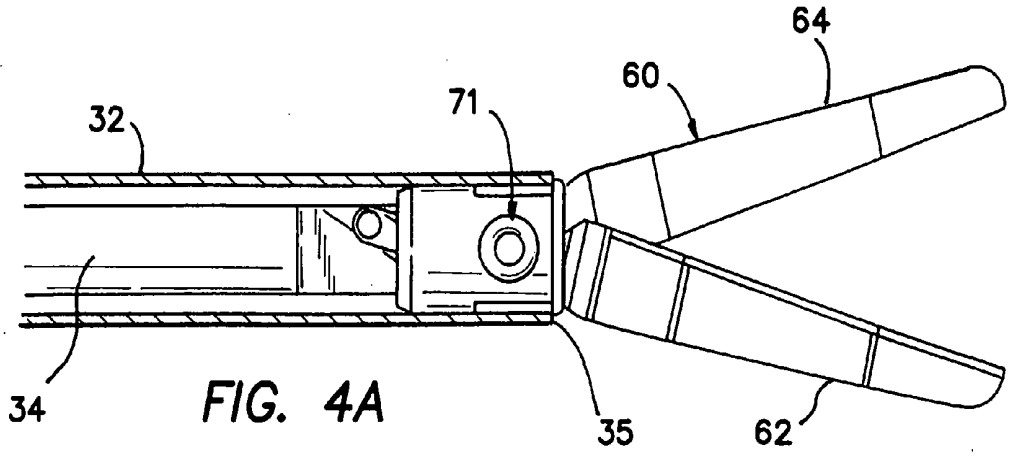
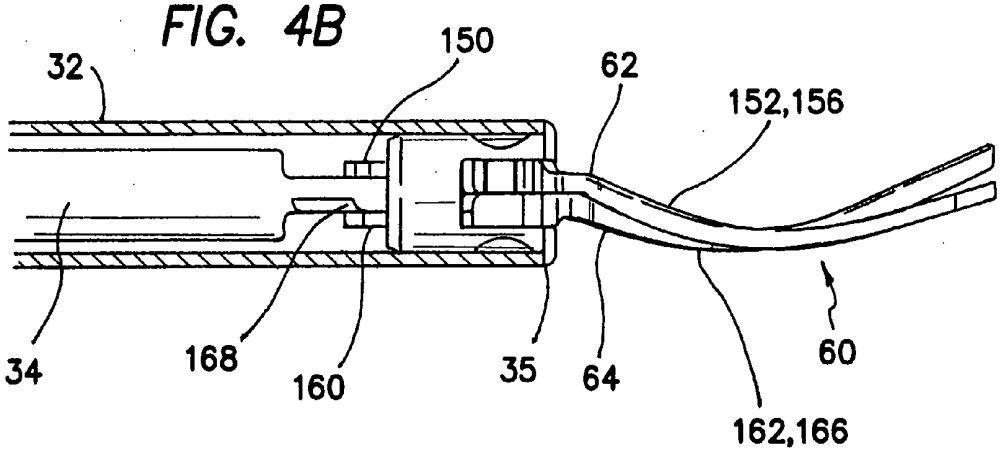


FIG. 4A

FIG. 4B



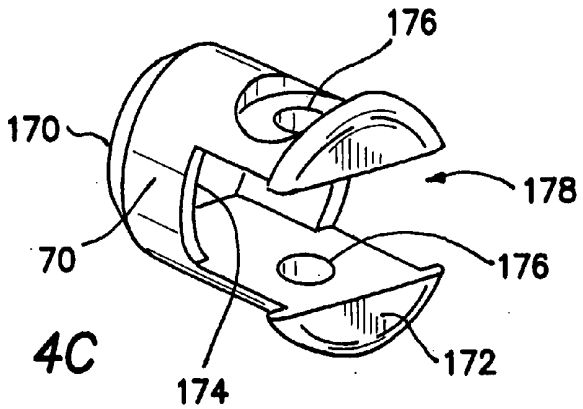


FIG. 4C

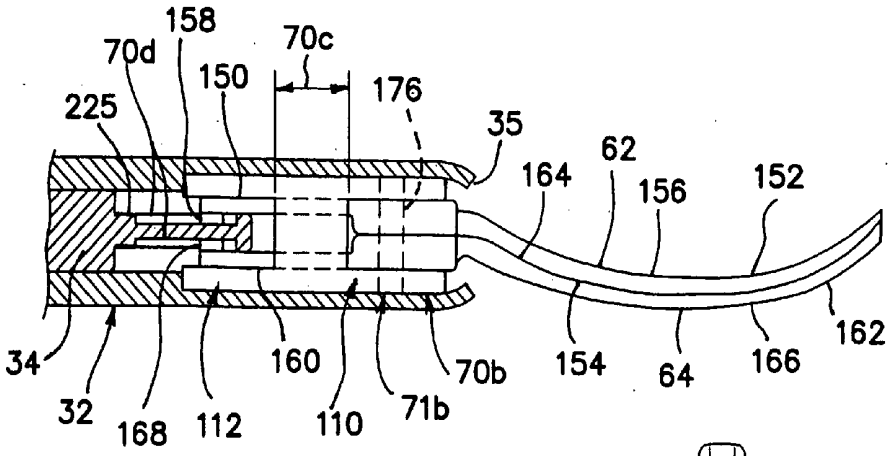


FIG. 4D

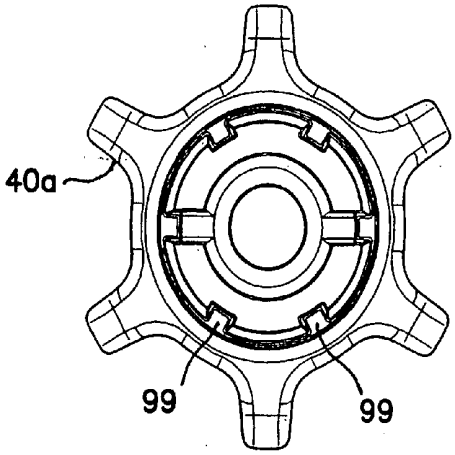


FIG. 7

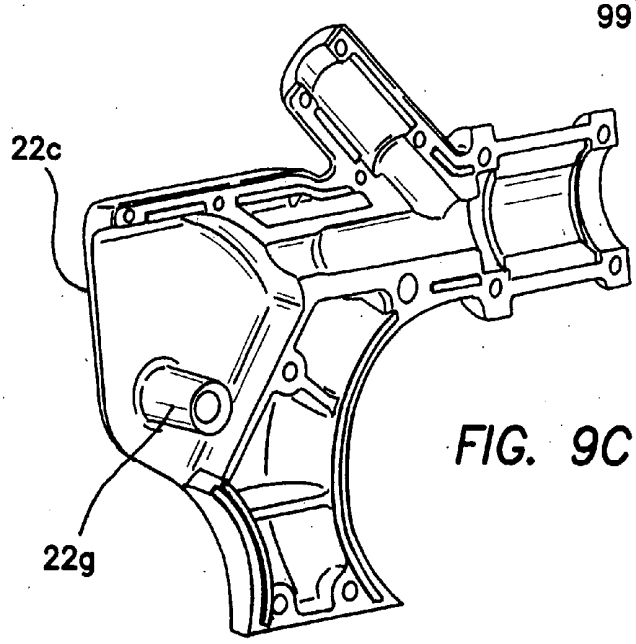


FIG. 9C

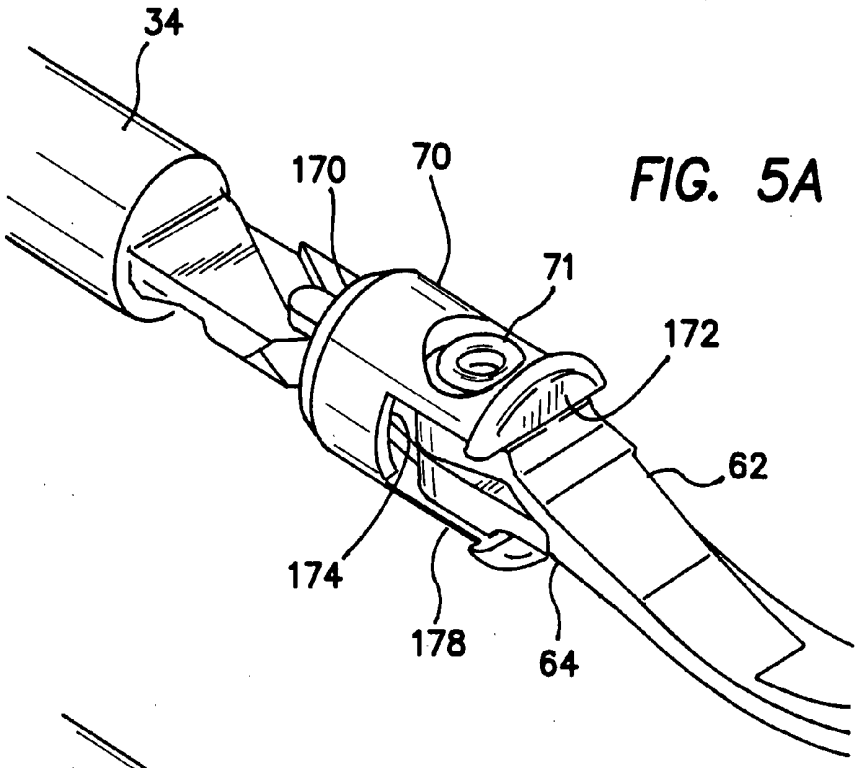


FIG. 5A

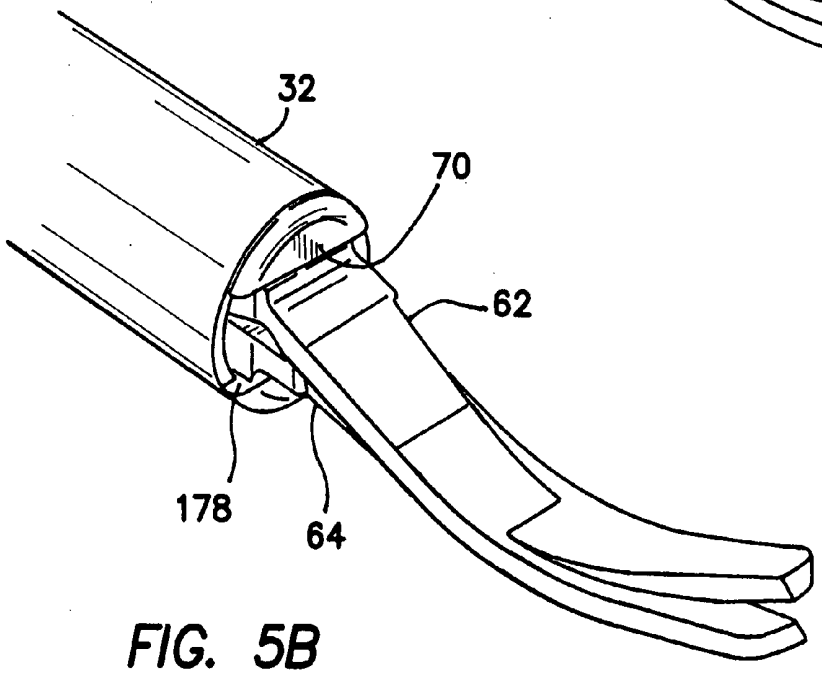
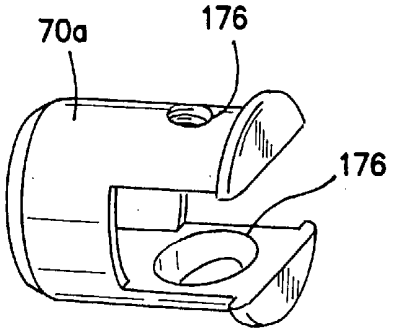


FIG. 5B

FIG. 5C



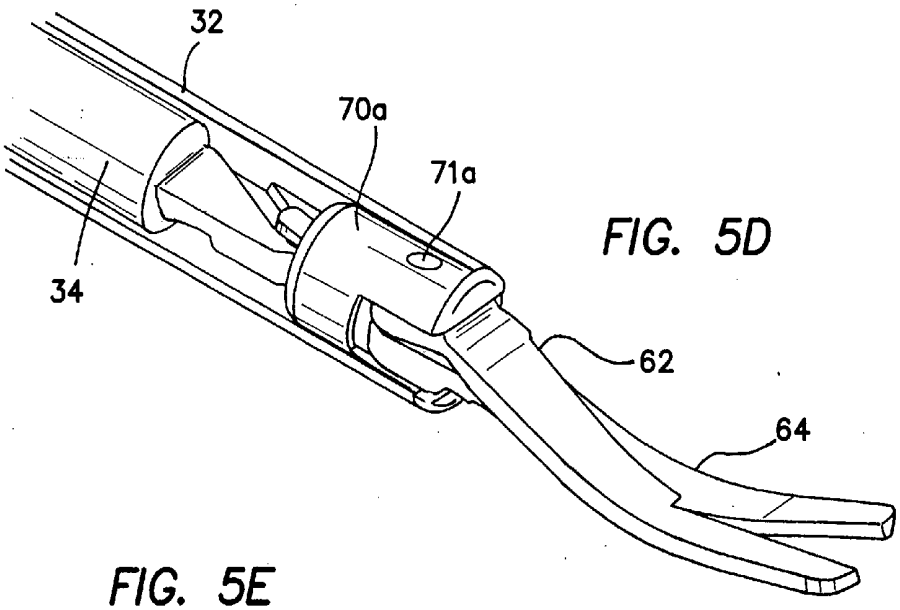


FIG. 5D

FIG. 5E

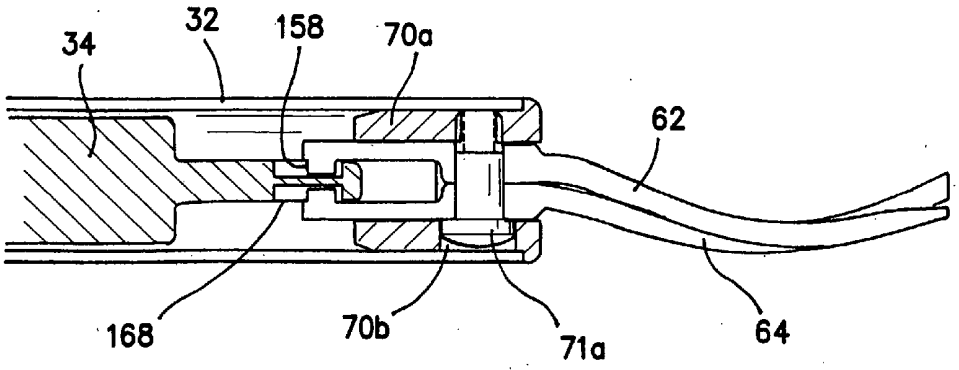
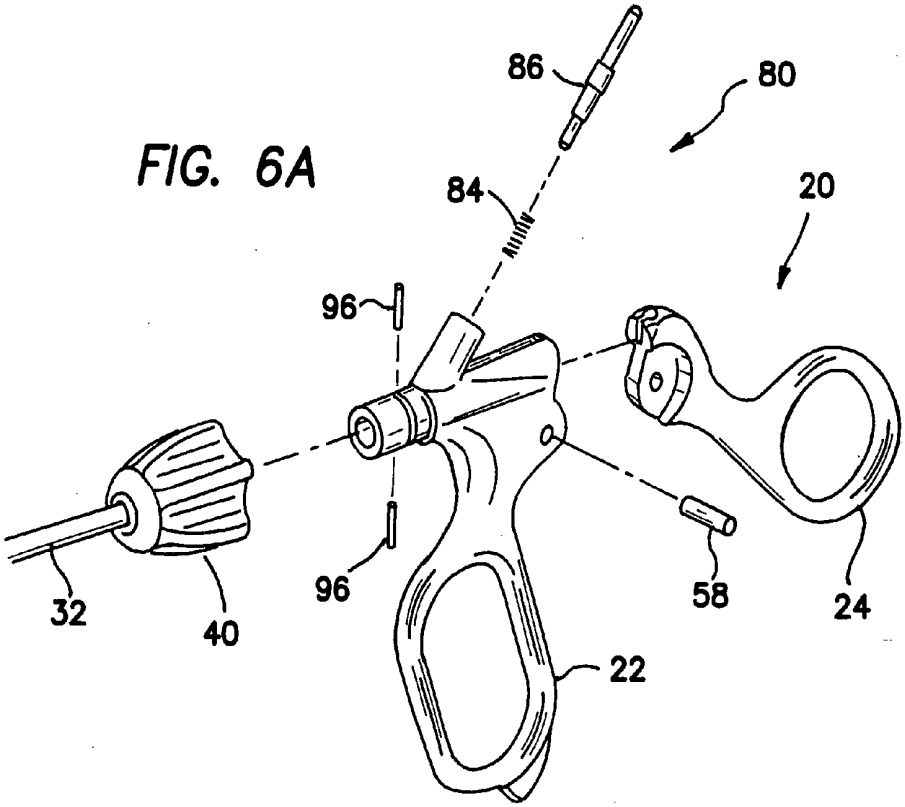


FIG. 6A



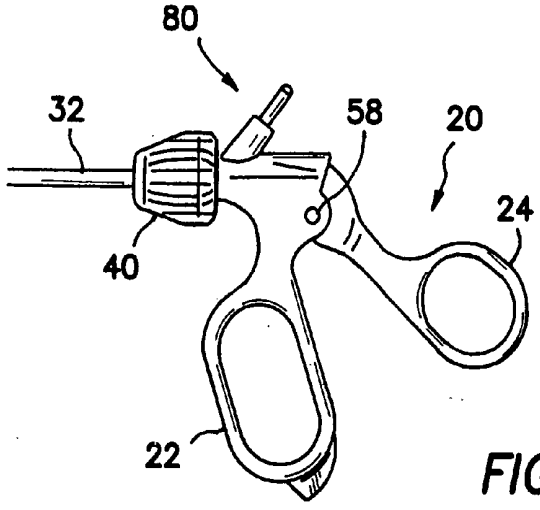


FIG. 6B

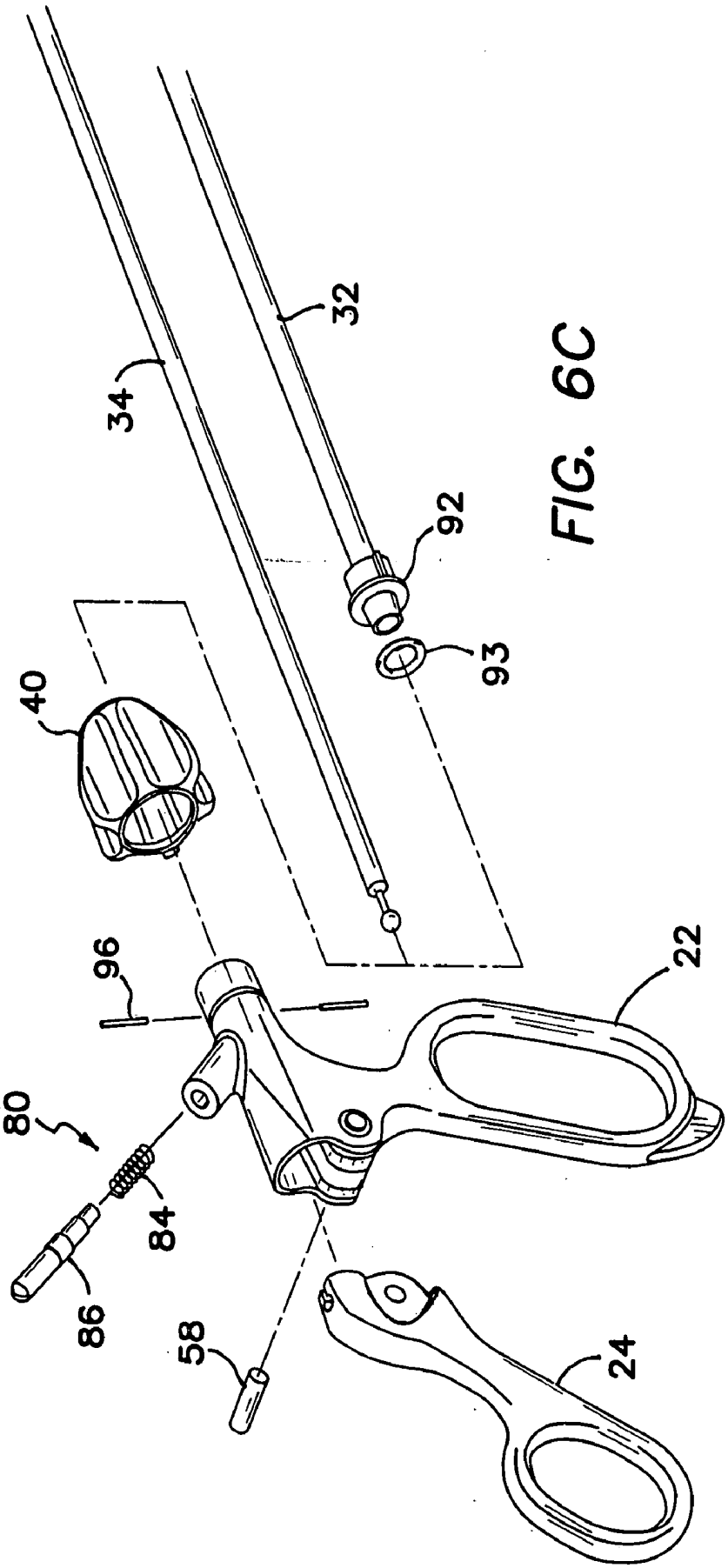


FIG. 6C

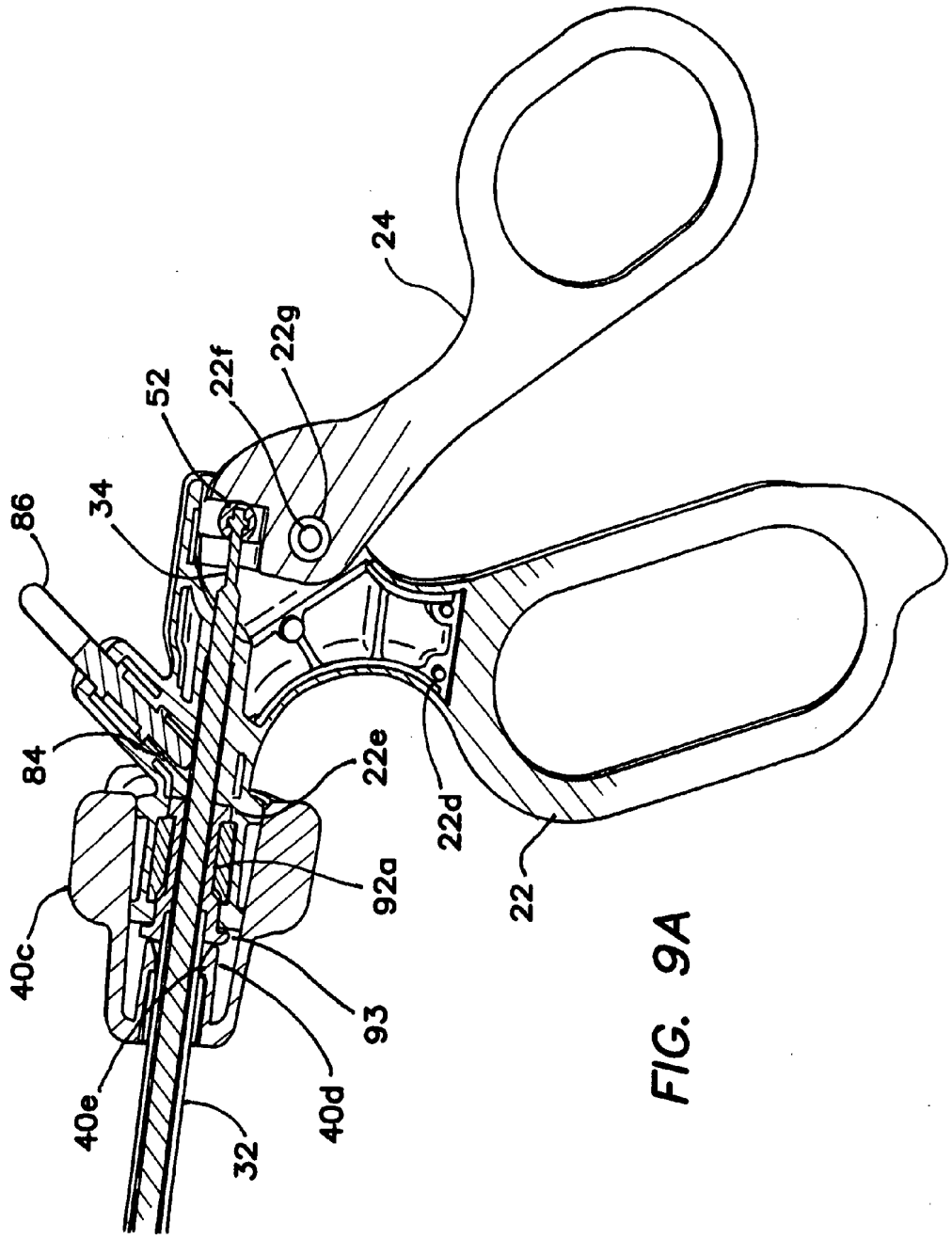
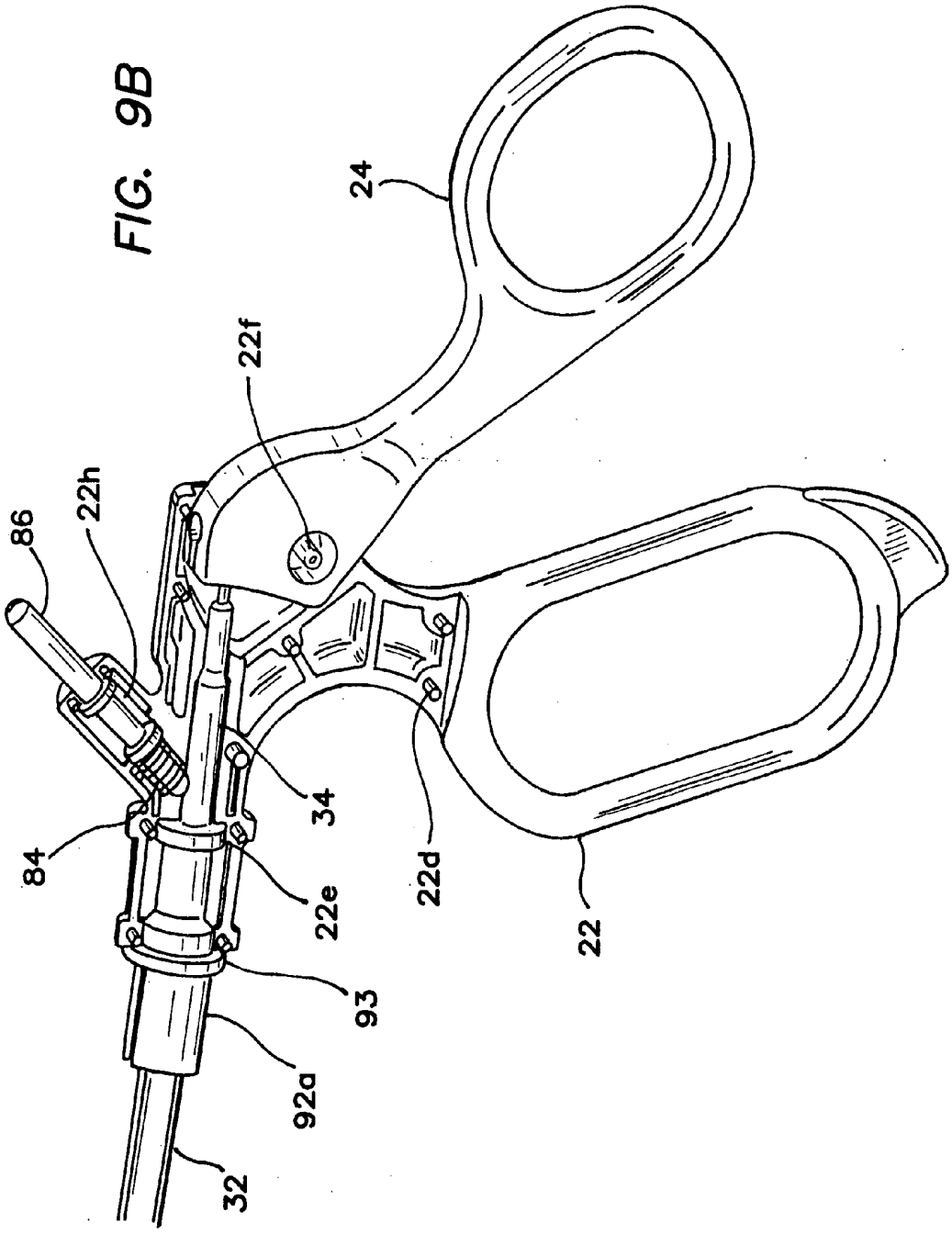


FIG. 9A

FIG. 9B



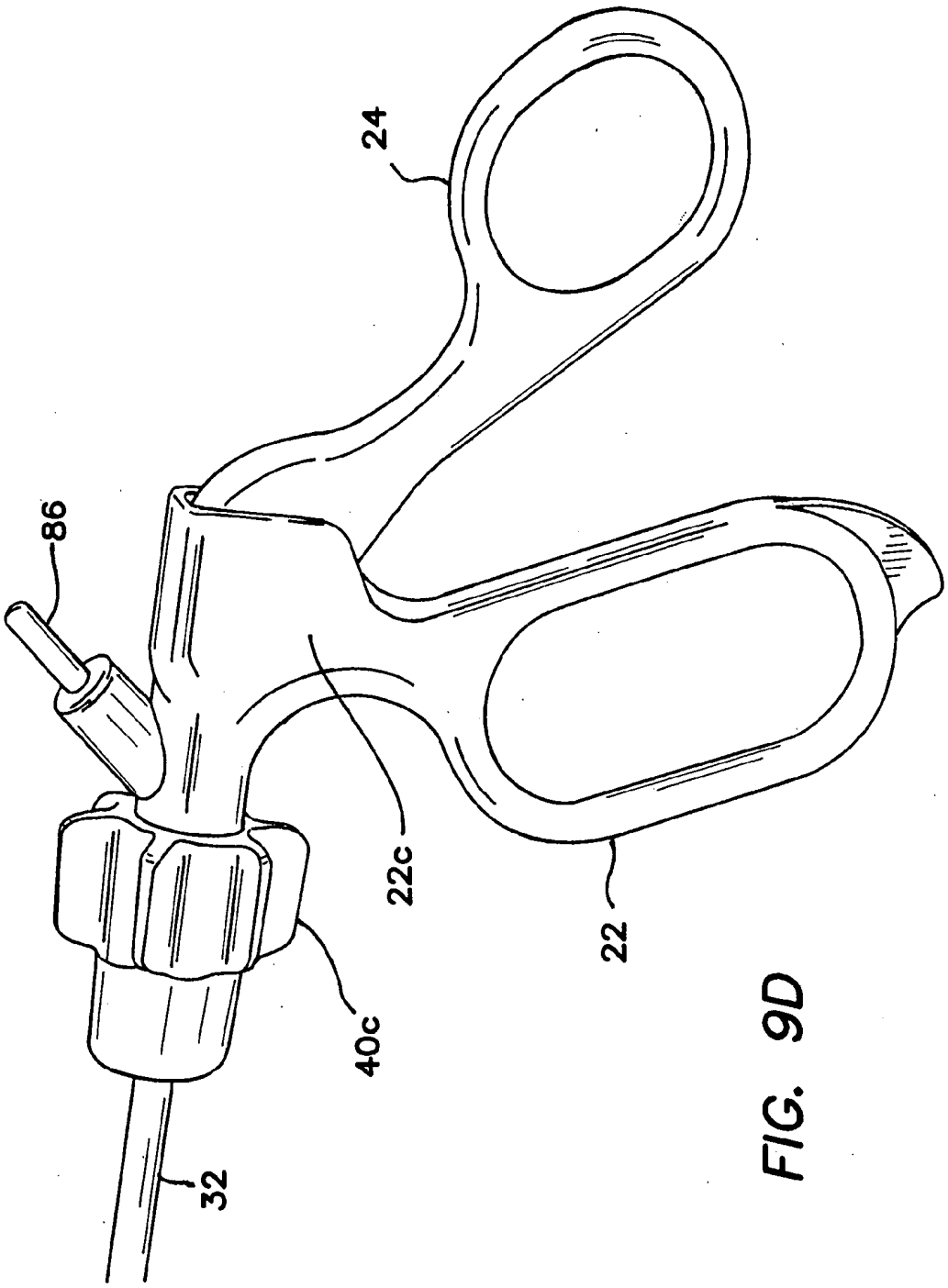


FIG. 9D

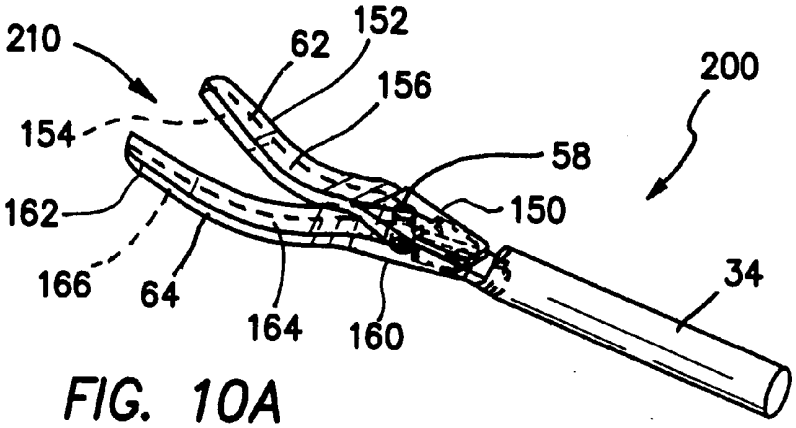


FIG. 10A

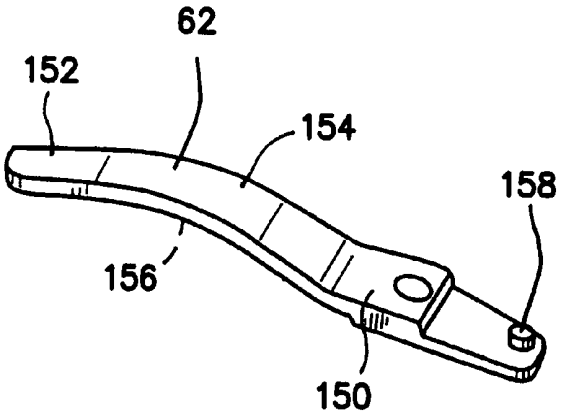


FIG. 10B

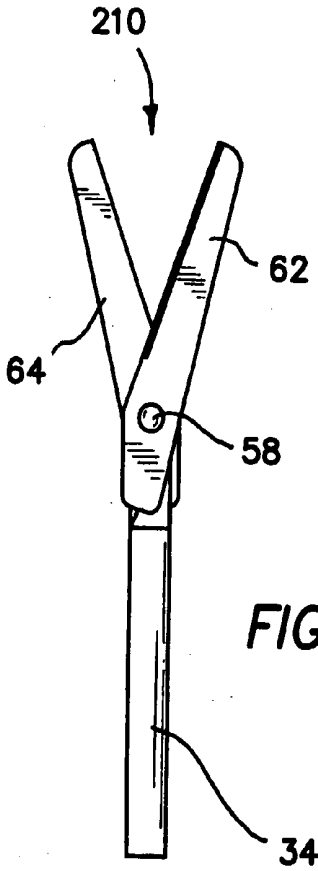


FIG. 10C

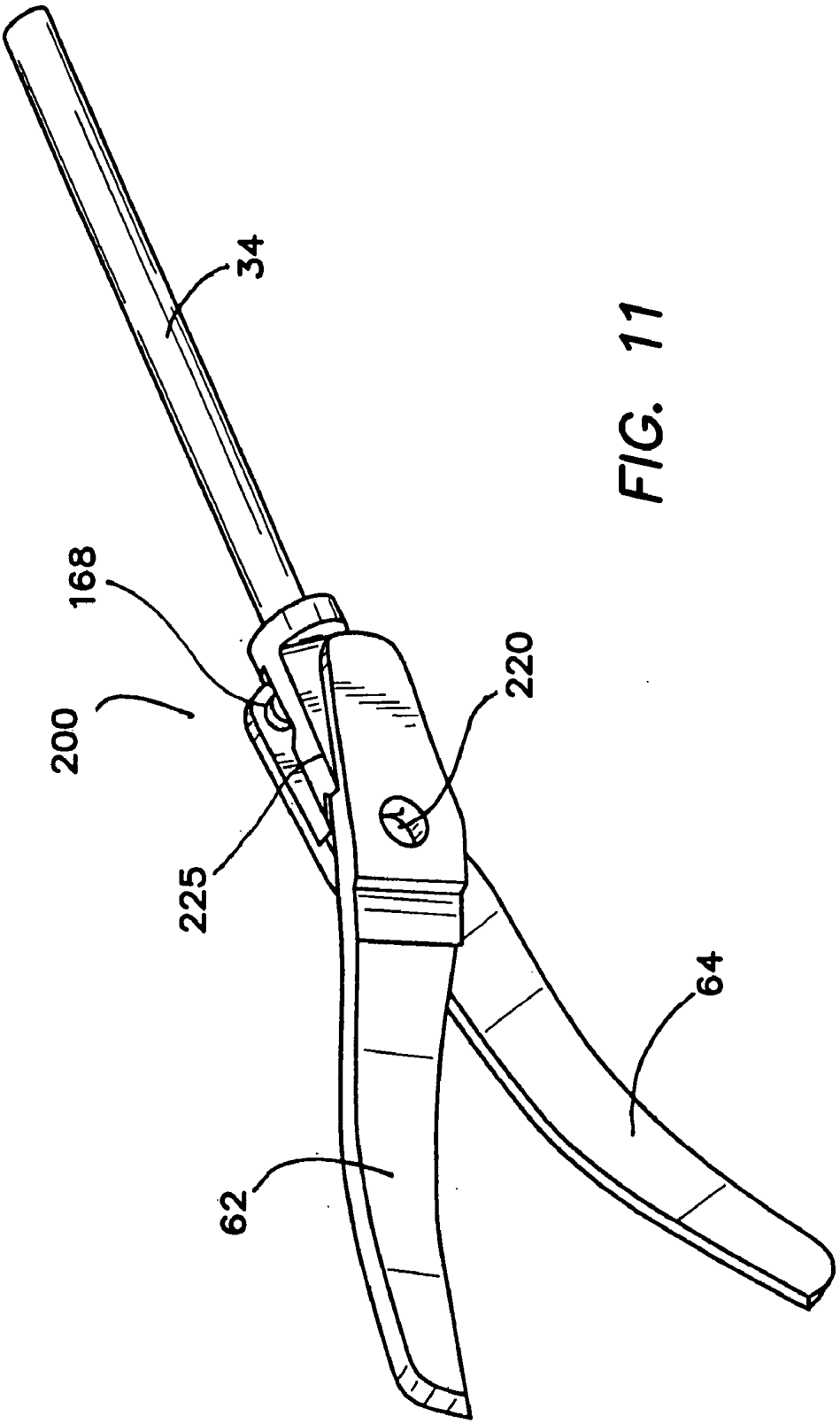


FIG. 11

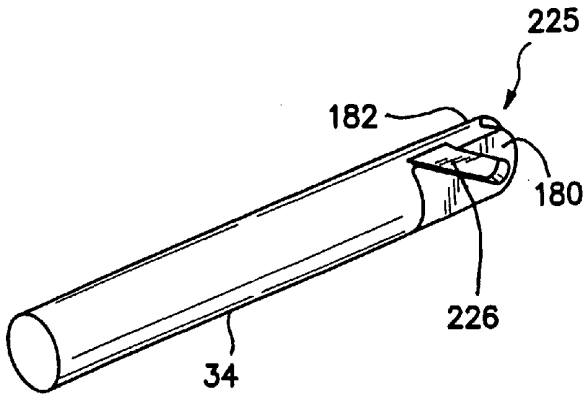


FIG. 12A

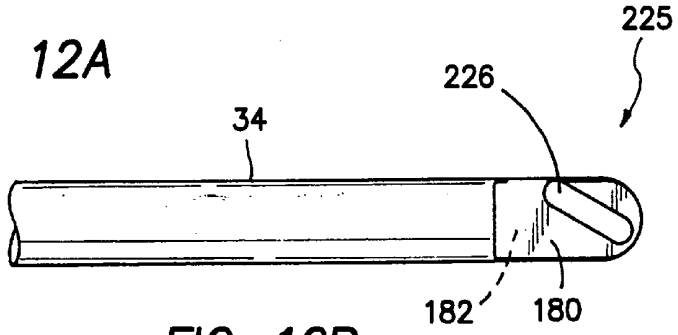


FIG. 12B

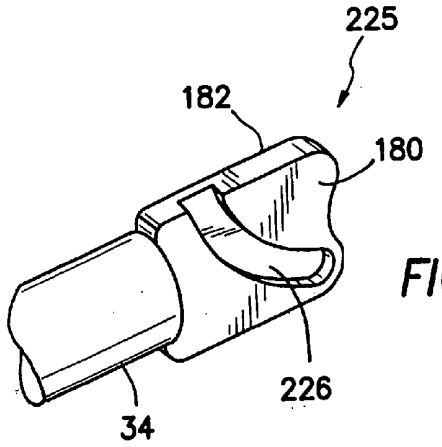


FIG. 12C

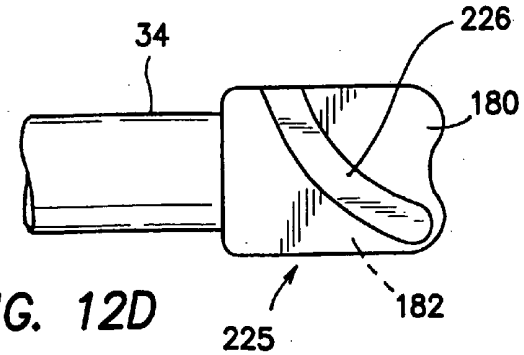


FIG. 12D

DISPOSABLE LAPAROSCOPIC INSTRUMENT

[0001] This application fully incorporates by reference and claims priority to: provisional application, Ser. No. 60/725,234, filed by Applicants on Oct. 11, 2005, entitled "Disposable Laparoscopic Instrument;" provisional application, Ser. No. 60/665,069, filed by Applicants on Mar. 24, 2005, entitled "Disposable Laparoscopic Instrument;" and provisional application, Ser. No. 60/645,319, filed by Applicants on Jan. 19, 2005, entitled "Disposable Laparoscopic Instrument."

BACKGROUND OF THE INVENTION

[0002] This invention generally relates to surgical instruments and, more specifically, to a disposable laparoscopic instrument having jaw members that pivot in response to the opening and closing of a handle member, where movement of the handles is translated through a shaft member to open and close the jaw members and to facilitate access to distant operative sites.

[0003] It is often desirable to cut tissue, occlude vessels or perform some other surgical procedure at a distant operative site. Under these circumstances, a surgical instrument having an elongate shaft assembly is typically required. Such a shaft assembly might have an operative mechanism, such as a clamp or scissors, at its distal end, and a handle assembly at its proximal end for operating the instrument through the shaft assembly.

[0004] In the past, each instrument was formed as a single structure with its own handle assembly, shaft assembly, and associated operative mechanism. For example, many of these instruments provide an intricate construction in which a linkage mechanism for opening and closing the jaw members requires numerous moving parts, while a sliding arrangement is provided between two extended rod members that activate the linkage mechanism in response to movement of the handle members. Unfortunately, the complexity of the mechanics involved in these instruments has not changed much and has made it difficult to achieve adequate sterilization for reuse. In one conventional clamp apparatus, for example, a cable is permanently secured in the handle assembly and the shaft may be detachable from the handle assembly. The typical means for joining the handle assembly and the shaft includes an externally threaded connector on the shaft that mates with an internally threaded barrel of the handle assembly. A drawback of this apparatus is the difficulty of connecting together the shaft and the handle assembly, as well as the complexity of internal components required to achieve a functional two-piece device. Moreover, as these instruments have continued to be manufactured as two-piece structures, the problems relating to sterilization, access and overall cost have remained.

SUMMARY OF THE INVENTION

[0005] The disposable laparoscopic instrument of the invention overcomes many of the disadvantages of the prior art and provides an instrument that is easy to manufacture and use. In one aspect, the invention is directed to a surgical instrument including a handle assembly and a shaft assembly. The handle assembly further includes a fixed handle and a pivoting handle. The shaft assembly extends from the handle assembly and further includes an outer tube and an inner actuation rod that slides coaxially with the outer tube. The shaft assembly may be a 5 mm diameter shaft having an accessible knob providing 360° rotation. The outer tube is coupled to the rotatable knob. The actuation rod has a proximal end and a distal end; the proximal end has a ball end that couples with the pivoting handle to form a rotatable ball-and-socket joint. The ball end of the actuation rod fits into a groove in the pivoting handle to permit the actuation rod of the shaft assembly to self-align as the pivoting handle moves. Once assembled, the fixed handle encloses the pivoting handle to prevent the ball end from pulling out of the groove under load.

[0006] The distal end of the actuation rod is coupled to an operative mechanism. In one embodiment, the operative mechanism includes a clamp having an inner blade and an outer blade. It is appreciated that the operative mechanism may be provided with a variety of different operative mechanisms having different body functions, thereby expanding the capabilities of the surgical instrument. For example, the operative mechanism may include a clamp, a pair of scissors, or a balloon device. It is further appreciated that the operative mechanism may include any device that utilizes the actuation rod to move between a first state and a second state. The inner blade and outer blade may be coupled to an insert having an aperture to accept a pin, such as a rivet pin, dowel pin or screw, that allows the operative mechanism to pivot during opening and closing. The insert may be coupled or press-fit to a distal-end portion of the outer tube. The insert and outer tube can be sized and configured so as to permit greater opening angles for the blades. The insert may be formed of a plastic or metallic material. The insert may also be coupled to the outer tube by adhesive or other coupling means. In one aspect, the insert may include a distal clevis and a proximal clevis. The proximal clevis extends over the proximal ends of the blades and sandwiches the proximal ends of the blades between the actuation rod and the walls of the proximal clevis to contain the proximal ends of the blades from moving away from the actuation rod and out of their drive slots within the actuation slots.

[0007] In another aspect of the invention, the handle assembly may further include a connecting post to provide for cauterization of tissue during a procedure. More specifically, the connecting post includes a spring and a connector and may be formed in the fixed handle so as to extend from the top either at an angle or perpendicular to the actuation rod. The connecting post may be contained in the fixed handle by means of a loose fit to allow it to freely rotate 360°, or by force fit, adhesive, threads or other means. With this aspect, the spring extends from the connecting post to make contact with the actuation rod as it rotates and/or moves axially to provide electrical contact. The spring may be a round helical compression spring or a flat wire cantilever spring. As the electrical charge is applied through the connecting post to the actuation rod and then to the operative mechanism such as the blades, the operator is protected from electrical shock as both the handle assembly and the outer tube of the shaft assembly are formed from plastic material and thus serve as an electrical insulation barrier. The outer tube is formed of a thermoplastic or a thermoset plastic. The outer tube fits over the actuation rod to function both as a structural member and as an insulator to prevent electrical shock. It is appreciated that the outer diameter of the actuation rod fits closely to the inner surface of the outer tube so as to support it. With this aspect, both the actuation

rod and the blades are formed of corrosion resistant steel, but it is appreciated that the actuation rod and the operative mechanism can be formed of any electrically conducting and corrosion resistant material.

[0008] In another aspect, the knob has internal key couplings for rotating the outer tube of the shaft assembly. Specifically, the knob may further include a hub, an alignment hole, and a retaining pin or other similar retention means for coupling the knob to the handle assembly to allow 360° rotation. The handle assembly may include a circumferential groove where a retaining pin of the knob is to be placed, inserted or extended to allow rotation. The knob may further include a spring washer between the distal end of the handle assembly and the proximal end of the hub to take up the linear play due to tolerance variations. The hub may be formed of a plastic material and may be overmolded onto the outer tube to provide secure coupling. The hub may also be coupled to the outer tube with an adhesive or other coupling means. The rotatable knob may also have a plurality of ribs on its inside diameter, providing a thin-walled knob while maintaining stability and reducing rotating friction with the handle assembly and the shaft assembly. The openings between the ribs allow for a generous draft angle, resulting in improved part ejecting during the molding process.

[0009] In another aspect of the invention, the fixed handle is provided with a first snap-in ring insert to fit a user's hand size and the pivoting handle is provided with a second snap-in ring insert to fit a user's hand size. A range of snap-in ring sizes for both the fixed handle and the pivoting handle may be provided the ring inserts are to be included with each handle assembly of the surgical instrument so a user can select, for example, a variety of sizes. The ring inserts are to be formed of a softer material than the handle material to provide comfort to the user. In addition, the ring inserts can be made of different colors for identification of various sizes. It is appreciated that the handle assembly of the surgical instrument can be used with or without the ring inserts.

[0010] In another aspect of the invention, a surgical instrument includes an elongate tube extending along an axis that includes an actuation rod that is coaxially slidable within the elongate tube. The surgical instrument also includes a first tip having a first pin formed on a proximal end surface of the first tip and a second tip having a second pin formed on a proximal end surface of the second tip. The second tip is pivotally coupled to the first tip at a common pivot pin that is operably connected to the elongate tube to open and close the tips in response to movement of the actuation rod. The actuation rod has at least one slot that accepts the pins of the first and second tips. The slot has camming surfaces for the pins to slide within the slot, and the proximal ends of the tips extend minimally outside the diameter of the elongate tube during actuation of the tips. In one aspect, the proximal ends of the tips do not extend outside the inner diameter of the elongate tube during actuation of the tips. In another aspect, the actuation rod includes a tongue portion at its distal end with two slots transverse to one another on opposing sides of the tongue. In another embodiment, the slots on the tongue portion are curved. In another embodiment, the slots on the tongue may be either open-end slots or closed-end slots. In another embodiment, the pins are formed on the proximal end surfaces of the tips by press fitting, threading, welding or bonding.

[0011] These and other features and advantages of the invention will become more apparent with a discussion of embodiments of the invention and reference to the associated drawings.

DESCRIPTION OF THE DRAWINGS

[0012] **FIG. 1** is a side view of one embodiment of the invention including a handle assembly, a shaft assembly and an operative mechanism;

[0013] **FIGS. 2A-2C** illustrate cross-sectional views of the connections between the handle assembly and the shaft assembly;

[0014] **FIGS. 3A-3C** illustrate a rear perspective view of the fixed handle, a front perspective view of the fixed handle, and a top perspective view of the pivoting handle, respectively;

[0015] **FIGS. 4A and 4B** illustrate a top view and a side view of an operative mechanism of the invention including an insert and a pair of blades, **FIG. 4C** illustrates a perspective view of the insert of the operative mechanism of **FIGS. 4A and 4B**, and **FIG. 4D** illustrates a cross-sectional view of an insert having a distal clevis and a proximal clevis in accordance with another aspect of the invention;

[0016] **FIGS. 5A and 5B** illustrate perspective views of the operative mechanism of the invention without the outer tube and with the outer tube of the shaft assembly, respectively;

[0017] **FIGS. 5C-5D** illustrate perspective and cross-sectional views of an insert for receiving a screw in accordance with another aspect of the invention;

[0018] **FIG. 5E** illustrates a side view of the device of **FIG. 5D**;

[0019] **FIGS. 6A-6C** illustrate perspective and side views of a handle assembly in accordance with another aspect of the invention including a connecting post to provide for cauterization of tissue during a procedure;

[0020] **FIG. 7** illustrates a proximal view of a rotatable knob in accordance with another aspect of the invention having a plurality of ribs providing a thin-walled knob while maintaining stability and reducing friction with the handle assembly and the shaft assembly;

[0021] **FIGS. 8A-8C** illustrate the handle assembly of the invention providing a variety of sizes of snap-in ring inserts to fit a user's hand size;

[0022] **FIGS. 9A-9D** illustrate cross-sectional and side views of a fixed handle being formed of two pieces in accordance with another aspect of the invention;

[0023] **FIGS. 10A-10C** illustrate a perspective view of a laparoscopic surgical instrument of the invention, a perspective view of a blade or tip of the operative mechanism of the invention, and a side view of **FIG. 10A**, respectively;

[0024] **FIG. 11** illustrates a perspective view of an assembled surgical instrument of the invention having mobile tips and an actuation rod;

[0025] **FIGS. 12A and 12B** illustrate a perspective view and a side view of an actuation rod having a slot with an open end in accordance with an aspect of the invention; and

[0026] **FIGS. 12C and 12D** illustrate a perspective view and a side view of an actuation rod having a curved slot in accordance with another aspect of the invention.

DESCRIPTION OF THE INVENTION

[0027] The invention and its various embodiments can now be better understood with the following detailed description wherein illustrated embodiments are described. It is to be expressly understood that the illustrated embodiments are set forth as examples and not by way of limitations on the invention.

[0028] A first embodiment of a surgical instrument is illustrated in **FIG. 1** and designated by the reference numeral **100**. The surgical apparatus **100** includes a handle assembly **20** and a shaft assembly **30**. The handle assembly **20** further includes a fixed handle **22** and a pivoting handle **24**. Referring to **FIGS. 2A and 2B**, there are shown cross-sectional views of the connections between the handle assembly **20** and the shaft assembly **30**. In particular, the shaft assembly **30** extends distally from the handle assembly **20** and further includes an outer tube **32** and an inner actuation rod **34** that slides coaxially within the outer tube **32**. The shaft assembly **30** may be a 5 mm diameter shaft having an accessible knob **40** providing 360° rotation as further described below. The outer tube **32** is an elongate tube of any cross-sectional shape that extends along an axis and includes a proximal end **33** (see **FIG. 2C**) and a distal end **35** (see **FIGS. 4A and 4B**). The outer tube **32** is coupled to a rotatable knob **40** as further described below.

[0029] The actuation rod **34** includes a proximal end and a distal end. The proximal end of the actuation rod extends proximally from the proximal end **33** of the outer tube **32** and the distal end of the actuation rod is positioned within a distal-end region of the outer tube. The proximal end of the actuation rod has a ball end **52** that couples with the pivoting handle **24** to form a rotatable ball-and-socket joint. The ball end **52** of the actuation rod **34** fits into a groove **56** in the pivoting handle **24** to permit the actuation rod **34** of the shaft assembly **30** to self-align as the pivoting handle **24** moves. The outer tube **32** can be formed of a plastic material and the actuation rod **34** can be formed of a plastic or metallic material, depending on the application.

[0030] In contrast to the invention, surgical instruments of the prior art are typically formed so as to have a metal outer tube and a metal actuation rod. More specifically, the actuation rod is typically a small metal round rod or a flat stamped rod extending through the lumen of the metal outer tube between the handle assembly and the jaw members. With the prior art instruments, the metal outer tube provides flexural strength to the shaft assembly as the actuation rod moves back and forth inside the shaft assembly to operate the jaw members. The metal outer tube is then covered with one or more layers of plastic shrink tubing that acts as an electrical insulator between the shaft assembly and the patient and/or user. Accordingly, these prior art instruments require at least three components: an actuation rod; a metal outer tube to provide flexural strength; and a plastic shrink tubing to provide electrical insulation.

[0031] In comparison, the invention discloses an outer tube **32** that is formed of a plastic material and an inner actuation rod **34** that can be formed of plastic or metal, depending on the application. The actuation rod **34** can be a round or any other cross-sectional shape well known in the art, stamped or formed member that provides flexural strength to the shaft assembly **30**. Because the outer tube **32** is formed of plastic, it is electrically nonconductive and does not require further insulating outer tubing. It should be noted that the plastic outer tube **32** provides both sufficient flexural and compression strength, yet it provides greater electrical insulative properties than a thin walled shrink tubing. The plastic outer tube **32** can be formed, for example, by extrusion. It is further appreciated that the process of assembling the plastic outer tube **32** is also simpler than that of forming the shrink tubing over the metal outer tube, and the costs involved with the process of the invention are also much less than those of the prior art. From the material supply standpoint, a plastic outer tube is also more timely available, since it can be extruded in-house, and any secondary operations, such as hole drillings through the proximal end for the handle assembly, cutting to precision length, insert molding a component onto the tube, and counterboring the distal end to provide an internal cavity and shoulder for the jaw members, can also be done in-house. The design of the invention thus facilitates and simplifies assembly.

[0032] Referring back to **FIG. 2B**, the ball end **52** can be formed from a plastic material at the proximal end of the actuation rod **34**, and the actuation rod may include barbs or have an enlarged outer diameter. The plastic ball end **52** can then be force-fit onto the actuation rod **34** and fitted into the groove **56** to form the ball-and-socket joint or coupling. The ball end **52** can also be formed in a plurality of pieces, for example, two halves that are then joined together by any coupling means including a snap-fit connection, press-fit posts, or with adhesive. The actuation rod **34** can also be machined to accept the pieces of the ball end **52**, and can be designed to provide s strength when the rod is experiencing a load. In one example, the ball end **52** may include a male half and a female half and the actuation rod **34** may be configured to accept the halves accordingly. Other benefits of having the ball end **52** made of plastic include lubricity of the plastic ball joint, ease of rotation, less likelihood of torsional lockup, and reduced stress on the pivot pin **58**.

[0033] Once assembled, the fixed handle **22** encloses the pivoting handle **24** to prevent the ball end **52** from pulling out of the groove **56** under load. **FIGS. 3A-3C** illustrate a rear perspective view of the fixed handle **22**, a front perspective view of the fixed handle **22**, and a top perspective view of the pivoting handle **24**, respectively. During assembly, the fixed handle **22** may be slid over the proximal end of the actuation rod **34** so as to expose the ball end **52**, which may then be placed into groove **56** of the pivoting handle **24**, and a pivot pin **58** (see **FIG. 2B**) may then be inserted or placed for retaining the fixed and pivoting handles **22**, **24**. The handle **24** pivots about the pivot pin **58** to move in relation to the fixed handle **22**.

[0034] Referring to **FIGS. 4A and 4B**, the distal end of the actuation rod **34** is coupled to an operative mechanism **60**. In one embodiment, the operative mechanism **60** includes a clamp or scissors having a first blade or tip **62** (inner blade) and a second blade or tip **64** (outer blade). The first tip **62** includes a proximal-end portion **150**, a distal-end portion **152**, an interfacing side **154** and an opposed side **156**, with a first pin **158** protruding from the interfacing side of the proximal-end portion proximate a proximal end of the first tip (see **FIGS. 10A and 10B**). The second tip **64** includes a

proximal-end portion **160**, a distal-end portion **162**, an interfacing side **164** and an opposed side **166**, with a second pin **168** protruding from the interfacing side of the proximal-end portion proximate a proximal end of the second tip. The interfacing side **154** of the first tip **62** and the interfacing side **164** of the second tip **64** interface with each other. It is appreciated that the operative mechanism **60** can be provided with a variety of different operative mechanisms having different functions, thereby expanding the capabilities of the surgical apparatus **100**. For example, the operative mechanism **60** can include a clamp, a pair of scissors, or a balloon device. It is further appreciated that the operative mechanism **60** can include any device that utilizes the actuation rod **34** to move between a first state and a second state.

[**0035**] Referring to **FIGS. 4C, 5A** and 5B, the first tip **64** and second tip **62** are coupled to an insert **70**. The insert **70** is a substantially cylindrical insert having a proximal end **170** and a distal end **172** with a lumen **174** therebetween. The insert **70** includes a radial hole or aperture **176** that is substantially perpendicular to an axis of the insert. The aperture **176** is substantially radial and is adapted to accept a rivet pin **71** or dowel pin that allows the operative mechanism **60** to pivot during opening and closing. The insert **70** includes a clevis **178** extending longitudinally in a proximal direction from its distal end **172**. The clevis **178** is substantially parallel to the axis of the insert **70** and substantially perpendicular to the aperture **176** of the insert. The insert **70** may be coupled or press-fit to the outer tube **32**. The first and second tips **62**, **64** are retained within the clevis **178** of the insert **70** by the rivet pin **71**. More particularly, at least a portion of the proximal-end portion **150** of the first tip **62** and the proximal-end portion **160** of the second tip **64** are positioned within the lumen **174** of the insert **70**. The insert **70** can then be inserted into a distal end **35** of the outer tube **32** and retained therein by force-fit, adhesive, or crimping the end of the outer tube **32** over the end of the insert **70**.

[**0036**] In another aspect, as illustrated in **FIG. 4D**, an insert **70***b* can have a distal clevis **110** and a proximal clevis **112**. The distal clevis **110** and the proximal clevis **112** are substantially rotatably aligned with each other about the axis of the insert, substantially parallel to the axis of the insert, and substantially perpendicular to the aperture of the insert. With this aspect, the distal clevis **110** operates to hold the blades **62**, **64** in place, a center portion **70***c* of the insert **70***b* provides a mechanical stop for blade travel (i.e., surfaces of the through hole or lumen **174** control the limits of blade travel in full open position), and the proximal clevis **112** extends over the proximal ends of the blades **62**, **64** to contain the proximal ends of the blades from moving away from the actuation rod **34** and out of their drive slots **70**d within the actuation rod. More particularly, the proximal portions **150**, **160** of the blade are sandwiched between the tongue portion **225** of the actuation rod **34** and the walls of the proximal clevis portion of the insert **70***b* in order to substantially prevent pins at the proximal portions of the blades **62**, **64** from becoming dislodged from the slots, as will be described below in greater detail. The opening in the proximal clevis **112** portion of the insert **70***b* permits the proximal portion of the blades **62**, **64** to move further outwardly with the blades in the open position. The walls of the proximal clevis **112** in the insert **70***b* provide a cantilever force for the proximal portions of the blades **62**, **64**, which provides more efficient use of the blades.

[**0037**] The insert **70** can be formed in a plurality of pieces, e.g., two halves, by a casting, molding or other processes, in either a plastic or metallic material. A benefit of forming the insert **70** in multiple pieces is it is suitable for high production, easier to assemble, and less costly than a machined part. It is further appreciated that the outer tube **32** can have a counterbore at the distal end **35** to control the insertion depth of the insert **70**, **70***b* and prevent the insert from being pulled further proximally into the outer tube. Alternatively, the outer tube **32** can be crimped or heat staked to retain the insert **70**, **70***b* in the tube when the actuation rod **34** applies scissor-opening force. The insert **70**, **70***b* and the outer tube **32** can also be sized and configured so as to permit greater opening angles for the blades **62**, **64**.

[**0038**] Referring to **FIGS. 5C-5E**, this aspect of the invention uses an insert **70**a having screw threads to accept a screw **71***a*. In comparison to the rivet pin **71** of **FIGS. 5A and 5B**, the screw **71***a* provides a means for adjusting the fit of the blades **62**, **64**, which in turn adjusts the tension between the cutting surfaces of the blades **62**, **64**, whereas use of a rivet pin allows the blade tensioning to be consistently set during assembly, which provides consistency between surgical instruments **100**. The hole or aperture **176** through the insert **70***a* permits the screw **71***a* to have a thicker head, as space is limited. It is appreciated that another configuration could employ a counterbore for the head of the screw **71***a* instead of the hole. The insert **70**, **70***a* can be formed of, for example, a plastic or metallic material, depending on the application. The insert **70**, **70***a* can also be coupled to the outer tube **32** by adhesive or other coupling means.

[**0039**] In another aspect of the invention, the handle assembly **20** may further include a connecting post **80** as illustrated in **FIGS. 6A-6C** to provide for cauterization of tissue during a procedure. More specifically, the connecting post **80** is formed in the fixed handle **22** so as to extend from the top either at an angle or perpendicular to the top. The connecting post **80** may be either freely contained in the fixed handle **22** or secured by force fit, adhesive, threads or other means, and may include a spring **84** and a connector **86**. With this aspect of the invention, the spring **84** extends from the connecting post **80** into contact with the actuation rod **34** to provide electrical contact as the actuation rod rotates and/or moves axially. The spring **84** may be a round helical compression spring or a flat wire cantilever spring. As the electrical charge is applied to the actuation rod **34** and then to the operative mechanism **60**, such as the blades **62** and **64**, the operator is protected from electrical shock as both the handle assembly **20** and the outer tube **32** of the shaft assembly **30** are formed from plastic material and thus serve as an electrical insulation barrier. In particular, the outer tube **32** is formed of a thermoplastic or a thermoset plastic that fits over the actuation rod **34** and functions as an insulator to prevent electrical shock with the operator and/or patient. In one aspect, the outer tube **32** may also function as a structural member. It is appreciated that the outer diameter of the actuation rod **34** may be formed to fit closely to the inner diameter of the outer tube **32** so as to support it. With this aspect, the actuation rod **34** and the blades **62**, **64** are formed of corrosion resistant steel, but it is appreciated that the actuation rod **34** and the operative mechanism **60** can be formed of any electrically conductive and corrosion resistant material.

[0040] Referring back to **FIGS. 2A and 2B**, the rotatable knob **40** is coupled to the exterior surface of the elongate tube **32** proximate the proximal end of the elongate tube and coupled to the handle assembly **20**. There are shown in **FIGS. 2A and 2B** cross-section views of the surgical apparatus **100** being provided with the rotatable knob **40** having an internal key coupling for rotating the shaft assembly **30** relative to the handle assembly **20**. In particular, the knob **40** includes a hub **92**, at least one alignment hole **94**, and at least one retaining pin **96** for coupling the knob **40** to the handle assembly **20** to allow 360° rotation of the shaft assembly **30** about an axis of the shaft assembly. The handle assembly **20** includes at least one circumferential groove **98** where the retaining pin **96** of the knob **40** can be placed, inserted or extended to allow 360° rotation. It is appreciated that rotation of the knob **40** and the shaft assembly **30** in relation to the handle assembly **20** requires at least one retaining pin **96** in the knob **40** extending into at least one circumferential groove **98** in the handle assembly **20**. The knob **40** may further include a spring washer **93** (see **FIG. 6C**) between the distal end of the handle assembly **20** and the proximal end of the hub **92** to take up the linear play due to tolerance variations. The hub **92** may be formed of a plastic material and overmolded onto the outer tube **32** to provide secure coupling. The hub **92** may also be coupled to the outer tube **32** with an adhesive or other coupling means, such as a snap-fit or thermal welded connection. For example, the hub **92** may include detent tabs in the lumen and the outer tube **32** may include holes or other complimentary openings to accept the detent tabs for a mechanical coupling. This aspect can reduce the cost and time associated with overmolding, and simplify and facilitate assembly. **FIG. 7** illustrates a proximal view of a rotatable knob **40***a* in accordance with another aspect of the invention having a plurality of ribs **99** providing a thin-walled knob while maintaining stability and reducing rotating friction with the handle assembly **20** and the shaft assembly **30**, as well as permitting greater draft angles in the spaces between the ribs to facilitate removal from the mold during molding.

[0041] It is appreciated that the knob **40** may be formed in at least two pieces, for example, two identical halves that are joined together by interlocking or coupling means. The coupling means may include a snap-fit connection, an interference-fit connection, force-fit posts, or interconnecting tabs. With this aspect, the retaining pin(s) **96** would not be needed and may be replaced with at least one annular rib **99** in the lumen of the knob **40***b* as illustrated in **FIG. 2C**. The annular rib **99** would fit into the circumferential groove **98***b* on the handle assembly **20**. In yet another aspect, the knob **40** may be molded as a single-piece component. With this aspect, the alignment hole(s) **94** and the retaining pin(s) **96** would not be needed and may be replaced with cantilever detent(s) that may be integrally molded with the knob **40**. The cantilever detent(s) operate to snap into the circumferential groove(s) **98** of the handle assembly **20**. Benefits of the above aspects include ease of assembly and smooth rotation of the knob.

[0042] In another aspect of the invention as illustrated in **FIGS. 8A-8C**, there are shown the fixed handle **22** and the pivoting handle **24** of the invention that can fit a variety of user's hand sizes. In particular, **FIG. 8A** illustrates the fixed handle **22** and the pivoting handle **24** without a snap-in ring installed for use with the largest size finger and thumb openings. **FIG. 8B** illustrates the fixed handle **22** with a small snap-in finger ring **22***a*, and the pivoting handle **24** with a medium snap-in thumb ring **24***a*. **FIG. 8C** illustrates the fixed handle **22** with the small snap-in finger ring **22***a*, and the pivoting handle **24** with a small snap-in thumb ring **24**b. **FIGS. 8A-8C** illustrate the possibility of a variety of sizes of snap-in ring inserts to fit a user's hand size. It is appreciated that any possible combination of thumb and finger ring inserts can be included with each handle assembly **20** as typified in examples **20***a*, **20***b* and **20***c* of the surgical apparatus **100** so a user can select, for example, sizes between small and large. All the ring inserts may be formed of a softer material than the handle material to provide comfort to the user. In addition, the ring inserts can be made of different colors for identification of various sizes. It is appreciated that the handle assembly **20** of the surgical apparatus **100** can be used with or without the ring inserts.

[0043] Referring to **FIGS. 9A-9D**, there is shown another aspect of the surgical instrument of the invention wherein the fixed handle **22** is formed of two pieces. In particular, the fixed handle **22** further includes a top cover **22***c* as illustrated in **FIG. 9C**, the top cover **22***c* being assembled onto the fixed handle **22** after the other components have been assembled or put in place, namely the pivoting handle **24**, actuation rod **34**, two-piece ball end **52**, connector **86**, spring **84**, spring washer **93**, and hub **92***a*. With this aspect, the top cover **22***c* may be fastened to the fixed handle **22** by means of press-fit posts **22***d*, or other means such as sonic welding, adhesive bonding, or other means well known in the art. The hub **92***a* may be formed of plastic and insert molded onto the outer tube **32**, thus eliminating the need to cut the tube **32** to a precision length. The hub **92***a* rotates inside a groove **22***e* within the handle **22**. A knob **40***c*, having cantilever detents **40***d*, slides onto the hub **92***a* and snaps into holes **40***e* of the hub **92***a*. Turning the knob **40***c* 360° rotates the hub **92***a*, which is coupled to the actuation rod **34** and the operative mechanism **210**. A feature of this aspect of the invention is it facilitates assembly of the entire device. Moreover, the fixed handle **22** and the top cover **22***c* incorporate a press-fit post **22***f* and boss **22***g* to replace the press-fit pin **58** (**FIG. 6C**). In addition, the connector post **86** can freely rotate within the cavity **22***h* in the handle.

[0044] Referring to **FIGS. 10A-10C**, there is shown a surgical instrument **200** in accordance with an embodiment of the invention having an operative mechanism **210** including a first blade or tip **62** and a second blade or tip **64**. As stated above, the first blade or tip **62** includes a first pin **158** protruding from the interfacing side **154** of the proximal-end portion **150** proximate a proximal end of the first tip and the second blade or tip **64** includes a second pin **168** (see **FIG. 11**) protruding from the interfacing side **164** of the proximal-end portion **160** proximate a proximal end of the second tip. The pins **158**, **168** are fixed, such as by welding or other well known means, at the proximal ends of the blades or tips **62**, **64**. The blades or tips **62**, **64** are overlapped in a scissors configuration and are held in a pivotal relationship by a common pin **220**. The operative mechanism **210** interacts with a slotted actuation rod **34**, as further explained below. It is appreciated that because the blades or tips **62**, **64** include pins **158**,**168**, rather than slots, the proximal-end portions **150**, **160** of the blades or tips **62**, **64** may include a smaller area than if the slots were positioned in the proximal-end portions of the blades or tips. This is beneficial because the

"wingspan" of the proximal-end portions **150**, **160** of the blades or tips **62**, **64** when opened is minimized, if not eliminated.

[**0045**] The actuation rod **34** includes a substantially flat tongue portion **225** at its distal-end region (see **FIGS. 11 and 12**A-**12**D). The tongue portion **225** includes a first substantially flat surface **180** and a second substantially flat surface **182** positioned opposite and substantially parallel to the first substantially flat surface. The tongue portion **225** may include a slot **226** on each of the first and second substantially flat surfaces **180**, **182**. Each slot corresponds to a pin **168**, **158** on the first or second blade or tip **62**, **64**. The actuation rod **34** can be formed in a number of different ways. For example, the desired features can be machined from a solid rod or tube of a desired diameter. Alternatively, a strip of metal can be stamped with the desired slots within the tongue portion. Furthermore, the tongue portion, including the slots, may be machined or overmolded onto the actuation rod. The end of the actuation rod may also be formed as a separate part, i.e., molded, machined, cast, metal injection molded (MIM), etc., with the feature detail in it and then coupled to a standard length shaft by means of a thread, snap, adhesive, welding process or some other coupling means that is well known in the art.

[**0046**] Referring to **FIG. 11**, there is shown a perspective view of the operative mechanism **210** of **FIGS. 10A-10C** being coupled to the actuation rod **34**. It is appreciated that there are numerous methods of manufacturing the blades or tips **62**, **64**. For example, the blades or tips **62**, **64** can be formed from conventional stamping and then heat-treated. In another example, the blades or tips **62**, **64** can be formed from a blank of pre-hardened material and then electro-discharge machine (EDM) cut, waterjet cut, laser cut or even machined to obtain the final shape. It should be noted that the pins **158**, **168** in the proximal portions of the blades or tips **62**, **64** can be formed directly onto the blades or they may be added in a later operation.

[**0047**] If the pins **158**, **168** are not formed directly onto the blades or tips **62**, **64**, the pins may be coupled to the blades or tips in any one or a combination of ways, including press-fitted, swaged, threaded and/or welded. To manufacture the pin as part of the blades or tips **62**, **64**, a multitude of processes may be used. A sheet of material can be machined to make a blade or tip **62**, **64** including a pivot hole and the pin. The sheet can then be heat treated and sent to a form grinder, which can grind one profile of the blade or tip. The ground plate can then be cut via EDM or other manufacturing method and the second profile can be cut out. This type of process can yield numerous components, with the drive pin integrally located, with relatively low cost.

[**0048**] There are other processes that can yield an entire blade or tip **62**,**64** from a minimum number of operations. These include, but are not limited to, MIM, casting, and power metallurgy (PM). Following one of these operations, the blade can be sharpened or receive other post-processing.

[**0049**] The pin and slot design of the invention provides a number of advantages. For example, the proximal portion of each blade or tip **62**, **64** is reduced in area in comparison to prior art blades or tips so that during full deflection, very little or no part of the blade or tip extends beyond the inside diameter of the outer tube or shaft. This ensures that nothing catches on the blades or tips during use. This result may be attained because the area required for slots on the blades or tips is not needed. Additionally, by moving the drive slots **226** to the actuation rod **34**, the usable area for the drive slots is increased. Further, with the slots positioned on the actuation rod, the depth of the slots can be varied in order to increase tension on the blades during actuation. Another advantage is that by moving the slot from the blades or tips to the actuation rod, the "wingspan" of the blades can be reduced or eliminated because the proximal portion of the blades or tips does not need to encase the slot. Instead, the proximal portion of the blades or tips include only a small pin, which minimizes the chance of the blades or tips catching on tissue, other instruments or sutures.

[**0050**] Referring to **FIGS. 12A and 12B**, there is shown a perspective view and a side view of the actuation rod **34** incorporating slots **226** on both sides of the tongue end, respectively. As explained above, the blades or tips can have pins at the proximal portions of the blades or tips that nest in the slots of the rod. The rod may be pushed forward or pulled backwards to cam the blades or tips, which are pivoted at a common pivot point and coupled to the insert **70**, **70***a*, and **70***b*. In some cases it may be beneficial to have different slot designs to actuate the tips to different opening angles or distances, at different speeds, for different length tips and for varying force. The slots **226** may include an open or closed end slot (or combination of both) as desired. **FIGS. 12C and 12D** illustrate an actuation rod having a curved slot in accordance with another aspect of the invention. A curved slot may be used to provide a more linear relation between the actuation rod and the jaw motion. For example, the slot can be shaped to provide more control as the blades or tips are nearing the closed position, and greater acceleration as the blades or tips are near the opened position. With this aspect, the instrument can be tuned to provide the desired control and user feedback.

[**0051**] It will be understood that many other modifications can be made to the various disclosed embodiments without departing from the spirit and scope of the invention. For these reasons, the above description should not be construed as limiting the invention, but should be interpreted as merely exemplary of preferred embodiments. It will be understood that many other modifications can be made to the various disclosed embodiments without departing from the spirit and scope of the invention. For example, various sizes of the surgical device are contemplated as well as various types of constructions and materials. It will also be apparent that many modifications can be made to the configuration of parts as well as their interaction. For these reasons, the above description should not be construed as limiting the invention, but should be interpreted as merely exemplary of embodiments.

1. A surgical instrument, comprising:

a single elongate tube extending along an axis, the elongate tube including a proximal end and a distal end, the elongate tube being made of an electrically nonconductive material;

an actuation rod including a proximal end and a distal end, the actuation rod being coaxially slidable within the elongate tube, the proximal end of the actuation rod extending proximally from the proximal end of the elongate tube, the distal end of the actuation rod being positioned within a distal-end region of the elongate

tube, a distal-end region of the actuation rod including a tongue portion, the tongue portion including a first substantially flat surface and a second substantially flat surface positioned opposite and substantially parallel to the first substantially flat surface, the first flat surface of the tongue including a first inclined slot, the second flat surface of the tongue including a second inclined slot transverse to the first slot, the actuation rod providing flexural strength to the surgical instrument;

a first tip including a proximal-end portion, a distal-end portion, an interfacing side and an opposed side, with a first pin protruding from the interfacing side of the proximal-end portion proximate a proximal end of the first tip;

a second tip including a proximal-end portion, a distal-end portion, an interfacing side and an opposed side, with a second pin protruding from the interfacing side of the proximal-end portion proximate a proximal end of the second tip; and

a pivot pin pivotally coupling the second tip to the first tip, the pivot pin being operably coupled to the elongate tube to open and close the tips in response to movement of the actuation rod,

wherein the first inclined slot of the tongue portion of the actuation rod accepts the first pin of the first tip and the second inclined slot of the tongue portion of the actuation rod accepts the second pin of the second tip,

the interfacing surface of the first tip and the interfacing surface of the second tip interface with each other,

the first inclined slot including camming surfaces for the first pin to slide along within the first inclined slot, and

the second inclined slot including camming surfaces for the second pin to slide along within the second inclined slot.

2. The surgical instrument of claim 1, wherein at least one of the first inclined slot and the second inclined slot is curved.

3. The surgical instrument of claim 1, wherein at least one of the first inclined slot and the second inclined slot is an open-end slot.

4. The surgical instrument of claim 1, wherein at least one of the first inclined slot and the second inclined slot is a closed-end slot.

5. The surgical instrument of claim 1, the actuation rod comprising an electrically conductive material.

6. A surgical instrument, comprising:

a handle assembly including a fixed handle and a pivoting handle;

a shaft assembly extending distally from the handle assembly, the shaft assembly including:

a single elongate tube extending along an axis, the elongate tube including a proximal end and a distal end, the elongate tube being made of an electrically nonconductive material;

an actuation rod including a proximal end and a distal end, the actuation rod being coaxially slidable within the elongate tube, the proximal end of the actuation rod extending proximally from the proximal end of the elongate tube, the distal end of the actuation rod being positioned within a distal-end region of the elongate tube, the proximal end of the actuation rod including a ball end that couples to the pivoting handle, a distal-end region of the actuation rod including a tongue portion, the tongue portion including a first substantially flat surface and a second substantially flat surface positioned opposite and substantially parallel to the first substantially flat surface, the first flat surface of the tongue including a first inclined slot, the second flat surface of the tongue including a second inclined slot transverse to the first slot, the actuation rod providing flexural strength to the surgical instrument; and

a knob adapted to provide 360° rotation of the sleeve assembly about the axis of the elongate tube relative to the handle assembly, the knob being coupled to the exterior surface of the elongate tube proximate the proximal end of the elongate tube and coupled to the handle assembly;

an operative mechanism including a first tip and a second tip, the first tip including a proximal-end portion, a distal-end portion, an interfacing side and an opposed side, with a first pin protruding from the interfacing side of the proximal-end portion proximate a proximal end of the first tip, the second tip including a proximal-end portion, a distal-end portion, an interfacing side and an opposed side, with a second pin protruding from the interfacing side of the proximal-end portion proximate a proximal end of the second tip, the interfacing side of the first tip and the interfacing side of the second tip interfacing with each other; and

a pivot pin pivotally coupling the second tip to the first tip, the pivot pin being operably coupled to the distal-end region of the elongate tube to open and close the tips in response to movement of the actuation rod,

wherein the first inclined slot of the tongue portion of the actuation rod accepts the first pin of the first tip and the second inclined slot of the tongue portion of the actuation rod accepts the second pin of the second tip,

the first inclined slot including camming surfaces for the first pin to slide along within the first inclined slot, and

the second inclined slot including camming surfaces for the second pin to slide along within the second inclined slot.

7. The surgical instrument of claim 6, the pivoting handle including a groove and the ball end of the actuation rod fitting into the groove to form a rotatable ball-and-socket joint.

8. The surgical instrument of claim 7, wherein the fixed handle encloses the pivoting handle.

9. The surgical instrument of claim 6, the operative mechanism including a pair of scissors.

10. The surgical instrument of claim 6, the operative mechanism including a clamp.

11. The surgical instrument of claim 6, the shaft assembly further comprising a substantially cylindrical insert having a proximal end and a distal end with a lumen therebetween, the insert including an aperture substantially perpendicular to an axis of the insert for accepting the pivot pin, the insert being coupled to the inner surface of the elongate tube proximate the distal end of the elongate tube, at least a

portion of the proximal-end portion of the first tip and the proximal-end portion of the second tip being positioned within the lumen of the insert.

12. The surgical instrument of claim 11, wherein:

the pivot pin includes a screw, and

the aperture in the insert includes threads for receiving the threads of the pivot pin.

13. The surgical instrument of claim 11, wherein the insert is press fit into the elongate tube.

14. The surgical instrument of claim 11, wherein the insert is coupled to the elongate tube via an adhesive.

15. The surgical instrument of claim 11, wherein the insert is formed of a plastic material.

16. The surgical instrument of claim 11, wherein the insert is formed of a metallic material.

17. The surgical instrument of claim 11, wherein the insert includes a proximal clevis extending longitudinally and a distal clevis extending longitudinally, the proximal clevis and the distal clevis being substantially rotatably aligned with each other about the axis of the insert, the proximal clevis and the distal clevis being substantially parallel to the axis of the insert, and the proximal clevis and the distal clevis being substantially perpendicular to the aperture of the insert, the proximal clevis sandwiching the proximal-end portions of the first tip and the second tip between the tongue portion of the actuation rod and the walls of the proximal clevis.

18. The surgical instrument of claim 6, wherein at least one of the first inclined slot and the second inclined slot is curved.

19. The surgical instrument of claim 6, wherein at least one of the first inclined slot and the second inclined slot is an open-end slot.

20. The surgical instrument of claim 6, wherein at least one of the first inclined slot and the second inclined slot is a closed-end slot.

21. A surgical instrument, comprising:

a handle assembly including a fixed handle and a pivoting handle, the pivoting handle including a groove;

a shaft assembly extending distally from the handle assembly, the shaft assembly including:

a single elongate tube extending along an axis, the elongate tube including a proximal end and a distal end, the elongate tube being made of an electrically nonconductive material;

an actuation rod including a proximal end and a distal end, the actuation rod being coaxially slidable within the elongate tube, the proximal end of the actuation rod extending proximally from the proximal end of the elongate tube, the distal end of the actuation rod being positioned within a distal-end region of the elongate tube, the proximal end of the actuation rod including a ball end that couples to the groove of the pivoting handle to form a rotatable ball-and-socket joint, a distal-end region of the actuation rod including a tongue portion, the tongue portion including a first substantially flat surface and a second substantially flat surface positioned opposite and substantially parallel to the first substantially flat surface, the first flat surface of the tongue including a first inclined slot, the second flat surface of the tongue including a second inclined slot transverse to the first slot, the actuation rod providing flexural strength to the surgical instrument;

a substantially cylindrical insert having a proximal end and a distal end with a lumen therebetween, the insert including an aperture substantially perpendicular to an axis of the insert, the insert being coupled to the inner surface of the elongate tube proximate the distal end of the elongate tube, the insert including a proximal clevis extending longitudinally and a distal clevis extending longitudinally, the proximal clevis and the distal clevis being substantially rotatably aligned with each other about the axis of the insert, the proximal clevis and the distal clevis being substantially parallel to the axis of the insert, and the proximal clevis and the distal clevis being substantially perpendicular to the aperture of the insert; and

a knob adapted to provide 360° rotation of the sleeve assembly about the axis of the elongate tube relative to the handle assembly, the knob being coupled to the exterior surface of the elongate tube proximate the proximal end of the elongate tube and coupled to the handle assembly;

an operative mechanism including a first tip and a second tip, the first tip including a proximal-end portion, a distal-end portion, an interfacing side and an opposed side, with a first pin protruding from the interfacing side of the proximal-end portion proximate a proximal end of the first tip, the second tip including a proximal-end portion, a distal-end portion, an interfacing side and an opposed side, with a second pin protruding from the interfacing side of the proximal-end portion proximate a proximal end of the second tip, the interfacing side of the first tip and the interfacing side of the second tip interfacing with each other; and

a pivot pin pivotally coupling the second tip to the first tip, the pivot pin being operably coupled to the distal-end region of the elongate tube to open and close the tips in response to movement of the actuation rod,

wherein the first inclined slot of the tongue portion of the actuation rod accepts the first pin of the first tip and the second inclined slot of the tongue portion of the actuation rod accepts the second pin of the second tip,

the first inclined slot including camming surfaces for the first pin to slide along within the first inclined slot,

the second inclined slot including camming surfaces for the second pin to slide along within the second inclined slot,

the aperture of the insert being adapted for accepting the pivot pin;

at least a portion of the proximal-end portion of the first tip and the proximal-end portion of the second tip being positioned within the lumen of the insert, and

the proximal clevis of the insert sandwiching the proximal-end portions of the first tip and the second tip between the tongue portion of the actuation rod and the walls of the proximal clevis of the insert.

22. The surgical instrument of claim 21, the operative mechanism including a pair of scissors.

23. The surgical instrument of claim 21, the operative mechanism including a clamp.

24. The surgical instrument of claim 21, wherein the fixed handle encloses the pivoting handle.

25. The surgical instrument of claim 21, wherein:

the pivot pin includes a screw, and

the aperture in the insert includes threads for receiving the threads of the pivot pin.

26. The surgical instrument of claim 21, wherein the insert is formed of a plastic material.

27. The surgical instrument of claim 21, wherein the insert is formed of a metallic material.

28. The surgical instrument of claim 21, the knob being formed in at least two pieces.

29. The surgical instrument of claim 28, the at least two pieces of the knob being joined together by a coupling means.

30. The surgical instrument of claim 28, wherein:

the handle assembly further including a circumferential groove at a distal portion of the handle assembly, and

the knob including at least one annular rib in a lumen of the knob, the at least one annular rib fitting into the circumferential groove on the handle assembly.

31. The surgical instrument of claim 21, the knob being formed as a single-piece component, a lumen of the knob including at least one cantilever detent.

32. The surgical instrument of claim 31, wherein:

the handle assembly further including a circumferential groove at a distal portion of the handle assembly, and

the at least one cantilever detent engaging the circumferential grove of the handle assembly.

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专利名称(译)	一次性腹腔镜仪器		
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申请号	US11/334027	申请日	2006-01-18
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发明人	GADBERRY, DONALD L. JOHNSON, GARY M. ALBRECHT, JEREMY J. OKIHISA, DAVID HILAL, SAID S. STROKOSZ, ARKADIUSZ A.		
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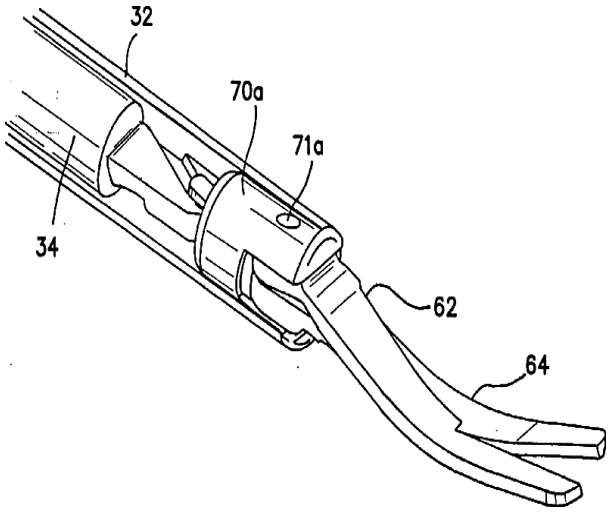
摘要(译)

本发明涉及一种手术器械，包括手柄组件和轴组件。手柄组件还包括固定手柄和枢转手柄。轴组件从手柄组件延伸，并且还包括外管和内致动杆，内致动杆与外管同轴滑动。轴组件包括可旋转的旋钮以提供360°旋转。致动杆具有近端和远端;近端具有球形端部，该球形端部与枢转手柄连接以形成可旋转的球窝接头。外管由塑料制成并安装在致动杆上以用作电绝缘体。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