US 20050137585A1

(19) United States
(12) Patent Application Publication
(10) Pub. No.: US 2005/0137585 A1
Landman et al.
(43) Pub. Date: Jun. 23, 2005

(54) BACK LOADING ENDOSCOPIC INSTRUMENTS

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(21) Appl. No.: **11/020,328**

(22) Filed: **Dec. 22, 2004**

Related U.S. Application Data

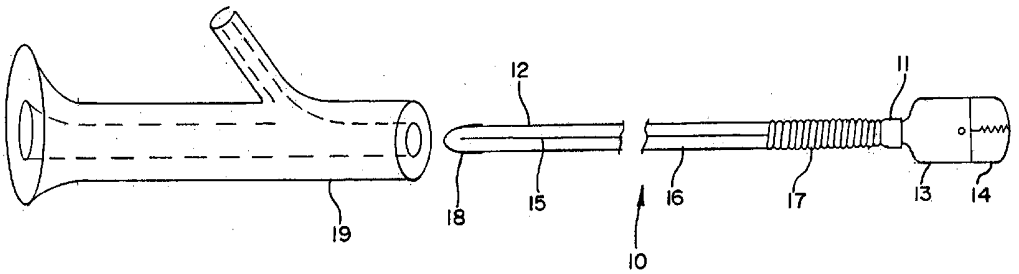
(60) Provisional application No. 60/532,397, filed on Dec. 23, 2003.

Publication Classification

(51) Int. Cl.[7] **A61B 17/00**
(52) U.S. Cl. **606/1**; 600/562; 606/27; 606/45

(57) **ABSTRACT**

A back loading instrument for use with a medical device, such as an endoscope or a colonoscope, features larger endoscopic instruments or end effectors and enables gathering of much larger samples, such as biopsies. The instrument also allows for superior grasping, mobilization, cutting, or removal of tissue or foreign bodies from a patient. The end effector, such as a biopsy forceps, of the back loading instrument has a cross-sectional area larger than that of the working channel of the endoscope or other medical device used to control the instrument. By using this medical device as part of a minimally-invasive procedure, trauma to the patient is minimized.



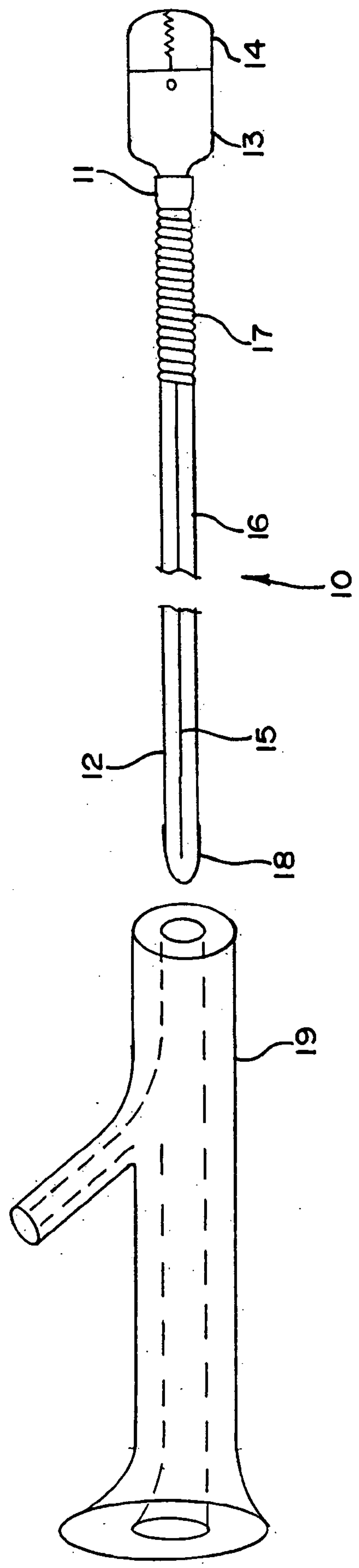


FIG. 1

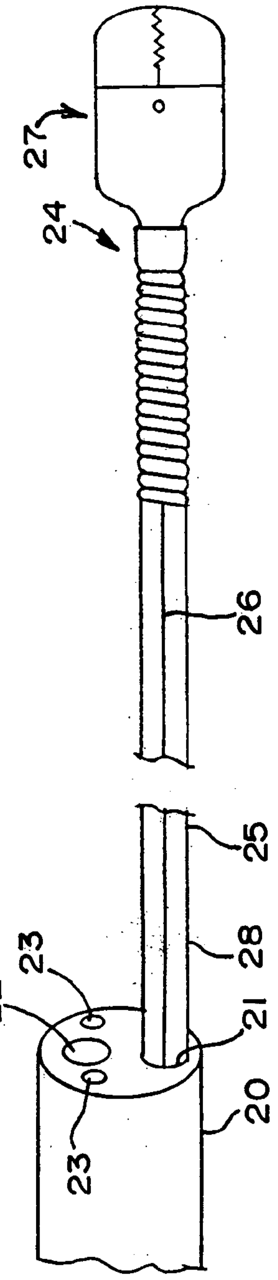


FIG. 2

FIG.3

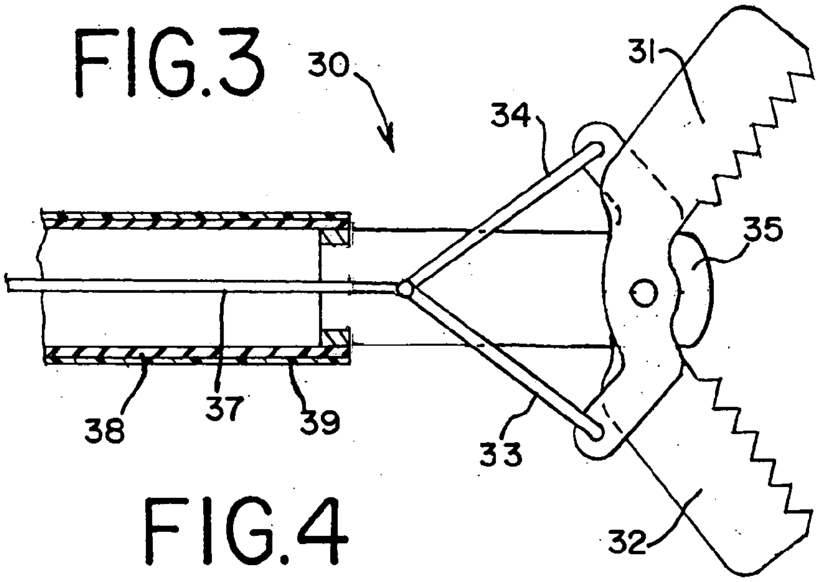


FIG.4

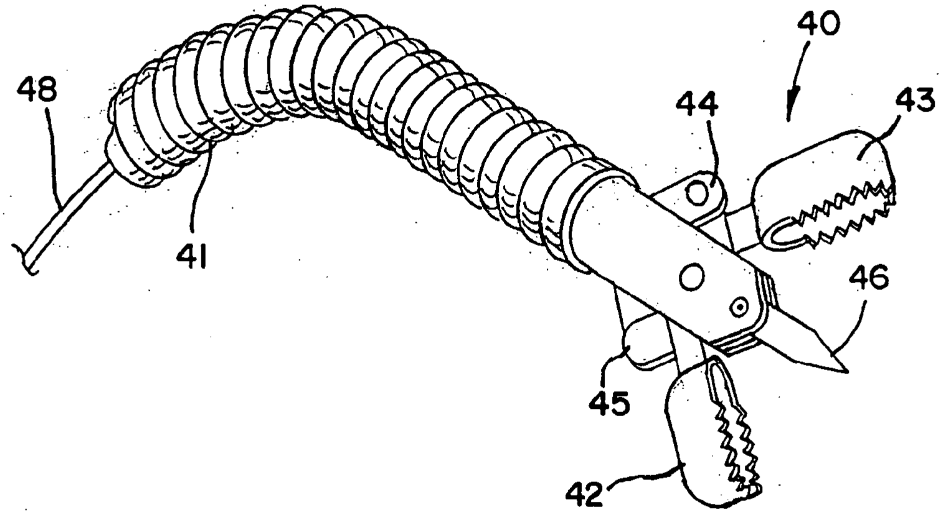


FIG.5

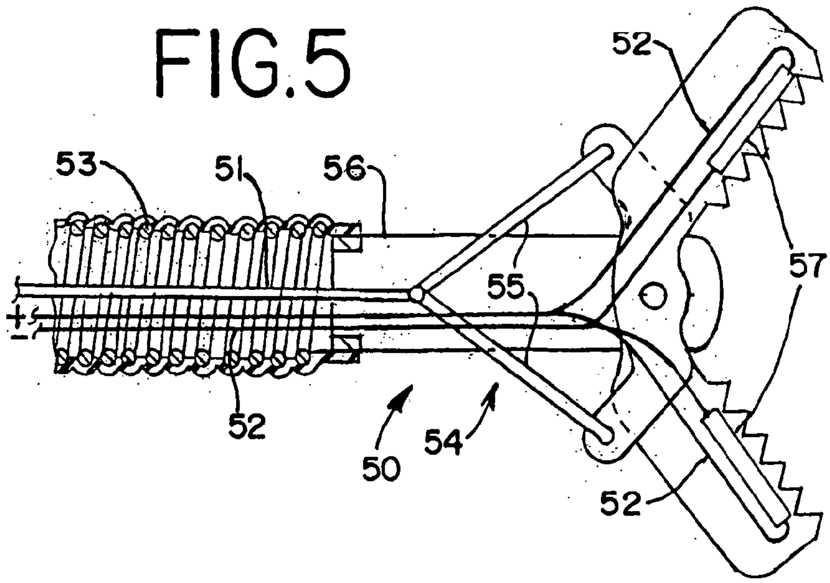


FIG. 6

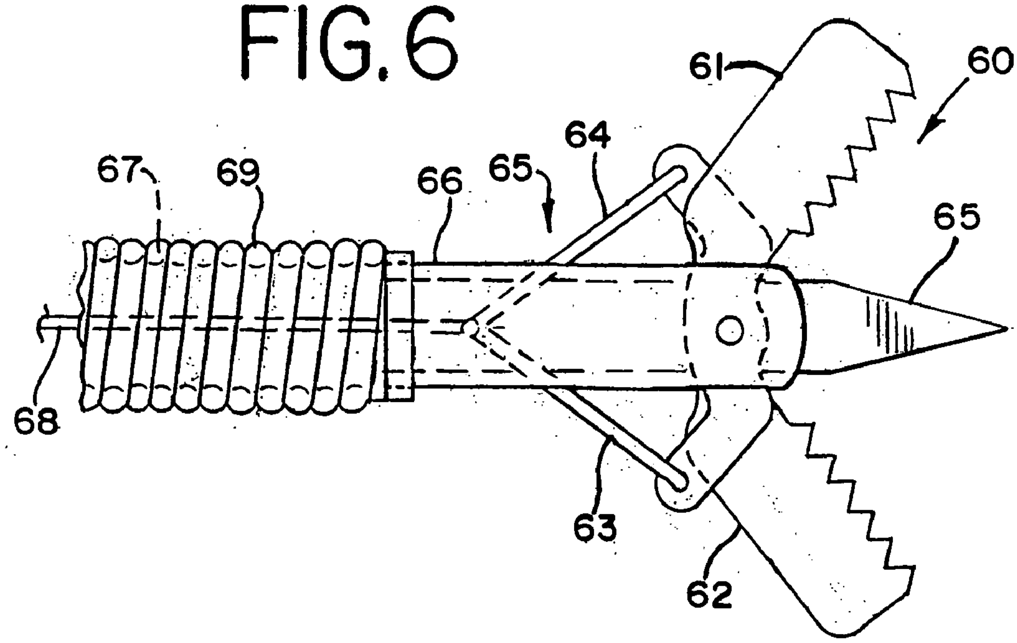


FIG. 7

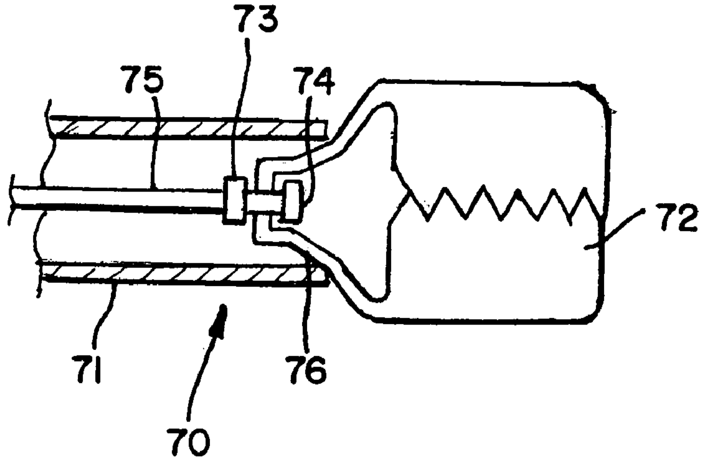


FIG.8

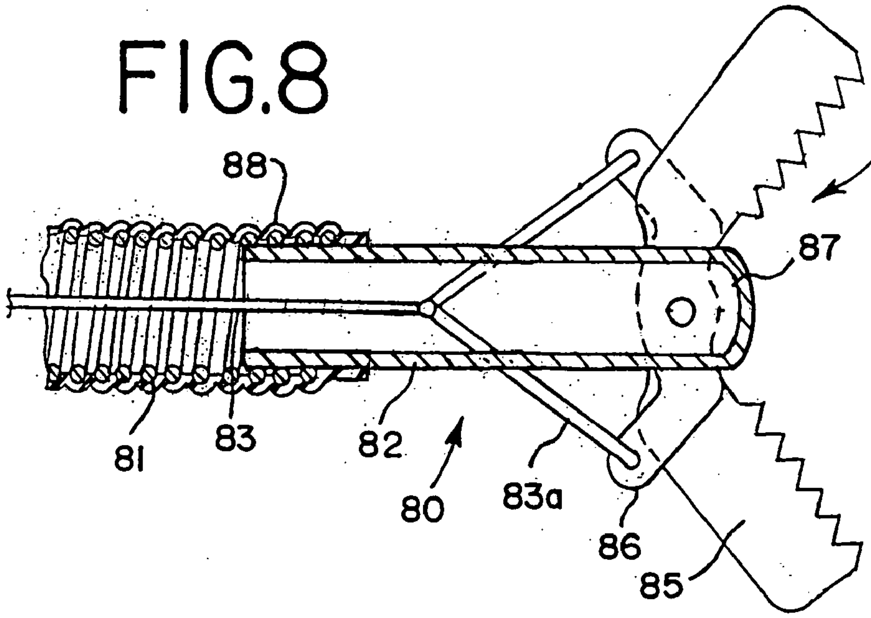


FIG.9

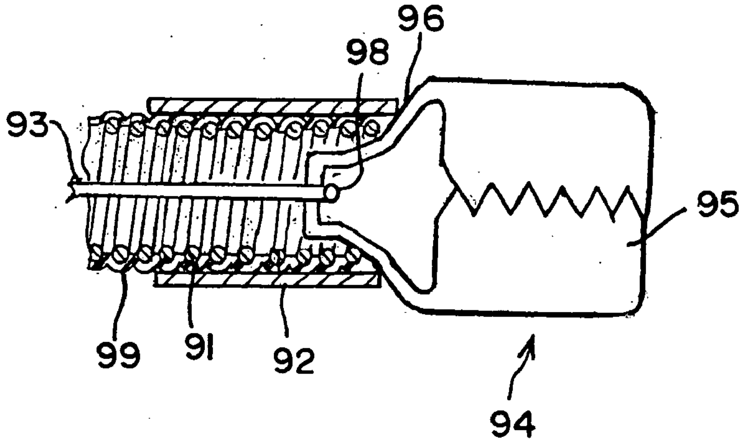
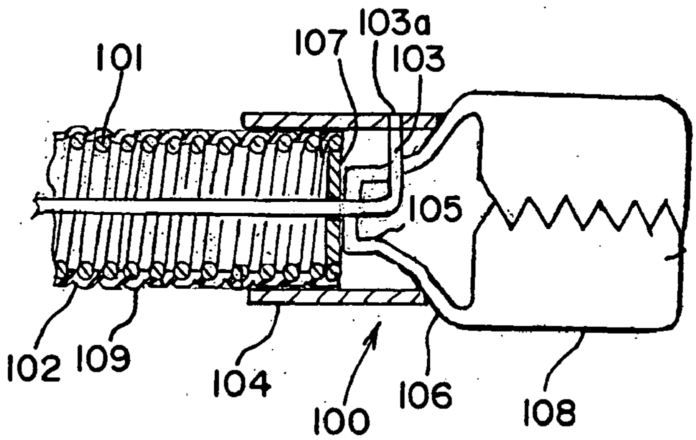


FIG.10



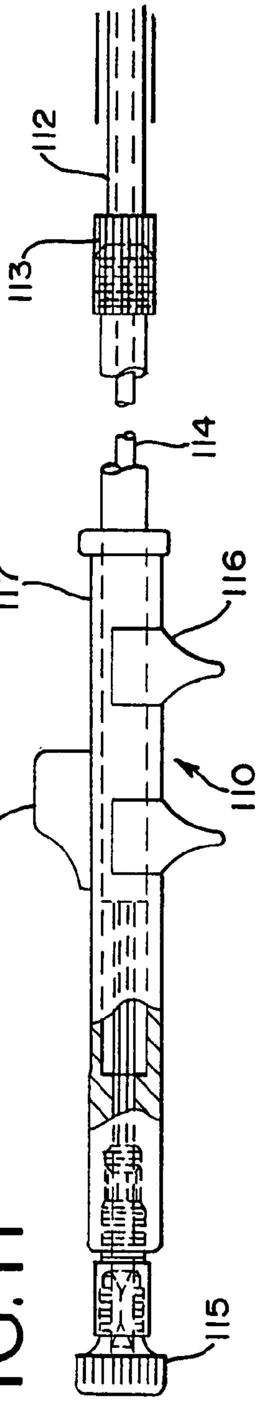


FIG.11

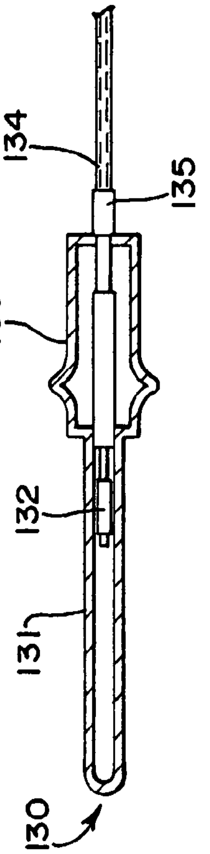


FIG.13

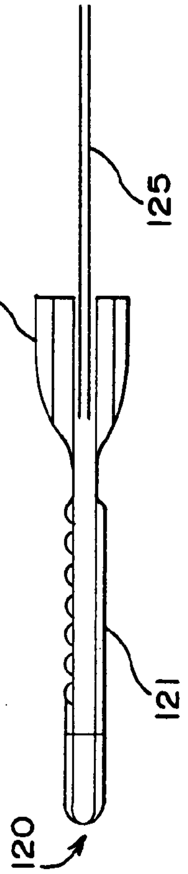


FIG.12

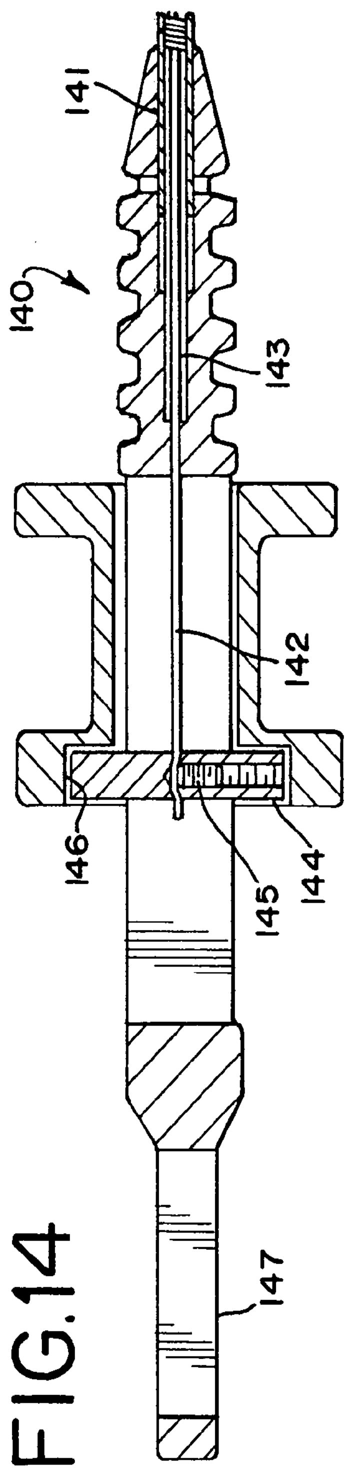


FIG.14

BACK LOADING ENDOSCOPIC INSTRUMENTS

[0001] This application claims the benefit of the filing date under 35 U.S.C. § 119(e) of Provisional U.S. Patent Application Ser. No. 60/532,397, filed on Dec. 23, 2003, which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The field of the invention is that of medical and surgical instruments, and in particular, medical and surgical instruments intended primarily for minimally-invasive procedures. These instruments typically have a small diameter for entering body spaces or orifices of limited size.

BACKGROUND

[0003] One trend in modern surgery is the trend toward minimally-invasive procedures, in which laparoscopic or endoscopic procedures are used. These procedures tend to be less invasive to the patient, using a body orifice or a puncture into a body cavity or a natural existing space as an entry point for a medical device. Examples of entry points include a component of the urinary tract or the gastrointestinal system. These procedures are used in order to avoid major incisions for surgical access, accomplishing the medical procedure in less time with less risk to the patient, and with reduced patient convalescence.

[0004] Minimally invasive procedures thus provide benefits to the patient, in the sense that the procedures may be accomplished more quickly and more economically, and with less discomfort and less overall invasion of the body when compared to traditional open surgical techniques. Minimally-invasive procedures are not without their problems, however. One significant problem is that body orifices tend to be small, and thus minimally invasive surgical procedures may be difficult to accomplish due to the very small access provided. For example, when entering the urinary tract, space in the urethra and the ureter is very limited, since these passages are only several millimeters in diameter. As a result, the majority of minimally invasive procedures are performed with an endoscope, or with instruments bearing some resemblance to an endoscope, such as a hysteroscope or a ureteroscope. These instruments typically have a working channel that limits instruments or surgical tools to a diameter of about 3 Fr (1 mm).

[0005] The size of the surgical tools is limited because they are routed to the operating site through the working channel of the endoscope or similar instrument. The working channel may vary from about 2.6 Fr to about 3.4 Fr, about 1 mm in diameter. To date, the size of the surgical tools that can be used with endoscopic equipment has been limited because the instrumentation is routed to the operating site through the working channel of the endoscope or similar instrument. These very small instruments can be challenging to design and build. Using these instruments is also difficult because the small size of the end-effector is not always effective to accomplish surgical goals, which may include grasping tissues, taking biopsy samples, or moving tissues. Engineering and materials limitations become very evident when instruments of such small diameters are created.

[0006] For the majority of minimally invasive procedures, the user accesses the desired site, perhaps with a wire guide, and then uses one or more wire guides, and perhaps a sheath, for greater access. Because the working instruments are deployed via the working channel of the endoscope being used to access the target site, it is frequently necessary to make repeated trips to the target location to achieve the desired end-point of the operation, such as the grasping of structures, biopsy of tissues, or manipulation of either tissues or structures. A tremendous improvement in current technology for minimally invasive surgery would be instruments or end-effectors which are not limited to the diameter of a working channel of existing endoscopes. What is needed is a surgical instrument which allows more freedom to operate while adhering to the principles of minimally-invasive surgery.

BRIEF SUMMARY

[0007] There are many aspects and embodiments of the invention. One aspect of the invention is a back-loading medical instrument comprising a flexible hollow tube, a control rod within the hollow tube, and a distal functional portion. The functional portion is attached to at least one of the flexible hollow tube and the control rod, and has a cross-sectional area larger than the tube and larger than a working channel of a therapeutic or diagnostic medical device for use with the back-loading medical instrument. This embodiment allows for large laparoscopic end-effectors deployed through a single, slightly larger incision, to be attached in the body cavity to smaller diameter control rods. Such smaller diameter rods may be passed through diminutive access sites for what may be termed very-minimally invasive access.

[0008] Another aspect of the invention is a back loading instrument for an endoscope. The instrument comprises a distal portion including a forceps, a control portion operatively connected to the forceps, and a proximal portion for insertion into a working channel of an endoscope. The cross-sectional area of the forceps is greater than a cross-sectional area of a working channel of the endoscope.

[0009] Another aspect of the invention is a back loading endoscopic biopsy instrument. The instrument comprises a flexible hollow member having a proximal end and a distal end, and a flexible inner member having a proximal end and a distal end and extending through said hollow outer member. The instrument also comprises a jaw assembly having a pair of jaws extending distally, the jaw assembly coupled to at least one of the hollow outer member and the flexible control member. In this embodiment, a circumference of the outer jaws in a closed state is greater than a circumference of a working channel of the endoscope.

[0010] Another aspect of the invention is a method of making a back loading endoscopic instrument. The method comprises forming an openable functional portion, a flexible inner member, and a hollow tubular member, and assembling the hollow tubular member outside the flexible inner member. The method also comprises attaching the functional portion to at least one of the flexible inner member and the hollow tubular member. In this embodiment, an outer periphery of the openable functional portion is greater than an outer periphery of a working channel of an endoscope when the functional portion is in a closed state.

[0011] There are many ways to practice the present invention, a few of which are shown in the following drawings and specification. The embodiments are not meant to limit the invention, but rather to describe and illustrate a few of the many ways that the present invention may be used.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] **FIG. 1** is a perspective view of an embodiment of a back-loading biopsy grasper mounted on a coil;

[0013] **FIG. 2** is a closer view of a back loading endoscopic forceps showing the relationship with a working channel of an endoscope;

[0014] **FIG. 3** is an embodiment of a back loading instrument with biopsy cups;

[0015] **FIG. 4** is another embodiment of a back loading instrument, an angled forceps;

[0016] **FIG. 5** depicts a back loading instrument with hot biopsy forceps;

[0017] **FIG. 6** depicts a back-loading instrument with a sharp cutting tool and a spike;

[0018] **FIG. 7** depicts a back loading forceps preferably deployed by retracting a sheath rather than actuating a distal control mechanism; and

[0019] **FIGS. 8-10** depict additional embodiments of the back-loading instrument.

[0020] **FIGS. 11-14** depict handles suitable for use in controlling the back-loading endoscopic devices.

DETAILED DESCRIPTION OF THE DRAWINGS AND THE PRESENTLY PREFERRED EMBODIMENTS

[0021] Several embodiments of the back-loading instruments are presented and explained in this portion. **FIG. 1** depicts a back-loading biopsy grasper **10** for back loading into an endoscope **19**. Grasper **10** includes a distal portion **11** and a proximal portion **12**, with a grasper control portion **13** and upper and lower jaws **14**. Control portion **13** may include pins, levers and connections for a control cable **15** and a flexible outer sheath **16** for the back loading biopsy grasper. Jaws **14** preferably do not extend more than about 1 cm from an endoscope or other diagnostic or therapeutic instrument with which the back-loading grasper is used.

[0022] The distal portion **11** may be as large as needed, but the distal portion will still have to be inserted into the patient, for example, through an access sheath into which the distal portion will fit. It is also preferred that the diameter of distal portion **11** not be so large as to interfere with light from the scope that is transmitted to the site of interest, or from light from the site reflected back into the scope for the physician or other health professional to see.

[0023] The outer sheath **16** is desirably not more than about 2.6 Fr, and may be as large as 3.4 Fr, in diameter, so that the proximal portion **12** of the back-loading grasper may be inserted into the distal end of a diagnostic or therapeutic instrument. The medical device may include an endoscope, a colonoscope, a bronchoscope, or a ureteroscope. In some embodiments, the outer sheath interacts with the forceps or other functional portion on the distal end of the endoscopic instrument. These functional portions may include any forceps, grasper, incisor, extractor, cutting instrument, or end-effector that may be desired. The larger end-effectors may have additional capabilities, such as a biopsy forceps for taking tissue specimens that also has an active electrosurgical component for coagulation (a "hot" biopsy forceps).

[0024] The functional portions, or end-effectors, may be made by any convenient manufacturing operations. They may be made by stamping or blanking from sheet metal and forming into the desired shapes, as in a process using progressive dies. For smaller volumes, they may be machined as desired and the movable jaws formed on an axis supplied by a rivet or other fastener. Alternately, the jaws may be formed from tubing by an electrical discharge machining (EDM) process, with or without additional forming. Forceps, extractors, incisors, or other desired functional distal portions may also be formed by machining stainless steel plate or other desired material. Components for end effectors may also be cast, and like other processes, the parts assembled, if necessary, into an articulable end effector.

[0025] The control cable **15** may be made from any convenient, flexible and strong material, such as stainless steel or a shape-memory alloy, such as Nitinol®. The cable should not elongate in use and may be made of a single wire or may be a bundle of smaller wires. The sheath **16** is ideally also strong and very flexible. It may be made from a polymer, such as a fluoropolymer or a polyimide-type polymer. Other polymers may also be used, such as PEEK (polyetheretherketone). The cable can be of very small diameter, allowing for minimal obstruction of the working channel while accomplishing deployment of the end-effector, i.e., opening and closing the jaws of an instrument.

[0026] Distal portion **11** may be attached to a flexible coiled wire **17** surrounded by the sheath, the coiled wire extending through to the proximal end for connection to endoscope **19**. The outer diameter of the sheath, as mentioned above, preferably is about 2.6 to about 3.4 Fr, or about 1 mm, in diameter. The control cable **15** inside the coil should not bind or chafe on the coil. When back-loading the control cable, coil, and sheath into the endoscope or other diagnostic of therapeutic instrument, the proximal ends should be shielded, perhaps by a soft cap or soft plastic end **18**, so that the ends do not scratch or damage the endoscope.

[0027] **FIG. 2** depicts a distal end **20** of an endoscope which may be used with any of the back-loading instruments of the present invention. The endoscope may include a working channel **21**, a lens **22**, and one or more fiberoptic light sources **23**. The proximal or back end **28** of the back-loading endoscopic instrument **24** is inserted into the working channel **21** on the distal end **20** of the endoscope. As discussed above, there are many types of endoscopic instruments which may be designed for back loading. The embodiment in **FIG. 2** includes a grasper **27** controlled by an outer sheath **25** and a control rod **26**.

[0028] In use, the surgeon may maneuver the endoscope to the area of interest within a patient. The endoscope includes a forceps or other tool on the distal end, along with a fiberoptic light source and lens, and a camera, or optical transmitter (not shown), to generate and transmit images through the endoscope. A forceps is an endoscopic tool used for grasping a structure, such as tissue, for maneuvering or for removal. Using the images from the endoscope, the surgeon maneuvers the endoscope and then the forceps to the desired position. Typically, a biopsy sample is then acquired and removed from the patient. Using the back-loading endoscopic tool, a much larger sample, more than the usual microscopic size, may be taken. This enables the pathologist or laboratory technician to more easily analyze the sample. A prognosis or a treatment may then be decided more easily.

[0029] **FIG. 3** depicts another embodiment of a back-loading endoscopic cup. The back loading endoscopic cup **30** includes a hollow urethane tube and a control wire **37** for controlling the cup. Urethane is tough and strong, as well as flexible, and may be formulated to be smooth and with a low coefficient of friction against control wire **37**. The distal portion **35**, which may be metallic, is mounted to tube **38** and includes first and second jaws **31**, **32**, control linkages **33**, **34** for the jaws, and a control portion **35**. The control portion and jaw portions have a larger diameter than that of tube **38**. Tube **38** is preferably about 1 mm outer diameter, preferably about 2.4 to 2.6 Fr. The control rod may preferably be stainless steel or Nitinol®. Tube **38** may be coated with a thin, smooth, lubricious coating **39**, such as Teflon® or other fluoropolymer, or other suitable smooth coating. A very thin film, such as from a fluoropolymer or PEEK, may be used instead.

[0030] The back loading instruments seen so far have largely been straight-forward, i.e., the deployed instruments, the cup or graspers or forceps, are in line with the endoscope and the sheath. **FIG. 4** depicts an embodiment in which the back-loading instrument, and the coil and control cable, may be at an angle to the advance of the endoscopic instrument. **FIG. 4** depicts an angle forceps **40**, with first and second jaws **42**, **43**, control portions **44**, **45**, and a spike **46**. The angle forceps **40** is angled at about 45° to the coil **41** and control cable **48**. The sheath and control cable may be made from shape memory alloys, such as Nitinol®.

[0031] Nitinol® forming techniques are used so that the control cable and coil will have a tendency to assume the shape in which they were trained. As is well known to those skilled in shape memory alloys, the sheath and the control cable may be formed in the desired shape, perhaps with forms or tools. They are formed at or below room temperature, and are then heat treated at a high temperature, typically from about 400° C. to about 500° C. Thus, the natural tendency of the angled forceps is to assume a position at about a 45° angle to the sheath and the control rod. This particular forceps allows the surgeon one more degree of freedom in diagnosing a patient or in conducting a biopsy, i.e. obtaining a desired sample for pathology.

[0032] Another embodiment is a hot biopsy forceps. The hot biopsy forceps is similar in concept to other back-loading instruments, but the forceps include heating elements integral to the forceps. Using the heating elements, the jaws of the forceps can be quickly heated to help free a biopsy sample or to coagulate small bleeding sites related or not related to the biopsy. When the sample has been obtained, the electric power may be turned off, and the jaws will quickly cool off to avoid any trauma to other nearby tissues.

[0033] The hot biopsy forceps **50** is depicted in **FIG. 5**. The hot biopsy forceps includes a control rod **51**, one or more wires **52** to conduct electricity, and a coil **53**. The forceps has a control portion **54** at the distal end, connected to coil **53** and including linkages **55** for control rod **54** to jaws **56**. The jaws **56** may include resistance heating elements **57** connected by wires **52**. The heating elements have much lower electrical resistance than the steel typically used for forceps jaws.

[0034] The surgeon maneuvers the endoscope into the desired area, such as the gastrointestinal tract. Biopsies in this area may include polyps. The hot biopsy forceps may include one or more heating elements, such as one heating element in one jaw and an optional heating element in the other jaw. The current may be bipolar, as in alternating or direct current electricity, or monopolar current may be used. The surgeon maneuvers the jaws in place around the desired sample and closes the jaws. Current is applied for a period sufficiently long to free the sample from its environment and to retrieve the sample inside the jaws for subsequent analysis.

[0035] **FIG. 6** depicts another embodiment of a back-loading instrument, a forceps with a sharp cutting tool and a spike. In this embodiment, the back loading forceps **60** constitutes the distal portion of a the instrument and includes an upper jaw **61**, a lower jaw **62**, a control linkage **63** for controlling upper jaw **61**, a control linkage **64** for controlling lower jaw **62**, a spike **65**, and a control portion **66** for connecting control linkages **63**, **64** to control cable **68**. Control cable **68** leads back through sheath **67**. In this embodiment, sheath **67** may be a coiled wire spring with a smooth coating **69**, such as a Teflon® coating. The outer diameter of sheath **67** preferably is about 2.4 to 2.6 Fr or narrower, and the inner diameter is sufficient so that control cable **68** does not bind or chafe during operation of the forceps. In the embodiment depicted in **FIG. 6**, the surgeon may maneuver the forceps to impale the spike **65** on a tissue or sample of interest. The surgeon then operates the forceps to sever the sample and remove it from the patient for later pathological examination.

[0036] Other embodiments with less complicated mechanical linkages may also be used. **FIG. 7** depicts a flexible forceps **70**, in which a sleeve **71** controls the opening and closing of forceps jaws **72**. In this embodiment, jaws **72** may be stamped from a single piece of metal and formed into the desired shape. The jaws are secured to a short cannula **73** and to control rod **75** with a joint **74**, which may be formed from a solder joint, a braze joint, a small rivet, or other desired form to secure the jaws to the cannula. Joint **74** could also take the form of a fastener threaded into the cannula to secure the jaws to the cannula. Cannula **73** is secured to control rod or cable **75** by swaging, soldering, brazing or other desired method, including a threaded joint.

[0037] Control rod **75** and sleeve **71** are back-loaded into a medical instrument, such as an endoscope or ureteroscope. In this embodiment, jaws **72** when closed are about 4 Fr in diameter, while sleeve **71** containing control rod **75** is about 2.6 Fr in diameter. The larger jaws enable the surgeon to take a larger biopsy sample from a patient in a single sampling procedure, thus taking less time and causing less trauma to the patient. There is a tapered or camming surface **76** to control the opening and closing of the jaws as sleeve **71** is retracted or control rod **75** is advanced.

[0038] Another embodiment uses a control rod that separates into two control wires to actuate the grasper or forceps at the distal end. **FIG. 8** depicts back-loading grasper having a hollow coil **81**, a control rod **83** and an end-effector **82** with a grasper **84**. The end-effector is firmly affixed to coil **81** by any suitable method, such as by soldering or brazing. Other methods of attachment may also be used. Grasper **84** at the distal end includes jaws **85** and control links **86** that are connected to wires **83***a* connected to the control rod. The jaws, even when closed, are too large to be drawn into coil **81**, and have a larger diameter or periphery than coil **81**. The coil may also have a smooth coating **88**, such as a PTFE coating. The grasper is preferably actuated by means of an endoscope or other therapeutic or diagnostic device. The device extends or retracts control rod **83**, causing the links **86** to pivot about pivot pin **87**, and causing jaws **85** to open or close. The sample or object is thus grasped and removed from the person.

[**0039**] Other embodiments may use a cylinder at the distal end to aid in a sampling procedure using a back-loading instrument. **FIGS. 9 and 10** depict such embodiments in a closed position. **FIG. 9** depicts a back loading extractor **90** that includes a spring-coil **91**. Coil **91** is reinforced on a portion of its distal end with a thin cylinder **92**. The cylinder is preferably metal, such as stainless steel, that does not interfere with patient care or with extraction of a sample or of an object from the body. The cylinder may be soldered or brazed to the coil, or otherwise attached firmly so that it will not come off the coil.

[**0040**] The extractor is controlled by a control rod **93** inside the coil, the control rod firmly attached to extractor **94** with jaws **95**. The attachment **98** may be made by a braze joint, solder joint, a fastener such as a rivet, or any other suitable joint. Extractor **94** may be made from stainless steel and is preferably made from Nitinol® or other shape memory metal so that the jaws automatically open when control rod **93** urges jaws **95** forward. The extractor has a tapered or camming surface **96**, allowing the jaws to spring open as control rod **93** urges jaws **95** forward. Coil **99** and proximal ends (not shown) of the outer coil spring and the control rod may be additionally coated with plastic or other atraumatic coating so that they do not damage an endoscope or other instrument into which the back loading instruments are placed.

[**0041**] **FIG. 10** depicts another embodiment of a back-loading endoscopic instrument **100** in the closed position. Instrument **100** includes a coil **101** firmly attached to a grasper **105** with connection **107**. Connection **107** may be a braze joint, a solder joint, a fastener, or other convenient joint, so that grasper **105** does not detach from coil **101**. Because grasper **105** is brazed or otherwise joined to coil **101**, jaws **108** can only open or close, and cannot translate relative to coil **101**. Control rod **103** passes through joint **107** and through a slot (not shown) in the proximal portion of grasper **105**, allowing the control rod and cylinder to translate relative to coil **101** and grasper **105**.

[**0042**] Control rod **103** controls the opening and closing of jaws **108** via a tapered or camming surface **106** of the grasper, using a cylinder **104** attached to control rod **103**. The attachment **103***a* may be any suitable attachment, such as a braze joint, a solder joint, a fastener, or a weld, so that the cylinder does not detach from the control rod. When control rod **103** retracts cylinder **104**, jaws **108** open as the camming surfaces **106** allow. When control rod **103** advances, jaws **108** close, following the same camming surfaces.

[**0043**] The outer diameter of cylinder **104** is preferably no more than 2.8 Fr, more preferably about 2.6 Fr, and that of coil spring **101** about 2.4 Fr or less. Grasper **105**, camming surfaces **106**, and jaws **108** are preferably made from spring steel, stainless steel or a shape memory alloy, such as Nitinol®. The grasper may be stamped from a single continuum of metal and formed into the desired shape. Alternatively, the grasper may be made from several smaller pieces and joined together, by brazing or soldering or by any other suitable method. In this embodiment, the outer diameter of jaws **108** in the closed position is greater than the outer diameter of cylinder **104** and of coil **101**. In one embodiment, the outer diameter of the jaws is about 4 Fr. Other embodiments may be smaller or larger, but in any case the outer periphery or circumference of the jaws is greater than the inner diameter of cylinder **104**, and the jaws are not able to be retracted into the cylinder.

[**0044**] A variety of handles or control devices may be used with embodiments of the endoscopic instruments of the present invention. Handles that may be suitable include those depicted in **FIGS. 11-14**. **FIG. 11** depicts one suitable handle or control device **110**. A sheath **112** and control rod **114** from a back-loading endoscopic instrument are attached to the control device **110**. In this instance, sheath **112** is fixed to an attachment **113** at a distal end of the control device, while control rod **114** is attached to a movable button **111** for movement by a user. The control rod may be tightened or loosened by knob **115** controlling an internal collet (not shown) or other attachment device. The user controls the device by gripping the handle with the body **117** and fixed finger handles **116** and manipulating control button **111**. In other embodiments, the control rod may be fixed and the sheath attached to the collet and movable button.

[**0045**] **FIG. 12** depicts a pin vise **120**, typically used to control only one of a control rod and sheath. Pin vise **120** may comprise only a handle **121** at its proximal end and a collet **124** at its distal end, used to attach a control element **125** from a back-loading endoscopic instrument. The control element may be a fixed or a movable control rod, or may be a fixed or a movable sheath. Two pin vises may be used, one for a control rod and one for a sheath, the control rod at least partially contained within the sheath.

[**0046**] **FIG. 13** depicts another handle or control device **130** for controlling both a fixed and a movable control element. Handle **130** includes a body **131** at a proximal end, a movable control button **133** and a distal end **135**. In this embodiment, a sheath **134** from a back-loading endoscopic instrument is fixedly attached to the distal end **135**, and a control rod **132** is attached to the movable control button **133**. A user controls the endoscopic instrument by manipulating control button **133** back and forth to extend or retract control rod **132**. In other embodiments, the sheath may be attached to the movable button and the control rod fixed to the distal end of the handle.

[**0047**] A thumb-ring type handle **140** is depicted in **FIG. 14**. The handle attached a sheath **141** fixedly and a control rod **142** movably. Control rod **142** is attached to a cross piece **144** by means of a set screw **145**. The cross-piece is attached to a movable finger-spool **146**. A user holds the handle securely with thumb-ring **147** and controls the device by manipulating movable finger-spool **146** back and forth, extending or retracting control rod **142** and thus operating the back-loading endoscope instrument. In grasper and forceps types of instruments, the control rod may comprise more than a single control rod, e.g., two rods operating two jaws. In other embodiments, the sheath may be movable and the control rod fixed to the distal end of the handle.

[0048] It should be understood that the use of larger instruments for back loading is not limited to endoscopes or ureteroscopes. Thus, back-loading instruments may be used on a variety of medical instruments, including hysteroscopes, colonoscopes, gastroscopes, laparoscopes, and so forth. The back-loading instruments may be used in these and in many other applications in which the surgeon wishes to keep trauma and invasiveness to a minimum. Of course, these instruments may also be used in other applications, such as a bronchoscope, in which their small size is still an advantage.

[0049] The details of the construction or composition of the various elements of the back loading medical instruments not otherwise disclosed are not believed to be critical to the achievement of the advantages of the present invention, so long as the elements possess the strength, sharpness, and flexibility needed for them to perform as disclosed. The selection of such details of construction is believed to be well within the ability of one of even rudimentary skills in this area, in view of the present disclosure, and are within the spirit of the invention and the scope of the claims. It will be understood that no limitation of the scope of the invention is intended by the above description and drawings, which is defined by the claims below. It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, that are intended to define the spirit and scope of this invention.

What is claimed is:

1. A back-loading medical instrument for a medical device, the back-loading medical instrument comprising:

a flexible hollow tube;

a control rod within the hollow tube; and

a distal functional portion attached to at least one of the flexible hollow tube and the control rod, the functional portion having a cross-sectional area larger than the tube and larger than a working channel of the medical device.

2. The instrument of claim 1, wherein the functional portion is selected from the group consisting of an end-effector, a biopsy forceps, a hot biopsy forceps, a biopsy mechanism, a cutting mechanism, and a grasping forceps.

3. The instrument of claim 1, wherein the control portion comprises a control cable and a mechanical linkage to the functional portion.

4. The instrument of claim 1, wherein the medical device is selected from the group consisting of an endoscope, a hysteroscope, a ureteroscope, a bronchoscope, a colonoscope, and a gastroscope.

5. The instrument of claim 1, wherein the tube is selected from the group consisting of a coil spring and a polymeric tube.

6. The instrument of claim 1, further comprising an atraumatic proximal end.

7. The instrument of claim 1, further comprising a removable control handle connected to the proximal portion.

8. The instrument of claim 1, wherein the function portion is attached to the control rod and further comprising a cylinder attached to the hollow tube.

9. A back loading instrument for an endoscope, comprising:

a distal portion including a forceps;

a control portion operatively connected to the forceps; and

a proximal portion for insertion into a working channel of an endoscope,

wherein a cross-sectional area of the forceps is greater than a cross-sectional area of a working channel of the endoscope.

10. The instrument of claim 9, wherein the forceps comprises at least one of a cutting portion and a spike.

11. The instrument of claim 9, wherein the distal portion is connected to the control portion by at least one of a crimp joint, a braze joint, a solder joint, a weld joint, and a threaded joint.

12. The instrument of claim 9, wherein the control portion further comprises a smooth exterior coating.

13. A back loading endoscopic biopsy instrument, comprising:

a flexible hollow member having a proximal end and a distal end;

a flexible inner member having a proximal end and a distal end and extending through said hollow outer member; and

a jaw assembly having a pair of jaws extending distally, the jaw assembly coupled to at least one of the hollow outer member and the flexible control member, wherein a circumference of the outer jaws in a closed state is greater than a circumference of a working channel of the endoscope.

14. The instrument of claim 13, wherein the jaw assembly is coupled to the flexible inner member, and the jaw assembly is opened by retracting the flexible hollow member.

15. The instrument of claim 13, wherein the jaw assembly is connected to the flexible hollow member and the flexible inner member, and the jaw assembly is opened or closed by translating the flexible inner member.

16. The instrument of claim 13, further comprising a smooth coating or a thin polymeric sheath on the flexible hollow member.

17. The instrument of claim 13, wherein each of the jaws comprises a cutting edge.

18. A method of making a back loading endoscopic instrument, the method comprising:

forming an openable functional portion, a flexible inner member, and a hollow tubular member;

assembling the hollow tubular member outside the flexible inner member; and

attaching the functional portion to at least one of the flexible inner member and the hollow tubular member, wherein an outer periphery of the openable functional portion is greater than an outer periphery of a working channel of an endoscope when the functional portion is in a closed state.

19. The method of claim 18, further comprising coating at least one of the flexible inner member and the hollow outer member with a smooth plastic coating.

20. The method of claim 18, wherein the functional portion is formed by at least one of machining, stamping, blanking, casting, and electrical discharge machining.

21. A method of using a back-loading medical instrument in a medical device, the method comprising:

providing a back loading medical instrument, wherein the back-loading medical instrument comprises a flexible hollow tube, a control rod within the hollow tube, and a distal functional portion attached to at least one of the flexible hollow tube and the control rod, the functional portion having a cross-sectional area larger than the tube and larger than a working channel of the medical device;

placing the back loading medical instrument into the distal end of the working channel; and

connecting the back loading medical instrument to a control device.

22. The method of claim 21, wherein the back-loading medical instrument is selected from the group consisting of an end-effector, a biopsy forceps, a hot biopsy forceps, a biopsy mechanism, a cutting mechanism, and a grasping forceps.

* * * * *

专利名称(译)	背负式内窥镜器械

公开(公告)号	US20050137585A1	公开(公告)日	2005-06-23
申请号	US11/020328	申请日	2004-12-22

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IPC分类号	A61B10/00 A61B10/06 A61B17/00 A61B17/28
CPC分类号	A61B10/06 A61B17/00234 A61B2017/2937 A61B2017/2905 A61B2017/2933 A61B2017/0046
优先权	60/532397 2003-12-23 US
外部链接	Espacenet USPTO

摘要(译)

用于医疗装置（例如内窥镜或结肠镜）的背负式仪器具有更大的内窥镜器械或末端执行器，并且能够收集更大的样品，例如活组织检查。该仪器还允许从患者体内抓取，动员，切割或移除组织或异物。后装载器械的末端执行器（例如活检钳）的横截面积大于内窥镜的工作通道或用于控制器械的其他医疗装置的横截面积。通过将该医疗设备用作微创手术的一部分，对患者的创伤最小化。