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Sievert, Jr. et al.

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(54) **OPTICAL FORCEPS SYSTEM AND METHOD OF DIAGNOSING AND TREATING TISSUE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(52) **U.S. Cl.** **600/564**; 606/205
(58) **Field of Search** 600/564, 565, 600/566, 567, 568, 569, 570, 571; 606/205, 206, 207

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,074,408	A	1/1963	Chester	128/328
3,924,608	A	12/1975	Mitsui	128/2 B
3,961,621	A	6/1976	Northeved	128/2 B
4,027,510	A	6/1977	Hiltebrandt	72/37
4,421,106	A	12/1983	Uehara	128/4
4,557,255	A	12/1985	Goodman	128/7
4,573,450	A	3/1986	Arakawa	128/6
4,620,547	A	11/1986	Boebel	128/754
4,646,751	A	3/1987	Maslanka	128/751
4,656,999	A	4/1987	Storz	128/4
4,887,612	A	12/1989	Esser et al.	128/751
5,228,451	A	7/1993	Bales et al.	128/751
5,280,788	A	1/1994	Janes et al.	128/665
5,291,010	A	3/1994	Tsuji	250/208.1
5,318,023	A	6/1994	Vari et al.	128/633
5,354,291	A	10/1994	Bales et al.	604/35

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

DE	3920706	1/1991	A61B/17/28
DE	19533856	3/1997	A61B/19/00
EP	316816	5/1989	A61B/17/28
EP	0321132	6/1989	A61M/25/00
EP	0593929	4/1994	A61B/17/00
WO	83/03189	9/1983	A61B/1/06
WO	94/12095	6/1994	A61B/5/00
WO	97/41776	11/1997	A61B/10/00

Primary Examiner—Erik F. Winakur
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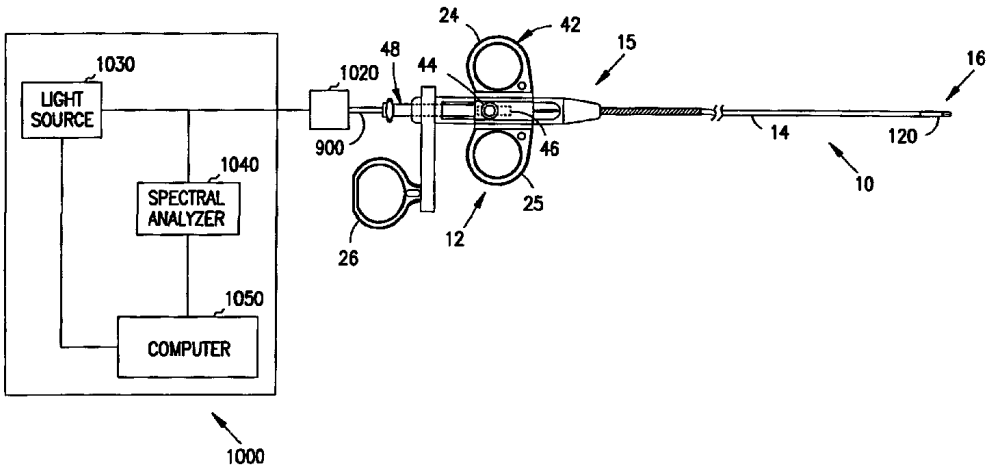
(57) **ABSTRACT**

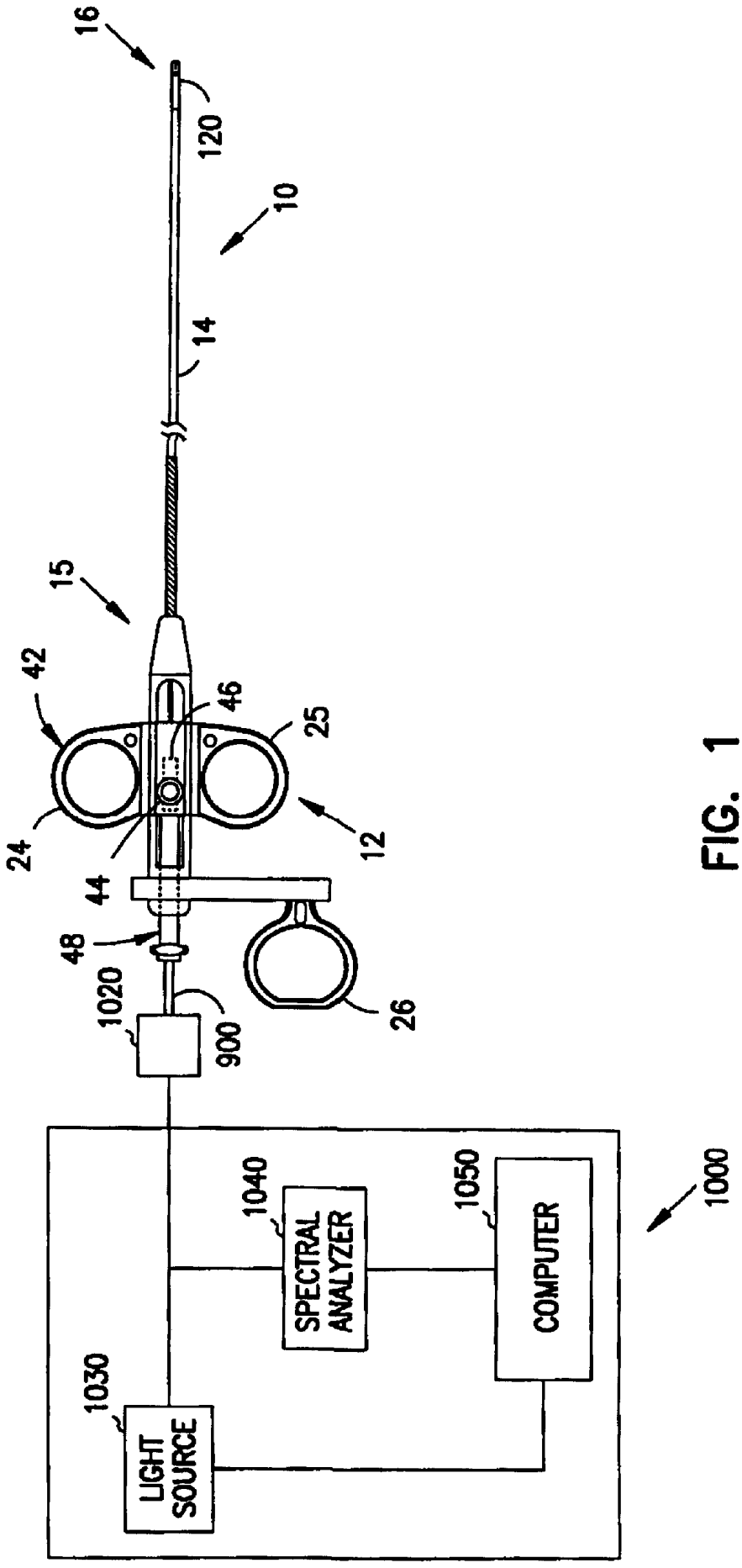
A biopsy forceps device is provided for obtaining tissue samples, or removing tissue for therapeutic reasons, at a site within a body, while maintaining access to the site through an access lumen of the biopsy forceps. The device includes an elongate tubular body for introduction into the body and navigation to an area of interest. An inner tubular member having a lumen, or a plurality of lumens, extends through or adjacent the outer tubular member, from the proximal end to the distal end, where cutting jaws are provided. The cutting jaws are rotatably mounted at the distal end of the device and are controlled by movement of the inner tubular member. The inner tubular member is coupled with a handle portion allowing control of the cutting jaws at the proximal end. Access to the lumen of the inner tubular member is gained at the proximal end, where a luer fitting is provided. The lumen of the inner tubular member has a removable optical fiber disposed therethrough or allows for a variety of medical instruments to be inserted so that the instruments can be used coaxially in the same location as where the biopsy sample is taken.

24 Claims, 13 Drawing Sheets



U.S. PATENT DOCUMENTS

5,373,854 A	12/1994	Kolozsi	128/749
5,439,000 A	8/1995	Gunderson et al.	128/664
5,471,992 A	12/1995	Banik et al.	128/751
5,482,054 A	1/1996	Slater et al.	128/751
5,536,248 A	7/1996	Weaver et al.	604/54
5,558,100 A	9/1996	Cox	128/751
5,562,102 A	10/1996	Taylor	128/751
5,571,129 A	11/1996	Porter	606/170
5,667,473 A	9/1997	Finn et al.	600/104
5,762,613 A	6/1998	Sutton et al.	600/564
5,843,000 A	12/1998	Nishioka et al.	600/566
5,848,978 A	12/1998	Cecchi	600/567
5,857,961 A	1/1999	Vanden Hoek et al.	600/104
5,908,381 A	6/1999	Aznoian et al.	600/104
6,066,102 A	5/2000	Townsend et al.	600/564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LIGHT SOURCE

FIG. 1

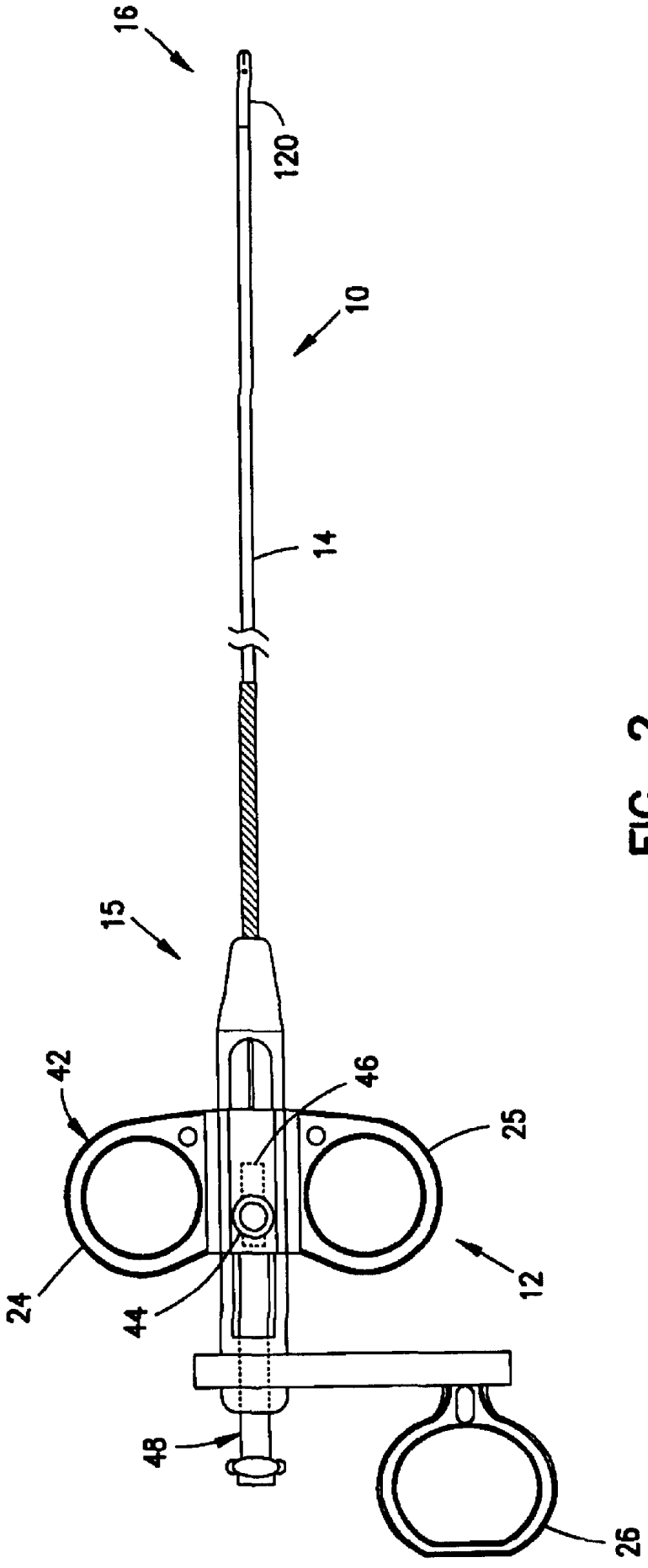

FIG. 2

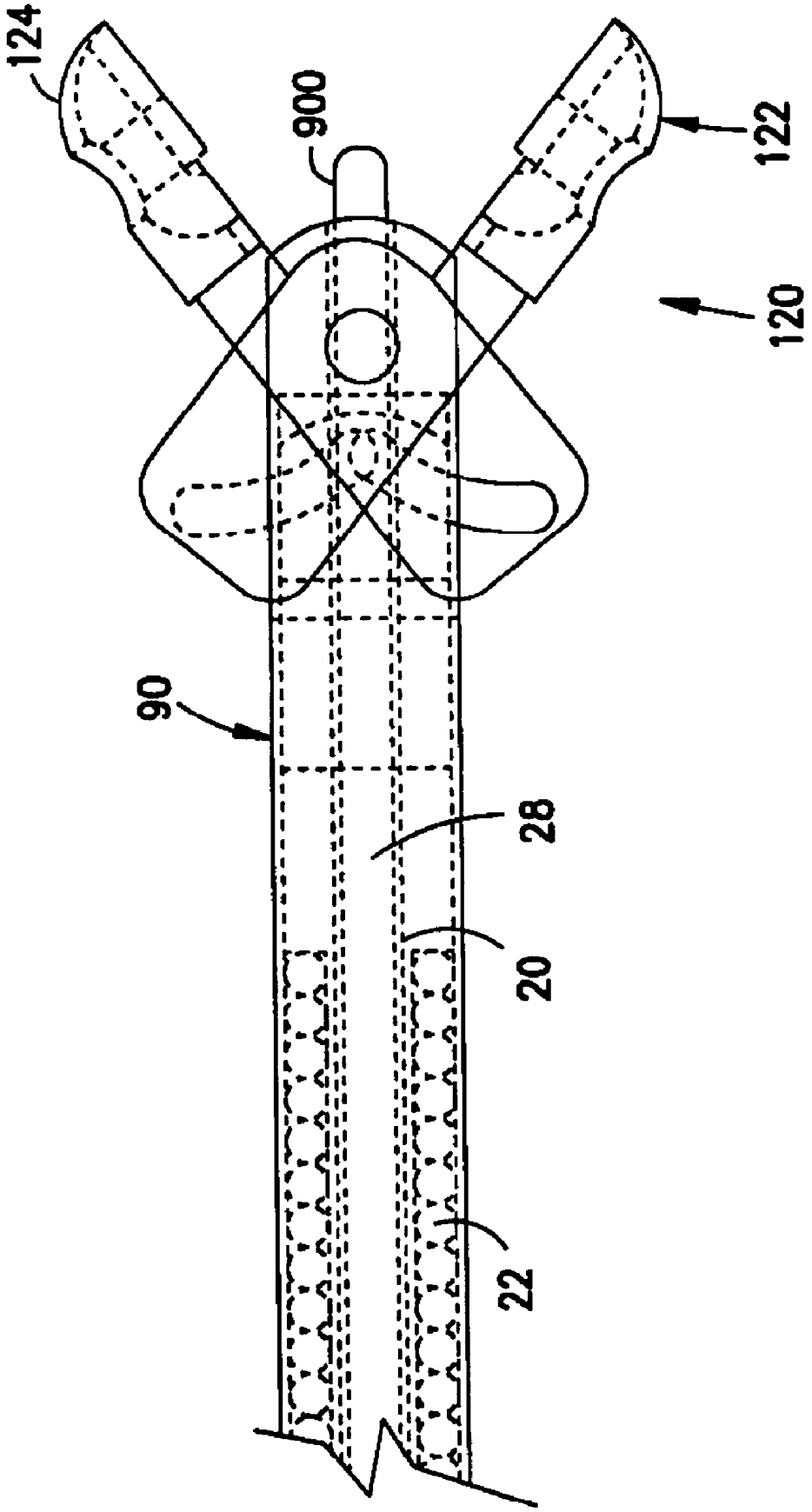

FIG. 3

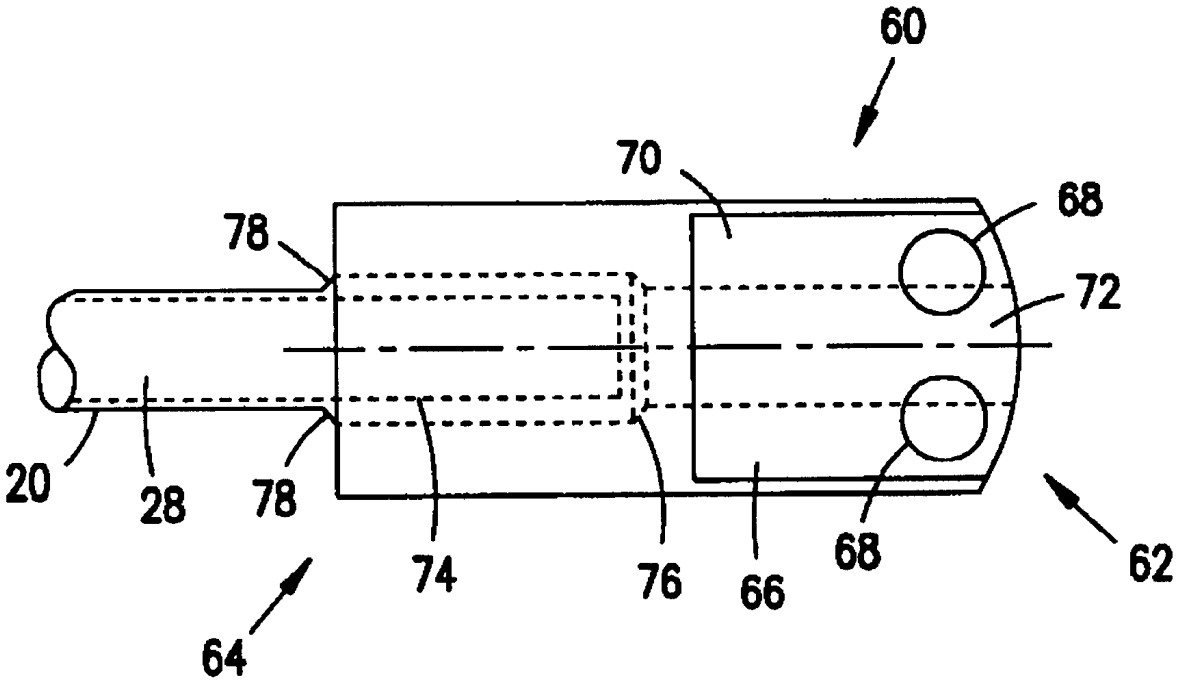

FIG. 4a

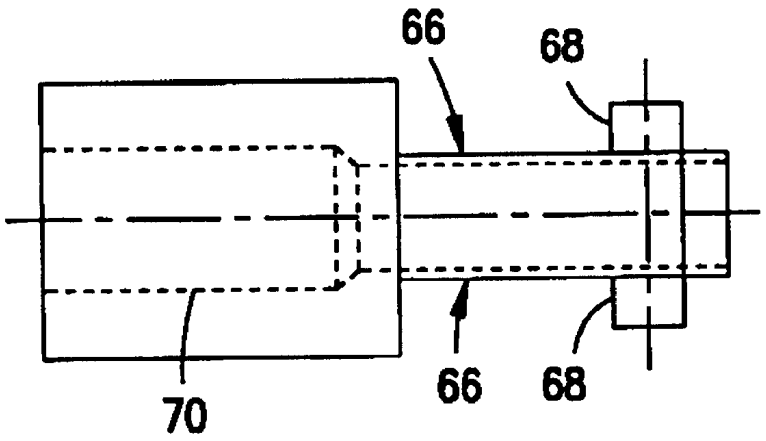

FIG. 4b

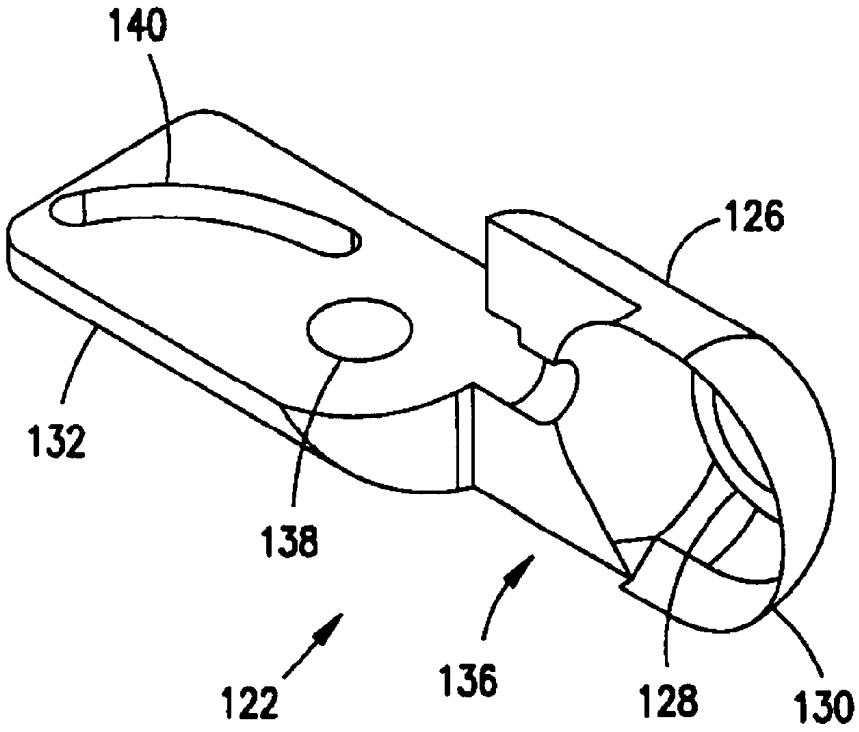

FIG. 5a

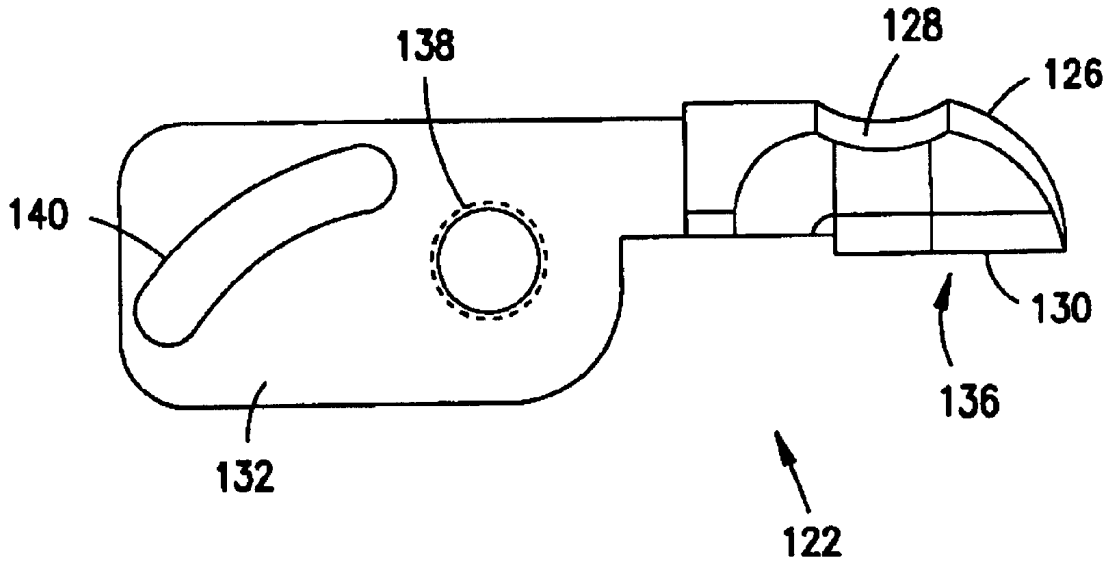

FIG. 5b

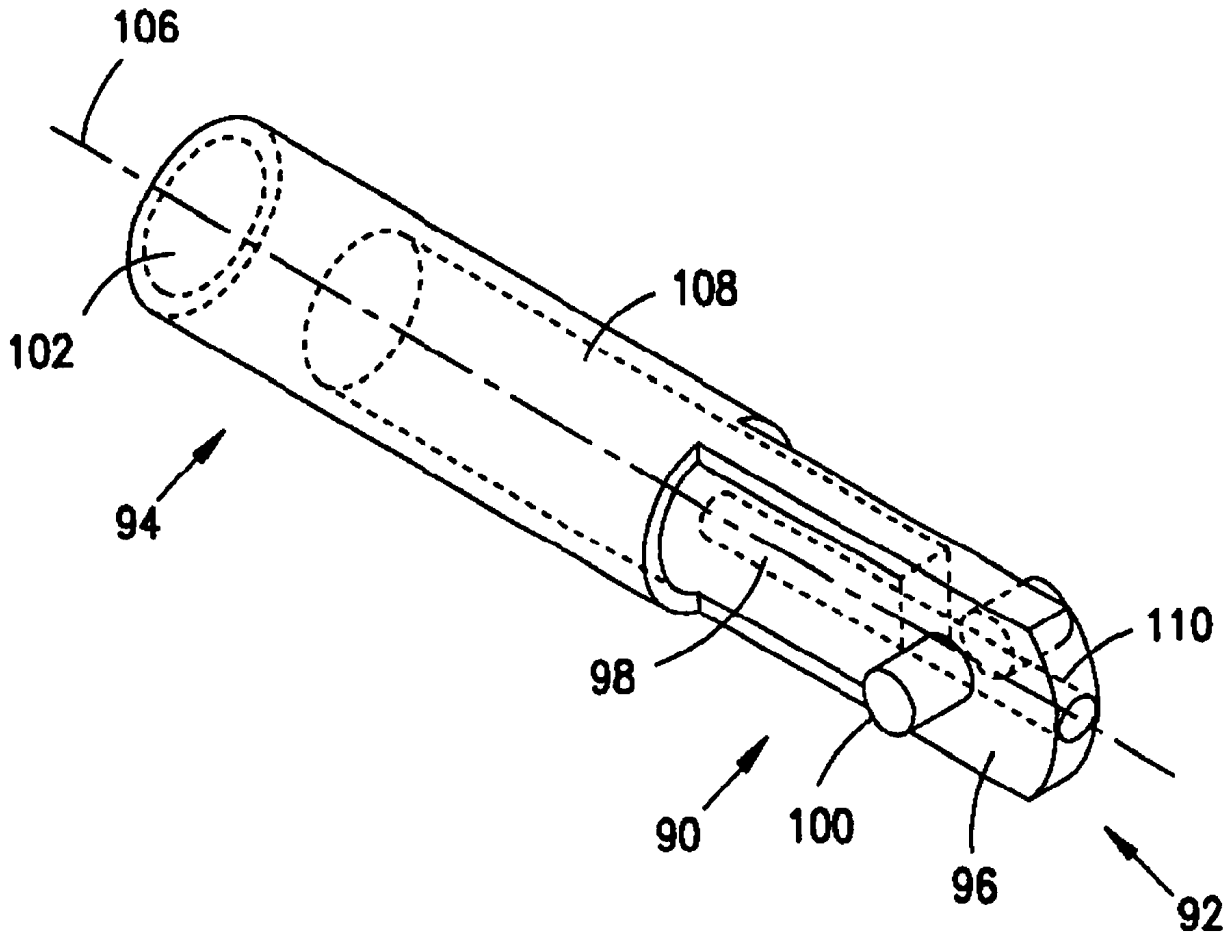

FIG. 6

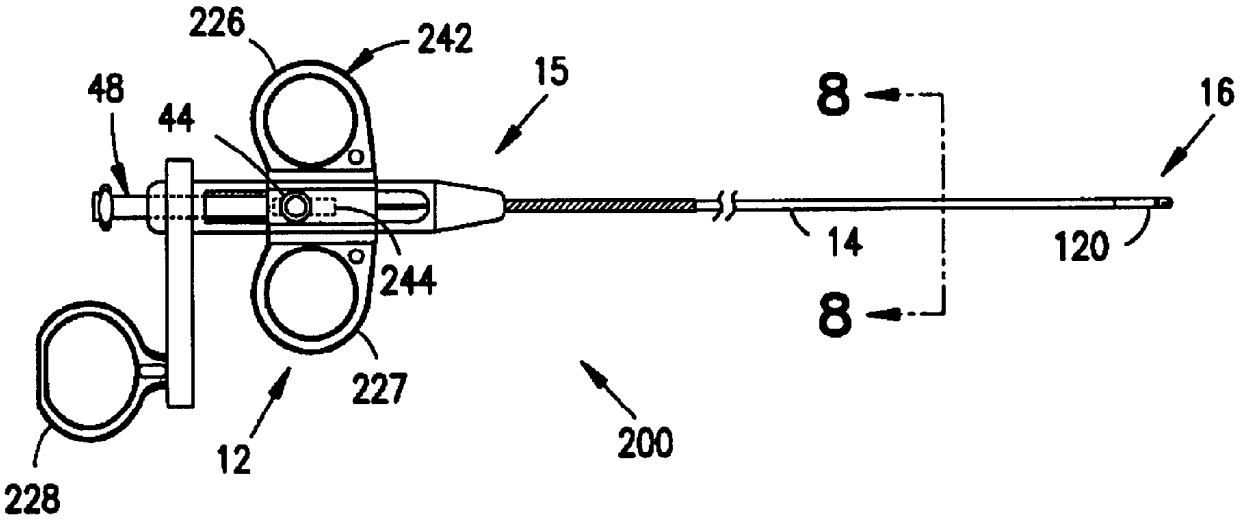
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FIG. 7

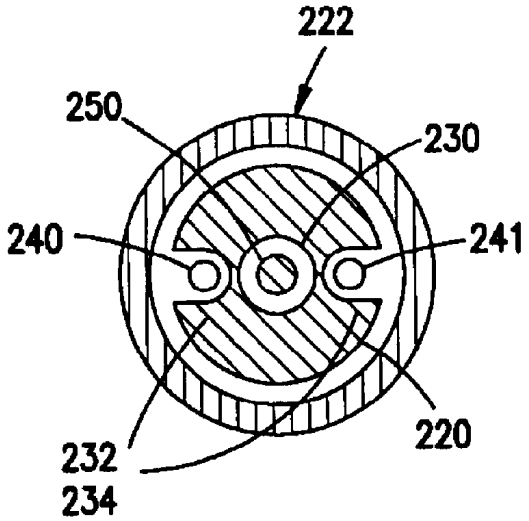
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FIG. 8

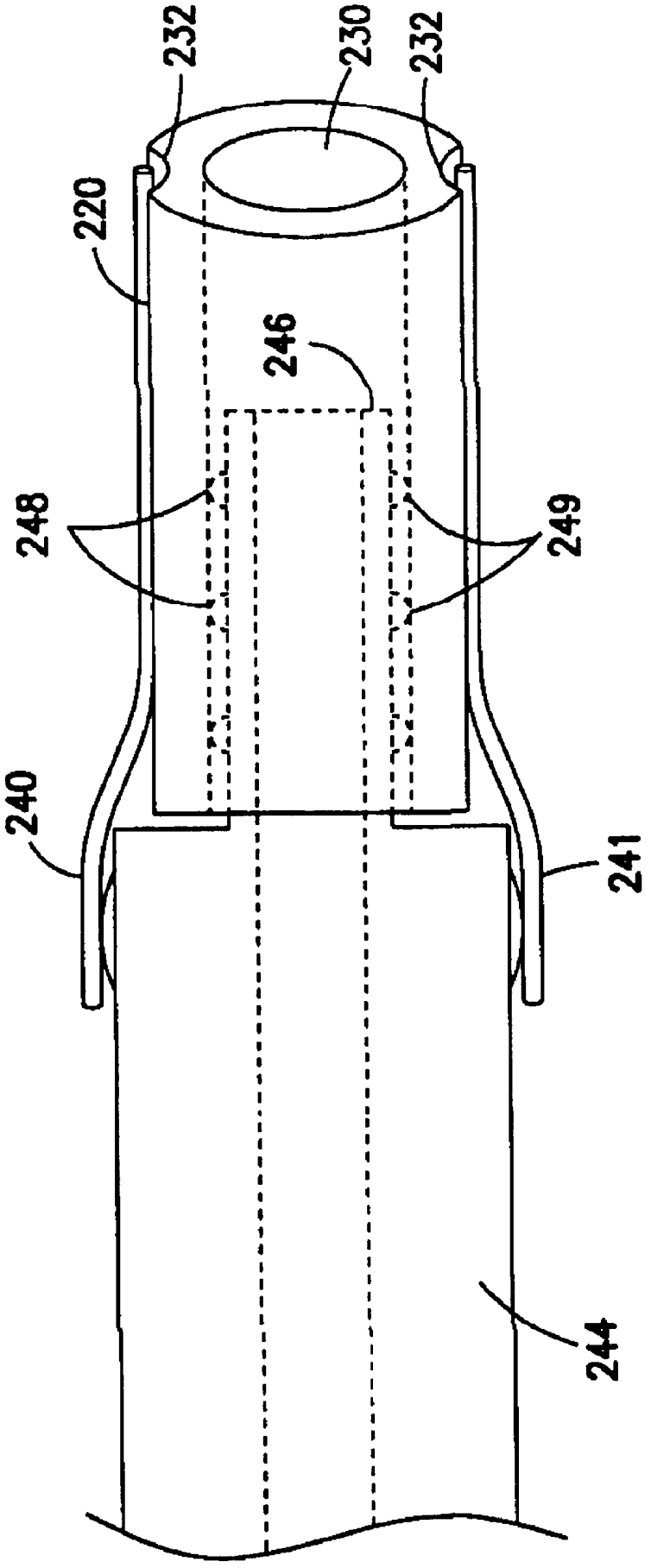

FIG. 9

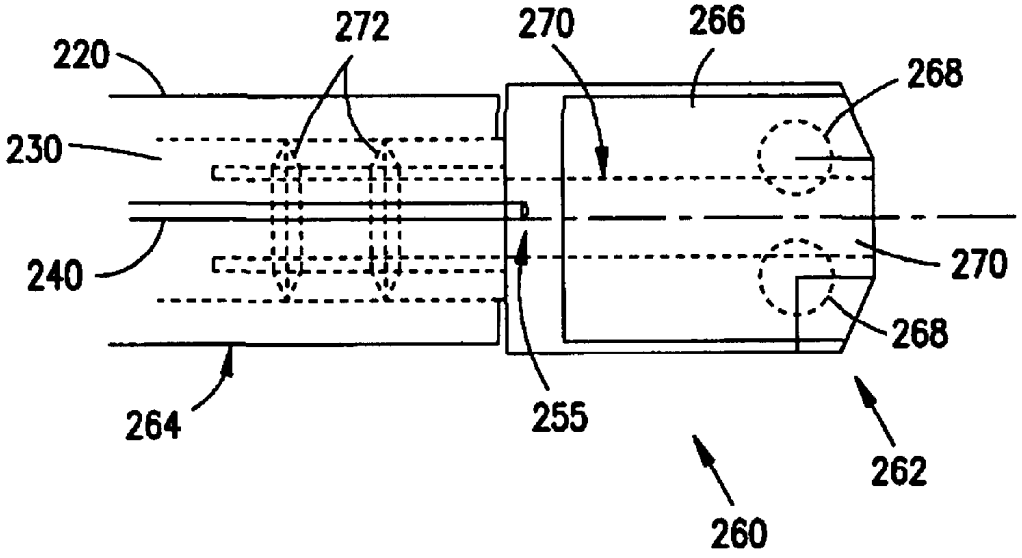
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FIG. 10

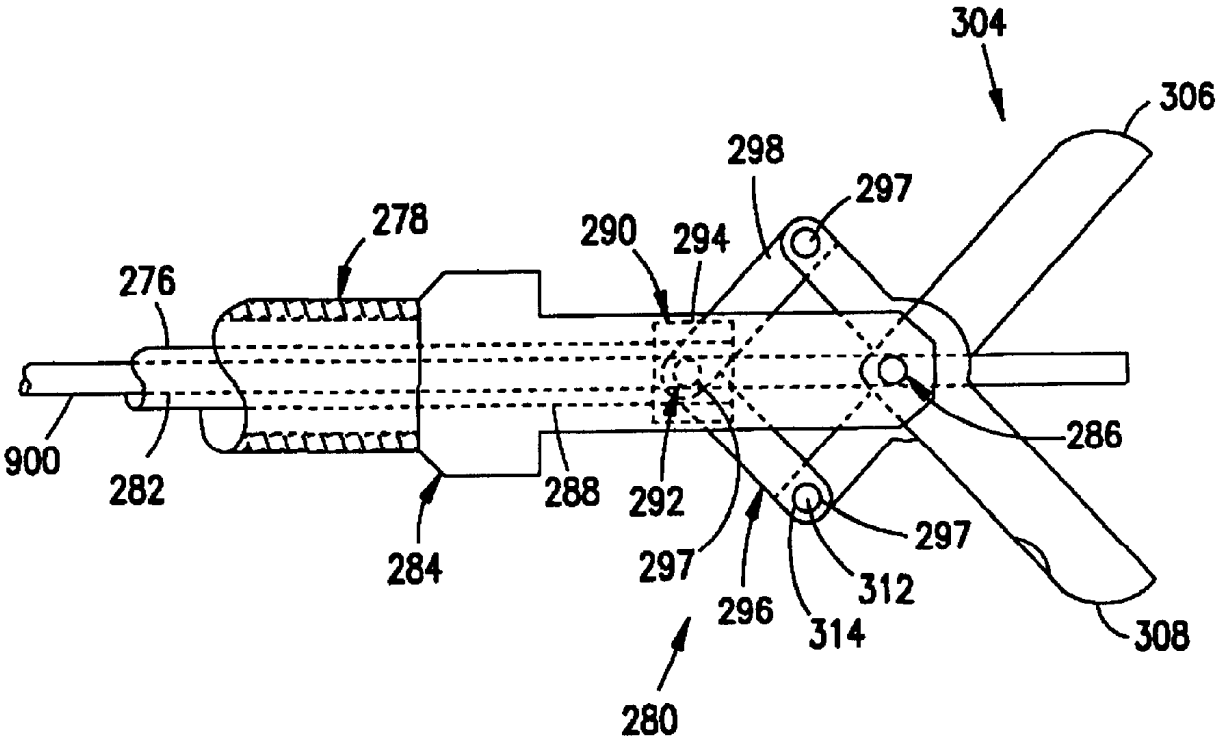
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FIG. 11

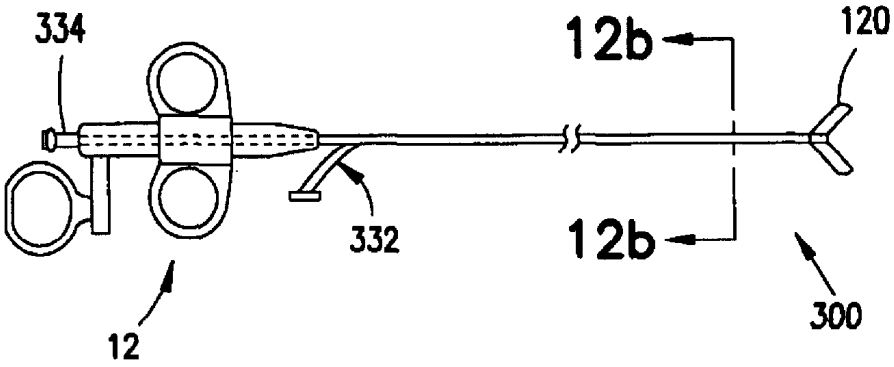

FIG. 12a

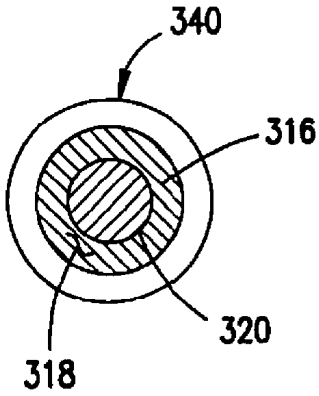

FIG. 12b

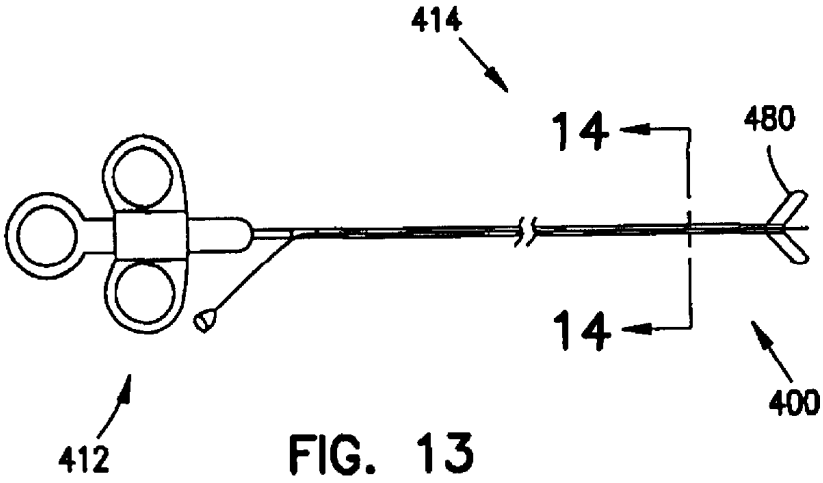

FIG. 13

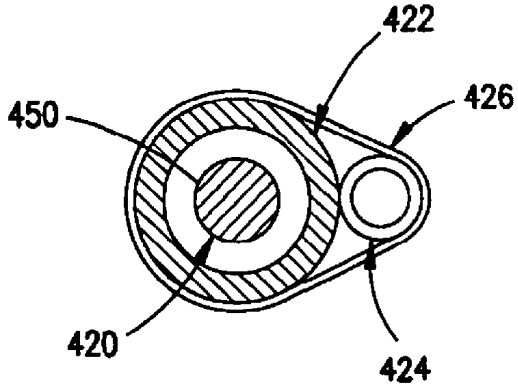

FIG. 14

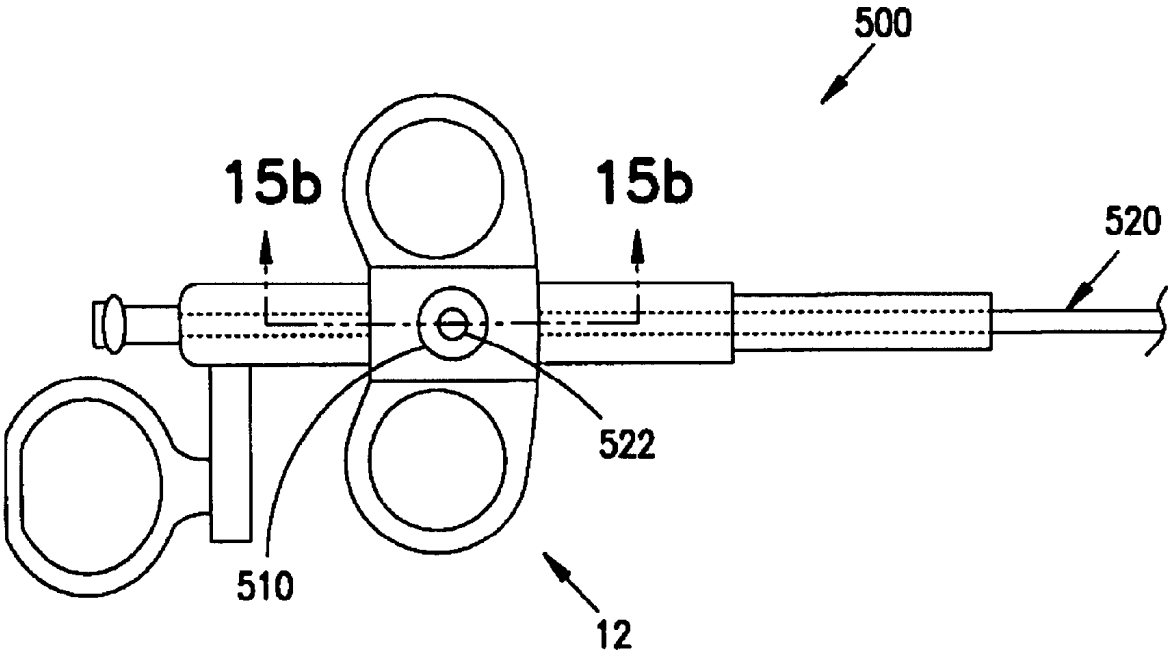

FIG. 15a

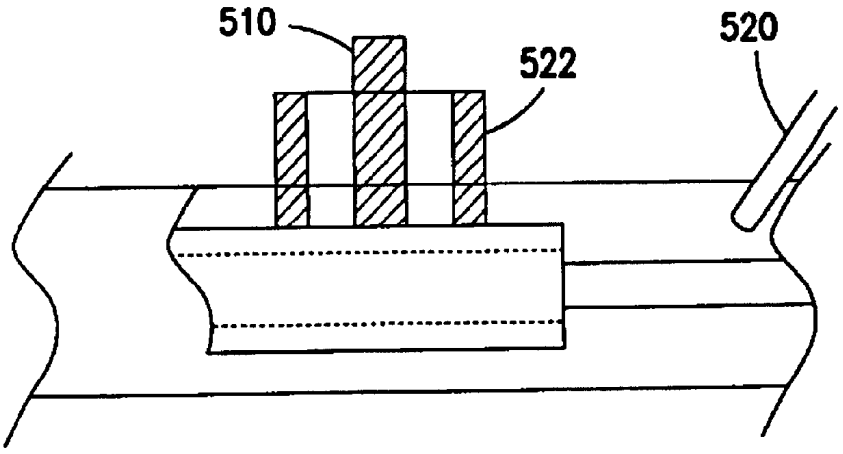

FIG. 15b

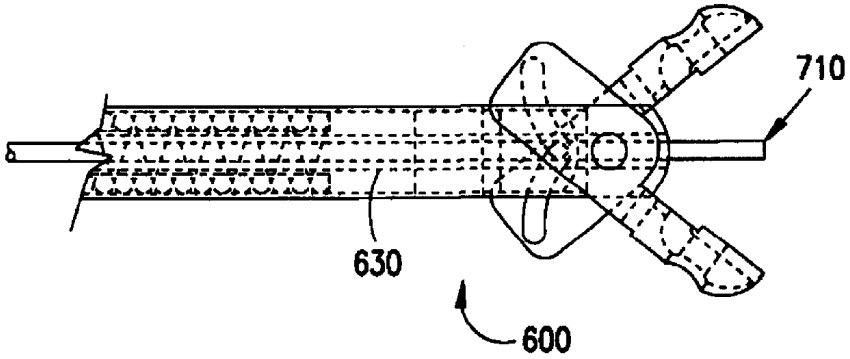

FIG. 16a

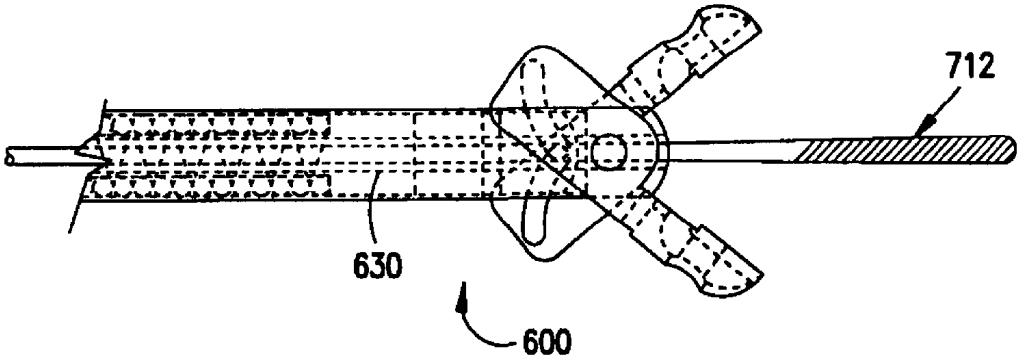

FIG. 16b

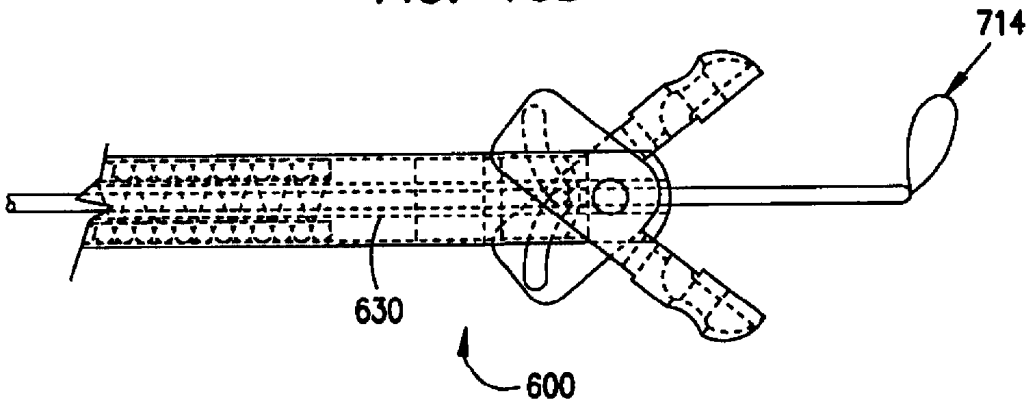

FIG. 16c

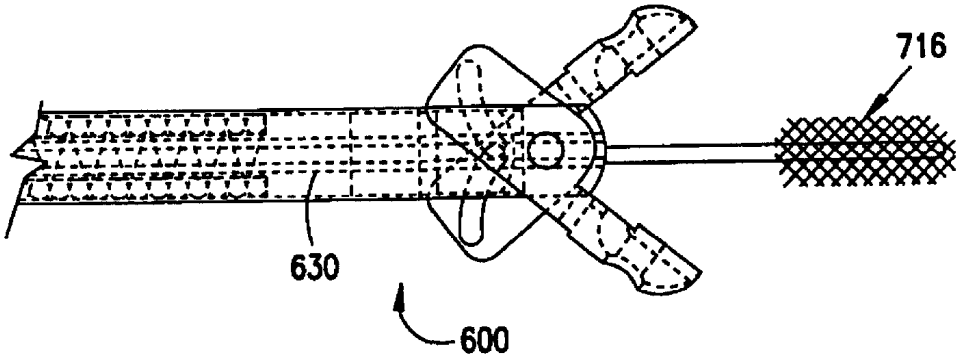

FIG. 16d

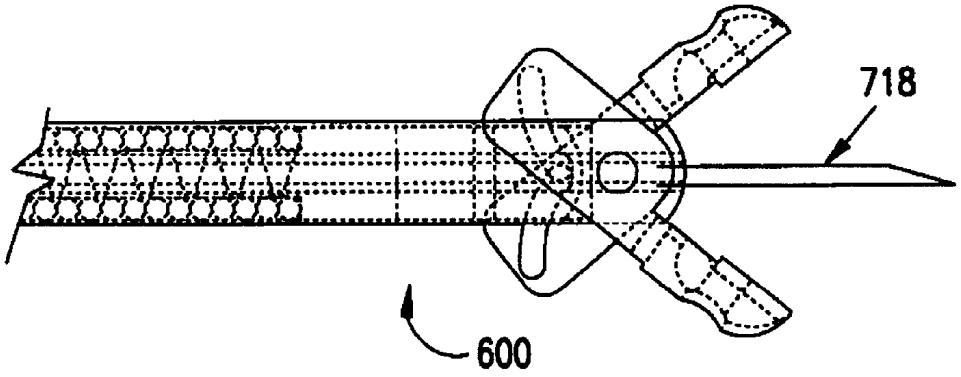

FIG. 16e

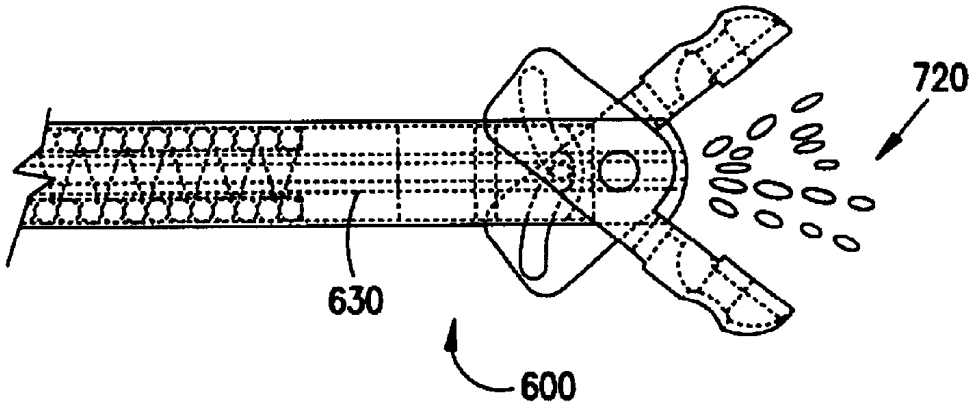

FIG. 16f

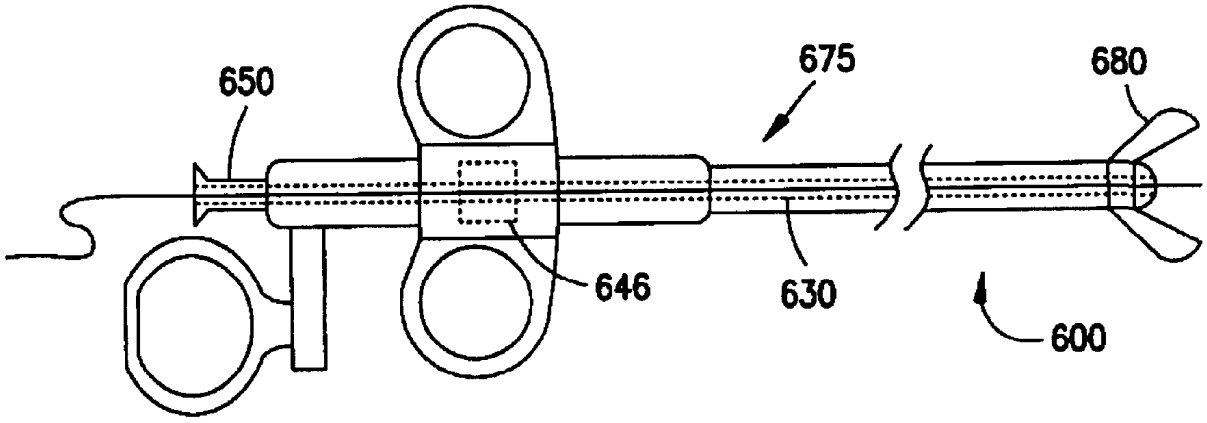

FIG. 16g

OPTICAL FORCEPS SYSTEM AND METHOD OF DIAGNOSING AND TREATING TISSUE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is related to the following, commonly assigned U.S. patent applications: application Ser. No. 09/037,722 entitled "OPTICAL BIOPSY SYSTEM AND METHODS FOR TISSUE DIAGNOSIS," filed on Mar. 9, 1998, now U.S. Pat. Nos. 6,174,291, and 5,762,613, application Ser. No. 08/644,080, entitled "OPTICAL BIOPSY FORCEPS," filed on May 7, 1996, and application Ser. No. 09/037,240 entitled "OPTICAL BIOPSY FORCEPS SYSTEM," filed on Mar. 9, 1998, now U.S. Pat. No. 6,066,102, each of which is assigned to the assignee of the present invention, and the entire disclosure of each being incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to medical diagnosis and treatment. More particularly, it pertains to a reusable and disposable biopsy forceps device having an optical fiber for optical biopsy and histopathological analysis of tissue.

BACKGROUND OF THE INVENTION

Numerous types of biopsy forceps have been developed for in vivo medical diagnosis and treatment of various conditions. Such devices are designed for sampling tissue within the body, for example in endoscopic, laparoscopic and vascular procedures to retrieve biopsy samples for analysis and identification of tissue types. These biopsy forceps devices generally include small cutting jaws at the distal end, operated remotely from the proximal end after the distal end of the device has been positioned or navigated to the site of interest.

One difficulty in using prior art biopsy forceps devices is in knowing for certain the exact positioning of the distal tip, in relation to the suspected disease area, especially when the area of interest is very small. Another difficulty of prior art biopsy forceps in combination with other endoscopic accessories is the exact positioning of both instruments. Various types of optical catheters or probes have been developed for use in locating or identifying sites within the body. A method of diagnosing in vivo using an optical guidewire is disclosed in U.S. Pat. No. 5,439,000, assigned to SpectraScience, Inc. An apparatus and method for identifying and obtaining a biopsy sample is disclosed in pending U.S. application Ser. No. 08/643,912, which licensed and assigned to SpectraScience, Inc. The application is entitled "Optical Biopsy Forceps and Method of Diagnosing Tissue."

One type of prior art system for internal biopsy uses an optical catheter to locate the site, followed by replacement of the optical catheter with a biopsy forceps for taking a tissue sample. However, this can result in errors and uncertainties in the final placement of the biopsy jaws with respect to a previously identified small structure or targeted area since the exact site identified by the optical catheter is not treated with the biopsy forceps or other instruments to treat the site.

Other prior art systems have been proposed which use optical viewing or imaging and a cutting device in the same device, to visually locate and then biopsy a suspected area. However, such devices have been hampered by their thickness which is needed to accommodate the imaging system and the cutting actuation system, and which precludes their use in very small areas. Another shortcoming of such prior art systems is the offset or 'parallax' between the viewing axis or the imaging system and the cutting position of the biopsy jaws, such that the biopsy sample actually is taken from a zone slightly displaced from the zone being viewed by the optics. This can result in a loss of accuracy in the case of very small structures of interest.

Another difficulty in conventional devices is accessing the area from which the biopsy sample is to be taken. Often the area to be sampled requires treatment before the sample is taken. An optical catheter is used to locate the biopsy site, followed by replacement of the optical catheter with a medical instrument for treating the area. The instrument is removed, and biopsy forceps is inserted for taking a biopsy sample. However, this can result in errors and uncertainties in the final placement of the biopsy jaws with respect to a previously identified small structure or biopsy area.

Other biopsy devices allow for a biopsy sample to be pierced with a spike before the biopsy sample is taken. However, these devices are limited to the fixed instrument disposed within the forceps. If additional instruments and treatment is necessary for the biopsy area, the biopsy device must be removed from the body, and a different device inserted into the body. Removing the device to insert another poses additional problems in that the exact biopsy location will not be treated.

Accordingly, a better way to treat biopsy areas is needed. What is further needed is a device to accommodate multiple methods of treatment for an exact biopsy area. What is also needed is a better way to obtain a biopsy sample.

SUMMARY OF THE INVENTION

To overcome these and other problems, an integrated biopsy forceps device is provided, which is very thin, with an access lumen enabling the device to be used in very small areas of interest, and which allows for accurate alignment with repetitive withdrawal or introductions of various adjunctive medical instruments to treat the biopsy sampling area. A system is also provided where an integrated biopsy forceps device is coupled with an electro-optical diagnostic apparatus for optical biopsy to perform histopathological analysis of tissue.

The present invention, in one embodiment, provides a biopsy forceps which is adapted for tissue treatment and identification through the access lumen and by biopsy sampling. The forceps device includes an elongated catheter body for introduction into the body and navigation to an area of interest. The distal end of the forceps device has a pair of cutting jaws, and a lumen extends through the forceps device aligning with the closed cutting position of the cutting jaws. The proximal end has a handle portion for manipulating the forceps device and actuating the jaws.

In accordance with one aspect of the invention, there is provided a method of treating tissue at a site within a body. The method comprises introducing into the body a biopsy forceps which includes a flexible catheter body with an access lumen extending therethrough with the distal end of the lumen aligned with a biopsy sampling area adjacent the distal tip of the catheter body. Instruments such as an optical fiber, are inserted into the device and through the lumen to treat the sampling area as appropriate. The biopsy forceps additionally include cutting jaws mounted at the distal end of the catheter body for selective opening and closing in a biopsy cutting movement in the biopsy sampling area, and an actuator mechanism operatively connected to the jaws for

selectively controlling the opening and closing of the cutting jaws. Then, tissue in the biopsy sampling area adjacent the distal end of the forceps is treated with the instruments inserted through the forceps or identified by the optical fiber coupled with the electro-optical diagnostic apparatus. Alternatively, the area is flushed with medicine or saline with or without the optical fiber inserted in the lumen. Then, a biopsy sample is cut from the location of the optical tissue analysis zone by actuating the actuator mechanism, and the biopsy sample is withdrawn from the body.

In one embodiment, the cutting jaws are mounted for pivoting about stationary pivot pins for cutting tissue placed there between, and coupled to and controlled by an inner tubular member forming the lumen that extends through the catheter body to the handle portion at the proximal end of the device. The inner tubular member extends through the handle and couples with an access portion on the handle portion. Instruments, medicine, or fluids are inserted into the access portion and through the lumen to treat, flush, or clean the biopsy sampling area. The inner tubular member is positioned coaxially with the jaws, so that the biopsy sample is taken exactly at the spot where treatment with instruments or fluids took place. In an alternative configuration, a second lumen is provided adjacent the lumen within the inner tubular member to provide additional access proximate the biopsy sampling area.

In another embodiment, the cutting jaws are mounted for pivoting about stationary pivot pins for cutting tissue placed therebetween, and controlled by control wires extending through the catheter body to the control handle and/or an inner member. Alternatively, the cutting jaws are rotatably coupled with a distal housing and are controlled by links. The links, in another embodiment, are operatively coupled with the actuator housing and the cutting jaws. The inner member has a lumen therein and extends through the device, from its proximal end for coupling with an access port. An optical fiber is disposed within the lumen of the inner member. The control wires are disposed in grooves formed in the inner member and the wires and the inner member are coupled with a handle for actuating the cutting jaws.

In yet another embodiment, the cutting jaws are mounted for pivoting about stationary pivot pins and are for cutting tissue placed between the cutting jaws, and coupled to and controlled by an inner tubular member that extends through the catheter body to the handle portion at the proximal end of the device. The inner tubular member has a plurality of lumens therein with an optical fiber disposed in at least one of the lumens, and extends through the handle and couples with an access portion on the handle portion. Instruments, medicine, or fluids are inserted into the access portion and through the lumen to treat the biopsy sampling area. The inner tubular member is positioned coaxially with the jaws, so that the biopsy sample is taken exactly at the spot where treatment with instruments or fluids took place.

According to one aspect of the invention, the biopsy forceps is reusable. When the optical fiber needs to be replaced, the entire biopsy forceps does not need to be discarded. Instead, a new optical fiber is inserted through the central access lumen when the use of the previous optical fiber is exhausted. Removing the optical fiber from the biopsy forceps also allows for the forceps to be cleaned and sterilized more extensively using more thorough and strenuous processes.

According to another aspect of the invention, the biopsy forceps is disposable. Using disposable biopsy forceps helps to reduce the chance of contamination between patients where a biopsy forceps is disposed after use on one patient, which is ideal for patients with highly contagious and dangerous diseases or patients highly susceptible to infection.

One important use of the invention is in connection with endoscopic treatment and diagnosis procedures, for example in gastrointestinal endoscopy or bronchoscopy. The present invention is also useful in many other endoscopic fields including, but not limited to: urology, cardiovascular, neurology, orthopedics, general surgery, laparoscopy, obstetrics/gynecology, etc. It can also be used in minimally invasive laparoscopic procedures for additional diagnostic information, and/or guidance of a therapeutic modality (e.g., laser or cutting/coagulation devices, such as a bipolar or monopolar electrocautery RF device).

These and other features and advantages of the invention will become apparent from the following description of the preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a first side elevational view of a biopsy forceps connected to a diagnostic apparatus shown in schematic diagram constructed in accordance with one embodiment of the present invention.

FIG. **2** is a first side elevational view illustrating biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **3** is a first side elevational view illustrating biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **4***a* is a first side elevational view illustrating an actuator housing for use with biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **4***b* is a second side elevational view illustrating the actuator housing for use with biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **5***a* is a perspective view illustrating a cutting jaw for use with biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **5***b* is a first side elevational view illustrating a cutting jaw for use with biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **6** is a perspective view illustrating a distal housing for use with biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **7** is a first side elevational view illustrating biopsy forceps constructed in accordance with another embodiment of the present invention.

FIG. **8** is a cross-sectional view taken along **6**—**6** of FIG. **7** illustrating biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **9** is a first side elevational view illustrating a translating member assembly for use with biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **10** is a first side elevational view illustrating an actuator housing for use with biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **11** is a first side elevational view illustrating biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **12***a* is a first side elevational view illustrating biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **12***b* is a cross-sectional view taken along **12***b*—**12***b* of FIG. **11** illustrating biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **13** is a first side elevational view illustrating biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **14** is a cross-sectional view taken along **14**—**14** of FIG. **13** illustrating biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **15***a* is a first side elevational view illustrating biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **15***b* is a cross-sectional view taken along **15***b*—**15***b* of FIG. **15***a* illustrating biopsy forceps constructed in accordance with one embodiment of the present invention.

FIG. **16***a* is a first side elevational view illustrating a biopsy forceps having an ultrasonic probe disposed therethrough in accordance with one embodiment of the present invention.

FIG. **16***b* is a first side elevational view illustrating a biopsy forceps having a guidewire disposed therethrough in accordance with one embodiment of the present invention.

FIG. **16***c* is a first side elevational view illustrating a biopsy forceps having a snare disposed therethrough in accordance with one embodiment of the present invention.

FIG. **16***d* is a first side elevational view illustrating a biopsy forceps having a cytology brush disposed therethrough in accordance with one embodiment of the present invention.

FIG. **16***e* is a first side elevational view illustrating a biopsy forceps having a needle disposed therethrough in accordance with one embodiment of the present invention.

FIG. **16***f* is a first side elevational view illustrating a biopsy forceps having saline flushed therethrough in accordance with one embodiment of the present invention.

FIG. **16***g* is a first side elevational view illustrating a biopsy forceps having an instrument inserted therethrough in accordance with one embodiment of the present invention.

DESCRIPTION OF THE EMBODIMENTS

In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural changes may be made without departing from the spirit and scope of the present invention. Therefore, the following detailed description is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

FIG. **1** illustrates a system including a biopsy forceps **10** and a diagnostic apparatus **1000**, such as a spectrophotometer. In one embodiment, the electro-optical diagnostic apparatus **1000** comprises a light source **1030**, a spectral analyzer **1040**, and a computer **1050**. Forceps **10** includes an optical fiber **900** disposed therethrough, as is explained in greater detail below. The optical fiber **900** is coupled with the fiber coupler **1020** and the light source **1030** of the diagnostic apparatus **1000**.

During use, the light source **1030** provides a source of optical radiation, where operation of the light source **1030** is, in one embodiment, controlled by the computer **1050**. Operation of the light source **1030** transmits radiation into the fiber coupler **1020**. The radiation emanates from the optical fiber **900** upon a tissue location, for example, at a cancerous site. The radiation returning from the tissue by reflection or fluorescence is received by the optical fiber **900** and the fiber coupler **1020** which then transmits the returning radiation to the spectral analyzer **1040**. As is known to those skilled in the art, the spectral analyzer **1040** is capable of determining different spectral signatures of tissue, for example, healthy tissue or unhealthy tissue, and is able to identify the type of tissue based on the spectral analysis. In another embodiment, the computer **1050** further analyzes the information from the spectral analyzer **1040** and outputs the information to a display. For example, the computer **1050** analyzes information taken by the forceps **10** at several locations at a cancer site to determine where a non-cancerous margin is located, for instance by comparing the spectral analysis done at each location to one another.

Once the margin is located, the forceps **10** can be used to treat the area without having to remove the forceps **10** from the patient. For example, and as described further below, after the optical fiber is removed, a second and/or a third instrument are inserted into the forceps **10** and are used to treat a patient. Alternatively, the optical fiber is not removed and is used to provide treatment to the tissue, for example a laser, such that additional instruments are optional. The optical fiber can then be reinserted into the forceps **10**, and the tissue is spectrophotometrically analyzed to determine if all of the cancerous tissue was treated, and/or if treatment is complete. Alternatively, fluid such as medicine is flushed through the forceps **10**, or a second instrument such as a needle, as further described below. Yet another option is to monitor a treated location, such as a treated cancer location, for example, to determine whether treatment was complete. The system is not limited to the diagnostic technique described above. Rather, the system according to the present invention is designed for use in methods utilizing any optically based diagnostic techniques, including laser induced fluorescence, time-resolved fluorescence, Raman spectroscopy, optical coherence tomography, etc. Alternative techniques of diagnosing tissue from the data received from the optical fiber will be known to those skilled in the art and will not be described further herein. In another option, the system is useful for optical therapeutic techniques, where the system includes an optical fiber useful for photo dynamic therapy (PDT), or the optical fiber is capable of providing a laser light.

The biopsy forceps **10** is shown in greater detail in FIG. **2**. The biopsy forceps **10** is adapted for tissue treatment and identification through an access lumen and by biopsy sampling. Further, the biopsy forceps **10** is adapted for use internally of the body, for example in connection with endoscopic, laparoscopic or vascular procedures. The forceps **10**, along with the optical fiber, is used, for example, to determine a location of a non-cancerous margin. In addition, the forceps **10** is useful for performing a therapeutic procedure, i.e. removing diseased tissue or treating tissue. In one example, the forceps **10** is used to treat tissue by transmitting a laser from the optical fiber.

The forceps **10** includes an elongated catheter body for introduction into the body and navigation to an area of interest. Forceps **10** includes a control handle portion **12** at a proximal end **15**, a middle portion **14** which extends over the main length of the device, and a distal end **16** which includes opposed forceps cutting jaws **120**, as is explained in greater detail below.

The main body or length of the forceps **10** consists of coaxial inner and outer tubular members **20**, **22**, as shown in

more detail in FIG. **3**. The outer tubular member **22** is small enough such that it can be inserted within a working channel of an endoscope. In one embodiment, the inner tubular member **20** is a stainless steel tube, and the outer tubular member **22** or catheter body is a coil. In another embodiment, the inner tubular member **20** comprises a coiled stainless steel tube. For either the inner tubular member **20** or the outer tubular member **22** having the coiled stainless steel configuration, the coil is a finely wound spiral coil of stainless steel as is generally known and used in catheters and guidewires. Alternatively, the outer tubular member **22** or the inner tubular member **20** could be made using a plastic tube, or a plastic/metal composite structure, in place of the coil.

The inner tubular member **20** is positioned within the outer tubular member **22** and these components are dimensioned with respect to each other so that inner tubular member **20** moves freely within the outer tubular member **22** to actuate the jaws, as is explained in more detail below. The inner tubular member **20** has a central access lumen **28** extending through the inner tubular member **20** from the proximal end **15** to the distal end **16**. The access lumen **28** is sized to receive the optical fiber **900** therethrough. The optical fiber **900**, in one embodiment, is removably disposed within the access lumen **28**. The access lumen **28** is sized larger than the optical fiber **900**, in one embodiment, such that a fluid (e.g. saline) can be flushed through the forceps **10** with or without the presence of the optical fiber **900** therein to clean the lumen **28**, the area of interest or to clean the distal portion of the optical fiber **900**. In another embodiment, a variety of medical instruments can be inserted through the lumen **28** when the optical fiber **900** is removed, as shown in FIGS. **16***a*–**16***g*, and as will be discussed further below. The inner tubular member **20** is coupled with an actuator housing **60**.

The actuator housing **60**, shown in more detail in FIGS. **4***a* and **4***b* is, in one embodiment, fabricated from stainless steel material. Alternatively, the actuator housing **60** can be formed from other substantially rigid materials. The actuator housing **60** extends from a first end **62** to a second end **64**, and generally comprises an elongate cylinder. In addition, the actuator housing **60** has flats **66** formed proximate the first end **62**. Disposed on the flats **66** are cam pins **68** having a generally circular cross-section, as shown. In one embodiment, the cam pins **68** are integral with the flats **66** of the actuator housing **60**. To form the cam pins **68** integrally with the flats **66**, the actuator housing **60** can be machined or molded from a single piece of material. Alternatively, the cam pins **68** can be integrally formed with the flats **66** by attaching the projections to the flats **66** using, for example, adhesive or welding processes. The cam pins **68** are for coupling with the jaws, as will be further explained below.

The actuator housing **60** has a bore **70** extending from the first end **62** to the second end **64**, where the bore has a first portion **72** and a second portion **74**. The first and second portions **72**, **74** form a shoulder **76** in between. The first portion **72** has a smaller diameter than the inner tubular member **20**, yet large enough to allow the optical fiber **900** to pass through the first portion **72**. In one embodiment, the first portion **72** is large enough to allow other medical devices to pass through, such as the devices shown in FIGS. **16***a*–**16***g*. The inner tubular member **20** is inserted within the second portion **74** of the actuator housing **60** until, in one embodiment, inner tubular member **20** contacts the shoulder **76** of the actuator housing **60**. In another configuration, the inner tubular member **20** can be placed proximate to shoulder **76**. The access lumen **28** of the inner tubular member **20** is substantially aligned with the bore **70** of the actuator housing **60**, thereby facilitating insertion of the optical fiber **900** or the medical devices through the access lumen **28** and through the bore **70**. The inner tubular member **20** is coupled with the actuator housing **60**, where in one embodiment, the inner tubular member **20** is secured to the actuator housing **60** with a weld **78**. Alternatively, the inner tubular member **20** can be joined with the actuator housing **60** by solder, brazing, or adhesive techniques as is known by those skilled in the art.

FIGS. **3**, **5***a* and **5***b* show the cutting jaws **120** in more detail. The cutting jaws **120** are comprised of a first jaw **122** and a second jaw **124** which, in one embodiment, are mirror images of each other. Since the first jaw **122** and the second jaw **124** are similar, only the first jaw **122** will be discussed. The jaw **122** has an actuation portion **132** and a cutting portion **136**. Within the cutting portion **136**, the jaw **122** has a hemispherical cup **126** with sharpened edges **130** for taking biopsy samples. The cup **126** of jaw **122** has, in one embodiment, a hole **128** disposed therein. The hole **128** advantageously facilitates cutting the biopsy sample at the site within the body, and also facilitates the removal of the biopsy specimens captured by each cup **126**.

Referring to the actuation portion **132**, the jaw **122** has a cut out **138** for forming a pivot point for the jaw **122**. The cut out **138** is generally circular in shape and sized to receive a projection of a distal housing, as will be further discussed below. The actuation portion **132** also includes a cam slot **140**, which in one embodiment is arcuately shaped. The cam slot **140** couples with the cam pin **68** of the actuator housing **60**. The cam slot **140** is sized to receive the cam pin **68** therein, and allows for radial movement of the jaw **122** about the pivot point as the cam pin **68** of the actuator housing **60** is moved along the axis of the biopsy forceps **10**. The movement of the jaw **122** about the pivot point allows for radial movement of the cutting jaws **120**, without axial movement of the cutting jaws **120**. This provides a further benefit since the jaws more accurately cut the biopsy sample at the exact position identified using the optical fiber **900**.

Biopsy forceps **10** also includes a distal housing **90**, as shown in more detail in FIG. **6**. The distal housing **90** is a generally elongate cylinder having a radial axis **106** and extending from a first end **92** to a second end **94**. The housing **90** is fabricated from, in one embodiment, stainless steel material. Disposed proximate the first end **92** are flats **96**. In one embodiment, the flats **96** each form a surface which is parallel to each other. The flats **96** each have a pivot pin **100** disposed thereon. The pivot pin **100** couples with the cut out **138** in each of the cutting jaws **120**, and allows the cutting jaws **120** to rotate about the pivot pin **100**. The flats **96** have a cut out **98** extending through the housing **90**. In one embodiment, the cut out **98** is generally square shaped and is disposed perpendicular to the radial axis **106** of the housing **90**, as shown in FIG. **6**. The cut out **98** is sized to allow the actuator housing **60** to travel along the radial axis **106** of the housing **90** sufficient to actuate the cutting jaws **120** without interference from the distal housing **90**.

Extending through the housing **90** is a bore **102**. The bore **102** is aligned with the radial axis **106** of the housing **90** and extends from the first end **92** to the second end **94**. The bore **102** has its largest diameter proximate the second end **94**, and tapers to a second bore portion **108**. The housing **90** has a third bore portion **110** proximate the first end **92** of the housing **90**. The bore **102** is sized to receive the outer tubular member **22** therein. The outer tubular member **22** is secured to the housing **90** by welding, brazing, soldering, adhesives,

or other equivalents known to those skilled in the art. The second bore portion **108** is sized to receive the actuator housing **60** therethrough, and to allow the actuator housing **60** to travel axially to actuate the jaws **120**. The third bore portion **110** is sized to freely receive the optical fiber **900** or medical devices such as those shown in FIGS. **16***a*–**16***g*, such that the fiber **900** or the devices can be used through the cutting jaws **120**.

Referring again to FIG. **1**, the biopsy forceps **10** includes the handle portion **12** for facilitating actuation of the inner tubular member **20**. The handle portion **12** includes a handle **42** and a translation member **46**, and loops **24**, **25**, **26**. Loops **24**, **25**, **26** are provided in the handle portion **12** to form finger holes useful in grasping and manipulating the forceps **10**. The handle **42** is fastened to the translation member with a fastener **44**. The inner tubular member **20** is fastened to the translation member by welding, brazing, soldering, adhesives, or other mechanical fasteners such that movement of the handle **42** results in movement of the inner tubular member **20**. In addition, a luer fitting **48** is threaded into the translation member **46**. The translation member **46** has a bore (not shown) therethrough, which provides a conduit between the luer fitting **48** and the inner tubular member **20**. The luer fitting **48** in combination with the bore of the translation member **46** provide access to the lumen **28** and allows for ease of cleaning and reusability of the biopsy forceps **10**. The handle portion **12** can include any type of actuating mechanism capable of imparting bidirectional axial movement to the inner tubular member **20** of biopsy forceps **10**.

Referring to FIGS. **1** and **2**, in operation, the handle **42** is retracted toward the back of handle portion **12** to close the jaws. Retraction of the handle **42** causes movement of the inner tubular member **20** and the actuator housing **60** toward the handle portion **12**, and closes the cutting jaws **120**. In this configuration, the distal end **16** of the forceps **10** is of the same narrow diameter as the main body of a forceps catheter, and the closed jaws have a smooth, rounded shape to facilitate introduction and navigation in the vascular, endoscopic or laparoscopic systems. In addition, the cutting jaws are coaxially positioned with respect to the distal end of the inner tubular member **20**.

The endoscopist advances the biopsy forceps **10** through a working channel of the endoscope to the general area of interest, i.e., such as a tissue site. Once in place in the general area of interest, the forceps jaws can be opened by advancing the handle **42** toward the distal end **16** of the forceps **10**, thereby advancing the translating member **46** away from the handle **42**. This causes the inner tubular member **20** to move away from the handle **42**, which in turn causes the actuator housing **60** to be axially moved towards the distal end **16** of the forceps. As the actuator housing **60** moves, the cam pins **68** on the actuator housing **60** move within the cam slots **140** of the cutting jaws **120**, causing the cutting jaws **120** to open.

When a biopsy area is identified by the optical fiber **900** using spectrophotometric analysis and/or selected by other methods, the area can now be treated through the lumen using various medical instruments, flushed with saline, or treated with medicine. If other medical instruments are necessary, the optical fiber **900** is removed from the lumen **28**, and a new instrument is inserted therein. If a biopsy of the area is necessary, the handle **42** is retracted toward the proximal end **15** of the forceps **10**, retracting the inner tubular member **20**, and causing the cutting jaws **120** to close and cut a biopsy sample at the exact place that had been treated and/or identified. As discussed above, tissue is identified by spectrophotometrically analyzing one or more tissue locations, for example, at a cancer site.

To take the tissue sample, the endoscopist holding the instrument by the handle portion **12**, gently pulls back on the handle **42**, retracting the inner tubular member **20**, and closing the cutting jaws **120** on the biopsy sample. When the jaws **120** are closed, the endoscopist pulls the entire assembly away from the tissue surface and out of the body. To retrieve the specimen sample from the cutting jaws **120**, an instrument is inserted into the hole **128** in the hemispherical cup **126** of one of the cutting jaws **120** or the cutting jaws **120** can be flushed with saline to remove the sample.

Referring to FIG. **7**, another embodiment of a biopsy forceps of the present invention is generally indicated by reference number **200**. The biopsy forceps **200** is generally similar to the biopsy forceps **10** shown in FIG. **1**, and accordingly, corresponding elements have been given the same reference number. The biopsy forceps is adapted for use internally of the body, for example in connection with endoscopic, laparoscopic or vascular procedures. The forceps **200** includes a handle portion **12** at the proximal end **15**, a middle portion **14** which extends over the main length of the device, and a distal end **16**. The distal end **16** includes forceps cutting jaws **120**.

The forceps **200** has a coaxial inner member **220** and an outer tubular member **222**, as shown in FIG. **8**. The outer tubular member **222** and the inner member **220** each extend generally from the proximal end **15** to the distal end **16** of the forceps **200**. The outer tubular member **222**, in one embodiment, comprises a finely wound spiral coil of stainless steel as is generally known and used in catheters and guidewires. Alternatively, the outer tubular member **222** could be made using a plastic tube, or a plastic/metal composite structure, in place of the stainless steel spiral coil. The outer tubular member **222** has a lumen therethrough which is sized to received the inner member **220** therein.

In one embodiment, the inner member **220** comprises a polymer tube which is extruded with a lumen **230** therein. Alternatively, the inner member **220** comprises a plastic tube or a combination of metal and plastic. The lumen **230** is sized to receive an optical fiber **250** therein. Secured to at least a portion of the optical fiber **250**, the inner member **220** forms a cladding for the optical fiber **250**. In addition, grooves **232**, **234** are formed in the perimeter of the inner member **220**. The grooves **232**, **234** form a cavity within the inner member **220** and can also take the form of an indentation or a lumen. In another embodiment, the grooves **232**, **234** are disposed on opposite sides of the lumen **230**. Positioned within the grooves **232**, **234** of the inner member **220** are a pair of control wires **240**, **241**, which in one embodiment comprise stainless steel cables. These components, together with outer tubular member **222** and inner member **220** extend over the main length of the device, from the distal end **16** to the handle portion **12** (FIG. **7**).

The handle portion **12** includes a translating member **244**, which in one embodiment, comprises an aluminum block. The handle **242** is fastened to the translation member **244** with fastener **44**. Both the inner member **220** and the control wires **240**, **241** are secured to the translating member **244**, shown in more detail in FIG. **9**. The translating member **46** has a projection **246** for securing the inner member **220** with the handle **242**. The projection **246**, comprising a generally elongate cylinder, has ridges **248**, **249** disposed around the perimeter of the projection **246**. The ridges **248**, **249** of the projection **246** engage the lumen **230** of the inner member **220** and prevent the inner member **220** from disengaging

from the handle **242**. The control wires **240**, **241** are secured to the translating member **244** by either welding, soldering, brazing, adhesives, a mechanical fastener, or other alternatives as known by those skilled in the art.

The inner member **220** and the control wires **240**, **241** are secured to translating member **244** which together, in one embodiment, form an actuator mechanism for the forceps **200**. Movement of translating member **244** causes axial movement of the inner member **220** and the control wires **240**, **241** relative to outer tubular member **222**, which is used to actuate the cutting jaws **120**. Loops **226**, **227**, and **228** are provided in handle portion **12** to form finger holes useful in grasping and manipulating the forceps **200** (FIG. **7**).

The inner member **220** extends from the handle portion **12** to the distal end **16**. Coupled to the inner member **220** and the control wires **240**, **241** at the distal end **16** is an actuator housing **260**. The actuator housing **260**, shown in more detail in FIG. **10** is, in one embodiment, fabricated from stainless steel material, and generally comprises an elongate cylinder. The actuator housing **260** extends from a first end **262** to a second end **264**, and has flats **266** formed proximate the first end **262**. Disposed on the flats **266** are cam pins **268** having a generally circular cross-section, as shown. In one embodiment, the cam pins **268** are integral with the flats **266** of the actuator housing **260**. To form the cam pins **268** integrally with the flats **266**, the actuator housing **260** can be machined or molded from a single piece of material. Alternatively, the cam pins **268** can be integrally formed with the flats **266** by attaching the cam pins **268** to the flats **266** using, for example, adhesive or welding processes. The cam pins **268** are for coupling with the jaws **120**, as will be further explained below.

The actuator housing **260** has a bore **270** which extends through the actuator housing **260** from the first end **262** to the second end **264** and is sized to receive the optical fiber **250** therethrough. The bore **270** of the actuator housing **260** aligns with the lumen **230** of the inner member **220** so that access to the distal end **16** is not prevented. The bore **270** allows for the optical fiber **250** to be inserted through the inner tubular member **220** and through the actuator housing **260** to the cutting jaws **120**.

The actuator housing **260** has attachment features so that the inner member **220** can be coupled with the actuator housing **260**. In one embodiment, the actuator housing **260** has ridges **272** disposed about the perimeter of the actuator housing **260**, proximate to the second end **264**. The ridges **272** engage the surface of the lumen **230** to retain the inner member **220** on the actuator housing **260**. Alternatively, the actuator housing **260** can be coupled with the inner member **220** in other manners, for example, adhesives. The control wires **240**, **241** are also secured to the actuator housing **260**. In one embodiment, the control wires **240**, **241** are secured to the actuator housing at reference number **255** by either welding, soldering, brazing, adhesives, or a mechanical fastener. During use, both the actuator housing **260** and the control wires **240**, **241** provide the axial force to the actuation portion **132** of the cutting jaws **120**.

The biopsy forceps **200** has a distal housing having the same structure as discussed above, and as shown in FIG. **6**. The outer tubular member **222** of the biopsy forceps **200** is secured to the housing, as in the previous embodiment, and therefore will not be further discussed. The biopsy forceps **200** also includes cutting jaws **120**.

The cutting jaws **120** are also the same as in the previous embodiment, and one of the cutting jaws **120** is as shown in FIGS. **5***a* and **5***b*. Referring to the actuation portion **132**, the jaw **122** has a cut out **138** and a cam slot **140**. The cut out **138** forms a stationary pivot point for the jaw **122**, and receives the pivot pins **100** of the housing **90** therein. The cam slot **140** couples with the cam pins **268** of the actuator housing **260**, and allows for radial movement of the jaw **122** about the pivot point as the cam pins **268** of the actuator housing **260** are moved along the axis of the biopsy forceps **200**. A further benefit is obtained since the cutting jaws **120** do not move axially during the cutting process. Instead, the cutting jaws **120** rotate about the stationary pivot point. This allows for more precise cutting of the biopsy site identified by the optical fiber.

During operation, referring to FIG. **7**, the handle **242** is retracted toward the back of handle portion **12** to close the jaws. This causes movement of the inner member **20**, the control wires **240**, **241**, and the actuator housing **260** toward the handle portion **12**, and closes the cutting jaws **120**. In this configuration, the distal end **16** of the forceps **10** is of the same narrow diameter as the main body of a forceps catheter, and the closed jaws have a smooth, rounded shape to facilitate introduction and navigation in the vascular, endoscopic or laparoscopic systems. In addition, the cutting jaws are coaxially positioned with respect to the distal end of the inner tubular member.

Once in place in the general area of interest, the cutting jaws **120** can be opened by pushing handle **42** of the control handle forward, away from the handle portion **12**. This causes movement of the translation member **244**, the inner member **220**, the control wires **240**, **241**, and the actuator housing **260** away from the handle portion **12**. The control wires **240**, **241** and the inner member **220** push against the actuator housing **260**. As the actuator housing **260** moves away from the handle portion **12**, the cam pins **268** on the actuator housing **260** move within the cam slots **140** of the cutting jaws **120**, and cause the jaws **120** to open. The distal end **16** of the forceps **10** is positioned at the area of contact. The optical fiber **250**, when connected to the electro-optic diagnostic apparatus, can then be used for optical biopsy to perform histopathological analysis of the tissue site. When an area of disease is identified and a biopsy of the area is needed, the handle **242** is pulled toward the proximal end **15** of the forceps **10**, causing the jaws **120** to close and cut a biopsy sample. The biopsy sample is cut from the exact tissue site identified as the biopsy site without requiring moving or repositioning of the catheter body. The forceps may then be withdrawn from the patient to recover the sample for analysis. The analysis of the withdrawn sample can be conducted using known laboratory techniques to confirm the identification of the tissue sample.

FIG. **11** illustrates another embodiment of an optical biopsy forceps **280**. The optical biopsy forceps **280** includes cutting jaws **304**, a coaxial inner member **276** and an outer tubular member **278** which each extend proximate the distal end of the forceps **280**. In one embodiment, the inner member **276** is extruded with a lumen **282** therein. Alternatively, the inner member **276** comprises a plastic tube or a combination of metal and plastic. The lumen **282** is sized to receive an optical fiber **900** therein.

The inner tubular member **276** is positioned within the outer tubular member **278** and these components are dimensioned with respect to each other so that inner tubular member **276** moves freely within the outer tubular member **278** to actuate the jaws **304**. The optical fiber **900**, in one embodiment, is removably disposed within the lumen **282**. The inner tubular member **276** is coupled with an actuator housing **290** such that movement of the inner tubular member **276** causes movement of the actuator housing **290**.

The actuator housing **290** is, in one embodiment, fabricated from stainless steel material. Alternatively, the actuator housing **290** can be formed from other substantially rigid materials. The actuator housing **290** includes at least one pin **292**. The pins **292** are adapted to couple with a link coupling **297** of a first and second link **296, 298**.

The actuator housing **290** has a bore **294** therethrough, which allows passage of the optical fiber **900** therethrough. The bore **294** of the actuator housing **290** is aligned with the lumen **282** of the inner tubular member **276**, thereby facilitating insertion of the optical fiber **900**, or other medical device through the access lumen **282** and through the bore **294**. The inner tubular member **276** is coupled with the actuator housing **290**, where in one embodiment, the inner tubular member **276** is secured to the actuator housing **290** with a weld. Alternatively, the inner tubular member **276** can be joined with the actuator housing **290** by solder, brazing, or adhesive techniques.

The cutting jaws **304** are comprised of a first jaw **306** and a second jaw **308**. The cutting jaws **304** each have a cut out **310** for forming a pivot point for each jaw **304**. The cut out **310** is generally circular in shape and sized to receive a projection of a distal housing **284**, as will be further discussed below. The cutting jaws **304** each have a coupling **312** for attaching the jaws **304** with a link coupling **297** the first and second links **296, 298**. In one embodiment, the coupling **312** comprises a lug **314** disposed on the jaws **304**, which couples with the link coupling **297** of the first and second links **296, 298**.

The forceps **280** also includes a distal housing **284**. The distal housing **284** includes at least one pivot pin **286** disposed thereon. Each pivot pin **286** is adapted to couple with the cut out **310** in each of the cutting jaws **304**, and allows the cutting jaws **304** to rotate about the pivot pin **286**. The distal housing **284** has a lumen **288** therein which allows passage of the optical fiber **900** therethrough.

In an alternative embodiment, control wires (See FIGS. **7–9**) could be coupled with the first and second links **296, 298**. For this configuration, the control wires would apply an axial force to the first and second links **296, 298**, and would be used to rotate the cutting jaws **304** about the pivot pins **286**. In addition, the inner tubular member **276** would be directly coupled with the distal housing **284**.

During operation, the handle **42** (FIGS. **1** and **2**) is retracted to close the jaws **304**. Retraction of the handle **42** causes axial movement of the inner tubular member **276** and the actuator housing **290** toward the handle **42**, and closes the cutting jaws **304**. After the endoscopist advances the biopsy forceps **280** through a working channel of the endoscope to the general area of interest, the jaws **304** can be opened by advancing the handle **42** toward the distal end of the forceps **280**. Advancing the handle **42** causes the inner tubular member **276** to move away from the handle **42**, which in turn causes the actuator housing **290** to be axially moved towards the distal end of the forceps. As the actuator housing **290** moves, the first and second links **296, 298** push upon the jaws **304** causing the first and second links **296, 298** to rotate around the couplings on both the actuator housing **290** and the jaws **304**. As the links rotate, the cutting jaws **304** rotate about the pivot pins **286** on the distal housing **284** and move to an open position. Optionally, a removable optical fiber is inserted into a lumen of the inner tubular member.

The above described embodiment provides many advantages over conventional forceps. For instance, the inner member **220** and the control wires **240, 241** (FIGS. **7**) both actuate the radial movement of the cutting jaws **120**. The combination of devices allows the operator to apply more axial force to the inner member **220** and the control wires **240, 241** thereby resulting in additional torque to the cutting jaws **120**. The additional torque provides better cutting actuation, particularly in biopsy sites with tissue that is difficult to cut with the relatively small cutting jaws **120**. Another advantage of this embodiment is that the biopsy forceps is disposable, although the biopsy forceps can be reusable. Forming the inner member **220** from the polymer material helps to provide an inexpensive forceps **10** for disposal after use. In addition, using disposable biopsy forceps eliminates the chance of contamination between patients where a biopsy forceps is disposed after use on one patient, which is ideal for patients with highly contagious and dangerous diseases or patients highly susceptible to infection.

FIGS. **12***a* and **12***b* illustrate yet another embodiment of the present invention. A biopsy forceps **300** is provided having multiple access lumens. The general configuration of the biopsy forceps **300** is the same as the first discussed embodiment where an inner tubular member **320** is slidably received by an outer tubular member **340**. The inner tubular member **320** actuates the cutting jaws **120**, as discussed above. In one embodiment, the inner tubular member **320** has a plurality of lumens disposed therein. In at least one of the lumens, an optical fiber is disposed therethrough. The plurality of lumens allow for other components or materials (such as fluids) to be inserted through the inner tubular member simultaneously with the optical fiber. Alternatively, in another embodiment, a gap **316** between the inner surface of the outer tubular member and the outer surface of the inner tubular member **320** provides a secondary lumen **318**. The secondary lumen **318** allows for fluids such as saline or medicine to be administered to the biopsy area. During use, the fluids travel through the secondary lumen **318** and are expelled through openings between the distal housing **90** and the cutting jaws **120** (FIG. **3**) to treat the biopsy area. Access to the primary lumen is at a primary port **334**. To access the secondary lumen **318** or the multiple lumens described above, a secondary port **332** is provided proximate the handle portion **12**. The secondary port, in one embodiment, comprises a luer fitting as known by those skilled in the art.

FIGS. **13** and **14** illustrate another embodiment of the present invention. In this configuration, a biopsy forceps **400** are provided with cutting jaws **480**, a handle portion **412**, and a main body **414** in between. The main body **414** has an inner tubular member **420**, which actuates the cutting jaws **480** and is disposed within an outer tubular member **422**, as discussed above. Disposed within the inner tubular member **420** is an optical fiber **450**. A third tubular member **424** is coupled with the main body **420**. In one embodiment, the third tubular member **424** is secured to the outer surface of the outer tubular member **422** as shown in FIG. **14** by welding, brazing, soldering, or adhesive. In another embodiment, a polymer heat-shrink jacket **426** is placed over the outer tubular member **422** and the third tubular member **424** to thereby couple the third tubular member **424** with the outer tubular member **422**. The outer jacket coating provides the forceps **400** with a smooth surface for ease of use within the patient.

In another embodiment of the invention, the above biopsy forceps **500** are provided with electro-cauterizing capability. In this configuration shown in FIGS. **15***a* and **15***b*, using the biopsy forceps **500** as described above, a connector pin **510** is provided on the handle portion **12**. The connector pin **510**

forms an electrical connection which is compatible with standard electro/surgical equipment. In one embodiment, a protective collar **522** surrounds the connector pin **510**, preventing inadvertent contact with the connector pin **510**. The collar **522** protects the connector pin **510** from being damaged. The inner tubular member **520** comprises a stainless steel tube, which is coupled with the connector pin **510**. Alternatively, the inner tubular member **520** comprises a polymer tube with steel control wires, as described above. During use, a radio frequency current is coupled with the connector pin **510**. The connector pin **510** allows a current path to the stainless steel tube, or the stainless steel pull wire, depending on the embodiment. The current path would follow the stainless steel tube or wires to the cutting jaws disposed at the distal end of the biopsy forceps. The jacket **426** acts as an insulator over the length of the forceps **500**, with the metallic jaws acting as the cauterizing device. The connector pin **510**, as known by those skilled in the art, is coupled with equipment having the electro-surgical standard for radio frequency current. The radio frequency current allows for cauterizing capability of the biopsy forceps **500** in the biopsy site using either mono or bipolar modes.

The lumen of the above biopsy forceps allows for a number of medical instruments to be inserted through the biopsy forceps once the optical fiber is removed, and the instruments are also axially aligned with the cutting jaws. Another embodiment of the present invention includes medical devices slidably engaged within the access lumen **630** of biopsy forceps **600**. As shown in FIGS. **16***a*–**16***e*, many instruments can be inserted into the lumen **630** of the inner tubular member **620**, including, but not limited to: ultra sonic probe **710**, guidewires **712**, a snare **714**, a cytology brush **716**, and a needle **718**. In addition, the area to be sampled by the biopsy forceps **600** can be flushed with saline **720**, medicine, or other fluids as shown in FIG. **16***f*. In another example, the area to be treated and/or sampled by the biopsy forceps **600** can be flushed with medicine through an instrument, such as the needle **718**. Alternatively, suction can be applied to the lumen **630** for removing excess loose material or fluid from the biopsy site. As shown in FIG. **16***g*, each instrument is inserted into an access port **650** and extends through a translating member **646**, through a middle portion **675**, and through cutting jaws **680** of the forceps **600**. The instruments are used for treating the tissue in the area adjacent the distal end of the forceps **600**, which is aligned with the axis of the lumen **630**.

The present invention has provided a biopsy forceps having an access lumen and an optical fiber. An important feature of the invention is that the lumen of the inner tubular member is coaxial with the zone where the two jaws intersect and the sample is taken. Thus, there is no offset error between the spot where the various medical instruments or treatments are used and the spot from which the biopsy sample will be taken. In addition, the physician has more options in treating the area where the biopsy sample is taken. For instance, the area can first be flushed with saline, or treated with medicine. The biopsy forceps provides a further advantage in that an area can be treated with saline and/or with medicine without having to remove the biopsy forceps from the body. Alternatively, one of many instruments can be used to treat the biopsy area prior to the biopsy. These features, together with the slim and compact profile of the device when the jaws are retracted, are a great improvement over prior art devices. One of the advantages of forceps **10** as compared to forceps **200** is, because the control wires **240**, **241** are not required, a larger diameter lumen can be used to accommodate larger sized instruments.

A further advantage of the present invention is that since the optical fiber **900** is removable from the biopsy forceps **10**, the biopsy forceps **10** is reusable. When the optical fiber **900** needs to be replaced, the entire biopsy forceps **10** does not need to be discarded. Instead, a new optical fiber **900** is inserted through the central access lumen **28** when the use of the previous optical fiber **900** is exhausted. Removing the optical fiber **900** from the biopsy forceps **10** also allows for the forceps **10** to be cleaned and sterilized more extensively using more strenuous processes. After removal of the optical fiber **900**, and sterilization of the forceps **10**, the optical fiber **900** can be re-inserted or another optical fiber **900** is inserted into the forceps **10**. In some sterilization techniques, the optical fiber **900** degrades during the cleaning process. Thus, removing the fiber **900** during the more strenuous cleaning processes prolongs the useful life of the optical fiber **900**.

It will be appreciated from the foregoing that the biopsy forceps and system provides the physician a greater degree of accuracy and control over the biopsy, treatment and sampling process than was previously possible.

It is to be understood that the above description is intended to be illustrative, and not restrictive. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

What is claimed is:

1. A system comprising:

biopsy forceps comprising:

a flexible outer tubular member having a first lumen therethrough, the outer tubular member extending from a proximal end to a distal end and adapted for insertion into a working channel of an endoscope;

cutting jaws mounted proximate to the distal end of the outer tubular member for selective opening and closing in a biopsy cutting movement, the cutting jaws mounted with the closed cutting position coaxially aligned with the first lumen;

an inner tubular member having a second lumen therethrough, the inner tubular member extending through the first lumen of the outer tubular member and operatively connected to open and close the cutting jaws;

an optical fiber removably disposed within the second lumen of the inner tubular member, the optical fiber extending from a proximal end to a distal end and adapted at its proximal end for connection to an electro-optical histopathological diagnostic apparatus system;

an actuator mechanism coupled with the proximal end of the outer tubular member and the inner tubular member, where the actuator mechanism is operatively coupled with the inner tubular member; and

an access port communicatively coupled with the second lumen; and

an electro-optical diagnostic apparatus for optical biopsy and histopathological analysis of tissue, the diagnostic apparatus comprising:

a source of optical radiation coupled with the optical fiber, the source of optical radiation providing optical radiation entering the proximal end of the optical fiber; and

a diagnostic member coupled with the biopsy forceps, the diagnostic member for analyzing returned illumination entering the distal end of the optical fiber to provide a diagnosis of the tissue.

2. The system as recited in claim 1, wherein the inner tubular member is adapted to cause radial movement of the cutting jaws about at least one fixed pivot pin upon axial movement of the inner tubular member.

3. A method of obtaining a biopsy sample at a site within a body, comprising:

introducing into the body an integrated biopsy forceps having a flexible outer tubular body;

inserting a removable optical fiber into a lumen in an inner tubular member disposed within the outer tubular body;

translating the inner tubular member towards a distal end of the forceps to open the cutting jaws coupled with the distal end of the forceps;

performing spectrophotometric analysis to locate a desired biopsy site while the optical fiber is disposed within the inner tubular member; and

translating the inner tubular member toward the proximal end of the forceps to close the cutting jaws and cut a biopsy sample.

4. The method as recited in claim 3, further comprising withdrawing the biopsy sample from the body.

5. The method as recited in claim 3, further comprising removing the optical fiber from the lumen, and sterilizing the biopsy forceps for re-use.

6. The method as recited in claim 3, further comprising removing the optical fiber from the lumen and inserting a first instrument through the lumen placing a proximal end of the instrument proximate to the cutting jaws.

7. The method as recited in claim 6, further comprising removing the first instrument and inserting a second instrument through the lumen placing a proximal end of the second instrument proximate to the cutting jaws.

8. The method as recited in claim 3, further comprising removing the optical fiber from the lumen and flushing the biopsy area with fluid.

9. The method as recited in claim 3, further comprising flushing fluid through the lumen while the optical fiber is disposed within the lumen.

10. The method as recited in claim 3, wherein performing spectrophotometric analysis includes performing spectrophotometric analysis at several tissue locations at a cancer site.

11. The method as recited in claim 10, further comprising determining a location of a non-cancerous margin.

12. The method as recited in claim 3, further comprising removing the optical fiber and inserting a second instrument and a third instrument and performing a treatment.

13. The method as recited in claim 12, wherein performing the treatment includes performing a cancer treatment.

14. The method as recited in claim 13, further comprising reinserting the optical fiber, and spectrophotometrically analyzing whether cancerous tissue was treated.

15. The method as recited in claim 14, further comprising monitoring a treated location.

16. The method as recited in claim 3, further comprising electrocauterizing tissue at the biopsy site.

17. The method as recited in claim 3, further comprising inserting an ultrasonic probe into the lumen of the inner tubular member.

18. The method as recited in claim 3, further comprising inserting a brush into the lumen of the inner tubular member.

19. The method as recited in claim 3, further comprising inserting a snare into the lumen of the inner tubular member.

20. The method as recited in claim 3, further comprising inserting a needle into the lumen of the inner tubular member.

21. The method as recited in claim 20, further comprising flushing a medicine through the needle.

22. The method as recited in claim 3, further comprising removing diseased tissue from the body.

23. The method as recited in claim 3, further comprising treating tissue with the optical fiber.

24. A method of obtaining a biopsy sample at a site within a body, comprising:

introducing into the body an integrated biopsy forceps having a flexible outer tubular body;

inserting an optical fiber into a lumen in an inner tubular member disposed within the outer tubular body;

coupling the optical fiber with an electro-optical histopathological system;

translating the inner tubular member towards a distal end of the forceps to open the cutting jaws coupled with the distal end of the forceps;

analyzing information transmitted by the optical fiber;

translating the inner tubular member toward the proximal end of the forceps to close the cutting jaws and cut a biopsy sample; and

withdrawing the biopsy sample from the body.

* * * * *

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摘要(译)

提供活检钳装置，用于在身体内的部位获得组织样本或出于治疗原因移除组织，同时通过活检钳的进入腔保持对该部位的进入。该装置包括细长的管状主体，用于引入身体并导航到感兴趣的区域。具有内腔或多个内腔的内管状构件从近端到远端延伸穿过或邻近外管状构件，其中提供切割钳口。切割钳可旋转地安装在装置的远端，并且由内管状构件的运动控制。内管状构件与手柄部分连接，允许控制近端处的切割钳口。在近端处获得进入内管状构件的内腔，其中提供鲁尔接头。内管状构件的内腔具有穿过其设置的可移除光纤或允许插入各种医疗器械，使得器械可以在与采集活检样本的位置相同的位置同轴使用。