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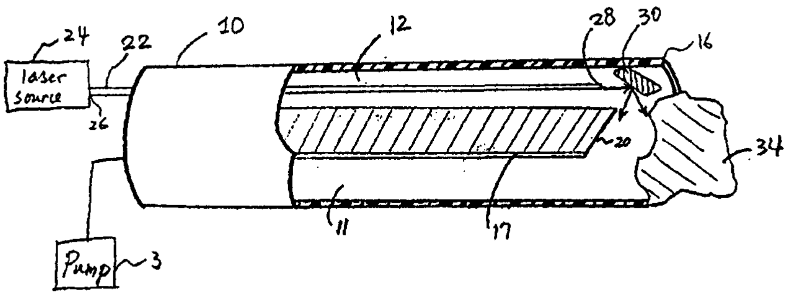

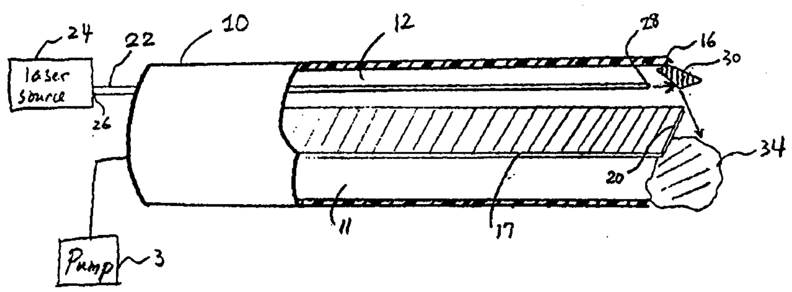

(57) Abstract

A medical device is provided which comprises a suction conduit and an energy-transmitting conduit wherein at least some of the transmitted energy is directed to the distal region of the suction conduit. The device may include an optical apparatus for directing the energy. The device has applications in lithotripsy and tissue-removal in a patient.

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LASER LITHOTRIPSY DEVICE WITH SUCTION

Cross-Reference to Related Applications

This application claims the priority to and the benefit of U.S. provisional patent application serial number 60/120,666 filed on February 19, 1999, which is incorporated by reference in its entirety.

Technical Field

The present invention relates to methods and devices for destroying and removing unwanted materials such as calculi, deposits and tissues (for example, polyps, tumor cells) from body lumens, and more particularly to laser lithotripsy treatment of urinary stones.

Background Information

Open surgical intervention was once the standard treatment for the removal of calculi or stones, especially when such calculi are deposited in a body lumen other than the bladder. But other less invasive techniques have emerged as safe and effective alternatives. Lithotripsy, the crushing of stones that develops in the body into fragments that are easier to remove, is one such technique. Lithotripsy devices have been developed which utilize electrohydraulic probes, ultrasonic probes, electromechanical impactors, or a pin driven by compressed air. These devices typically use percutaneous endoscopic techniques and are configured to be introduced into the body through small puncture sites to avoid open surgical intervention. Focused shock waves can also be delivered from an external source in a non-invasive procedure known as extracorporeal shock wave lithotripsy (ESWL).

Recently, lasers have been used as an alternative source of energy in lithotripsy, especially for the destruction of renal and bilary stones. Lasers are suited for minimally invasive lithotripsy because the diameter of the laser fiber is small and the aperture of the working channel can be minimized. An extensive review of the use of lasers for lithotripsy is provided in the book entitled "Laser Lithotripsy," edited by R. Stein, Springer Verlag, 1988. A fiber optic that travels along the longitudinal axis of a rigid or flexible endoscope typically transmits the laser beam. Various types of laser lithotripsy systems with a variety of laser sources, including pulsed dye laser, alexandrite laser, neodymium laser and holmium laser, have been developed.

A common problem in intracorporeal lithotripsy treatment is the difficulty in restricting target movement. For example, when using pulsed lasers such as the holmium yttrium-aluminum-garnet (Ho:YAG) laser, higher frequency pulsation and higher energy in each pulse produce quicker fragmentation of the stone, but also produce significant stone mobility, which decreases treatment efficiency. Lower frequency of pulsation and lower pulse energy may result in less significant stone mobility, but the treatment time will be prolonged. Regardless of energy level of each emission, stones of smaller sizes present an inherent mobility problem. Incomplete lithotripsy treatment of smaller stones or debris can leave a nidus for future stone growth.

Another problem often encountered by a lithotripsy endoscopist involves the suction tube that is found in some endoscopes. Such a conduit is generally connected to a pump that produces a vacuum when in operation and clogging at distal ends by stones and their fragments has been widely reported. *See, e.g.* U.S. Patent No. 4,146,019 to Bass et al. Severe clogging may necessitate repeated removal, cleaning and reinsertion of the endoscope during an operation.

Summary of the Invention

An object of the present invention is thus to restrict the movement of targets of lithotripsy treatment, especially small stones and stone fragments. Another object of the invention is to remove stone fragments resulting from a lithotripsy treatment in a more complete and immediate manner. Yet another object of the invention is to solve the problem of clogging at the distal region of a suction conduit used in lithotripsy.

The present invention provides devices and related methods for the destruction and removal of unwanted materials such as calculi, deposits and tissues (e.g., polyps and tumor cells) from a patient's body lumen. The invention achieves these objects by combining a suction conduit with a high-energy delivery system such that at least some of the high energy transmitted is directed to a region near the distal end of the suction conduit. For example, some of the energy can be directed inside, outside, at the face of the tip or a combination thereof. As a result, the energy destroys materials stuck at the distal end of the suction conduit and provides the user with a suction device that is equipped with a non-clogging tip.

The devices of the invention comprises a suction conduit connected to a pump for suction and a second conduit connected to an energy source for transmitting high energy. Once the suction conduit is in operation, it keeps stones or stone fragments near its tip, stabilizing the movement of the stone. The second conduit is designed to direct a portion of the high energy into, across, and/or outside of the distal end of the suction conduit and thus onto the stones or stone fragments. The energy fragments, pulverizes or erodes stones, including those caught by the force of suction onto the tip of the suction conduit, into smaller parts or dusts, and the suction conduit can instantaneously evacuate the stone debris. For example, in a preferred embodiment where Ho:YAG laser is used as the energy source, the laser energy continues to break down fragments that are still too large to enter the suction conduit while knocking them off the suction tip temporarily thus preventing clogging of the tip. A portion of the energy may also be directed into a portion of the lumen of the suction conduit, thereby preventing clogging that would have occurred after debris entered the conduit.

The devices and methods of the invention take full advantage of the suction force in removing debris instantaneously from the site of the treatment, allowing a more complete and speedy treatment. Also, by directing a high energy towards the distal region of the suction conduit, the devices point the energy into a region where targets are accumulated and relatively immobilized by the suction. The devices and methods thus offer enhanced treatment efficiency by permitting a more thorough removal of debris and by avoiding operational difficulties associated with a clogged suction conduit.

In one aspect, the devices of the invention can also be equipped with structures such as barriers or shields in the distal region of the suction conduit to help block large particles. In another aspect, the devices of the invention use multiple energy conduits bundled or dispersed in or around the wall of the suction conduit. Yet in another aspect, the devices use multiple conduits bearing indicia or marking that permit their identification during a procedure. In still another aspect, the devices of the invention direct energy towards the distal region of the first suction conduit with or without a separate optical apparatus such as mirrors, lenses, prisms for example.

The devices and methods of the invention can be used for the removal of stones and calcifications throughout the body. First, the device is inserted into the body lumen of a patient and the distal end of the suction conduit is positioned near a stone. Then, a high energy is transmitted by the energy conduits and directed to the distal region of the suction conduit, thereby breaking up stones stuck at the distal region and removing its fragments through suction.

The devices can also be utilized for the removal of soft tissue such as polyps or tumor cells. For example, the device is first inserted into the body lumen of a patient and the distal end of the suction conduit is positioned near the tissue to be removed. Then, a high energy is transmitted by the energy conduits and directed to the distal region of the suction conduit and thereby shearing off the tissue and removing it through suction. Additionally, the devices can be used for orthopedic applications and endoscopic applications such as arthroscopy and endoscopic retrograde cholangio-pancreatiography (ERCP).

The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the claims.

Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

FIG. 1A is a perspective view of an embodiment of a medical device with two conduits configured in accordance with the subject invention.

FIG. 1B is a perspective view of an embodiment of a medical device with two conduits and an energy-directing apparatus configured in accordance with the subject invention.

FIGS. 2A-2D are longitudinal cross-section views of various embodiments of the distal end of the suction conduit taken along line 6-6 in FIG. 1A.

FIG. 2E is a perspective view of an embodiment of a suction conduit with a mesh-cap in accordance with the subject invention.

FIG. 2F is a perspective view of an embodiment of a device with a curved barrier at the distal end of the suction conduit in accordance with the subject of the invention.

FIG. 3A is a perspective view of an embodiment of a device with an energy-transmitting conduit that has endoscopically discernable external markings in accordance with the invention.

FIG. 3B is a perspective view of an embodiment of an energy-transmitting conduit with an alternative marking pattern in accordance with the invention.

FIG. 3C is an elevated perspective view of an embodiment of a medical device with a twisted bundle of laser fibers in accordance with the invention.

FIG. 4 is a partly cross-sectional view of an embodiment of a laser lithotripsy device with a housing configured in according with the invention.

FIG. 5A is a perspective view of an embodiment of a device with a multi-channel housing configured in accordance with the invention.

FIG. 5B is a longitudinal cross-section view of the device in FIG. 5A taken along line 6-6 in FIG. 5A.

FIGS. 6A-6C are schematic views of modified distal ends of laser fibers in accordance with the invention.

FIG. 7A is a schematic longitudinal cross-section view of an angled tip of a laser fiber manufactured by etching.

FIG. 7B is a side view of laser fiber tip applied with a reflective coating in accordance with the invention.

FIGS. 8A-8B are partly cross-sectional views of embodiments of a laser lithotripsy device with an optical apparatus configured in accordance with the invention.

FIG. 9 is a schematic longitudinal cross-section view of an embodiment of the invention with an optical apparatus.

FIG. 10A is a perspective view of an embodiment of a device with multiple channels for laser fibers surrounding a suction conduit.

FIG. 10B is a radial cross-section view of the device in FIG. 10A taken along line 6-6 in FIG. 10A.

FIG. 11 is a schematic view of a tissue-removing device with an optical apparatus in accordance with an embodiment of the invention.

Description

Definition

Distal region: a region near or around, both inside and outside and including, an end that is farther away from the origin of attachment.

Conduit: a channel or a tubing for conveying energy or matter.

Detailed Description

The devices and methods of the present invention combine an energy-transmitting means with a suction means to enhance the efficiency of material removal from a body lumen. In doing so, they solve both the problem of calculi mobility and clogging at the distal region of a suction means used in such medical procedures. The devices comprise at least a suction conduit and a high-energy conduit, and the energy transmitted is at least partly directed to the distal region of the suction conduit. Other elements such as viewing instruments, an illumination means or an irrigation conduit can be further combined with these elements.

Referring to FIGS. 1A and 1B, an embodiment of the devices of the present invention comprises a suction conduit **1** and an energy-transmitting conduit **2**. The suction conduit **1** is connected at its proximal end to a pump **3** that creates a vacuum. The energy-transmitting conduit **2** is connected at its proximal end to a high-energy source **4** and transmits and directs the high energy to the distal region **5** of the suction conduit **1**. The suction conduit **1** and the energy-transmitting conduit **2** can be co-extruded, otherwise attached to each other or remain separate. Further, one can be inside the other. Directing the high energy to the distal region **5** may be achieved without additional apparatuses, as in FIG. 1A, or may involve at least one additional optical apparatus **30**, as illustrated in FIG. 1B.

The suction conduit can be made of a variety of flexible or rigid materials or a combination of both, such as stainless steel or plastics. To improve conduit's resistance against kink-formation or against collapse under vacuum pressure, and to preserve flexibility in the meantime, either or both of the conduits can be braided or wound with fibers made of materials such as metals or plastics. The conduit may have coatings on its inside or outside for various purposes, for example, for protection against corrosion by body fluids or for insulation against the high energy emitted towards its distal region. It can be of any dimension convenient for its intended use. It can be further inside a housing or a sheath. It can house the energy-transmitting conduit by itself. It can be fixedly integrated into a larger instrument or slidingly inserted into the instrument such as described in U.S. Patent No. 4,146,019 to Bass et al., incorporated herein by reference. A stainless steel conduit can be passed through a rigid endoscope. A suction conduit made of a flexible material (such as plastic or a super elastic alloy such as Nitinol) can be passed through a flexible endoscope. A preferred embodiment is an elongated polypropylene tubing of 1/8 inch outside diameter that can be used in an endoscope. The devices of the invention may include multiple suction conduits.

The proximal end of the suction conduit is connected to a pump **3**, which provides a vacuum when operated. A control mechanism can be further added to the system to modulate the intensity of the vacuum.

The distal end **8** of the suction conduit **1** may assume any shape convenient for its intended use. For example, a suction conduit **1** may have a planar face **7** at its distal end, as depicted in FIGS. 2A and 2B. In FIG. 2B, the face **7** of the distal end is at a beveled angle to the conduit **1**'s longitudinal axis. The face **7** may also assume a curved form, for example, ellipsoidal as shown in FIG. 2C. Alternatively, as shown in FIG. 2D, the suction conduit **1**'s distal end may contain at least one side aperture **39**. Configurations of the distal end such as those in FIGS. 2B-2D will effectively provide at least one side opening, resulting in direct flow **41** from both the side and the front of the suction conduit **1**. Where the devices of the invention are used to remove materials from the walls of a body lumen, embodiments having side openings are preferable, because these side openings readily access target materials, avoiding having to bend the tip. Furthermore, the distal end of the suction conduit can be made of a material different from the body of the conduit. For example, one might want to make the distal end with a more heat-resistant material to withstand high energy directed to it. It may also be desirable to use a more impact-resistant material to withstand the initial impact from stones drawn by the suction force.

Additional structures at the distal region may help prevent clogging of the suction conduit. For example, a filter, a screen, a mesh, a shield or other barriers can be molded onto or otherwise attached to the distal region of the suction conduit. Referring to FIG. 2E, a mesh **9** is attached onto the distal end **8** of the suction conduit **1**. The mesh **9** may be placed further inside or outside the distal end **8**. Alternatively, several such barriers may be placed along the length of the suction conduit **1**.

FIG. 2F shows an example of a barrier positioned outside the distal end of the suction conduit. A channel **12** enclosing an energy-transmitting conduit (a laser fiber **22** in this case) is inserted directly in the suction conduit **1**. The distal end of the channel **12** is a curved barrier **25**, forming a cap over the distal end **8** of the suction conduit **1**, and leaving a gap **33** preferably for about 1-10 mm. The gap **33** is set to admit stone fragments having a size smaller than the suction conduit **1** or than the space between the suction conduit **1** and the channel **12**. The distal end **28** of the laser fiber **22** is disposed in the distal region of the channel **12**. In the particular embodiment in FIG. 2F, the end **28** is outside the barrier **25**, but it can be flush with or receded closely inside the barrier **25**. Also, there may be multiple laser fibers enclosed in the channel **12**. The barrier **25** can be made of any solid material that can withstand the energy emitted from the distal end **28** and be of sufficient hardness to withstand the impact of stones drawn by the suction force. The barrier **25** is preferably made of light-transmitting materials such as glass or quartz so that it acts as a lens for the laser emitted from the tip **28**. The tip **28** can be inside, flush with or outside the barrier **25** and it may be modified, as detailed in later sections, to diffuse or deflect light side-wise or backward. Once the pump **3** is in use, fluid flow will direct mobile particles, such as stone fragments **39**, towards the periphery of the barrier **25** and away from the fiber tip **28**. As a result, particles must go through the gap **33** between the barrier **25** and the distal end **8** to enter the suction conduit **1**. The size of barrier **25** can vary as long as the gap **33** is narrow enough to effectively prevent clogging of the suction conduit. In embodiments where the energy-transmitting conduit is closely receded inside the barrier **25**, the large surface area of the barrier exposed to the flow of liquid will help cooling the barrier off rapidly.

The invention contemplates energy sources known to one of ordinary skills in the medical profession for fragmenting, coagulating, or vaporizing various unwanted materials from a body lumen. Such an energy could be mechanical, electric, chemical or a combination thereof. The energy may be delivered in the form of heat, electric current, sparks, laser radiation, radio frequency (RF), ultrasonic wave, mechanical vibrations, ballistic impact, hydraulic shock or chemical corrosives. These techniques are well known in the art and are described in publications, such as U.S. Patent Nos. 5,281,231 to Rosen et al. and 5,443,470 to Stern et al., and "The Swiss Lithoclast: a New Device for Intracorporeal Lithotripsy" by Denstedt et al. in September 1992's The Journal of Urology; the entirety of all three are incorporated herein by reference.

In a preferred embodiment, the energy is laser energy with a wavelength that is highly absorbable in a liquid medium. Typically such wavelength regions are the mid-infrared portion of the spectrum from about 1.4 to about 11 micrometers and in the ultraviolet portion of 190-350 nanometers. Lasers which can be utilized in the present invention are thulium (Th), holmium (Ho), Erbium:yttrium-aluminum-garnet (Er:YAG), HF, DF, CO, and CO_2 in the mid-infrared region, and excimer lasers in the ultraviolet region.

In a preferred embodiment, Ho:YAG laser is utilized. The holmium laser is useful because it produces fine dust and small debris rather than stone chunks, and thus facilitates removal of the stone. The Ho:YAG laser can be used not only for the treatment of calculus, but also for soft tissue. The holmium laser energy is typically transmitted through a fiber. When a holmium laser, after travelling the length of the fiber, is fired into a liquid medium the laser energy produces a vaporization bubble.

The Ho:YAG laser produces light at a wavelength of 2.0 to 2.1 microns, depending on the precise formulation of the holmium rod, in a pulsed fashion. In one configuration, the laser produces light at a wavelength of 2.09 microns. These wavelengths are well absorbed by water and other liquid mediums. All stones in a body lumen (including cystine calculi) absorb this wavelength well, regardless of the stone color because of the water in the stone and on the stone surface. This is a major improvement over previous laser sources such as pulsed dye laser, the effectiveness of which depends on pigmentation on the target. The pulse duration of Ho:YAG laser also produces photoacoustic effects that aid stone fragmentation. In a particular embodiment, the Sharplan 2025 Holmium:YAG Surgical Laser is utilized as a source of laser energy.

In suitable laser systems, the energy of each pulse and the pulsation frequency can be varied. Generally, high frequency of pulsation and high energy produce a quick fragmentation but also produces a significant amount of stone mobility. Lower frequency of pulsation and lower energy is more precise but the overall treatment time is prolonged. High frequency of pulsation and high energy can be used by the devices of the present invention because the suction force limits stone movement. By combining suction with a laser delivery system in accordance with the methods of the invention, the overall efficiency of treatment is improved. In particular, higher powers, more efficient lasers, such as holmium lasers, can be used even when small stones are present because the suction helps keep the small stones in the path of the laser. Preferably, the energy levels used are between about 0.2 and 2.8 Joules per pulse and the frequency is between about 5 and 20 Hertz. Typical pulse durations are about 200-400 microseconds. Preferably, the pulse duration is 250 microseconds.

Referring again to FIGS. 1A and 1B, a high-energy source **4** is connected to the proximal end of the energy-transmitting conduit **2**. This conduit **2** should be made of a material that is suitable for the transmission of the energy used in the device and variables of its dimension (such as length, diameter and shape) should be suitable for the intended use of the device. It can be further inside a housing or a sheath, such as the suction conduit itself. The invention can have more than one conduit transmitting the high energy. Some or all of them can be fixedly integrated into a larger instrument or slidingly inserted into an instrument.

In a preferred embodiment, this energy-transmitting conduit is a low density, optical quartz fiber that can be used to transmit laser energy. Generally, the laser fiber extends from about 50 to 500 cm. Preferably, the laser fiber extends from about 80 to 100 cm. These fibers range in their core size from about 200 to 1000 microns. Preferably the core size of the laser fiber is between 300 and 550 microns.

In another embodiment, the medical device comprises a plurality of mobile components within a housing, and at least one of the mobile components has a discernable pattern of indicia disposed on the outer surface of its distal region. The plurality of mobile components may be at least two of any components of a medical device used in a body lumen, including but not limited to, laser fibers, fiber optics, catheters and guidewires.

For example, in FIGS. 3A and 3B, the energy-transmitting conduit **2** is a laser fiber jacketed with a pattern of indicia **23** that aids detection of its movement inside a body lumen through a viewing instrument. An example of a viewing instrument is an endoscope that contains a fiber optic illumination source and a fiber optic lens for viewing. Typically, the scope view **29** shows a small section of the laser fiber near the fiber's distal end. However, commercially available laser fibers generally have no distinguishing marking on the outside--they are generally jacketed in a monochromatic (e.g., black) and glossy plastic wrapping. One aspect of the invention is to provide discernable markings or indicia **23** for the energy-transmitting conduit and other mobile components in the device. The markings only needs to appear on the section that is to be seen through the viewing instrument--in the case of an endoscope, the distal region of the fiber visible under the scope view **29**. The spiral and checkered patterns, as shown in FIGS. 3A and 3B respectively, are examples of preferred embodiments because these patterns indicate, in the scope view **29**, conduit movements both along and about the longitudinal axis. Further, the energy-transmitting conduit and any tubular components (such as a guidewire) viewable through the endoscope should have different markings for the user to tell them apart.

This can be accomplished through different colors or patterns. This inventive aspect contributes to the overall goal of the invention when movements of the components are desired for operating the device or the movements actually take place, and where direct visual monitoring of such movements will aid the operation of the device.

To make components of the devices further discernable when combined with a viewing instrument such as an endoscope, a non-reflective or low-reflective coating as a pattern of indicia can be applied to these conduits to soften light reflected from them. In an endoscope with a means of illumination, the light is often so intense that the user finds it difficult to view through the viewing instrument. A coating that reduces light reflection from the laser fiber jacket, for instance, will solve that problem.

Referring to FIG. 3C, multiple laser fibers **13-15** are housed in a channel **12** of a larger instrument, such as an endoscope and the arranged fibers provide markings, as a whole, that are endoscopically discernable. There can be a variety of ways of bundling multiple conduits, such as spirally twisting the bundle (as in FIG. 3C), braiding into a bundle, gluing, tying or fitting tightly into a channel of a housing. Twisting, braiding or otherwise tightening the association of multiple fibers retains much of the flexibility of individual fibers. It is easier to move bundled fibers than unbundled ones inside a housing, whether along or about the housing's longitudinal axis. In a preferred embodiment, each of the three fibers is jacketed in a sleeve of a different color, forming an overall spiral pattern when inserted into an endoscope. The same principle applies to other numbers of energy-transmitting conduits as long as endoscopically discernable patterns are provided by the overall bundle.

Directing at least a portion of the energy emitted towards the distal region of the suction conduit can be accomplished with the laser fiber itself as an integral optical feature or with a separate optical apparatus.

For example, spatial relationship between the two conduits is one solution. In FIG. 4, a suction conduit, channel **11,** is integral to an instrument **10** that houses a laser-transmitting fiber **22** inside its other channel **12**. A divider **17** having a distal end **20** partly separates channel **11** from channel **12**. The housing **10** has a distal end **16** that comes into contact with a stone **34** that is to be removed. The laser fiber **22** is connected to a laser source **24** at its proximal end **26**. The laser fiber **22**'s distal tip **28** is close to both the distal end **16** of the housing **10** and the distal end **20** of the divider **17,** so that stones caught at either of the distal ends **16** and **20** can be exposed to laser radiation emitted from tip **28**.

In the particular embodiment shown in FIG. 4, both the laser fiber's distal tip **28** and the divider **17**'s distal end **20** are disposed within the distal end **16** of the housing **10**. This illustration is not meant to put any structural limit on the devices of the invention. In other embodiments, both or either of the distal tip **28** and the distal end **20** may be flush with the distal end **16** of the housing or may extend beyond it so long as at least a portion of the laser radiation from tip **28** can effectively fragment a stone caught at the distal region of the suction conduit **11**.

In FIGS. 5A-5B, the divider **17** is positioned so that it facilitates the placement of a laser fiber **22** at a beveled angle with the longitudinal axis of the housing **10**, thereby directing laser radiation emitted from tip **28** of the energy-transmitting conduit **22** towards the distal region of suction conduit **11**. Furthermore, because the diameter of the suction conduit increases towards its proximal end, clogging along the body of the suction conduit is prevented.

In other embodiments, a portion of the energy emitted from the tip **28** may be directed towards the distal end of the suction conduit through modifications to the energy-transmitting conduit. For example, the distal end of a typical, commercially available laser fiber can be modified so that a larger surface area will be radiated by the laser. FIGS. 6A-6C disclose examples of modifications with various optical lenses disposed at the laser fiber tips to diffuse the laser energy. These optical lenses are easily manufactured by removing the plastic jacket from the distal region of the fiber, then using a torch to thermally heating up the remaining optical core at the distal end, including its usual silicon clad. The tip will melt, and after cooling off in room temperature, will form a ball as shown in Fig. 6A. If the molten tip is pressed against a nonporous, flat surface at a right angle, a flat-end tip resembling that shown in FIG. 6B will result. Further pressing the same flat surface on the lateral sides of the tip will result in an extended tip resembling what is shown in FIG. 6C. An extended tip, of about 5 mm, is especially advantageous for continued use of the same laser fiber.

Other means of affecting the direction of laser path without resorting to additional apparatus include etching near the distal end of the energy-transmitting conduit or bending the distal tip for side-firing (described in U.S. Pat. No. 5,416,878 and incorporated herein by reference). Cutting at multiple spots in the distal region of a laser fiber results in light emission along the distal region, in addition to the distal end. FIG. 7A provides a specific example of etching, where the distal end **28** of a laser fiber is cut so that an angled tip is formed. In a schematically depicted laser fiber **22**, laser light **42** travels along the optical core **37** via bouncing between the silicon clad **36**, which is further wrapped in a plastic jacket **35**. As shown here, because in the angled tip, one side of the fiber is longer than the other, some of the laser light **42** will be deflected side-wise once it reaches the end of the optical core **37**.

Reflective coatings on the laser fiber may also be used to affect the laser path. Referring to FIG. 7B, a portion of the distal region of the laser fiber **22** has been stripped of the plastic jacket **35** and the silicon clad **36** (therefore "unclad"), and at least one layer of reflective coating **50** has been selectively applied to the remaining unclad optical core, including the distal face **48**. The reflective coating **50** is not applied to certain areas on the unclad optical core so that reflected laser light can "escape" from these areas and reach a target such as the distal region of the suction conduit. Depending on the effectiveness of the coatings, however, some of the light might still go through the coated areas.

An optic, separate from the energy-transmitting conduit may be placed near the distal end of the energy-transmitting or of the suction conduit to help direct the emitted energy towards the distal region of the suction conduit. In preferred embodiments where the energy is a Ho:YAG laser, the devices of the invention include an optical apparatus.

Several optics known in the art that guide laser emission to a certain area can be used in the invention. They can be a surface, a series of surfaces, a medium, a series of media, or a combination of any of the above that alters the path of light. For example, a light diffusing apparatus is described in U.S. Patent No. 5,151,096 to Khoury, incorporated herein by reference. Examples of other optics include and are not limited to a lens, a mirror (U.S Pat. No. 4,445,892), a series of mirrors (U.S. Pat. No. 5,496,306), a prism (U.S. Pat. No. 5,496,309) and a parabolic reflector (U.S. Pat. No. 4,672,961) (the disclosure of these patents are incorporated herein by reference).

In the present invention, the optical apparatus is operatively associated with the two conduits to help direct laser light from the distal end of the energy-transmitting conduit toward the distal region of the suction conduit. In FIGS. 8A-8B, an embodiment has an optical apparatus **30** coupled near the distal end **16** of a housing similar to that shown in FIG. 4. In the embodiment shown in FIG. 8A, the divider **17** is receded proximal to the optical apparatus **30**, which, in turn, is receded inside the distal end **16** of the housing **10**. In the embodiment shown in FIG. 8B, the divider **17** extends all the way to the distal end **16** of the housing **10**, and the optical apparatus **30** is also positioned more outward. The angle of the optical apparatus **30** may be varied to direct a larger portion of the energy emitted from the laser fiber **22** inside, across or outside the face of the distal end **16**.

The optical apparatus **30** can be made of a variety of materials that are known in the art to be suitable for reflecting, deflecting, diffusing, or refracting the particular energy emitted from the tip **28** of the laser fiber. Such materials include, but are not limited to, crystal, quartz, garnet, stainless steel or gold. The optical apparatus **30** may assume a variety of configurations such as a planar surface, an ellipsoidal surface, a convex surface or a pyramid.

The device with an optical apparatus may utilize Ho:YAG laser energy which produces a vaporization bubble, a semi-circle of energy, extending from the tip of a firing laser fiber to a target stone when the laser tip is immersed in liquid. While the body lumen where the device is operating generally has plenty of water, a separate irrigation conduit can be added to the device to ensure that the tip is constantly immersed in water. The optical apparatus **30** in FIGS. 8A and 8b directs the vaporization bubble (not shown) into the distal region of the suction conduit **11** and onto the stone **34**. A shock-wave is then produced by the collapse of the vaporization bubble at the interface between water and the stone.

Referring to FIG. 9, another preferred embodiment of the device has a reflective surface **31** (a mirror, for example) fixedly attached to the distal end of an energy-transmitting conduit (a laser fiber **22** in this case). A housing **32**, preferably made with a light-transmitting hard material such as quartz, fixedly encloses the distal region of the laser fiber **22**. The housing **32** protects the laser fiber **22** and acts as a lens for the laser. Laser energy emitted from distal end **18** of fiber **22** is reflected by the reflective surface **31** and travels through the housing **32** to the distal region of the suction conduit **11**. Alternatively, the housing can be made of an opaque material with an opening for the laser light to travel to the distal region **5** of the suction conduit **11**.

Different embodiments and various features of the invention can be combined in the same device in accordance with the invention. An embodiment may contain multiple optical features and any of the distal barriers mentioned earlier. For example, multiple laser fibers modified with an optical lens-tip as illustrated in FIGS. 6A-6C, and braided together as shown in FIG. 3C, may be disposed inside the distal end of the barrier **25** of the device shown in FIG. 2F--the barrier **25** is made of glass, quartz or sapphire and serves as a lens at the same time.

There are several ways to direct a larger portion of emitted energy towards the distal region **5** of the suction conduit. In one embodiment, the diameter of the energy-transmitting conduit is increased. In other embodiments, an optical apparatus is added. Alternatively, more energy-transmitting conduits can be incorporated into the device. In a preferred embodiment, these conduits are intertwined and bundled before being incorporated into the device. Again, all these measures can be implemented in the same embodiment. In another preferred embodiment shown in FIGS. 10A and 10B, multiple energy-transmitting conduits such as multiple laser fibers **22** are housed in multiple channels of a housing **10**. In this particular embodiment, these channels surround the suction conduit **1**. Some of the channels may enclose other functional components. As shown in FIGS. 10A and 10B, one of the channels is an irrigation channel **45**, which transfers a cooling agent from an irrigation source **38**. Another channel contains a guidewire **46**. Two other channels each contain a pullwire **47**. A pullwire is a wire fixedly attached to the distal end **16** of an endoscopic instrument and a user can deflect the distal end **16** upon pulling such a wire.

The devices of the invention may be combined with, or incorporated into, a catheter, an endoscope or other medical devices customarily used for the destruction and removal of unwanted materials from body lumens. Preferably, when incorporated into an endoscope, the devices of the invention combine a guidewire, a fiber optic for illumination, a fiber optic for visualization, a conduit for irrigation and pullwires for active deflection.

The devices of the invention have applications in lithotripsy. In the methods of the invention, the device **10** shown in FIGS. 10A and 10B, is placed with its distal end **16** in the vicinity of a calculus. Upon application of vacuum in the suction conduit **1**, the suction pulls large stone fragments toward the distal end **16** of the housing **10**. The laser system **24** delivers laser energy to the tip of the laser fibers **22**. The laser energy is then emitted from the tip of the laser fibers **22**. The laser energy may be in the form of a vaporization bubble. Optionally, an optical apparatus further directs the laser energy released from the laser fiber **22** into, across the face of, and/or outside of the suction conduit **1** and onto a stone. The laser energy impacts the stone caught by the suction at the distal region of the suction conduit **1**, causing it to be propelled off the tip and fragmented into smaller stone fragments. The suction then pulls the smaller fragments back into the distal region of the conduit **1**. Fragments small enough will enter the suction conduit and be evacuated from the treatment site. Large fragments will be held at the distal end of the suction conduit. The laser energy impacts the stone fragment causing it to be propelled off the tip and fragment into even smaller fragments. This process is repeated until the stone fragments are small enough to be all evacuated through the suction conduit **1**. Directing at least some of the laser energy into the suction conduit **1** keeps the conduit clear of obstruction.

In addition to removing stones, the devices of the invention can be utilized to remove soft tissue, for example, to facilitate the treatment of tumors or soft growths in both the gastrourinary

(GU) and the gastrointestinal (GI) tract. Specifically, the devices can be utilized to shear off and evacuate soft tissue such as polyps. Papillary lesions can be fragmented and evacuated while the base of the lesion is coagulated.

In one embodiment for treatment of soft tissue, illustrated in FIG. 11, the laser lithotripsy device is modified to facilitate the removal of polyps. The tip **28** of the laser fiber **22** and the optical apparatus **30** attached to the distal end **16** are both disposed within the channel **12** about 2 millimeters from the distal end **16**. Soft tissue **40** such as a polyp or tumor is sucked into the suction channel **11**, is sheared off by the laser energy emitted by the laser fiber **22**, and then is evacuated by the suction. The angle of the optical apparatus **30** may be varied to change the direction of the laser energy emitted from the tip **28**. The laser lithotripsy device with an angled laser fiber tip but without a separate optical apparatus may also be modified to accommodate soft tissue by moving the tip **28** of the laser fiber **22** further within the channel **12** several millimeters from the distal end **16**. Alternatively, the device can be equipped with fluoroscopic guidance so that the laser can be directed onto the polyp or tumor.

Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and the scope of the invention as claimed. Accordingly, the invention is to be defined not by the preceding illustrative description but instead by the spirit and scope of the following claims.

What is claimed is:

1. A medical device, comprising:

a first conduit having a proximal end connected to a pump which provides suction at a distal region of the first conduit; and

a second conduit having a proximal end connected to a high energy source and which transmits a high energy to a distal end;

wherein the distal end of the second conduit directs at least a portion of the high energy emitted to at least a portion of the distal region of the first conduit.

2. The device of claim 1, wherein the high energy is of at least one of the following forms: heat, electricity, light, sound, radio frequency, mechanical forces or chemical agents.

3. A lithotripsy device, comprising:

a first conduit having a proximal end connected to a pump which provides suction at a distal region of the first conduit; and

a second conduit having a proximal end connected to a laser energy source and which transmits a laser energy to a distal end;

wherein the distal end of the second conduit directs at least a portion of the laser energy emitted to at least a portion of the distal region of the first conduit.

4. The device of claim 3, wherein the first conduit comprises at least one opening on its side.

5. The device of claim 3, further comprising a barrier disposed near the distal region of the first conduit.

6. The device of claim 3, wherein the second conduit is inside the first conduit.

7. The device of claim 3, wherein the second conduit comprises endoscopically discernable markings.

8. The device of claim 3, wherein the first conduit or the second conduit or both comprise a non-reflective coating or a low-reflective coating.

9. The device of claim 3, further comprising a channel for illumination and a channel for visualization.

10. The device of claim 3, further comprising a guidewire.

11. The device of claim 3, further comprising a pullwire.

12. The device of claim 3, wherein the second conduit is at least one laser fiber.

13. The device of claim 12, wherein the second conduit comprises multiple laser fibers.

14. The device of claim 13, wherein the multiple laser fibers intertwine together in a bundle.

15. The device of claim 12, wherein the laser fiber comprises an optical core and the optical core further comprises an enlarged distal end.

16. The device of claim 12, wherein the laser fiber has an angled tip.

17. The device of claim 12, wherein a distal region of the laser fiber comprises an unclad optical core and a reflective coating.

18. The device of claim 12, wherein a distal region of the laser fiber defines at least one side opening to allow emission of laser energy along the laser fiber's distal region, in addition to its distal end.

19. The device of claim 12, wherein the laser energy is a holmium laser.

20. A lithotripsy device, comprising:

a first conduit having a proximal end connected to a pump which provides suction at a distal region of the first conduit; and

a second conduit having a proximal end connected to a laser energy source and which transmits a laser energy to a distal end;

an optical apparatus which directs at least a portion of the laser energy emitted from the distal end of the second conduit to at least a portion of the distal region of the first conduit thereby preventing or breaking up unwanted materials clogging at the distal region of the first conduit.

21. The device of claim 20 wherein the optical apparatus is a mirror.

22. The device of claim 20 wherein the optical apparatus is a lens

23. The device of claim 20, further comprising a barrier disposed near the distal region of the first conduit.

24. The device of claim 23, further comprising a housing having a distal end, and wherein the distal end of the second conduit is receded inside the distal end of the housing.

25. A lithotripsy method comprising the steps of:

a. providing a first conduit having a proximal end connected to a pump which provides suction at a distal region of the first conduit;

b. providing a second conduit having a proximal end connected to a high energy source and which transmits a high energy to a distal end;

c. inserting both conduits into a body lumen of a patient and positioning the distal region of the first conduit near a calculus in the body lumen;

d. directing at least a portion of the high energy emitted from the distal end of the second conduit to at least a portion of the distal region of the first conduit and a portion of the calculus; and

e. removing the calculus fragmented by the high energy through the first conduit.

26. A tissue-removing method, comprising the steps of:

a. providing a first conduit having a proximal end connected to a pump which provides suction at a distal region of the first conduit;

b. providing a second conduit having a proximal end connected to a high energy source and which transmits a high energy to a distal end;

c. inserting both conduits into a body lumen of a patient and positioning the distal region of the first conduit near a tissue in the body lumen;

d. directing at least a portion of the high energy emitted from the distal end of the second conduit to at least a portion of the distal region of the first conduit and a portion of the tissue; and

e. removing tissue separated from the body by the high energy through the first conduit.

27. A medical device comprising multiple mobile components wherein at least one of said mobile components comprises a distal region bearing a discernable pattern of indicia.

28. The device of claim 27, wherein at least one of the mobile components is a laser fiber.

29. The device of claim 27, wherein the discernable pattern of indicia comprises a non-reflective coating or a low-reflective coating.

30. A medical device comprising a laser fiber having a distal region bearing a discernable pattern of indicia.

31. The device of claim 30, further comprising another mobile component having a distal region bearing another discernable pattern of indicia.

32. The device of claim 31, wherein said another mobile component is a guidewire.

33. A medical device comprising multiple laser fibers, wherein the multiple laser fibers are associated in a bundle.

34. The device of claim 33, wherein the multiple laser fibers intertwine together in a bundle.

FIG. 1A

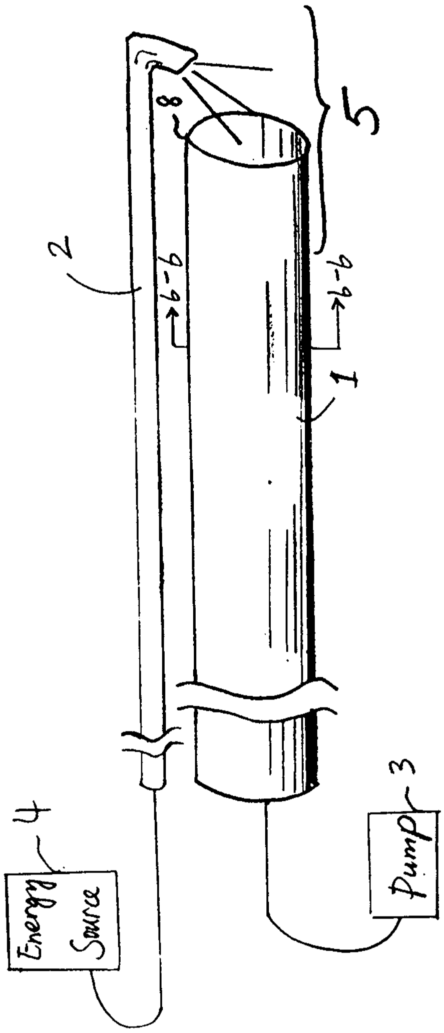
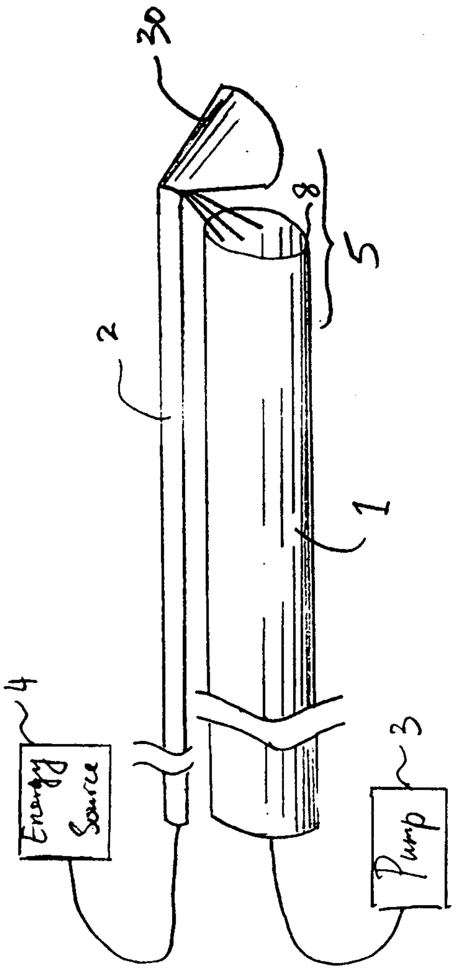

2
8
5
6-6
6-6
1
4
Energy Source
Pump
3

FIG. 1B


30
8
5
2
1
4
Energy Source
Pump
3

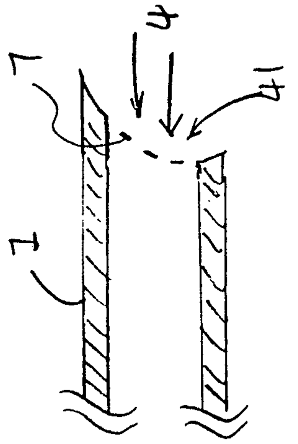


FIG. 2C

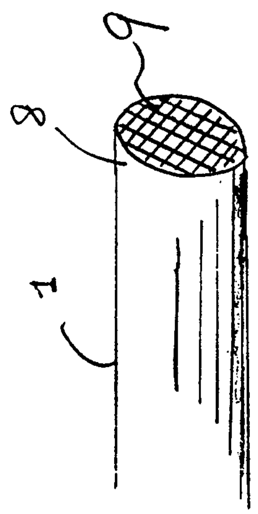


FIG. 2E

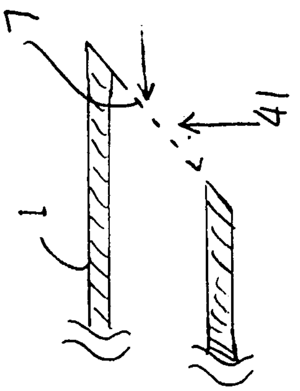


FIG. 2B

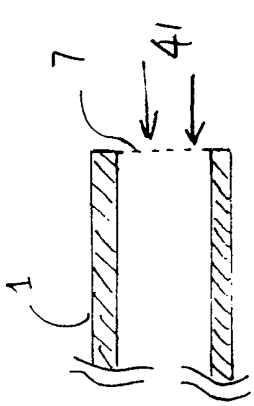


FIG. 2A

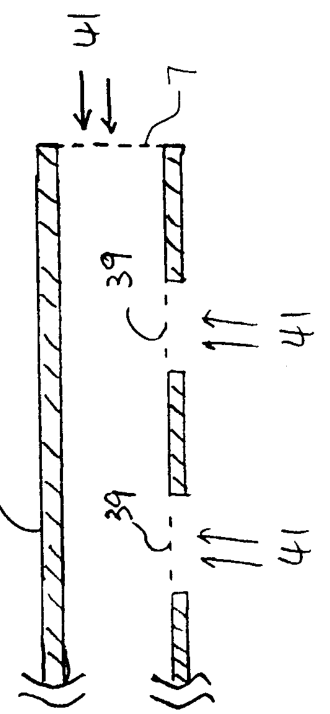


FIG 2D

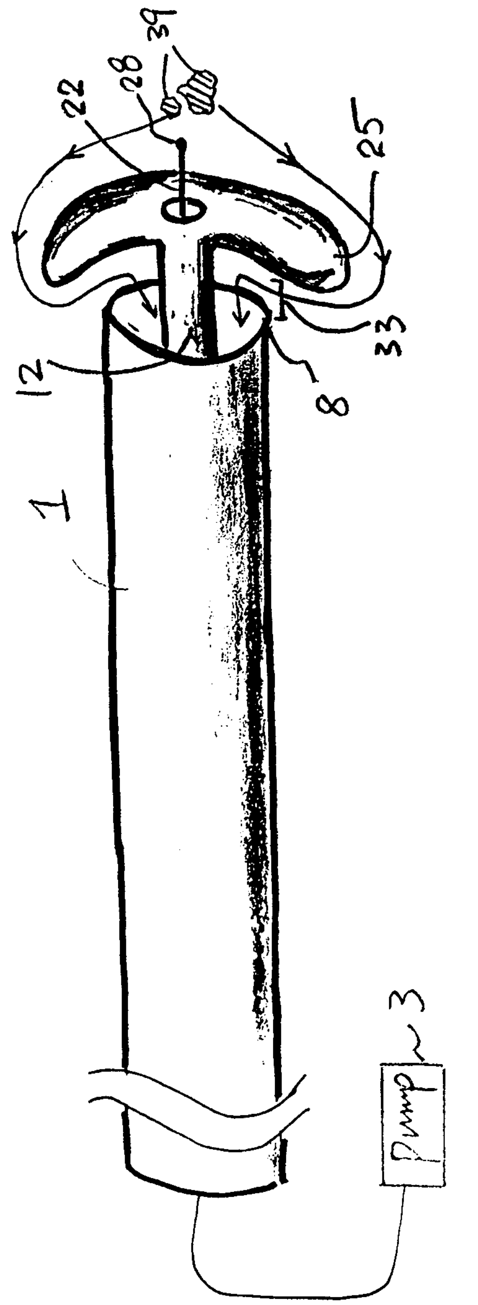


FIG 2F

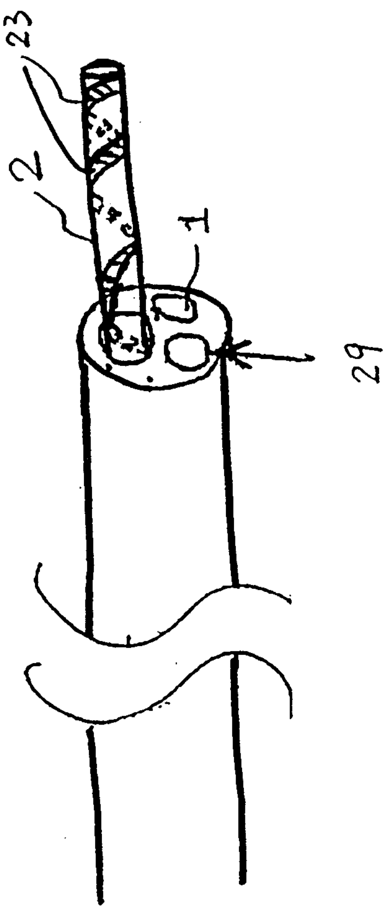


FIG. 3A

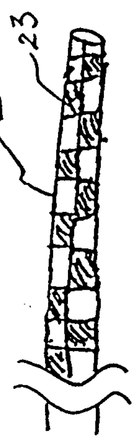


FIG. 3B

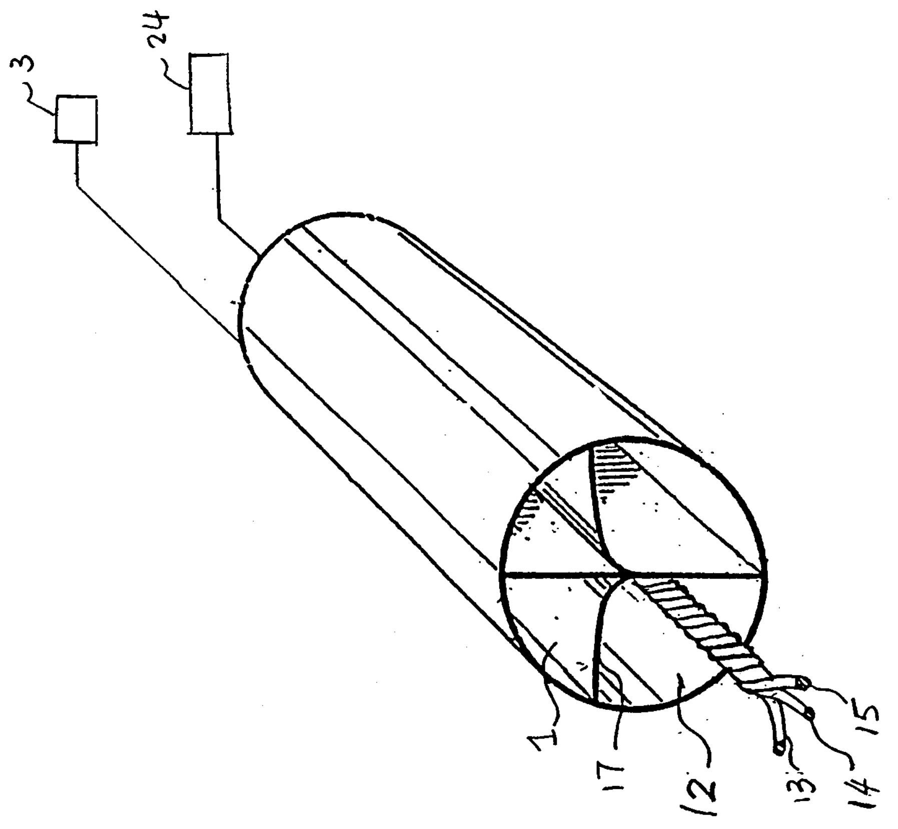


FIG. 3C

FIG. 4

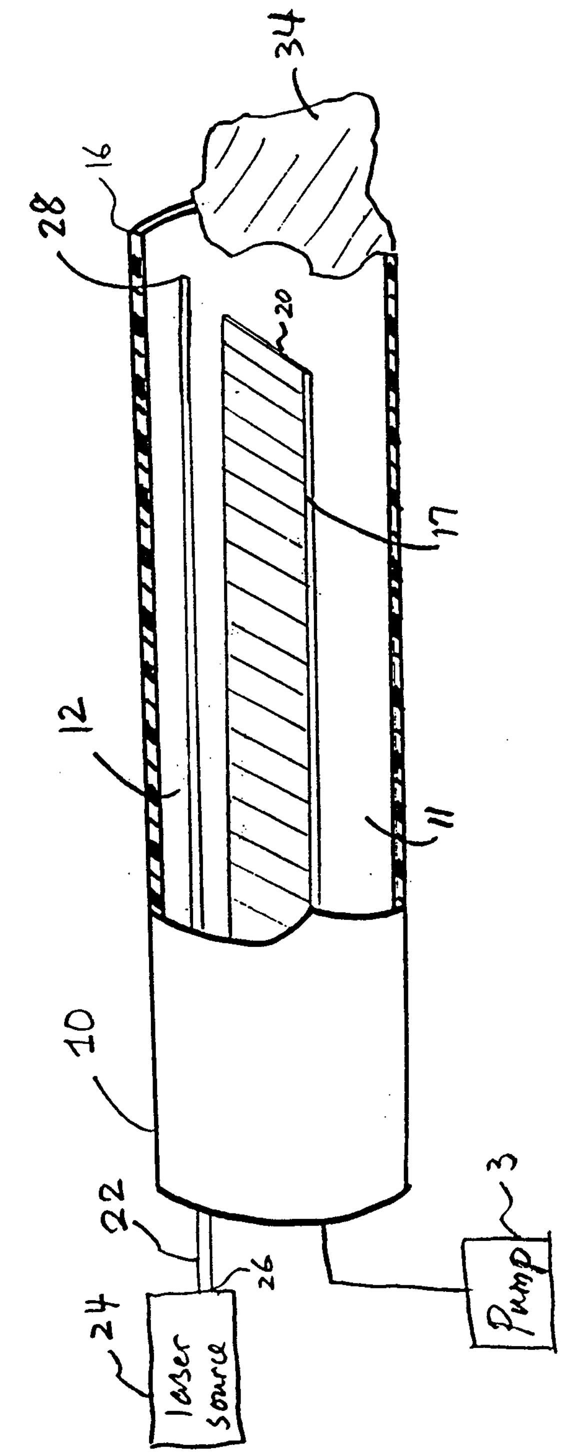


FIG. 5A

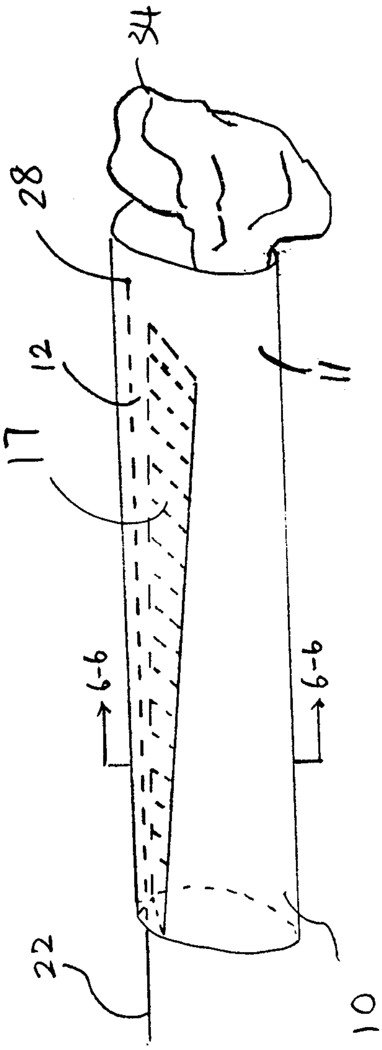
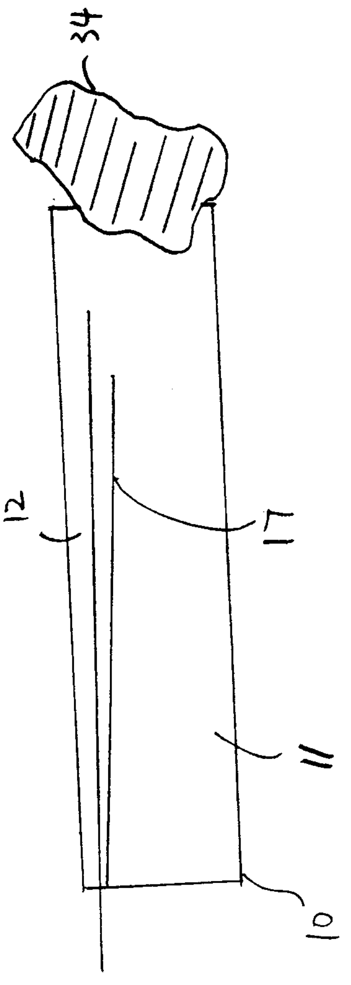


FIG. 5B



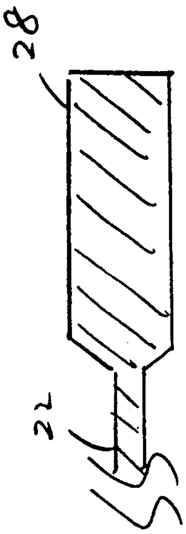


FIG. 6C

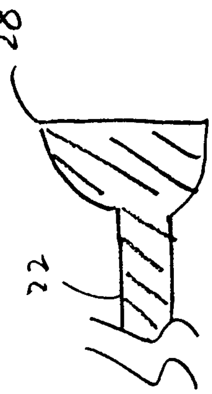


FIG. 6B

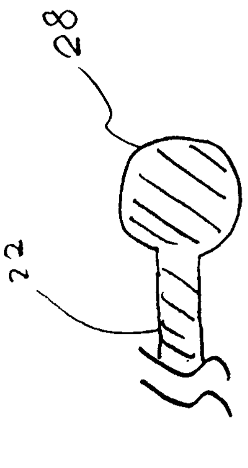


FIG 6A

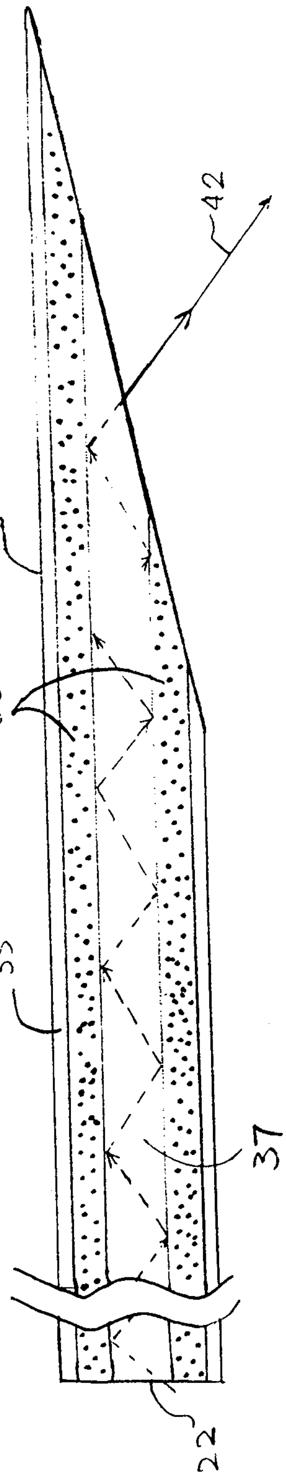


FIG. 7A

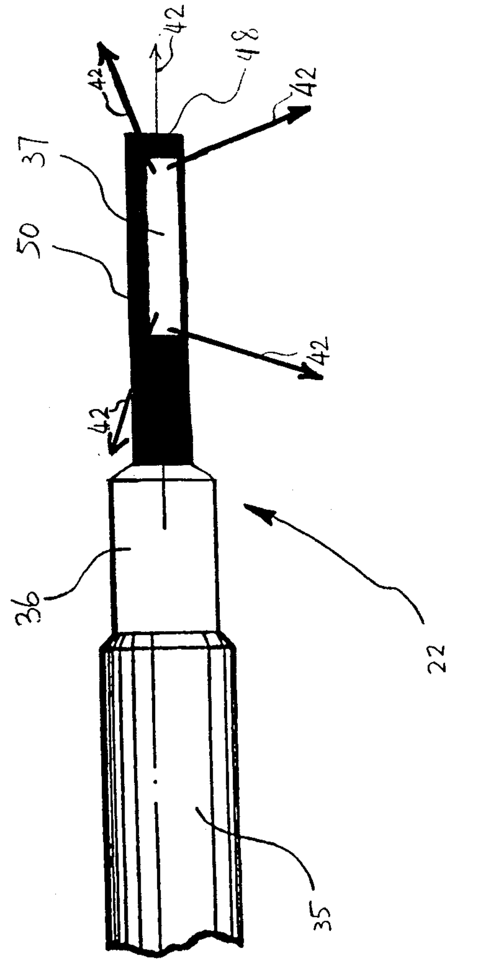


FIG. 7B

FIG. 8A

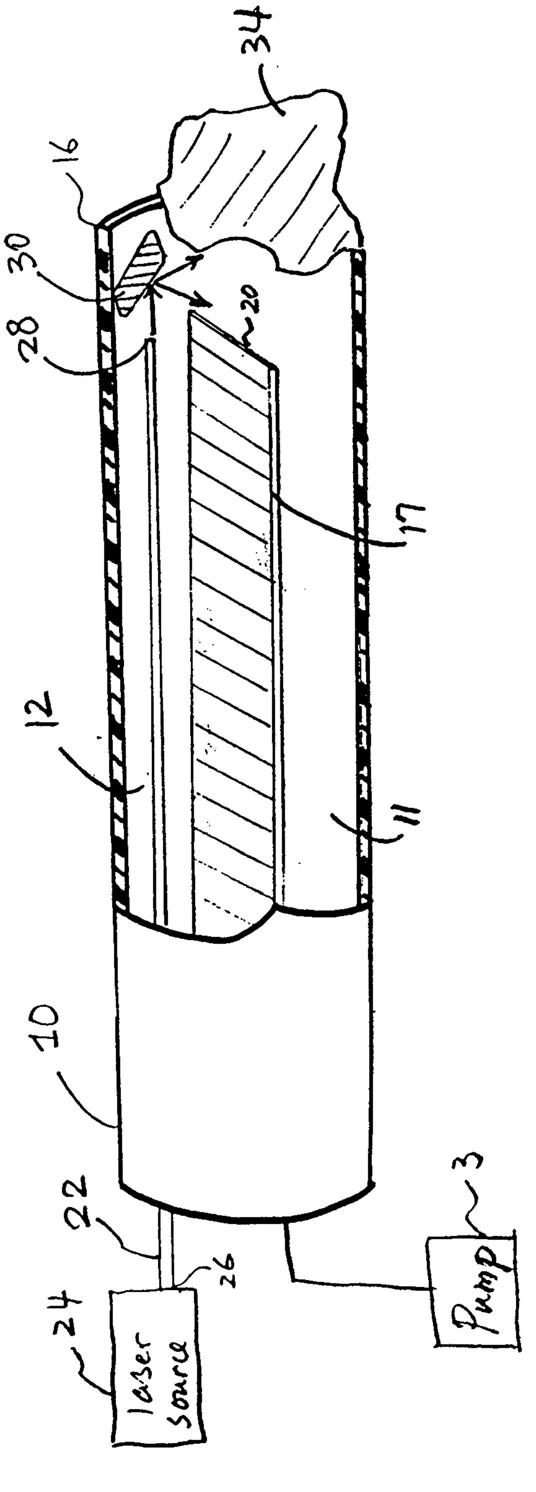
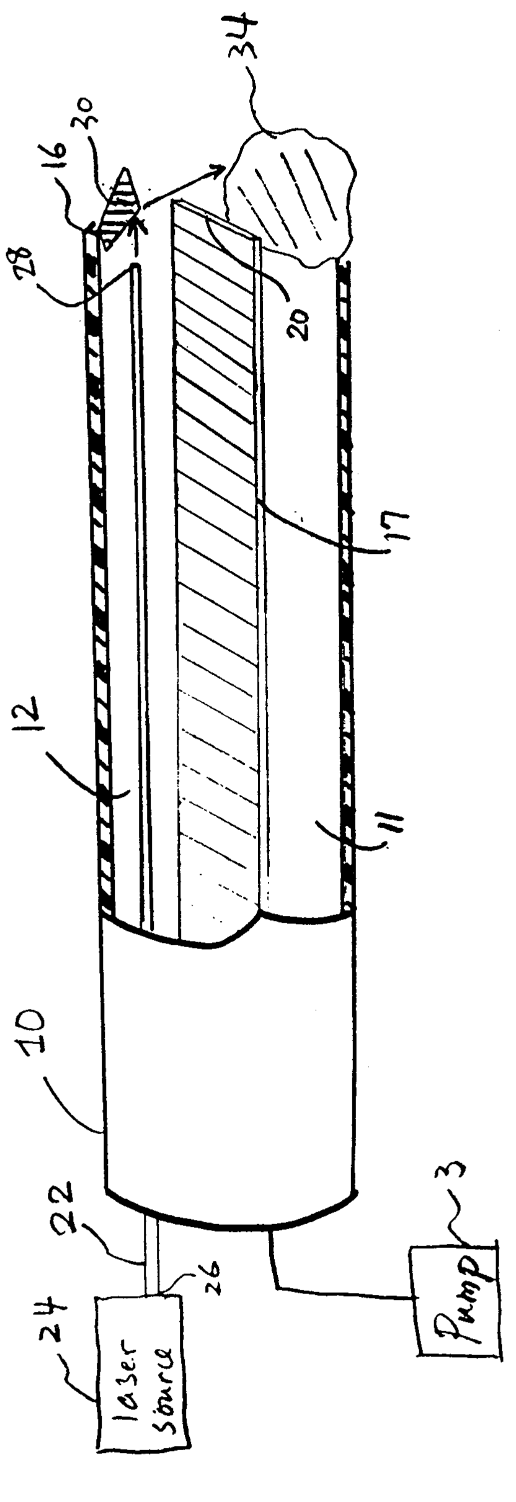

34
16
30
28
20
17
12
11
10
22
26
24
laser source
3
Pump

FIG. 8B


34
30
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28
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17
12
11
10
22
26
24
laser source
3
Pump

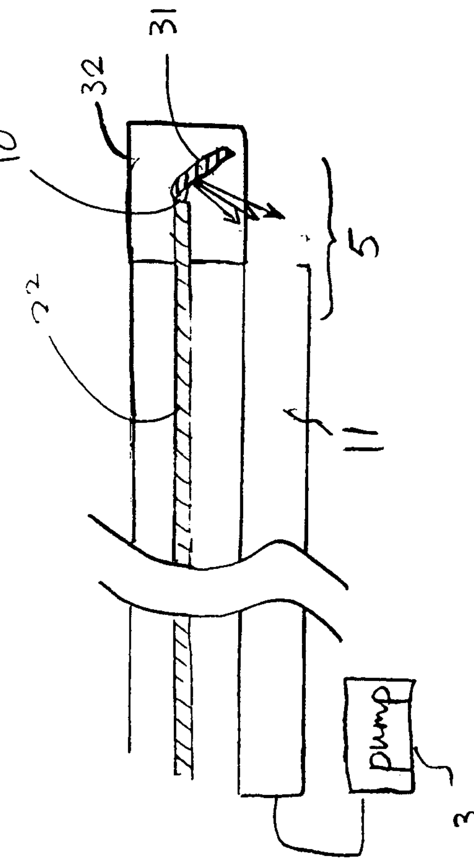


FIG. 9

FIG. 10A

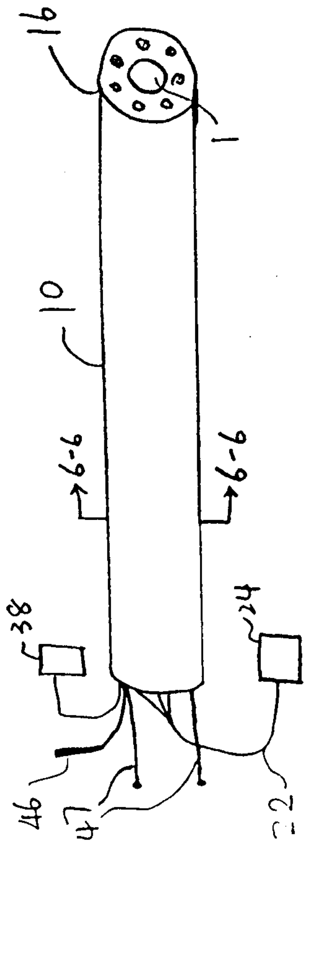
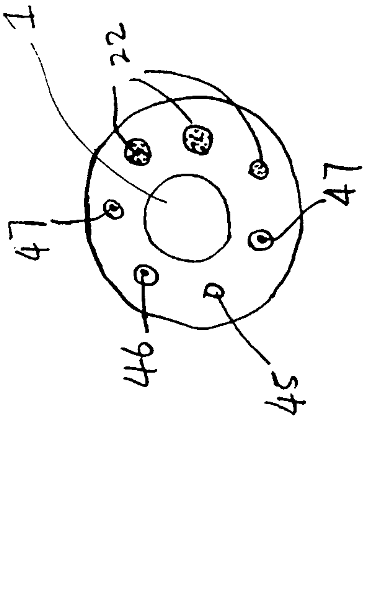


FIG 10B



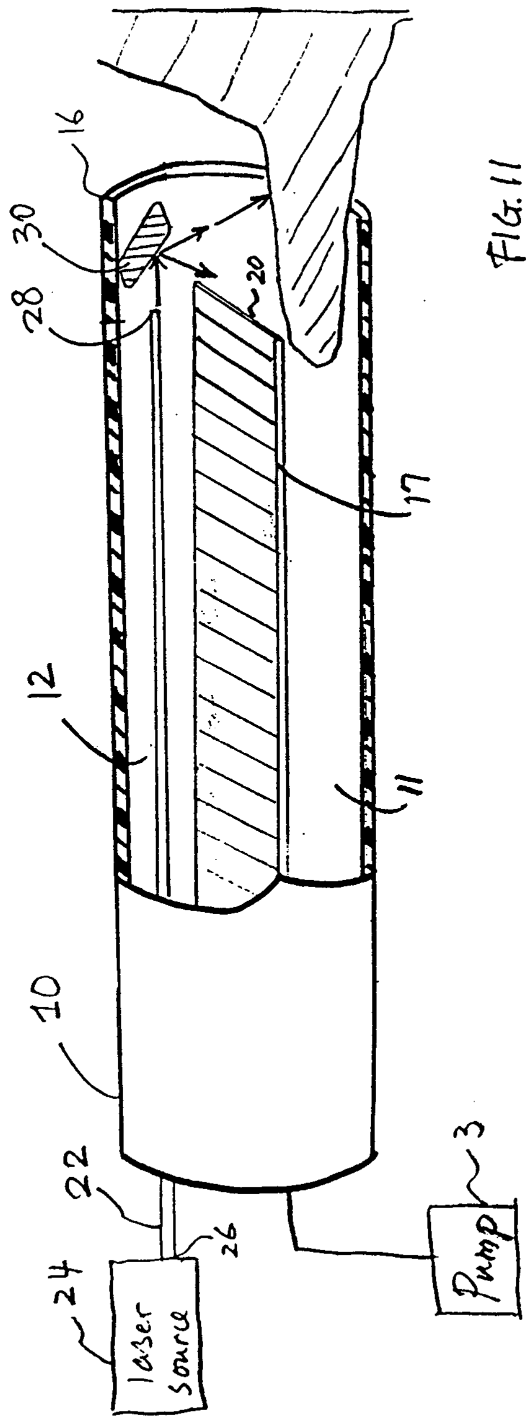


FIG. 11