Title: SURGICAL SUCTION DEVICE USING A LASER FIBER

Abstract: A medical device for fragmenting objects and aspirating remaining debris enables a physician or other medical personnel to quickly and easily remove objects, such as kidney stones (206), from a patient. The medical device includes a dual-lumen elongated member (102) and a handle coupled to the elongated member. A first one of the lumens provides a suction passageway and a second one of the lumens receives a laser fiber (118) for delivering laser energy to an object, such as a kidney stone, within the patient. The handle includes a positioning mechanism (112) which enables the physician to move the laser fiber longitudinally within the second lumen by manual manipulation of the positioning mechanism.
SURGICAL SUCTION DEVICE USING A LASER FIBER

Technical Field

The invention relates generally to dual-lumen suction devices and more particularly to dual-lumen suction devices that use a laser fiber.

Background Information

Dual-lumen suction devices including laser fibers have been used to fragment objects or unwanted tissue in a patient’s body. One lumen houses the laser fiber which is used to deliver laser energy to the object, such as a kidney stone, in order to fragment the object. The other lumen provides suction to remove the fragmented object from the body. Typically these devices include a fixed position laser fiber.

Summary of the Invention

The invention relates generally to dual-lumen suction devices and more particularly to dual-lumen suction devices that use a laser fiber. Such devices are typically used with a variety of scopes, such as rigid, semi-rigid, and flexible nephroscopes, to fragment and aspirate objects, such as kidney stones and/or other unwanted tissue.

In one aspect, the invention involves a medical device. The medical device includes a dual-lumen elongated member. The dual-lumen elongated member includes a proximal end and a distal end. A first one of the lumens provides a suction passageway and a second one of the lumens receives a laser fiber which delivers laser energy through the second lumen and beyond the distal end of the elongated member. The medical device further includes a handle coupled to the proximal end of the elongated member. The handle includes a housing which defines a cavity, a first proximal opening, and a second proximal opening. The first proximal opening receives the laser fiber and allows the laser fiber to pass through the cavity and the second lumen
and out of the distal end of the elongated member. The handle further includes a suction tube
disposed within the cavity and in fluid communication with the first lumen and the second
proximal opening. The suction tube is flexible and selectively collapsible to control suction
through the first lumen. The handle further includes a positioning mechanism. At least a portion
of the positioning mechanism is disposed within the cavity and another portion is external to the
housing. The positioning mechanism contacts the laser fiber and allows the laser fiber to be
moved longitudinally within the second lumen by manual manipulation of the external portion of
the positioning mechanism by an operator of the medical device.

In one embodiment, the handle further includes a suction control mechanism for
controlling a suction path within the suction tube. The suction control mechanism crimps the
suction tube and sealing the suction path when the suction control mechanism is in a first
position and uncrimps the suction tube and opening the suction path when the suction control
mechanism is in a second position. The suction control mechanism includes a button or a lever.

In another embodiment, the distal end of the dual-lumen elongated member includes
radiologically opaque material, and in still another embodiment, the distal end of the dual-lumen
elongated member includes a brightly colored marker.

In one embodiment, the dual-lumen elongated member includes a rigid material, and in
another embodiment, the dual-lumen elongated member includes a flexible material.

In some embodiments, the portion of the positioning mechanism external to the housing
includes a thumb wheel, a slide bar, or a plunger.

In one embodiment, the positioning mechanism further includes a lock to secure the laser
fiber in a fixed position.

In another embodiment, the medical device further includes a drainage tube that is
external to the housing. The drainage tube includes a proximal end and a distal end. The distal
end of the drainage tube is in fluid communication with the second proximal opening and the
proximal end of the drainage tube is in fluid communication with a suction pump.

In still another embodiment, the distal end of the dual-lumen elongated member includes
a tapered end. An outside diameter the first one of the lumens at the tapered end is smaller than
an outside diameter of the first one of the lumens at the proximal end.

In another aspect, the invention involves a medical device. The medical device includes
a dual-lumen elongated member. The dual-lumen elongated member includes a proximal end
and a distal end. A first one of the lumens for provides a suction passageway and a second one
of the lumens receives a laser fiber which delivers laser energy through the second lumen and
beyond the distal end of the elongated member. The medical device further includes a handle
coupled to the proximal end of the elongated member. The handle includes a housing which
defines a cavity, a first proximal opening, and a second proximal opening. The first proximal
opening receives the laser fiber and allows the laser fiber to pass through the cavity and the
second lumen and out of the distal end of the elongated member. The handle further includes a
suction tube disposed within the cavity and in fluid communication with the first lumen and the
second proximal opening. The suction tube is flexible and selectively collapsible to control
suction through the first lumen. The handle further includes a positioning mechanism disposed
entirely within the cavity. The positioning mechanism is in contact with the laser fiber and
retains the laser fiber in a position within the second lumen while allowing the laser fiber to be
moved longitudinally within the second lumen by manual manipulation of a portion of the laser
fiber external to the handle by an operator of the medical device.

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 an illustrative side view of a dual-lumen suction device according to one embodiment of the invention.

Fig. 1B is an illustrative perspective view of a distal end of the dual-lumen suction device shown in Fig. 1A.

Fig. 1C is an illustrative side view of the distal end of the dual-lumen suction device shown in Fig. 1A.

Fig. 1D is an illustrative top view of the dual-lumen suction device shown in Fig. 1A.

Fig. 2 is an illustrative view of a dual-lumen suction device with a distal end disposed in a kidney according to one embodiment of the invention.

Fig. 3A is an illustrative view of inside the housing of a dual-lumen suction device depicting the suction function deactivated according to one embodiment of the invention.

Fig. 3B is an illustrative view of inside the housing of the dual-lumen suction device shown in Fig. 3A with the suction function activated.

Fig. 4 is an illustrative cross-sectional side view of a dual-lumen elongated member according to one embodiment of the invention.

Fig. 5 is an illustrative cross-sectional top view of a dual-lumen suction device depicting a laser fiber positioning mechanism according to one embodiment of the invention.

Fig. 6 is an illustrative cross-sectional top view of a dual-lumen suction device depicting a laser fiber positioning mechanism according to another embodiment of the invention.

Fig. 7 is an illustrative cross-sectional top view of a dual-lumen suction device depicting a laser fiber positioning mechanism according to still another embodiment of the invention.
Fig. 8 is an illustrative cross-sectional top view of a dual-lumen suction device depicting
a laser fiber positioning mechanism according to yet another embodiment of the invention.

Fig. 9 is an illustrative diagram of a device used to clean a dual-lumen suction device
according to one embodiment of the invention.

Description

The invention relates generally to dual-lumen suction devices and more particularly to
dual-lumen suction devices that use a laser fiber. Such devices are typically used with a variety
of scopes, such as rigid, semi-rigid, and flexible nephroscopes, to fragment and aspirate objects,
such as kidney stones and/or other unwanted tissue.

Referring to Figs. 1A, 1B, and 1C, in one embodiment, the dual-lumen suction device
10 includes a dual-lumen elongated member 102 and a handle 126. The dual-lumen elongated
member 102 includes a distal end 104, a proximal end 106, a first lumen 122, and a second
lumen 124. The dual-lumen elongated member 102 includes on the distal end 104 a tapered tip
134. The tapered tip 134 includes a bright color marker 132. In one embodiment, the dual-
lumen elongated member 102 is constructed of a clear or translucent material which enables a
user to easily identify any blockage in the first lumen 122. In other embodiments, the dual-
lumen elongated member 102 can be constructed of polymeric or metallic material and can be
rigid, semi-rigid, or flexible. The dual-lumen elongated member 102 is typically produced
through an extrusion process.

20 The handle 126 includes a housing 110, a strain relief 108, a suction actuation button
(“suction button”) 112, a suction port 120, a suction connector 130, a laser fiber port 116, a slide
bar 114, and a fiber clip 138. The housing 110 includes a first housing portion 142 and a second
housing portion 140. The suction connector 130 is in communication with the first lumen 122
via a suction tube (discussed in further detail below) and extends out of the suction port 120. In
some embodiments, the handle 126 is constructed of a polymeric or metallic material and is
typically produced through an injection molding or machining processes. In some embodiment, the housing 110 is constructed of a polymeric, ceramic, or metallic material and is typically produced through a stamping, molding, or machining process.

Referring to Figs. 1A and 2, in one illustrative use, an incision is made in a patient 202 and a scope, such as nephroscope 218, for example, is inserted into a patient’s organ, such as a kidney 204. The distal end 144 of a laser fiber 118 is inserted into the laser fiber port 116, fed through the housing 110, and into the second lumen 124. The laser fiber 118 is advanced through the second lumen 124 until the distal end 144 of the laser fiber 118 reaches the end of the second lumen 124. The laser fiber 118 is then secured to a portion of the slide bar 114 that is disposed in the housing 110 and discussed in further detail below. The proximal end 146 of the laser fiber 118 is then connected to an energy source, such as a Holmium laser 216, for example. Any excess laser fiber 118 extending between the laser fiber port 116 and the laser 216 can be coiled and secured by the fiber clip 138.

The dual-lumen elongated member 102 is inserted into the nephroscope 218 through port 220 and advanced through the nephroscope 218 until at least the distal end 104 extends out of the nephroscope 218 and into the patient’s kidney 204. An external suction tube 214 is connected to a suction pump 212 and the suction connector 130. Suction through the first lumen 122 is controlled by the suction button 112. When the suction button 112 is in a first (default) position, suction through the first lumen 122 is deactivated. When the suction button 112 is pressed, suction through the first lumen 122 is activated.

After a physician, or other medical personnel, inserts the dual-lumen elongated member 102 into the patient’s kidney 204 through the nephroscope 218, the physician looks through the nephroscope eyepiece 222 to locate an object for removal, such as a kidney stone 206, and moves the distal end 104 of the dual-lumen elongated member 102 close to the kidney stone 206. The physician can also manually move the laser fiber 118 longitudinally into or out of the second
lumen 124 by moving the slide-bar 114 longitudinally. Moving the laser fiber 118 in this manner allows the physician to more accurately position the laser fiber 118 near the kidney stone 206. In one embodiment, after the laser fiber 118 is positioned, the laser fiber 118 can be locked in place to prevent inadvertent movement during use.

After the laser fiber 118 is positioned, the laser 216 is activated. The laser beam (indicated by arrow 208), which can be either a constant beam or an intermittent pulse, strikes the kidney stone 206 and breaks the kidney stone 206 into smaller debris. As (and/or after) the kidney stone 206 breaks up, the physician presses the suction button 112. When the suction button 112 is pressed, suction is activated in the first lumen 122 and the debris in the kidney 204 is aspirated into (as indicated by arrow 210) the first lumen 122. The debris is drawn through the first lumen 122, through the housing 110, and out of the suction connector 130. The debris is further drawn through the external suction tube 214 and ultimately discarded. In one embodiment the first lumen 122 can aspirate an object of up to one and a half millimeters in diameter. After the debris in the kidney 206 is completely removed, the suction button 112 is released and suction through the first lumen 122 is deactivated. This process is repeated until all the kidney stones 206 in the kidney 204 are removed. Alternatively, suction from the first lumen 122 can used to prevent the kidney stone 206 from moving before laser energy is applied. As the kidney stone 206 is fragmented, the debris is drawn into the first lumen 122. A benefit of this method is that the kidney stones 206 are removed more easily and quickly.

Referring again to Fig. 1B, in one embodiment, the distal end 104 of the dual-lumen elongated member 102 includes a tapered tip 134. The opening 136 of the first lumen 122 at the tapered tip 134 has a smaller diameter than the diameter of the rest of the first lumen 122. The tapered tip 134 minimizes clogging of the first lumen 122 by only allowing in debris that is smaller than the diameter of the first lumen 122. In one embodiment, the length of the tapered tip 134 is five millimeters. In another embodiment, the tapered tip 134 includes a bright color
marker 132. The bright color marker 132 allows the physician to easily locate the distal end 104 of dual-lumen elongated member 102 when the distal end 104 is disposed within a patient and being viewed through a nephroscope. Additionally, the bright color marker 132 allows the physician to be able to distinguish the first (suction) lumen 122 from the laser beam emanating from the second lumen 124. The bright color marker 132 can also be used as an ultrasonic or fluoroscopic marker for locating the distal end 104 within the patient’s body.

In some embodiments, the tapered tip 134 is produced by heat forming or heat bonding polymeric or metallic material to the distal end 104 of the dual-lumen elongated member 102. In other embodiments, the bright color marker 132 is a molded component coupled to the tapered tip 134. In still other embodiments, the bright color marker 132 is painted on the tapered tip 134, or produced by a chemical process.

Referring to Figs. 3A and 3B, in one embodiment, a suction tube 302 disposed within the housing 110 connects the dual-lumen elongated member 102 to the suction connector 130. The suction connector 130 is positioned such that the portion of the suction connector 130 that connects to the suction tube 302 is disposed within the housing 110 with the rest of the suction connector 130 extending through the suction port 120. When the suction button 112 is not pressed (default position), the suction button 112 is positioned such that a rigid member 304 presses against the suction tube 302 thereby crimping the suction tube 302 and preventing suction from the pump 212 (Fig. 2) from extending through the first lumen 122. This feature allows the physician to manipulate the dual-lumen suction device 100 within the patient’s body without removing excessive amounts of body fluids.

When the suction button 112 is pressed, the suction button 112 is positioned such that the rigid member 304 no longer presses against the suction tube 302 resulting in suction extending through the first lumen 122. As long as the suction button 112 is pressed, suction through the first lumen 122 is active. As soon as the suction button 112 is released, suction through the first
lumen 122 is deactivated. In another embodiment, a lever is used to selectively enable and
disable suction in the same way the suction button 112 is used to selectively enable and disable
suction. In some embodiments, the suction tube 302 is constructed of an elastomeric material
with a memory. In other embodiments, the suction connector 120 is constructed of a polymeric
material with a smooth bore and is typically produced through an injection molding or machining
process.

In another embodiment, before the dual-lumen suction device 100 is first used, a shipping
tab (not shown) is first removed from the handle 126. The shipping tab is positioned proximate
to the suction button 112 and holds the suction button 112 in the pressed position thereby
keeping the suction tube 302 uncrimped. After the shipping tab is removed, the suction button
112 functions as previously described.

Referring to Figs. 3A, 3B, and 4, in one embodiment, an access hole 402 is cut into a wall
of the dual-lumen elongated member 102 to provide an separate access point to the second lumen
124. An extension tube 306 is inserted into the access hole 402 and is held in place by glue or
friction. The intersection of the dual-lumen elongated member 102 and the extension tube 306 is
held together and reinforced by strain relief 108. The strain relief 108 also prevents the dual-
lumen elongated member 102 from kinking when inserted into a scope and acts as a plug to
prevent body fluids from flowing back through the scope. The extension tube 306 provides a
path for the laser fiber 118 to enter the second lumen 124 from within the housing 110 because
the end of the dual-lumen elongated member 102 is coupled to the suction tube 302. The
extension tube 306 also blocks the suction from the suction tube 302 and provides support for the
laser fiber 118.

In some embodiments, the access hole 402 can be created by a hole punch, a hot stamp, a
scalpel, or a drill press. The extension tube 306 is constructed of polymeric or metallic material
and is typically produced through an extrusion or dipping process. The strain relief 108 is
constructed of polymeric or metallic material and is typically produced through a machining or molding process.

Referring to Figs. 1A, 1B, 4, and 5, in one embodiment, the distal end 144 of the laser fiber 118 is inserted into laser fiber port 116 and fed through the housing 110 and into the extension tube 306. The laser fiber 118 is then fed through the extension tube 306 and into the second lumen 124. The laser fiber 118 is fed through the second lumen 124 until the distal end of the laser fiber 118 reaches the tapered tip 134. However, prior to entering the extension tube 306, the laser fiber 118 is fed through a clamp 504 which is part of a laser fiber positioning system 502 that is disposed within the housing 110 and coupled to at least one slide-bar 114 through an opening 128. As the laser fiber 118 is fed though the various parts of the dual-lumen suction device 100, the clamp 504 is held in an unclamped state thereby allowing the laser fiber 118 to move through the clamp 504. Once the distal end 144 of the laser fiber 118 reaches the tapered tip 134, the clamp 504 clamps the laser fiber 118. Thereafter, the laser fiber 118 is manually advanced and retracted by longitudinally sliding the slide bar 114 as shown by arrow 506.

In some embodiments, the clamp 504 is constructed of a polymeric, ceramic, or metallic material and is typically produced through a molding or machining process. Additionally, the clamp 504 includes elastomeric pads or covers which cushion and prevent damage to the laser fiber 118 when clamped. In other embodiments, the slide bar 114 is constructed of a polymeric or metallic material and is typically produced through an injection molding or machining process.

Referring to Fig. 6, in another embodiment, the laser fiber 118 is positioned between two thumbwheels 602 and fed through a grommet 604. The laser fiber 118 is held in position by the grommet 604 through friction and can be retracted or advanced along the second lumen 124 when the thumbwheels 602 are manually rotated clockwise and counterclockwise. In another
embodiment, the thumbwheels 602 are not in constant contact with the laser fiber 118. In this embodiment, the thumbwheels 602 must be squeezed or pressed inward toward the housing 110 to first make contact with the laser fiber 118 and held in the squeezed positioned while being rotated in order to advance and retract the laser fiber 118.

Referring to Fig. 7, in still another embodiment, the laser fiber 118 is fed through and gripped by a plunger 702 that moves in and out of laser fiber port 120. In this embodiment, the laser fiber 118 is selectively retracted and advanced by sliding the plunger 702 in and out of the laser fiber port 120 using a thumb-ring 704. When the plunger 702 is not manually moved, the plunger 702 held motionless through a friction connection with laser fiber port 120.

Referring to Fig. 8, in yet another embodiment, the laser fiber 118 is fed through and a grommet 802 and held in position by friction. In this embodiment, the laser fiber 118 is selectively retracted and advanced by gripping the laser fiber 118 between two fingers at, or near, location 802 and pulling the laser fiber 118 out of the housing 110 or pushing the laser fiber 118 into the housing. The selected position of the laser fiber 118 is maintained by the friction from the grommet 802. In yet another embodiment, the selected position of the laser fiber 118 is maintained by the combined friction from the second lumen 124, the extension tube 306, and the laser fiber connector port 116.

Referring to Fig. 9, in some embodiments, a cleaning device 900 is included with the dual-lumen access device 100. The cleaning device includes handle 906, shaft 902, and bristles 904. The cleaning device is used to remove debris trapped in the first lumen 122 by inserting the cleaning device 900 into the distal end 104 of the first lumen 122 and manually moving the cleaning device 900 longitudinally in the first lumen.

Variations, modifications, and other implementations of what is described herein may occur to those of ordinary skill in the art without departing from the spirit and scope of the
invention. Accordingly, the invention is not to be defined only by the preceding illustrative description.

What is claimed is:
Claims

1. A medical device, comprising:
   a dual-lumen elongated member comprising a proximal end and a distal end, a first one of
   the lumens for providing a suction passageway, a second one of the lumens for receiving a laser
   fiber for delivering laser energy through the second lumen and beyond the distal end of the
   elongated member; and
   a handle coupled to the proximal end of the elongated member, the handle comprising:
   a housing defining a cavity, a first proximal opening, and a second proximal
   opening, the first proximal opening for receiving the laser fiber and allowing the laser
   fiber to pass through the cavity and the second lumen and out of the distal end of the
   elongated member;
   a suction tube disposed within the cavity and in fluid communication with the first
   lumen and the second proximal opening, the suction tube being flexible and selectively
   collapsible to control suction through the first lumen; and
   a positioning mechanism comprising at least a portion disposed within the cavity
   and another portion external to the housing, the positioning mechanism contacting the
   laser fiber and allowing the laser fiber to be moved longitudinally within the second
   lumen by manual manipulation of the external portion of the positioning mechanism by
   an operator of the medical device.

2. The medical device of claim 1 wherein the handle further comprises a suction control
   mechanism for controlling a suction path within the suction tube, the suction control mechanism
   crimping the suction tube and sealing the suction path when in a first position and uncrimping
   the suction tube and opening the suction path when in a second position.

3. The medical device of claim 2 wherein the suction control mechanism comprises a
   button.
4. The medical device of claim 2 wherein the suction control mechanism comprises a lever.

5. The medical device of claim 1 wherein the distal end of the dual-lumen elongated member comprises radiologically opaque material.

6. The medical device of claim 1 wherein the distal end of the dual-lumen elongated member comprises a brightly colored marker.

7. The medical device of claim 1 wherein the dual-lumen elongated member comprises a rigid material.

8. The medical device of claim 1 wherein the dual-lumen elongated member comprises a flexible material.

9. The medical device of claim 1 wherein the portion of the positioning mechanism external to the housing comprises a thumb wheel.

10. The medical device of claim 1 wherein the portion of the positioning mechanism external to the housing comprises a slide bar.

11. The medical device of claim 1 wherein the portion of the positioning mechanism external to the housing comprises a plunger.

12. The medical device of claim 1 wherein the positioning mechanism further comprises a lock to secure the laser fiber in a fixed position.

13. The medical device of claim 1 further comprising a drainage tube external to the housing comprising a proximal end and a distal end, the distal end of the drainage tube in fluid communication with the second proximal opening and the proximal end of the drainage tube in fluid communication with a suction pump.

14. The medical device of claim 1 wherein the distal end of the dual-lumen elongated member comprises a tapered end, an outside diameter the first one of the lumens at the tapered end being smaller than an outside diameter of the first one of the lumens at the proximal end.

15. A medical device, comprising:
a dual-lumen elongated member comprising a proximal end and a distal end, a first one of
the lumens for providing a suction passageway, a second one of the lumens for receiving a laser
fiber for delivering laser energy through the second lumen and beyond the distal end of the
elongated member; and

a handle coupled to the proximal end of the elongated member, the handle comprising:
a housing defining a cavity, a first proximal opening, and a second proximal
opening, the first proximal opening for receiving the laser fiber and allowing the laser
fiber to pass through the cavity and the second lumen and out of the distal end of the
elongated member;
a suction tube disposed within the cavity and in fluid communication with the first
lumen and the second proximal opening, the suction tube being flexible and selectively
collapsible to control suction through the first lumen; and

a positioning mechanism disposed entirely within the cavity, the positioning
mechanism contacting the laser fiber and retaining the laser fiber in a position within the
second lumen while allowing the laser fiber to be moved longitudinally within the second
lumen by manual manipulation of a portion of the laser fiber external to the handle by an
operator of the medical device.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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* Further documents are listed in the continuation of box C.  
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10 July 2002

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