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(54) **SYSTEM AND METHOD FOR GUIDED REMOVAL FROM AN IN VIVO SUBJECT**

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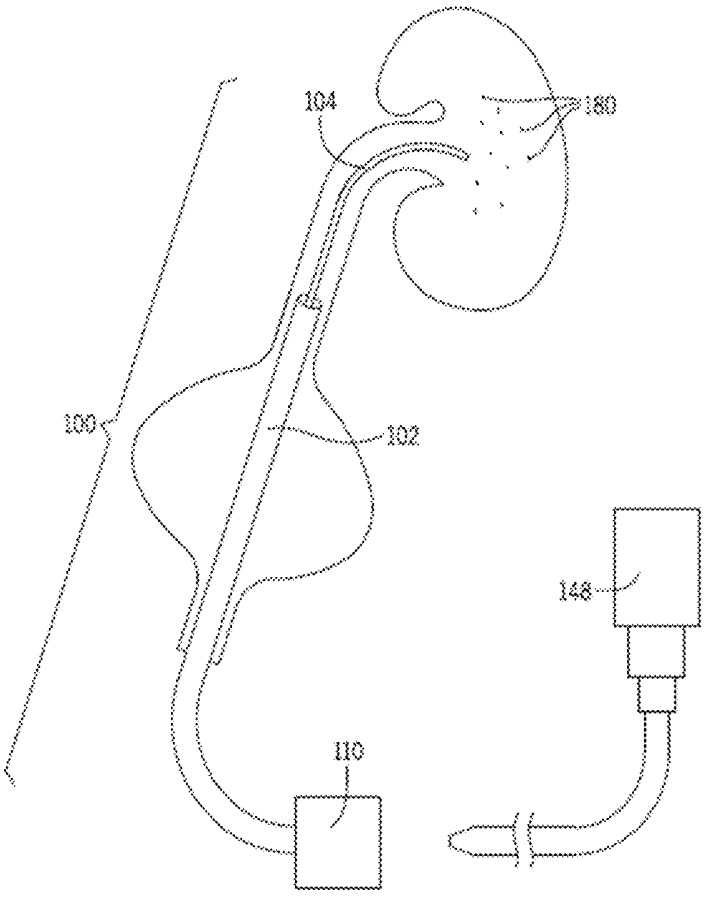
(57) **ABSTRACT**

In accordance with some configurations, systems and methods for guided removal from an in vivo subject are provided. In some configurations, a method for removing an object is provided. The method comprising, guiding a flexible tube through an in vivo subject's ureter, wherein the flexible tube comprises at least a first passageway and a second passageway. Positioning a distal end of the first passageway adjacent to the object. Infusing saline solution through the second passageway while suction is off. Removing the object through the first passageway with at least a portion of the saline solution.



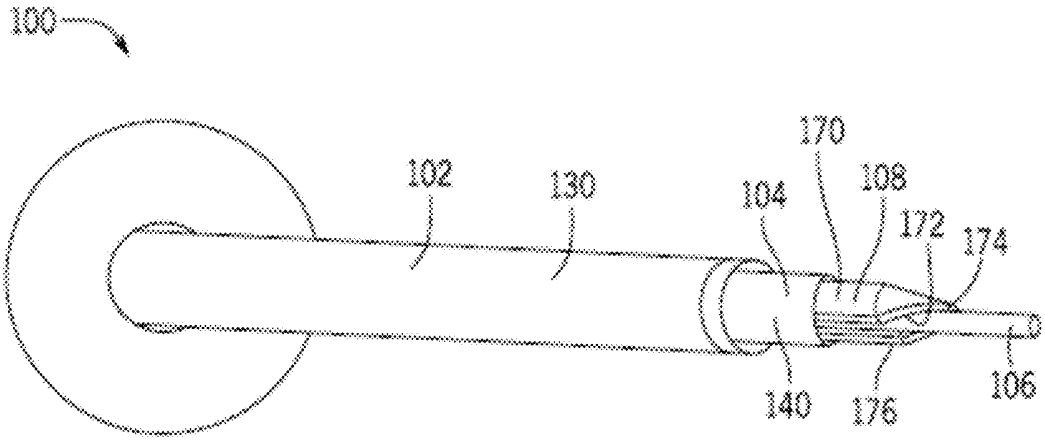


FIG. 1

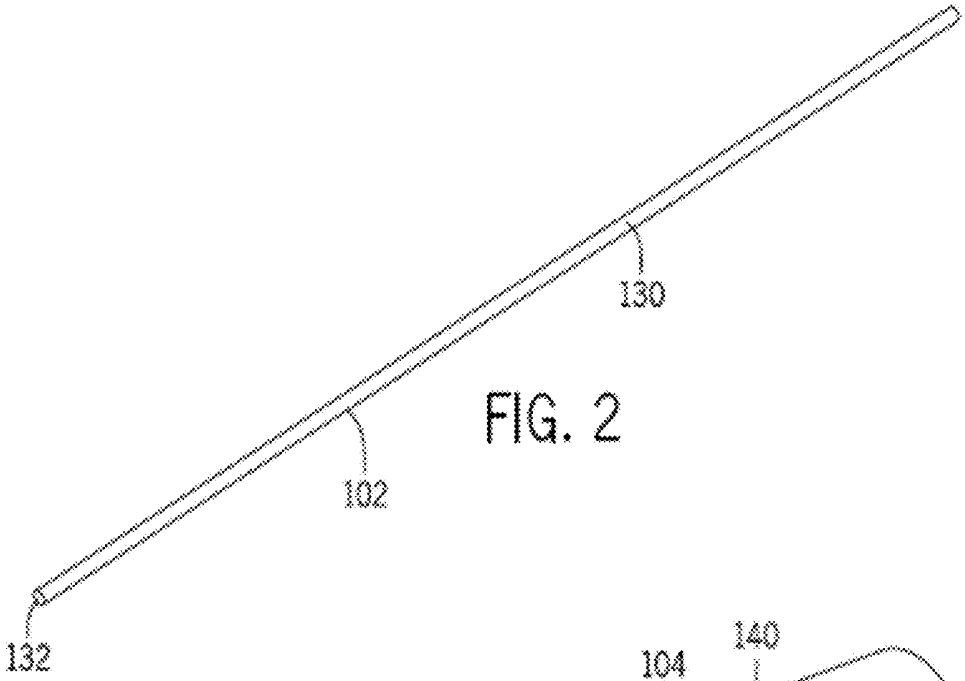


FIG. 2

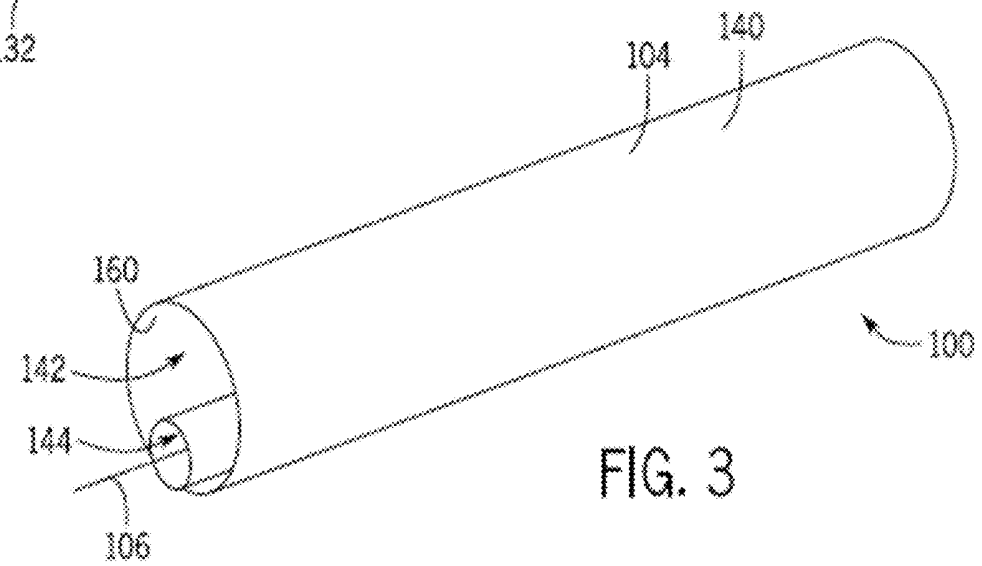


FIG. 3

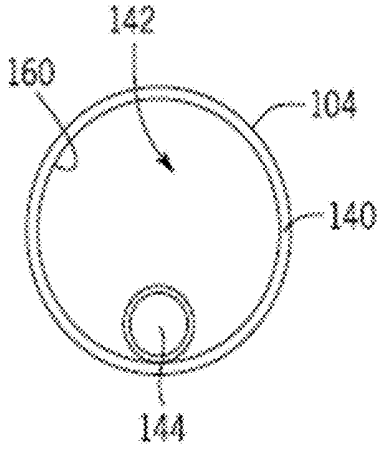


FIG. 4

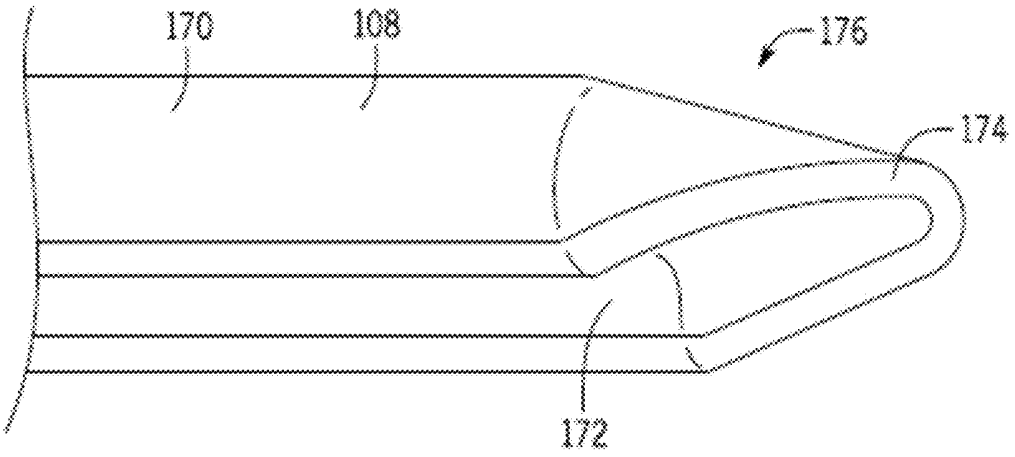


FIG. 5

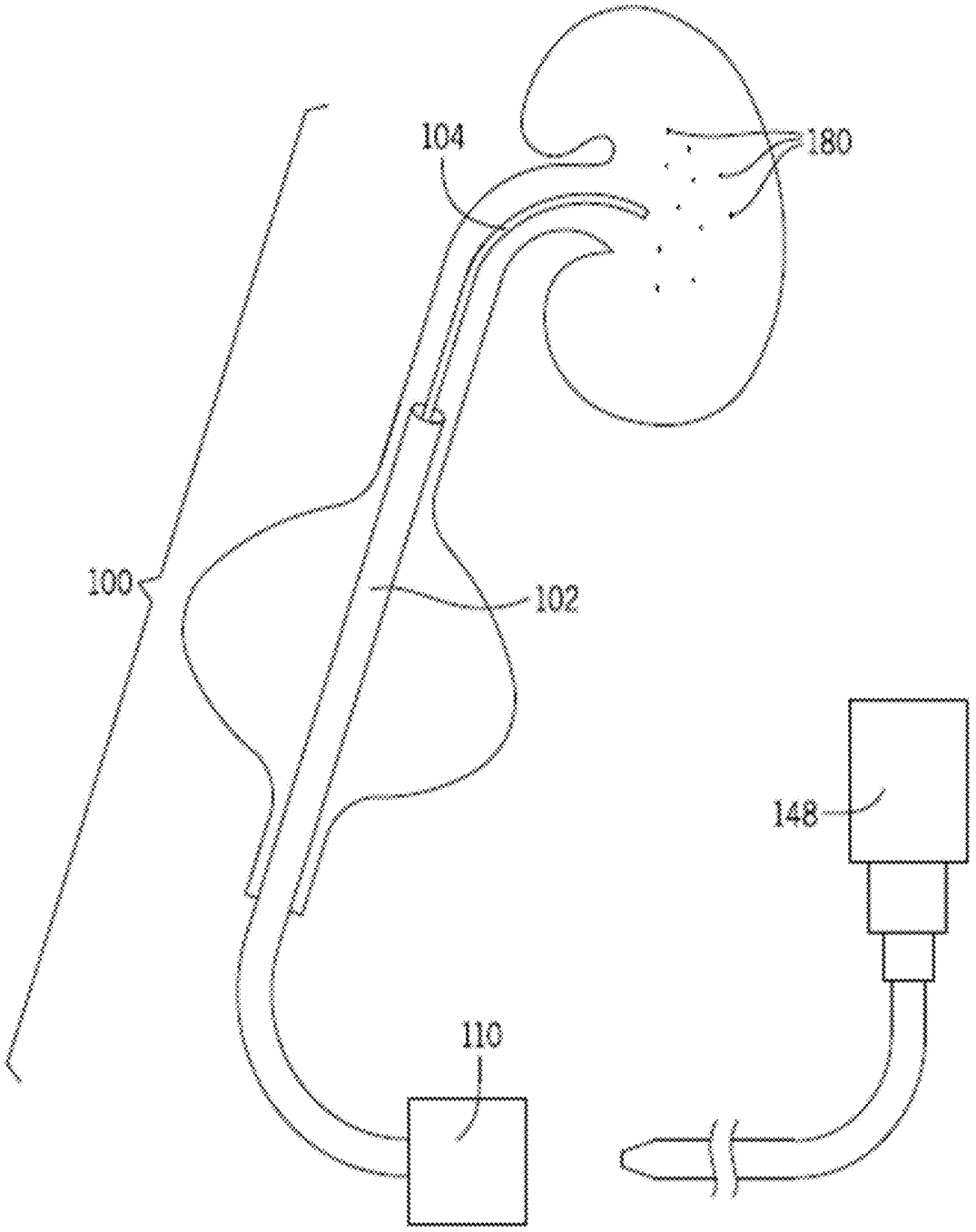


FIG. 6

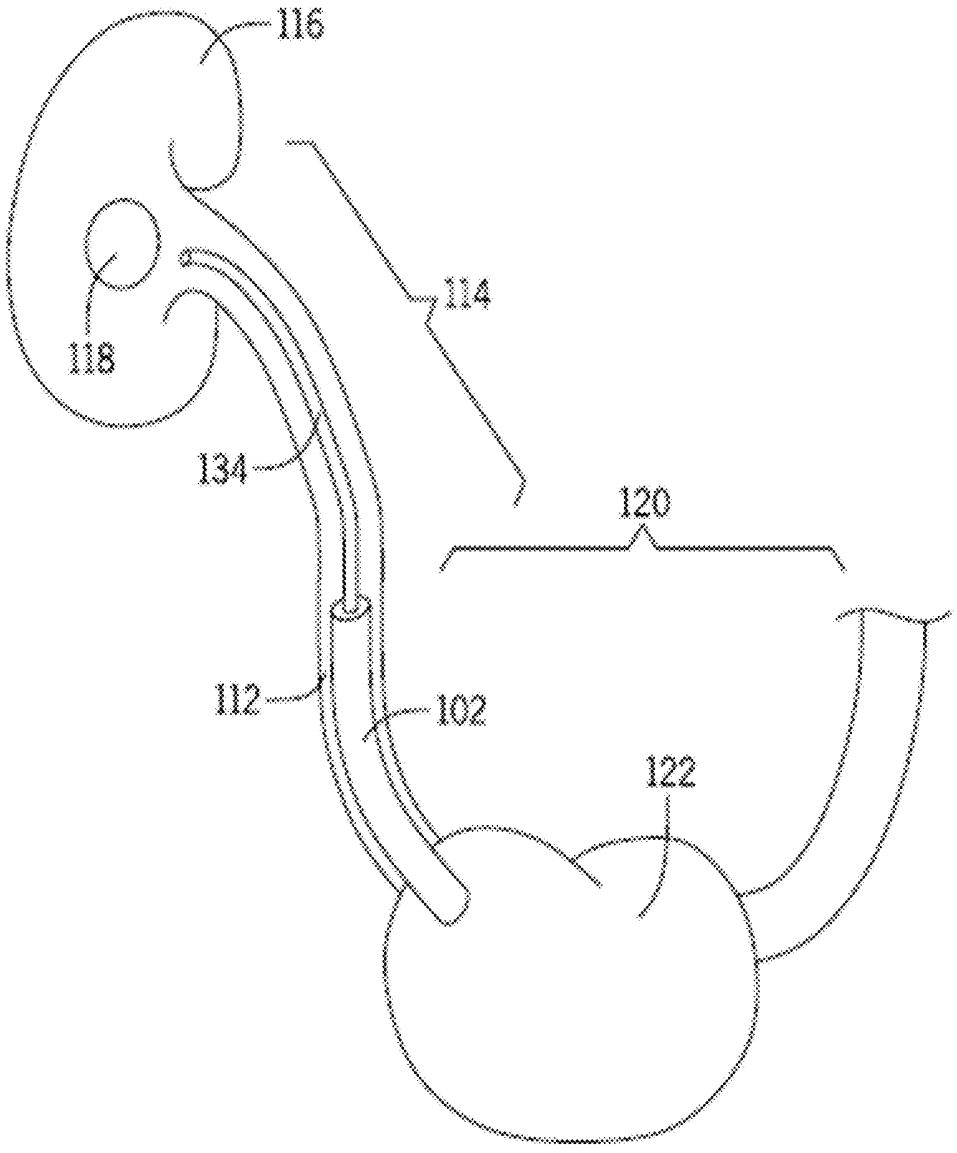


FIG. 7

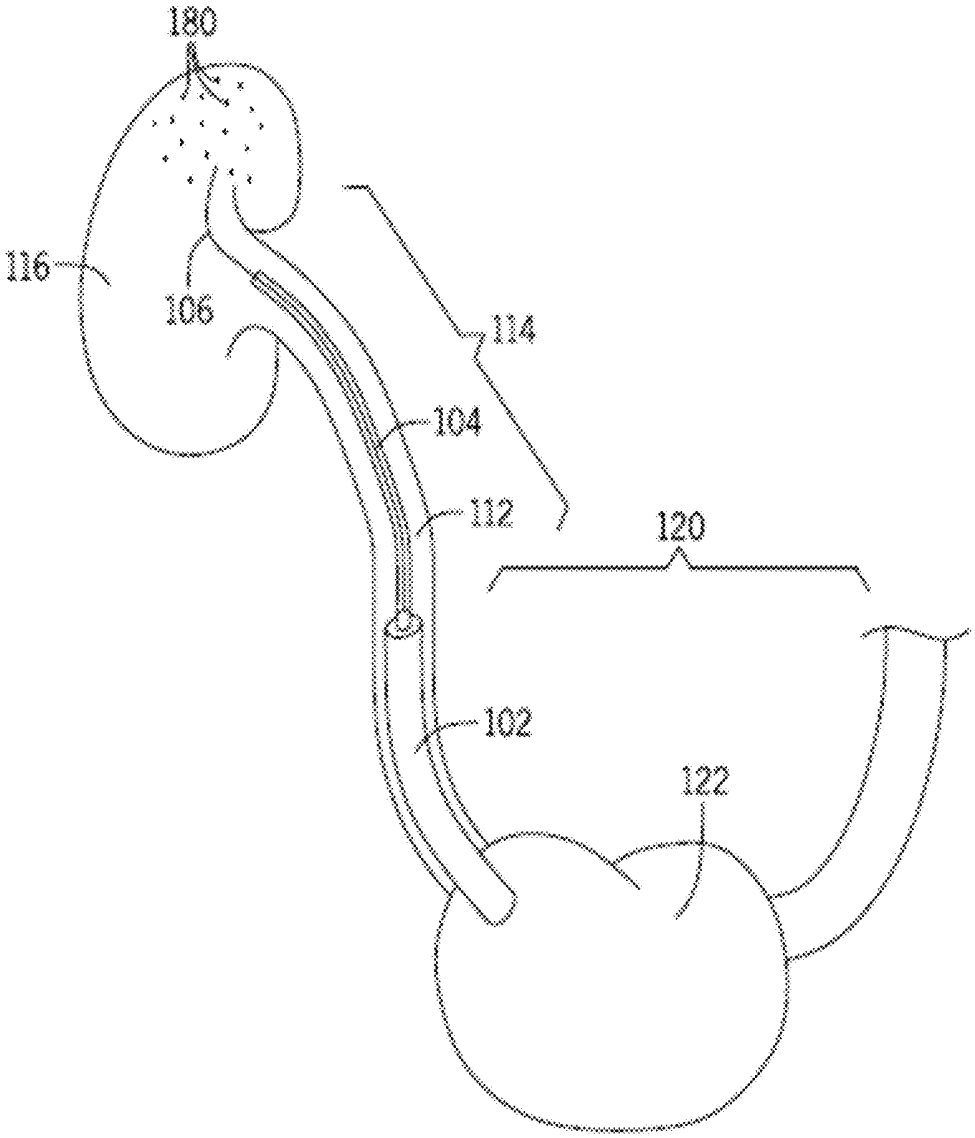


FIG. 8

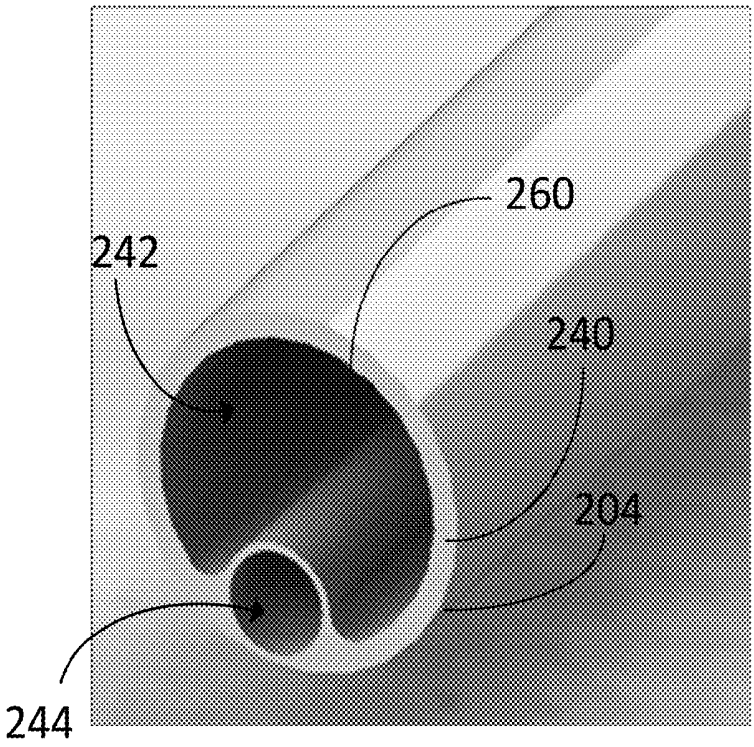


FIG. 9A

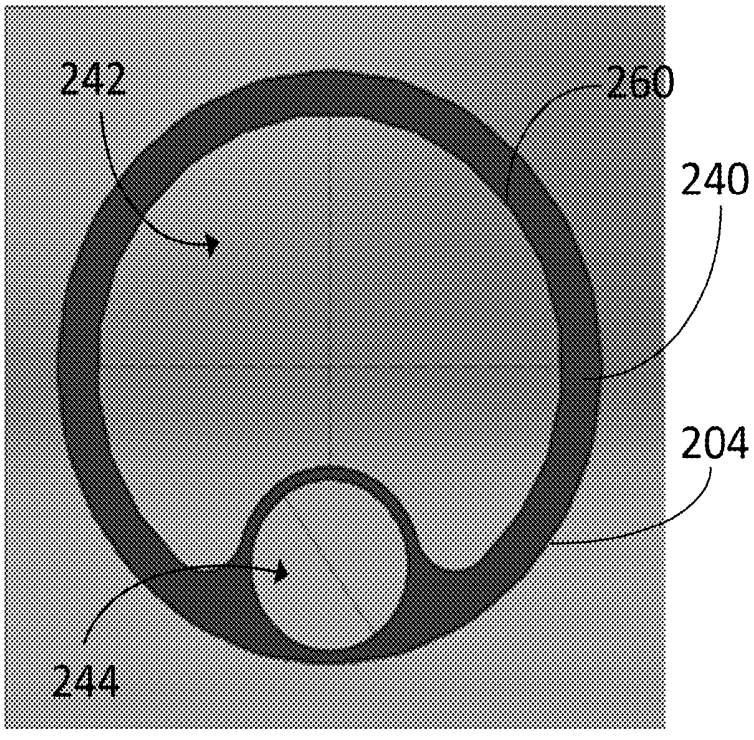


FIG. 9B

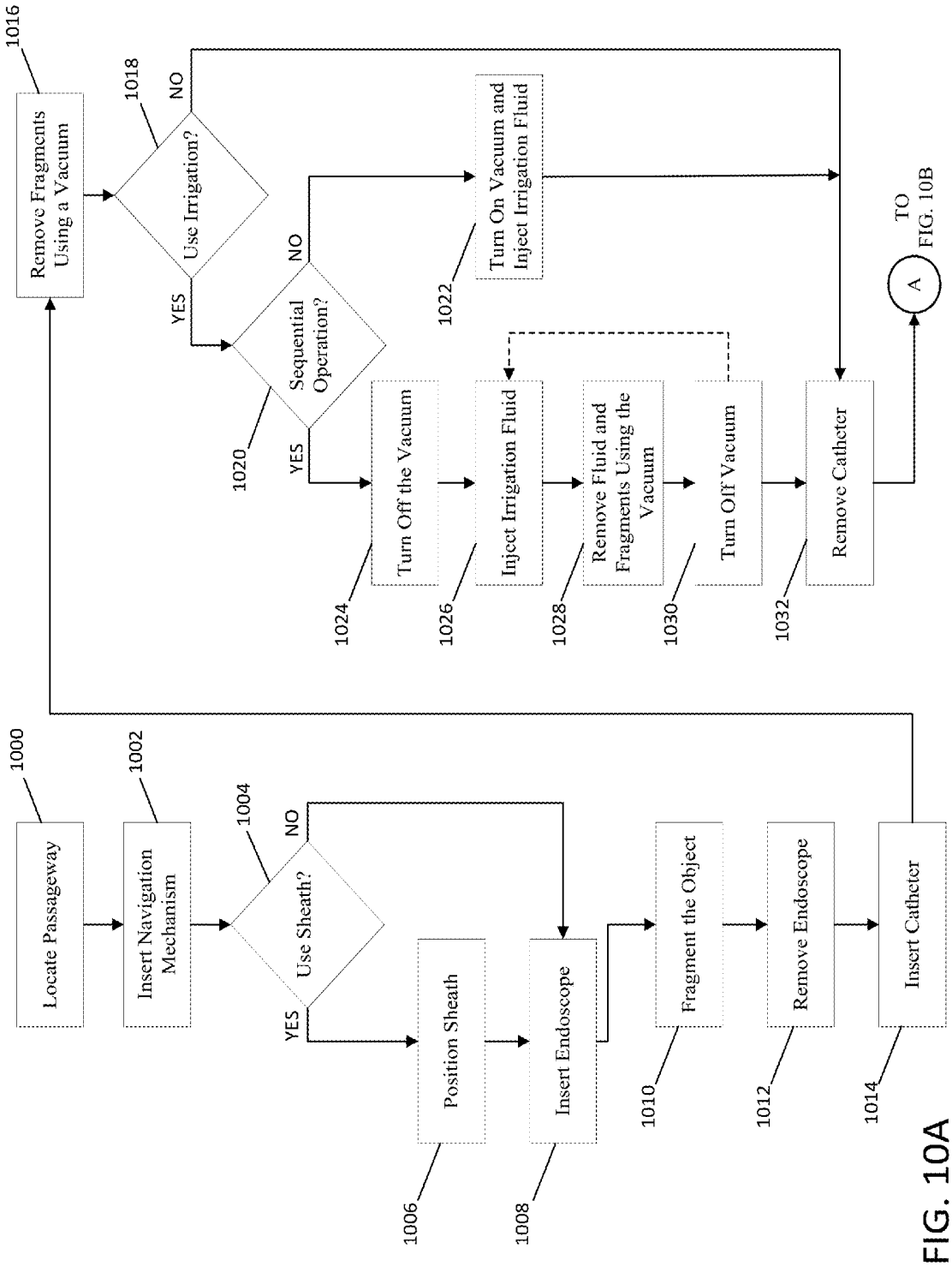

1000
Locate Passageway
1002
Insert Navigation Mechanism
1004
Use Sheath?
NO
YES
1006
Position Sheath
1008
Insert Endoscope
1010
Fragment the Object
1012
Remove Endoscope
1014
Insert Catheter
1016
Remove Fragments Using a Vacuum
1018
Use Irrigation?
NO
YES
1020
Sequential Operation?
NO
YES
1022
Turn On Vacuum and Inject Irrigation Fluid
1024
Turn Off the Vacuum
1026
Inject Irrigation Fluid
1028
Remove Fluid and Fragments Using the Vacuum
1030
Turn Off Vacuum
1032
Remove Catheter
A
TO FIG. 10B

FIG. 10A

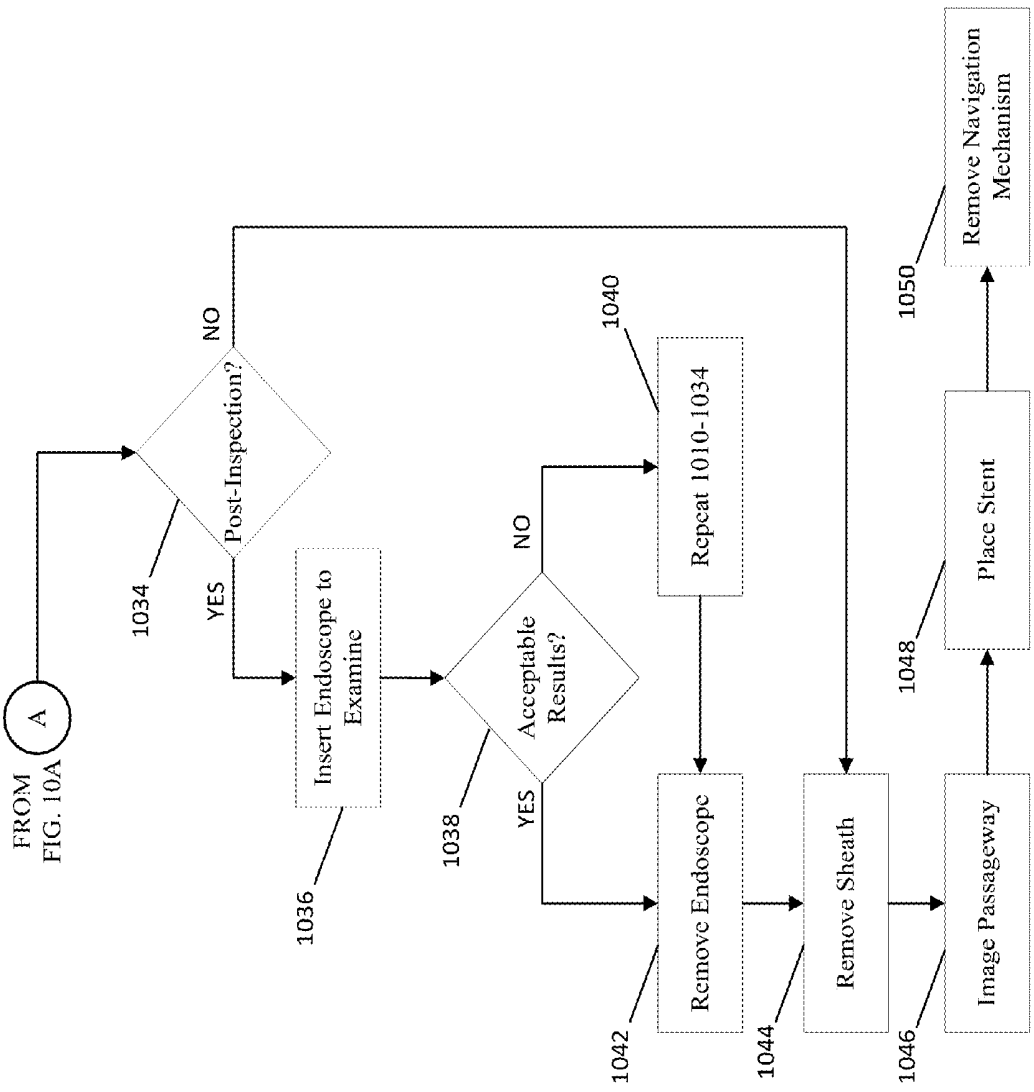

FROM FIG. 10A
A
Post-Inspection?
1034
NO
YES
Insert Endoscope to Examine
1036
Acceptable Results?
1038
NO
YES
Repeat 1010-1034
1040
Remove Endoscope
1042
Remove Sheath
1044
Image Passageway
1046
Place Stent
1048
Remove Navigation Mechanism
1050

FIG. 10B

SYSTEM AND METHOD FOR GUIDED REMOVAL FROM AN IN VIVO SUBJECT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part, under 35 U.S.C. §120, of U.S. application Ser. No. 14/774,418, filed Sep. 10, 2015, which is a National Stage, under 35 U.S.C. §371, of International Application No. PCT/US2014/026037, filed Mar. 13, 2014, which claims the benefit, under 35 U.S.C. §119(e), of U.S. Provisional Application No. 61/783,239, filed Mar. 14, 2013. Each of the foregoing applications is hereby incorporated herein by reference in its entirety for all purposes.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to systems and methods for the guided removal of objects in vivo. In particular, the invention is directed to a removal device adapted to traverse compact areas utilizing a navigation mechanism, and more specifically, to capture and/or remove debris through a vacuum tube that is in communication with a suction source.

[0003] Kidney stones are a common medical problem that negatively impact millions of individuals worldwide. Kidney stones include one or more solid masses of material that are usually made of crystals and form in parts of the urinary tract including in the ureter, the kidney, and/or the bladder of the individual. Kidney stones range in size from smaller (less than about 1 cm) to very large (more than 4 cm) and may cause significant pain to the individual and damage to the kidney. The overwhelming majority of stones that are treated by surgeons are less than 1 cm.

[0004] The recommended treatment for removal of the kidney stones varies according to numerous factors including the size of the kidney stones, the number of kidney stones, and the location of the kidney stones. The most common treatments for kidney stones are shock wave lithotripsy (ultrasound waves used to fracture the stones), ureteroscopy (fracture and removal of the stones using an endoscope that is introduced through the bladder), and percutaneous nephrolithotomy (fracture and removal of the stones using an endoscope that is introduced through a sheath placed through the patient's back into the kidney).

[0005] The largest kidney stones are usually removed through percutaneous nephrolithotomy or nephrolithotripsy, or through other similar procedures. In these procedures, a small incision is made through the patient's back adjacent the kidney and a sheath is passed into the kidney to accommodate a larger endoscope used to fracture and remove stones. The stone may be removed directly through the tube or may be broken up into small fragments while still in the patient's body and then removed via a vacuum or other known methods (nephrolithotripsy).

[0006] There are numerous drawbacks associated with nephrolithotomy, nephrolithotripsy, and other invasive surgeries requiring an incision in the skin. Namely, such surgical techniques may require significantly more anesthesia administered to the patient, the surgeries are more complicated and pose a higher risk of infection and complications for the patient, and the surgeries require a substantial incision in the patient, which may leave a scar. Additionally, given the invasiveness of the procedure, percutaneous procedures are usually not preferred for smaller kidney stones (e.g., less than 1 cm) depending on the size and location of the stones.

[0007] In contrast, traditionally, smaller kidney stones have been treated using other, less invasive techniques including through ureteroscopy. In ureteroscopy, the surgeon typically inserts a ureteroscope into the urethra through the bladder and the ureter to provide the surgeon with a direct visualization of the kidney stone(s) which may reside in the ureter or kidney. The surgeon then removes the kidney stone directly using a basketing device if the kidney stone is small enough to pass through the urinary tract without difficulty, or the surgeon fractures the kidney stone into smaller pieces using a laser or other breaking device. After breaking the kidney stone into smaller pieces, the surgeon removes the laser or breaking device and inserts a basket or other object to capture the kidney stone fragments. Upon retrieving some of the kidney stone fragments, the surgeon removes the basket from the patient and empties the kidney stone fragments therefrom. This process is repeated until clinically significant kidney stones and kidney stone fragments are broken up and removed from the body.

[0008] It should be apparent that this process is extremely time consuming, costly, and inefficient because the surgeon is required to insert and remove the scope and basket into and out of the patient many times to completely remove the kidney stones and kidney stone fragments therefrom. Using a basket removal device to capture kidney stones or kidney stone fragments suffers from other drawbacks in that the basket is difficult to position adjacent the kidney stone fragments and maneuver in a manner that effectively retrieves the fragments. The training required for such a procedure is not insignificant and the aforementioned basket removal technique is difficult for even the most skilled surgeons. Additionally, the surgeon is susceptible to hand fatigue due to the extended amount of time required to operate the kidney stone retrieval baskets. Further, the patient is required to be under local anesthesia and/or remain immobile over an extended amount of time. Still further, the basket retrieval devices cause irritation to the urinary tract due to the repeated insertion and removal therefrom.

[0009] Other kidney stone removal techniques may utilize suction devices to remove kidney stones and kidney stone fragments from the patient. Such techniques use a flexible tube designed to be disposed within a working channel of a ureteroscope. The flexible tube is designed to have a diameter of between 2 French and 3 French and includes a suction source therethrough. Utilization of this type of device necessarily restricts the size of the passageway available to remove kidney stones and portions thereof from the patient. Indeed, the diameter of the ureteroscope occupies a significant portion of the limited passageway into the patient. Therefore, the size of the flexible tube is bounded by the size of the working channel of the ureteroscope and is defined by a diameter of under about 3 French. The utilization of the working channel of a ureteroscope or other viewing instrument has heretofor been utilized to assist the surgeon in locating the matter to be removed from the patient and to assist in guiding the removal instruments to an appropriate location. The use of these devices is necessarily restricted to removal of debris that is smaller than the size of the tube disposed in the working channel (i.e., under about 3 French). Accordingly, the prior art devices of this type are unable to remove debris greater than about 2 mm and removal of even

smaller stones becomes problematic given the narrow lumen size in the prior art devices and their resulting propensity to clog, even with stones of 1 mm or less.

[0010] Kidney stone removal techniques may also make use of irrigation systems, devices, and methods to remove stone fragments from the patient. Irrigation is often used during a ureteroscope procedure.

[0011] For example, some prior-art devices use irrigation to introduce a liquid, such as water or saline solution, into the kidney. Such irrigation can be used to perform a cleansing that washes very small particles out of the remote interior regions of the kidney. However, any liquid that is introduced must drain from the kidney both during and after the procedure. Therefore, the volume of liquid that can be introduced is necessarily limited, and there is no strong liquid flow to remove fragments that are wetted by the liquid from the kidney. A more effective irrigation procedure is needed to rapidly and reliably remove particles, fragments and debris from the kidney.

[0012] A stent may be introduced following removal of stones from a kidney. A retrograde Pyelogram contrast study can be used to both verify that all clinically-relevant fragments have been removed, and to evaluate the extent of injury to the urinary collecting system. In particular, a contrast study provides information on the extent of extravasation of blood and other bodily fluids, which is indicative of the extent of injury. Information gained from a contrast study is useful in making decisions on where to place a stent and how long to leave it in place.

[0013] Thus, to further facilitate adoption of new systems, methods, and devices for kidney stone removal, it is desirable to ensure compatibility with stent placement. Placement of a stent after the removal procedure results in improved drainage and accelerated healing. It is not uncommon for edema of the ureter to occur post-procedure, resulting in significant pain. Improving drainage through placement of a stent can reduce the extent of such edema and associated pain. Furthermore, studies show that dilation of the ureter by a stent contributes to more rapid healing. For these reasons, a stent is used in the majority of such procedures worldwide, and in the overwhelming majority of stone removal procedures in the United States. Accordingly, new methods and devices that address the removal of debris greater than about 3 mm and are compatible with stent placement are desirable.

SUMMARY

[0014] In accordance with some configurations of the disclosed subject matter, methods for removing an object through a passageway of an in vivo subject are provided.

[0015] In accordance with some configurations, a method for removing an object through a passageway of an in vivo subject is provided, the method comprising: inserting a ureteroscope into the passageway; positioning the ureteroscope adjacent to an object to break the object into fragments; removing the ureteroscope from the passageway; guiding a multi-lumen catheter into the passageway adjacent to the fragments of the object using a fluoroscopic imaging device and a guide wire; opening a valve to apply suction to remove at least a portion of the fragments; removing the multi-lumen catheter from the passageway; placing a stent in the passageway; and removing the guide wire from the passageway.

[0016] In some configurations, the method further comprises re-inserting the ureteroscope following removal of multi-lumen catheter to confirm removal of the fragments.

[0017] In some configurations, re-inserting the ureteroscope following removal of multi-lumen catheter is performed prior to placing the stent.

[0018] In some configurations, the method further comprises injecting an irrigation fluid along a first lumen in the multi-lumen catheter and simultaneously or intermittently providing suction through a second lumen in the multi-lumen catheter to remove the fluid and debris along the second lumen.

[0019] In some configurations, the method further comprises injecting an irrigation fluid along a first lumen in the multi-lumen catheter by first closing the suction valve and introducing a controlled amount of fluid, then opening the valve to provide suction through the first lumen to remove the fluid and debris.

[0020] In some configurations, a first lumen of the multi-lumen catheter has a diameter between 0.5 Fr to 8 Fr.

[0021] In some configurations, a second lumen of the multi-lumen catheter has a diameter between 3 Fr to 30 Fr.

[0022] In some configurations, the object is a kidney stone.

[0023] In some configurations, the passageway is accessed laparoscopically or arthroscopically.

[0024] In some configurations, the object is diseased tissue and the passageway is located in an organ or an orifice of an in vivo subject.

[0025] In some configurations, the object includes a bladder stone or percutaneous stone.

[0026] In accordance with some configurations of the disclosed subject matter, a method for removing an object from a passageway within an in vivo subject is provided, the method comprising: inserting a guide wire along the passageway; positioning a sheath over the guide wire; inserting a ureteroscope into the passageway; positioning the ureteroscope adjacent to an object to break the object into fragments; removing the ureteroscope from the sheath; guiding a multi-lumen catheter into the passageway adjacent to the fragments of the object using fluoroscopic imaging and a guide wire; opening a valve to apply suction to remove fragments; removing the multi-lumen catheter from the passageway; placing a stent in the passageway; and removing the guide wire from the passageway.

[0027] In some configurations, the method further comprises re-inserting the ureteroscope following removal of multi-lumen catheter to inspect fragment removal.

[0028] In some configurations, the method further comprises re-inserting the ureteroscope following removal of multi-lumen catheter and prior to placing the stent to inspect fragment removal.

[0029] In some configurations, the method further comprises injecting an irrigation fluid along a first lumen in the multi-lumen catheter, while simultaneously or intermittently providing suction to remove the fluid and fragments along a second lumen.

[0030] In some configurations, the method further comprises injecting an irrigation fluid along a first lumen in the multi-lumen catheter by closing the suction valve, then opening the valve to provide suction to remove the fluid and fragments along a second lumen in the multi-lumen catheter.

[0031] In some configurations, the object is a kidney stone.

[0032] In some configurations, the passageway is a urinary tract of a human.

[0033] In some configurations, at least one of the fragments of the object is at least a portion of a kidney stone having a diameter less than 3.3 mm.

[0034] In some configurations, the object is bladder stone or percutaneous stone.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] FIG. **1** is an isometric view of a removal device including a sheath, a vacuum tube, an introducer, and a navigation mechanism;

[0036] FIG. **2** is an isometric view of a sheath of the removal device of FIG. **1**;

[0037] FIG. **3** is an isometric view of the vacuum tube and navigation mechanism of FIG. **1**;

[0038] FIG. **4** is a front elevational view of the vacuum tube of FIG. **3**, with the navigation mechanism removed therefrom for clarity;

[0039] FIG. **5** is a partial isometric view of the introducer of the removal device of FIG. **1** enlarged for magnification purposes;

[0040] FIG. **6** is a partial schematic view of the removal device of FIG. **1** further including a valve that is in communication with a suction source;

[0041] FIG. **7** is a partial schematic view depicting a possible installation of a removal device in a urinary tract of a patient in a first state, wherein a ureteroscope is disposed in the sheath of FIG. **1** adjacent a kidney stone; and

[0042] FIG. **8** is a partial schematic view of the removal device of FIG. **7** in a second state, wherein the vacuum tube and navigation mechanism of FIG. **1** is disposed adjacent kidney stone fragments.

[0043] FIG. **9**A is a perspective view of a dual lumen vacuum tube that can be used with the removal device of FIG. **1**.

[0044] FIG. **9**B is a front elevational view of the vacuum tube of FIG. **9**A.

[0045] FIGS. **10**A and **10**B show an example of a flow chart setting forth some examples of steps in a process for removing an object from a passageway using the removal device described herein.

DETAILED DESCRIPTION OF THE INVENTION

[0046] Referring generally to FIGS. **1-8**, a removal device **100** includes a sheath **102**, a vacuum tube **104**, and a navigation mechanism **106**. The removal device **100** optionally includes an introducer core **108** adapted to assist in positioning one or more portions of the removal device **100** in a passageway. The removal device **100** further optionally includes a valve **110** that is in communication with, and assists in controlling suction that is supplied to the vacuum tube **104**. One or more of the sheath **102**, navigation mechanism **106**, and/or introducer core **108** may be optional for use with the removal device **100**. For example, in one configuration, the sheath **102** is omitted from the removal device **100**.

[0047] As best seen in FIGS. **7** and **8**, the removal device **100** is designed to be positioned in a passageway of a patient (e.g., urinary tract), and in particular, into a patient's ureter **112**. The removal device **100** includes a renal end **114** designed to be positioned proximate the patient's kidney **116**, and more particularly, adjacent to one or more kidney stones **118**. The removal device **100** includes a bladder end **120** that is designed to extend through the bladder **122** and out of the patient through the urethra (not shown). The removal device **100** provides an uninterrupted passageway from the kidney stones **118** or kidney stone fragments in the kidney **116**, through the ureter **112** and bladder **122**, and out of the patient.

[0048] Now turning to FIGS. **1** and **2**, the sheath **102** is provided as at least one substantially cylindrical tube **130** defining a lumen. The tube **130** includes at least one passageway **132** extending substantially longitudinally therethrough, although additional passageways may be included in the sheath **102** as desired. The passageway **132** extends through the entirety of the sheath **102** and is adapted to receive a ureteroscope **134** (see FIG. **7**) and/or other viewing instrument. The ureteroscope **134** preferably includes a laser (not shown) or other mechanism that fractures the kidney stone **118** into smaller fragments (or dust). The passageway **132** is also designed to accommodate the vacuum tube **104** and/or navigation mechanism **106** therein, as described in more detail hereinbelow. The tube **130** is preferably substantially cylindrical to conform to the orifice and/or passageway of the patient in which the removal device **100** is designed to be utilized. In other configurations, the tube **130** includes other shapes as desired. It should also be noted that the sheath **102** may be omitted from the removal device **100** altogether such that the vacuum tube **104** is utilized and serves the function of the sheath **102**, which is discussed hereinbelow.

[0049] The sheath **102** is preferably made of a biocompatible material that is rigid enough to support the other components of the removal device **100** (e.g., the vacuum tube **104** and navigation mechanism **106**), but elastic enough to conform to the contours of the passageway of the patient. For example, suitable materials for use as the sheath **102** include polymers and copolymers such as polyurethane, polyvinyl chloride, polyethylene, polypropylene, and polyamides. Other useful materials include other biocompatible plastics, e.g., polyester, nylon based biocompatible polymers, polytetrafluoroethylene polymers, silicone polymers, and other thermoplastic polymers.

[0050] The sheath **102** is preferably defined by a length dimension of about 15 cm to about 45 cm. In a different configuration, the sheath **102** includes a length dimension of about 20 cm to about 35 cm. In a further configuration, the sheath **102** has a length dimension of about 25 cm to about 30 cm. It should be apparent that the length of the sheath **102** may be adjusted in view of numerous factors including, for example, patient size.

[0051] The sheath **102** is further defined by an interior diameter dimension of the tube **130**. In one configuration, the interior diameter of the tube **130** is between about 2 Fr. to about 30 Fr. In a different configuration, the interior diameter of the tube **130** is between about 10 Fr. to about 16 Fr. In another configuration, the interior diameter is between about 12 Fr. to about 14 Fr.

[0052] Now turning to FIGS. **3** and **4**, the vacuum tube **104** is characterized by an elongate dual lumen **140** defined by a first (larger) passageway **142** and a second (smaller) passageway **144** extending longitudinally therethrough. The vacuum tube **104** may optionally include a specialized tip (not shown) at an end thereof that assists in maintaining the patency of the vacuum tube **104**. The tip may also allow the

vacuum tube **104** to be positioned in areas that are difficult to access (e.g., the lowest part of the kidney).

[0053] The first passageway **142** is designed to accommodate the introducer **108**, which is used to assist in positioning one or more portions of the removal device **100** in the patient, as explained in more detail hereinbelow. The first passageway **142** is also designed to accommodate the suction provided from a suction source **148** (see FIG. **6**) that is utilized with the removal device **100**. The first passageway **142** of the vacuum tube **104** guides the suction to an area adjacent the kidney stones **118** (and/or kidney stone fragments) and facilitates the kidney stones **118** being removed therethrough. The first passageway **142** acts as a primary passageway for removal of the kidney stones **118** (and/or kidney stone fragments).

[0054] Still referring to FIGS. **3** and **4**, the second passageway **144** of the vacuum tube **104** is disposed adjacent an internal surface **160** of the lumen **140** and is designed to accommodate the navigation mechanism **106** as shown in FIG. **3**. In a different configuration, the second passageway **144** may also accommodate a ureteroscope or other viewing instrument. In still a further configuration, the second passageway **144** may accommodate other devices that may be utilized in conjunction with the removal device. For example, in one particular configuration, a miniature camera, ureteroscope, or other visualization device may be utilized through either the first or second passageway **142**, **144**. Although depicted adjacent the internal surface **160**, the second passageway **144** may be disposed in any other location within the vacuum tube **104**, or may be omitted all together. Further, the size of the first and second passageways **142**, **144** may be adjusted as desired.

[0055] In a different configuration, the removal device **100** and/or vacuum tube **104** includes additional lumens extending therethrough. For example, in one configuration, the removal device **100** includes a first passageway adapted to receive a suction source, a second passageway adapted to receive a camera or other visual aid, and a third passageway adapted to receive a guidewire.

[0056] The vacuum tube **104** is preferably made of a flexible biocompatible material such that the vacuum tube **104** is able to move through the contours of the passageway of the patient. The vacuum tube **104** is preferably made of a material that is not susceptible to kinks and knots during insertion, use, and removal. For example, in some configurations, the vacuum tube **104** is constructed of a thermoplastic elastomer, or a natural or synthetic polymer such as silicone. In other configurations, suitable materials for use include other polymers and copolymers such as polyurethane, polyvinyl chloride, polyethylene, polypropylene, and polyamides. Other useful materials include other biocompatible plastics, e.g., polyester, nylon based biocompatible polymers, polytetrafluoroethylene polymers, silicone polymers, and other thermoplastic polymers.

[0057] One or more portions of the vacuum tube **104** may include a coating and/or may comprise a hydrophilic or hydrophobic material. The coating may assist in positioning the vacuum tube **104** within the sheath **102**, positioning the navigation mechanism **106** within the vacuum tube **104**, and/or assisting in debris removal through the first passageway **142**.

[0058] The vacuum tube **104** may also include a reinforcement mechanism (not shown) along a portion (or all) thereof that assists in maintaining the patency and the flexibility thereof. In one configuration, the reinforcement mechanism is provided in the form of a spiral or non-spiral wire. In a different configuration, the reinforcement mechanism is provided in other forms as known in the art.

[0059] In one configuration, the vacuum tube **104** includes a hydrophilic or hydrophobic coating and the vacuum tube **104** is used without the sheath **102**. In a different configuration, the vacuum tube **104** is designed to be disposed at least partially within the sheath **102** during use. Therefore, the circumference of the vacuum tube **104** is smaller than that of the sheath **102**. The lumen **140** of the vacuum tube **104** is defined by a diameter of between about 3 Fr. to about 30 Fr., more preferably between about 10 Fr. to about 18 Fr., and most preferably between about 11 Fr. to about 13 Fr. In one configuration, the lumen **140** of the vacuum tube **104** is about 10 Fr. In a different configuration, the lumen **140** of the vacuum tube **104** is about 11 Fr. In still a different configuration, the lumen **140** of the vacuum tube **104** is about 12 Fr.

[0060] The diameter of the second passageway **144** of the vacuum tube **104** is smaller than the diameter of the lumen **140** and is characterized by a diameter of between about 0.5 Fr. to about 8 Fr., and more preferably between about 3 Fr. to about 6 Fr. In one configuration, the second passageway **144** of the vacuum tube **104** is about 3 Fr. In a different configuration, the second passageway **144** of the vacuum tube **104** is about 4 Fr. In still a different configuration, the first passageway **144** of the vacuum tube **104** is about 7 Fr.

[0061] Still referring to FIG. **3**, as discussed previously, the second passageway **144** of the vacuum tube **104** is designed to accommodate the navigation mechanism **106** as shown in FIG. **3**. The navigation mechanism **106** is preferably provided in the form of a guidewire. Guidewires suitable for use in the removal device **100** are characterized by a diameter of between about 0.014 in. to about 1 in. In one configuration, the guidewire is characterized by an elongate flexible material having a diameter of about 0.035 in. or about 0.038 in. Guidewires suitable for use with the removal device **100** include, for example, the Sensor™ guidewire provided by Boston Scientific (Natick, Mass.), or the Glidewire™ provided by Terumo International Systems (Tokyo, Japan). Additionally, the removal device **100** may be utilized in conjunction with the guidewire described in U.S. patent application Ser. No. 12/660,891, filed on Mar. 5, 2010, and incorporated by reference in its entirety. In other configurations, the navigation mechanism **106** may comprise other devices or mechanisms that assist in positioning portions of the removal device **100**.

[0062] The vacuum tube **104** and/or other portions of the removal device **100** may be controlled using various control mechanisms. For example, in one configuration, the vacuum tube **104** is controlled using a knob, a lever, a button, a foot pedal, combinations thereof, and the like. Various operational parameters may be controlled with the aforementioned control mechanisms including positioning and/or navigating one or more components of the vacuum tube **104**, and/or controlling (e.g., increasing or decreasing) the level of suction.

[0063] In one configuration, the guidewire is designed to be inserted into the patient and navigated to the kidney **116**. The removal device **100** is passed over the guidewire through one of the passageways described herein (e.g., the second passageway **144**). In some instances, the sheath **102**

is optionally inserted into the patient first, followed by one or more of the guidewire and/or removal device **100**.

[0064] In a different configuration, the removal device **100** is designed to interact with and pass over the guidewire. In one configuration, the guidewire is inserted into the sheath **102**. In a different configuration, the guidewire is inserted into a portion of the vacuum tube **104** (e.g., through the first or second passageway **142**, **144**, respectively). The guidewire may be utilized in one or more of the passageways in the removal device **100**. In a preferred configuration, the guidewire is initially inserted into the flexible tube **130** of the sheath **102** in conjunction with the ureteroscope **134**. The guidewire is also preferably utilized in conjunction with the second passageway **144** as a guidance mechanism for the vacuum tube **104** as described in more detail hereinbelow.

[0065] Now turning to FIG. **5**, portions of the removal device **100** may optionally be positioned in the passageway with the assistance of a positioning device, for example, such as an introducer core **108**. The introducer core **108** includes a rigid, elongate body **170** with a rounded groove **172** extending longitudinally therethrough. The groove **172** preferably has a contour that accommodates the navigation mechanism **106** (e.g., guidewire). For example, in one configuration, the groove **172** is preferably rounded to accommodate a substantially cylindrical guidewire.

[0066] The body **170** of the introducer core **108** terminates at a tapered tip **174** at an end **176** thereof. The tip **174** includes a taper that allows the introducer core **108** to be more easily inserted into the patient (i.e., through the patient's urethra). The introducer core **108** is adapted to be disposed in at least one of the passageways of the removal device **100** to provide support thereto. In one configuration, the introducer core **108** is inserted into the sheath **102**. In a different configuration, the introducer core **108** is inserted into a portion of the vacuum tube **104** (e.g., through the first or second passageway **142**, **144**, respectively).

[0067] The introducer core **108** may be utilized in one or more of the passageways in the removal device **100** to assist with positioning thereof. In a preferred configuration, the introducer core **108** is inserted into the first passageway **142** of the vacuum tube **104** to assist in placement thereof. The introducer core **108** preferably extends substantially the entire length of the first passageway to provide a rigid support for the vacuum tube **104** as the vacuum tube **104** is being positioned in the passageway (e.g., urinary tract). The introducer core **108** is preferably detachable such that it may be removed from the second passageway **142** (or other portion of the removal device **100**) after placement of the vacuum tube **104** is complete.

[0068] The removal device **100** is designed to be optionally utilized with the valve **110** (See FIG. **6**) that is in fluid communication with the suction source **148** and is capable of controlling the suction associated with the vacuum tube **104**. In one configuration, the valve **110** is a gate valve and may be designed to accommodate tubes and/or portions of the removal device **100** having varying diameters. The valve **110** preferably includes at least two different states, whereby the suction is supplied to the removal device **100** in a first state (i.e., via the vacuum tube **104**), and whereby the suction is not supplied to the removal device **100** in a second state. The valve **110** may also include intermediate states that allow the suction to be supplied at a specified level. The valve **110** may further include a safety feature such as an auto-shut down mechanism that terminates the suction once a threshold pressure is breached. Other types of valves may be utilized in conjunction with the removal device as known in the art.

[0069] The valve **110** is adapted to be in communication with the suction source **148** via a tube or other mechanism. In one configuration, the suction source **148** is a wall suction as known in the art. In a different configuration, the suction source **148** may be a standard suction unit that is stationary or otherwise portable. In a further configuration, the suction source **148** may be supplied in some other way. In one configuration, a suction source **148** capable of supplying a pressure of about −22 mmHg is utilized, although it should be appreciated that the suction source **148** may supply other pressures as desired.

[0070] The removal device **100** may optionally include a sealable port (not shown), for example, such as one that uses a stopcock valve, for infusing or otherwise providing a liquid or other substance into the device **100**. In one configuration, saline is infused through one or more of the passageways of the removal device **100** described herein. In this configuration, the suction may be off or paused. In a different configuration, the suction may be used to assist in transporting or otherwise moving the substance through the removal device **100**.

[0071] Now turning to the use of the removal device **100**. In one configuration, the removal device **100** is adapted to be used in a medical setting. In particular, the removal device **100** may be used to remove debris or another foreign object (e.g., kidney stone, diseased tissue, and the like) from a patient (not shown). The debris may reside in one or more organs, orifices, or passageways. Accordingly, the removal device **100** may be utilized in any passageway to assist in removing debris therefrom or adjacent thereto.

[0072] In one configuration best seen in FIGS. **7** and **8**, the removal device **100** is designed to be positioned in a patient's urinary tract. As depicted in FIG. **7**, the sheath **102** is inserted into the patient's urethra (not shown) and extends through the bladder **122** and ureter **112** until being positioned proximate a kidney stone(s) **118**, which is most likely disposed in a portion of the urinary tract (e.g., adjacent the kidney **116**). The ureteroscope **134** (or other viewing instrument) is inserted into the sheath **102** along with the navigation mechanism **106**. The ureteroscope **134** and navigation mechanism **106** are pushed through the sheath **102** until extending through substantially the entirety thereof. The ureteroscope **134** is used to fracture the kidney stone(s) **118** into fragments **180** (see FIG. **8**) via a laser or other similar device. After the kidney stone(s) **118** are fractured, the ureteroscope **134** is removed from the sheath **102**, and preferably, the navigation mechanism **106** is retained within the sheath **102**. Alternatively, in a different configuration, the navigation mechanism **106** may be removed.

[0073] As shown in FIG. **8**, the vacuum tube **104** is thereafter inserted into the sheath **102** and utilizes the navigation mechanism **106** for guidance thereof. The introducer **108** is disposed within the vacuum tube **104** (e.g., in the first passageway **142**) to maintain open communication through the passageways in the vacuum tube **104** during insertion into the patient. Additionally, the second passageway **144** of the vacuum tube **104** is aligned with the navigation mechanism **106**. As the vacuum tube **104** is pushed through the sheath **102** (via the introducer **108**), the navigation mechanism **106** aligns the second passageway **144** and guides the vacuum tube **104** to the fragments **180**.

Once the vacuum tube **104** is positioned adjacent the fragments **180**, the introducer **108** is detached and removed therefrom. Once the introducer **108** has been removed, the valve **110** is opened to allow access to the suction source **148** and the fragments **180** are pulled from the patient through the removal device **100**. A catch or basket (not shown) may be utilized outside of the patient (or in a portion of the removal device **100**) to collect the fragments **180**, biopsied tissue, and/or other debris.

[0074] Another configuration for a vacuum tube **204** that can be used in connection with removal device **100** is shown in FIGS. **9**A and **9**B. As shown in FIGS. **9**A and **9**B, the vacuum tube **204** can be characterized by an elongate dual lumen **240** defined by a first (larger) passageway **242** and a second (smaller) passageway **244** extending longitudinally therethrough. The second passageway **244** can be disposed adjacent an internal surface **260** of the dual lumen **240**. For example, as illustrated, the second passageway **244** can share a portion of a wall with the internal surface **260** and/or be fused to the internal surface **260**. In one configuration, the first passageway **242** can be used to accommodate suction from the suction source **148** (e.g., as described above in connection with FIG. **6**).

[0075] Still referencing FIGS. **9**A and **9**B, the second passageway **244** of the vacuum tube **204** can be configured to accommodate the navigation mechanism **106** (e.g., a guidewire) and/or another device (e.g., ureteroscope **134**, another viewing instrument, etc.). Additionally, in some configurations, the first passageway **242** of the vacuum tube **204** can be configured to accommodate the navigation mechanism **106** (e.g., a guidewire) and/or another device (e.g., ureteroscope **134**, another viewing instrument, etc.). In some configurations, the second passageway **244** can accommodate the flow of an irrigation fluid from a fluid irrigation source to a distal end of the vacuum tube **204** to facilitate the removal of debris through an in vivo passageway of a patient (e.g., after removal of the navigation mechanism **106** and/or any other device). For example, in one particular non-limiting configuration, the fluid irrigation source can be a syringe connected through any suitable connection, such as a needle that is in fluid communication with the second passageway **244** of the vacuum tube **204**, a luer-type connector that is in fluid communication with the second passageway **244** of the vacuum tube **204**, and/or any other suitable connector. Pressure can be applied to the syringe to dispense the irrigation fluid through the second passageway **244** in the direction of the object to be removed. In other non-limiting examples, in addition to, and/or in lieu of, the syringe described above, the fluid irrigation source can include a wash bottle, a positive displacement pump, or any other suitable fluid irrigation sources known to those skilled in the art.

[0076] The vacuum tube **204** can be configured to selectively provide suction (e.g., through the first passageway **242**) from the suction source (e.g., suction source **148** described above in connection with FIGS. **1**-**8**) before, during and/or after flushing a target region of the in vivo passageway with the irrigation fluid. For example, as described above, the valve **110** (as shown in FIG. **6**) can be used to control suction that is supplied to the vacuum tube **204**. The first passageway **242** and the second passageway **244** can be configured to be any suitable sizes.

[0077] Operation of the removal device **100** when removing a kidney stone **118** from a patient's kidney **116** through the patient's ureter **112** is described below with reference to FIGS. **10**A and **10**B. The removal device **100** can include any suitable configuration, such as configurations described above in connection with FIGS. **1** to **9**B. Additionally or alternatively, in some configurations, the removal device **100** can be configured for other medical uses such as treating bladder stones, and/or for use with other procedures, such as percutaneous stone removal, laparoscopic procedures, spine procedures, arthroscopic surgery, and microsurgery (e.g., to treat knee, ankle, foot, and hand issues). The removal device **100** can also be used to remove dead tissue, masses, and other debris. In a further configuration, the removal device **100** can be used in biopsy procedures.

[0078] At **1000**, the removal device **100** can be configured to locate the passageway that contains the object for removal. In one non-limiting configuration, the passageway can be located using a cystoscope, which can be inserted into the bladder and used to find the opening to the patient's ureter **112**.

[0079] At **1002**, the navigation mechanism **106** can be inserted into the passageway **132** of the patient. In some configurations, the navigation mechanism **106** includes a guide wire that is inserted into the patient's ureter **112**, and passed through to the patient's kidney **116**. A sheath **102** can then be optionally positioned over the navigation mechanism. If the sheath **102** is being used in the procedure ("YES" at **1004**), the sheath can be positioned in the patient's ureter **112** at **1006**.

[0080] At **1008**, an endoscope can be inserted into the passageway of the patient and positioned adjacent to the target object (e.g., a kidney stone). Note that the endoscope can be used regardless of whether the sheath is being used at **1004**. In a non-limiting example, the endoscope can be a ureteroscope (e.g., the ureteroscope **134**) that can be positioned adjacent to a kidney stone **118** within a patient's kidney **116**.

[0081] At **1010**, the endoscope can be used to fragment the object using any suitable technique or combination of techniques. For example, in some configurations, the ureteroscope includes a laser that can be used to break the kidney stone **118** into fragments until the fragments have reached a suitable sized, such as roughly 3 mm or smaller. It is to be appreciated that, in some configurations, the ureteroscope can be maneuvered without the assistance of the guide wire **106**. At **1012**, the endoscope can be removed from the patient's ureter **112** and/or from the sheath **102**.

[0082] At **1014**, a catheter can be inserted into the passageway of the patient and/or the sheath **102** of the removal device **100**. In some configurations, the catheter can include multiple lumens. For example, as described above in connection with FIG. **3**, the first lumen can be the first passageway **142** of vacuum tube **104**, and the second lumen can be the second passageway **144**, which can, among other things, accommodate the navigation mechanism **106**, and/or can be in fluid communication with the irrigation fluid source. Alternatively, a variety of catheters with various configurations can be used, such as the configuration described above in connection with FIGS. **9**A and **9**B. Note that, in some configurations, the catheter can be inserted through sheath **102** and/or the in vivo passageway of the patient and the endoscope can be inserted through the catheter. For example, as described above in connection with FIGS. **9**A and **9**B, the second passageway of the vacuum tube **204** can

accommodate an appropriately sized endoscope (e.g., an endoscope having an external diameter less than or equal to about 1 millimeter).

[0083] At **1016**, the fragments within the passageway of the patient can be removed using the vacuum tube. In one non-limiting configuration, a fluoroscope may be used as a visual guide to position the vacuum adjacent to the fragments to be removed. In some configurations, an irrigation fluid can be used to assist in the removal of the fragments from the passageway **134**. If irrigation is to be used ("YES" at **1018**), in one non-limiting configuration, an irrigation fluid source (e.g., a syringe containing irrigation fluid, a pump, etc.) can be coupled to at least one lumen of the catheter to place the irrigation fluid source into fluid communication with the at least one lumen in the catheter. If irrigation fluid is to be used, the suction and irrigation provided through the removal device **100** can be configured to operate sequentially ("YES" at **1020**) or simultaneously ("NO" at **1020**). If suction and irrigation are to be provided simultaneously ("NO" at **1020**), at **1022**, the valve **110** in fluid communication with the catheter can be opened to provide suction through a first lumen of the catheter (e.g., the first passageway **242** of the vacuum tube **204**) during injection of the irrigation fluid through a second lumen of the catheter (e.g., the second passageway **244** of the vacuum tube **204**). Alternatively, if suction and irrigation are to be provided sequentially ("YES" at **1020**), at **1024**, the valve **110** in fluid communication with the catheter can be closed and/or can remain closed while irrigation fluid is injected through the catheter, at **1026**.

[0084] At **1028**, the valve **110** can be opened to provide suction through a lumen of the catheter (which may be the same or different than the lumen through which irrigation fluid was provided). At **1030**, the valve **110** can be closed to stop suction through the lumen of the catheter through which suction was being provided. In some configurations, injecting irrigation fluid at **1026**, providing suction to remove irrigation fluid and/or fragments at **1028**, and stopping suction at **1030** can be repeated any suitable number of times. At **1032**, the catheter can be removed from the passageway of the patient.

[0085] If a post-inspection of the passageway **132** is to be performed ("YES" at **1034**), at **1036**, an endoscope can be inserted into the sheath **102** and/or the passageway **134** to inspect whether there are any remaining fragments to be removed. If there are remaining fragments to be removed ("NO" at **1038**), **1010** through **1034** can be repeated as necessary until there are no longer fragments to be removed. Otherwise, if the results are acceptable ("YES" at **1038**), at **1042** the endoscope (and if present, at **1044**, the sheath **102**) can be removed from the passageway **134**.

[0086] At **1046**, the passageway **134** can be imaged to inspect for any remaining fragments or other debris and any potential damage (e.g., caused by the procedure). In one non-limiting example, any suitable technique or combination of techniques can be used to image the passageway of the patient. For example, a retrograde pyelogram, an intravenous pyelogram (IVP), and/or any other suitable technique can be performed to provide images of the patient's kidneys **116**, the patient's ureter **112**, and/or the urinary tract in order to identify problems with the structure or the presence of kidney stones **118**, tumors, infection, etc. In some configurations, the retrograde pyelogram or IVP can be performed in association with another suitable imaging technique or combination of techniques, such as an ultrasound, a computed tomography (CT) scan, etc.

[0087] At **1048**, in some embodiments, a stent can be placed in the passageway **132** of the patient, and the navigation mechanism **106** can be removed at **1050**. Note that, in some configurations, the navigation mechanism **106** can be removed at any suitable time, such as prior to providing irrigation fluid (e.g., in configurations where the same lumen is used for the navigation mechanism **106** and irrigation).

[0088] It should be noted that the removal device **100** may be utilized in the manner described herein without fracturing the kidney stone(s) **118**. In particular, the kidney stone(s) may be removed directly so long as they are sized to pass through the removal device **100**. The removal device **100** described herein is capable of removing debris having varying sizes. For example, the removal device **100** is designed to remove debris that are characterized as particles of dust (e.g., about 0.001 μm to about 10,000 μm).

[0089] The removal device **100** is also designed to remove small, medium, and large kidney stones or other debris. For example, in one configuration, the removal device **100** is designed to remove kidney stones having an approximate diameter of between about 0.0001 mm to about 8 mm. In a different configuration, the removal device **100** is designed to remove kidney stones having an approximate diameter of between about 0.1 mm to about 6 mm. In a different configuration, the removal device **100** is designed to remove kidney stones having an approximate diameter of between about 1 mm to about 5 mm. In still a different configuration, the removal device **100** is designed to remove kidney stones having an approximate diameter of between about 2 mm to about 4 mm. It should be noted that, in one configuration, the removal device **100** described herein is designed to be utilized as described and does not utilize the working channel of a device (i.e., a ureteroscope).

[0090] In a further configuration, the removal device **100** is designed for other medical uses, such as, to treat bladder stones and for use with other less invasive procedures, such as percutaneous stone removal, laparoscopic procedures, spine procedures, arthroscopic surgery, and microsurgery (e.g., to treat knee, ankle, foot, and hand issues). The removal device **100** may also be used to remove dead tissue, masses, and other debris. In a further configuration, the removal device **100** is used in a biopsy procedure.

[0091] The removal device **100** may be utilized in conjunction with visualization mechanisms including with, for example, fluoroscopy, ultrasound, computerized tomography (CT) scans, and magnetic resonance imaging. One or more portions of the removal device **100** may further comprise one or more radio opaque markers (not shown) and/or radio opaque materials to assist in inserting, positioning, and/or removing the removal device **100**. For example, a radio opaque marker may be disposed adjacent an end of the vacuum tube **104** and/or navigation mechanism **106** to assist in the positioning thereof. The marker may be visible to a physician under X-ray, fluoroscopy, or other visual aids. The removal device **100** may include one or more radio opaque markers on other portions thereof, including on the sheath **102**, the introducer core **108**, or other portions thereof. In use, the physician may use the mark(s), for example, to facilitate placement of the removal device **100** in the patient.

[0092] In one particular configuration, the removal device **100** is used in conjunction with fluoroscopy. In another

configuration, the removal device **100** is used in conjunction with a cystoscope, miniature camera, or other visualization device. In this configuration, the removal device **100** is not inserted into or utilized by the working channel of the cystoscope. Rather, the cystoscope should have a relatively small diameter (e.g., less than about 3 mm) and the removal device **100** is used in conjunction (separately) therewith or designed as a system with direct visualization and the removal device. A navigation mechanism **106** may optionally be used in this configuration to guide the cystoscope and/or the removal device **100** to the desired location.

[0093] Thus, systems and methods are disclosed that are particularly advantageous for addressing the ureter and kidney using an aspirator. For example, some traditional devices attempt to meet clinical needs with a separate or dedicated aspirator. However, in the present disclosure, the aspirator may be inserted over a guidewire after a treatment, such as a ureteroscopy with laser, has been performed.

[0094] The present invention has been described in terms of one or more preferred embodiments, and it should be appreciated that many equivalents, alternatives, variations, and modifications, aside from those expressly stated, are possible and within the scope of the invention.

What is claimed is:

1. A method for removing an object, comprising:

guiding a flexible tube through an in vivo subject's ureter, wherein the flexible tube comprises at least a first passageway and a second passageway;

positioning a distal end of the first passageway adjacent to the object;

infusing saline solution through the second passageway while suction is off; and

removing the object through the first passageway with at least a portion of the saline solution.

2. The method of claim **1**, further comprising causing suction to be applied simultaneous with further infusion of saline solution through the second passageway.

3. The method of claim **1**, wherein the flexible tube has an external diameter of at least about 11 French.

4. The method of claim **1**, further comprising:

inserting a sheath into the in vivo subject's ureter;

inserting a ureteroscope through the sheath;

positioning the ureteroscope adjacent to a second object;

using the ureteroscope to break the second object into a plurality of objects including the object; and

wherein the flexible tube is guided through the sheath.

5. The method of claim **4**, wherein the flexible tube is guided through the sheath subsequent to removal of the ureteroscope.

6. The method of claim **4**, wherein the ureteroscope is guided through the flexible tube, and wherein the object is removed through the first passageway subsequent to removal of the ureteroscope.

7. The method of claim **4**, wherein the second object is a kidney stone that has a diameter greater than about 10 millimeters and cannot be removed through the first passageway, and the object is a fragment of the kidney stone that has a diameter of less than about 4.33 millimeters.

8. A device for removing an object, comprising:

a flexible tube comprising at least a first passageway and a second passageway, wherein the flexible tube is configured to be inserted through an in vivo subject's ureter;

a navigation mechanism configured to be inserted through the second passageway to guide the flexible tube through the ureter;

a port coupled to the second passageway and configured to be coupled to a source of saline solution that is to be provided through the second passageway subsequent to removal of the navigation mechanism; and

wherein the object is removed through the first passageway while saline solution is infused through the second passageway.

9. The device of claim **8**, further comprising a valve coupled to the first passageway and configured to be coupled to a suction source.

10. The device of claim **8**, wherein the navigation mechanism is a guidewire.

11. The device of claim **8**, further comprising a sheath comprising a third passageway through which the flexible tube is inserted, wherein the sheath is configured to be inserted through the in vivo subject's bladder and into the in vivo subject's ureter.

12. The device of claim **11**, wherein the sheath is sized to accommodate a ureteroscope.

13. The device of claim **8**, wherein the flexible tube has an external diameter of at least about 11 French.

14. The device of claim **8**, wherein the first passageway has a diameter of at least about 10 French.

* * * * *

专利名称(译)	用于从体内受试者引导移除的系统和方法		
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摘要(译)

根据一些配置，提供了用于从体内受试者引导去除的系统和方法。在一些配置中，提供了一种用于移除对象的方法。该方法包括引导柔性管穿过体内受试者的输尿管，其中柔性管包括至少第一通道和第二通道。将第一通道的远端定位在与物体相邻的位置。在抽吸关闭时，通过第二通道注入盐水溶液。用至少一部分盐水溶液通过第一通道移除物体。