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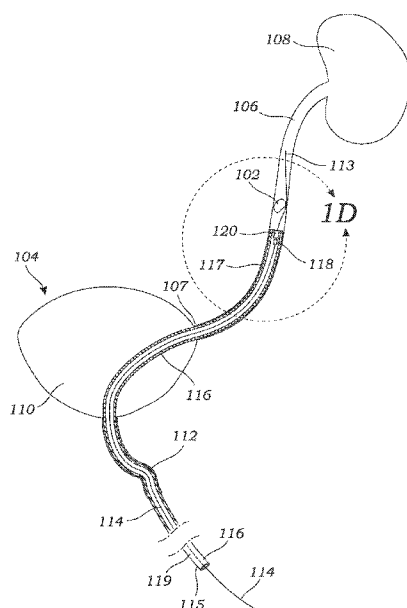


Fig. 1C

(57) Abstract: Systems and methods for performing minimally-invasive, intracor-
poreal treatment of occlusions of body tubes and cavities, such as ureteral stones.
The systems and methods utilize a catheter having an acoustic energy transducer
configured to be advanced into a patient in a minimally-invasive procedure via a
natural body pathway of a patient to apply acoustic energy to an occlusion to break
up the occlusion so that it can be extracted or naturally passed by the patient.

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METHODS AND SYSTEMS FOR TREATMENT OF OCCLUSIONS IN ANATOMICAL CAVITIES USING ACOUSTIC WAVE ENERGY

RELATED APPLICATION DATA

- 5 [0001] The present application claims benefit of co-pending U.S. provisional application Serial No. 63/200,825, filed March 31, 2021, the entire disclosure of which is expressly incorporated by reference herein.

TECHNICAL FIELD

- 10 [0002] The present application relates to medical devices, and, more particularly, to systems and methods for treating occlusions (e.g., kidney stones, gall bladder stones, clots, calcium/calcified plaque, soft plaque, etc.) in anatomical cavities, such as body tubes, blood vessels, organs, etc., using acoustic wave energy.

BACKGROUND

- 15 [0003] Occlusions may form in various cavities of the human body, which cause pain and/or damage to the blocked anatomical system. For instance, “kidney stones” or “stones” can form in the urinary system. The presence of stones in the urinary system can cause severe pain and, in some cases, systemic infections. Stones form in the kidney and can
20 travel towards the bladder via the ureter. Obstruction of urine from stones can result in renal colic, ureteral stricture and tissue damage in the ureteral system. More than 75% of patients with stones in the urinary system are symptomatic, and it is one of the most frequently cited reasons for emergency room (ER) visits. Approximately 80% of renal stones are calcium-based. Stones form in the presence of supersaturated solutions in the kidney followed by
25 nucleation, growth, aggregation and retention of crystals in the kidneys. The majority of stones (>80%) measuring less than or equal to 3 millimeters (mm) in size pass spontaneously through the urinary system without the need for procedural intervention. For stone size greater than 3 mm, the rate of spontaneous passage decreases by approximately 10% for every 1 mm increase in stone size.
- 30 [0004] There are currently four main treatment modalities for removing ureteral stones, i.e., kidney stones: medical expulsion therapy (MET), ureteroscopy with laser lithotripsy (URS), extracorporeal shockwave lithotripsy (ESWL) and percutaneous nephrolithotomy (PCNL). MET is only recommended for ureteral stones less than ten millimeters to aid in

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stone expulsion without surgical procedures. MET involves administering medication to the patients, and having the patient drink extra fluids to help flush the urinary system. The medications may include alpha-blockers, calcium channel blockers, corticosteroids, and phosphodiesterase-5 (PDE5) inhibitors. The patients are typically asked to wait three to
5 four weeks to allow the stone(s) to pass naturally. During this waiting period, patients often take oral pain relief medications (over the counter and/or opioid) and Flomax to also help with flushing the urinary system. If the stones do not pass in four weeks or if they develop severe pain or infection or hydronephrosis, their urologist will schedule them for a procedure because following the waiting period, it is clear their chances of passing the stone
10 are low.

[0005] URS is the gold standard for treating ureteral stones that is offered for patients with stones less than 20 millimeters in size and has the highest stone-free rate. However, it also is relatively invasive, often causing ureteral trauma. URS involves insertion of a uteroscope, under general anesthesia, into the urinary tract up to the ureter to visualize the
15 stones. Then, a laser beam on the uteroscope is used to break the stone into smaller pieces which may then be extracted using a basket, or allowed to naturally pass through the ureter. A ureteral stent is then placed in the ureter to keep the ureter open, and to allow edema and inflammation caused the stone and/or treatment. The ureteral stent must be retained for at least seven days after the procedure. The stent is then removed through another cystoscopy
20 procedure. Ureteral stents themselves cause a lot of pain, often even more than the stone itself, and require an additional cystoscopy procedure for removal of the stents.

[0006] ESWL is a non-invasive procedure and is recommended for stones less than 20 mm in size. ESWL involves placing a shock wave machine on the outside of the patient's body against the abdomen and transmitting shock waves through the patient's body directed
25 at the stone to break up the stone into fragments small enough to naturally pass through the urinary tract. A mild anesthetic may be administered to the treatment area. However, ESWL has an efficacy of only about 50% and is associated with post-procedural pain and bleeding. Very few physicians prefer this procedure due to its low efficacy and high re-intervention rates.

30 [0007] PCNL is an invasive surgical procedure for removing stones in the kidney or upper ureter which are too large for the other forms of treatment such as ESWL and URS. PCNL is typically performed under general anesthesia. A small incision is made in the patient's back adjacent the location of the stone. A cannula and/or endoscope is inserted

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through the incision into the kidney to visual the stone, break it up, and remove the stone fragments from the body. An ultrasonic, mechanical or laser lithotripsy device may be used to break up the stone into small pieces which are extracted out through the cannula. PCNL entails a prolonged hospital stay, whereas ESWL is typically an outpatient procedure.

5 However, PCNL has a superior stone clearance rate as compared to ESWL, especially for lower pole stones. In addition, PCNL is more suitable for large stones and when ancillary procedures are required (e.g., endopyelotomy).

[0008] Similarly, gallstones can form in the gallbladder of the digestive system.

Gallstones can block the entrance to the bile duct and/or can cause a blockage within the
10 bile duct, which can cause extreme pain, discomfort, nausea, and/or vomiting. There are currently no highly effective methods for treating gallstones, other than removing the gallbladder. However, this removing the gallbladder requires surgery, and the lack of a gallbladder can result in other discomfort and ailments. Although extracorporeal shock wave lithotripsy was once considered to be a promising nonoperative alternative for the
15 management of symptomatic gallstones but had its limitations, including relatively low efficacy rates.

[0009] Clots (e.g., soft plaque) and plaque (e.g., calcium/calcified plaque) can form in blood vessels and other cavities and organs of the circulatory system of the human body. There are currently various treatment modalities for occlusions in the blood vessels caused
20 by clots and plaque, including atherectomies (e.g., ablative removal to cut, sand, shave or vaporize atherosclerotic plaque), angioplasty, insertion of stents, bypass surgery, etc. However, each of these types of procedures has drawback, such that there is a need for improved methods and devices treating clots and plaque in the circulatory system.

[0010] Accordingly, there is a need for more effective, less-invasive, systems and
25 methods for treating ureteral stones.

SUMMARY

[0011] The present disclosure is directed to improved systems and methods for performing minimally-invasive, intracorporeal treatment of occlusions within anatomical
30 cavities of a patient using acoustic wave energy. The systems and methods may be configured to specifically adapted to treat each of the various types of occlusions, such as kidney stones in the urinary tract, gallstones in the digestive system, clots and plaque occlusions in the circulatory system, etc. The systems and methods utilize a minimally-

invasive approach using a small catheter having an acoustic energy transducer configured to be advanced through tubular pathways and/or cavities of the body to break up the occlusion so that it can be extracted or naturally passed by the patient. The catheter is designed to be inserted through a very small incision, or a natural opening in the body (e.g., the urethra), and then advanced through natural body pathways to the location of the occlusion. For example, in one example, the catheter is adapted to be advanced through the urethra and bladder of a patient to apply acoustic energy to a ureteral stone to break up the stone so that it can be extracted or naturally passed by the patient. In the case of kidney stones, the methods and systems disclosed herein utilize minimally-invasive approach which can be performed in an office or operating room setting, which is effective on stone sizes and has an efficacy rate equivalent to, or better, than the URS, i.e., the current best practices procedure. The method and systems utilize a trans-urethral approach, similar to cystoscopy. The catheter may be positioned in the ureter or bladder, depending on the example, using a guidewire, or without using a guidewire.

[0012] Accordingly, one example disclosed herein is directed to an anatomical occlusion treatment catheter. The anatomical occlusion treatment catheter includes an elongated, flexible, tubular member having a proximal end and distal portion. The tubular member is sized and configured to be inserted through the small pathways within the body of a patient. For example, the tubular member may have a diameter of 15 French (15 Fr; 1 Fr = 0.33 mm) or less, or in another aspect 9 Fr or less. An acoustic energy transducer is disposed on a distal portion of the tubular member. The acoustic impedance of the acoustic energy transducer is designed to match the acoustic impedance of the particular occlusion matter (e.g., kidney stone, gallstone, calcium/calcified plaque, soft plaques, clot, etc.) within +/- 20% difference for maximum energy transfer to the occlusion, and to reduce any off-target effects to the surrounding tissue, muscles or organs. As used herein, the term "impedance" means acoustic impedance (as opposed to electrical impedance), unless otherwise specified. For instance, for a catheter designed to break up a kidney stone, the acoustic energy transducer has an impedance within +/- 20% of a typical kidney stone. The acoustic energy transducer may be any suitable acoustic transducer, such as a piezoelectric transducer, capacitive based transducer, electrohydraulic transducer, electromechanical transducer, capacitive micromachined ultrasonic transducer (CMUT), piezoelectric micromachined ultrasonic transducer (PMUT), optical micromachined ultrasonic transducer

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(OMUT), other ultrasound transducer, or similar transducer which generates an acoustic wave in an acoustic medium.

[0013] In another aspect, the acoustic energy transducer has one or more acoustic matching layers on the transducer material (e.g., on a piezoelectric transducer) to match the acoustic impedance of the acoustic energy transducer to the occlusion.

[0014] In another aspect, the acoustic energy transducer may be cylindrical in shape or a concave or convex rectangular shape with a thickness of less than 3 mm (or in another aspect less than 2 mm), for achieving the necessary focusing to break the occlusion. The size (height) of the acoustic energy transducer is at least 50% that of the size of the occlusion. The size of an occlusion is the longest length dimension of the occlusion. As some examples, the size of an approximately spherical shaped occlusion is the diameter, the size of an approximately rectangular shaped occlusion is the length of the longest side, the size of an approximately elliptical shaped occlusion is the major diameter, etc. As different occlusion types, as well as different occlusions of the same type, have varying shapes, multiple configurations of catheters may be available that meet the at least 50% coverage requirement of the occlusion.

[0015] In another aspect of the occlusion treatment catheter, the catheter may be configured to be deployed into the body and advanced to position the acoustic energy transducer within about five mm of the occlusion in order to fragment the occlusion.

[0016] In yet another aspect, the occlusion treatment catheter may also include one or more detection sensors for detecting the location of the occlusion within the body pathways (e.g., the urinary tract) and/or assisting in navigation of the catheter through the body pathways (e.g., the urinary tract). Although many examples described herein are directed to use in the urinary tract, the occlusion treatment catheter may be adapted for use, and used, in any suitable system of the human body, including without limitation, the circulatory system, the digestive system, etc. The detection sensor(s) are also disposed on the distal or lateral portion of the tubular member. The detection sensor(s) may be forward-facing in the distal direction and/or side facing (laterally facing). The detection sensor(s) may be any suitable type, for example, transducers, including but not limited to camera, pressure, impedance, optical coherence tomograph (OCT), doppler, regular ultrasound, radio opaque marker, radio frequency, temperature, or combination of the foregoing, which can provide a signal for detecting the location of a stone and/or the catheter within the urinary tract. The detection sensor can also be used to determine the proximity of the acoustic energy

transducer to the stone to be broken up and removed from the ureter, the size of the stone, the size of the stone fragments, etc. The combination of the tubular member and detection sensor(s) have a diameter of less than 15 Fr, or in another aspect, less than 9 Fr.

[0017] In another aspect, the detection sensor(s) may be a part of a detection system which includes the sensor(s) and a sensor signal processing system configured to receive the sensor signals and generate sensor data that can be used by a clinician in operating the ureteral stone treatment catheter. For instance, the detection system may use the sensor signals to generate images, distance information, location information and the like, which indicates one or more of the location of the stone, the location of the catheter, the proximity of the acoustic energy transducer to the occlusion, the size of the occlusion, the size of the occlusion fragments after fragmenting with acoustic energy, etc.

[0018] In yet another aspect, the occlusion treatment catheter may have a single transducer having dual modes including a detection mode for performing the function of the detection sensor(s) and an acoustic wave mode for performing the function of the acoustic energy transducer. In other words, the acoustic energy transducer and detection sensor may be integrated into a single transducer.

[0019] In another aspect, the detection sensors can be fixed or rotational in all directions to generate a complete imaging of the urinary tract for accurate location tracking. All of these sensors (forward or side facing) can potentially serve as the detection system to aid the physician in determining the precise location of the catheter inside the urinary tract and accurately locating the stone.

[0020] In still another aspect, the occlusion treatment catheter may have a working channel or lumen for providing access to the distal portion of the catheter from the proximal end of the catheter. For example, an imaging catheter or other detection catheter can be deployed through the working channel to the distal portion of the catheter to assist in detecting the location of the occlusion within the body pathways (e.g., the urinary tract) and/or assisting in navigation of the catheter through the body pathways (e.g., the urinary tract, similar to the detection sensor described above. Additionally, the working channel or lumen can be used to irrigate the area of the stone inhibit any trauma or damage to the ureter which could be caused by the acoustic energy applied to break up a stone, and/or to remove the stone fragments after the stone has been broken up by the acoustic energy.

[0021] In yet another aspect, the occlusion treatment catheter may include one or more balloons disposed on the distal portion of the tubular member. For instance, in one example,

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the catheter may have a distal balloon disposed on the tubular member distal to the acoustic energy transducer, and/or a proximal balloon disposed on the tubular member proximal to the acoustic energy transducer. In an alternative example, the catheter may have a single balloon having a distal balloon portion, disposed on the tubular member distal to the acoustic energy transducer, and a proximal balloon portion disposed on the tubular member proximal to the acoustic energy transducer. The balloon(s) is deployed in an uninflated state to the target location proximate the occlusion for applying the acoustic energy, and is then inflated by inserting an inflation fluid into the balloon(s). The balloon(s) may serve several useful purposes. First, the balloon(s) may be used to stabilize the distal portion of the catheter including the acoustic energy transducer during the therapy. In addition, the balloon(s) may contain the occlusion in position during therapy to prevent stone fragments from moving around. Furthermore, the proximal balloon, or proximal balloon portion may be positioned proximal to the occlusion to assist in removing the occlusion fragments by applying irrigation proximal to the occlusion fragments to flush out the fragments, while the distal balloon, or distal balloon portion, may be positioned distal to the occlusion such that it can be used assist in pulling out the occlusion fragments as the catheter is retracted from the body pathways (e.g., the urinary tract).

[0022] In another aspect, the occlusion treatment catheter may include an end effector disposed on the distal end of the tubular member for holding the occlusion in place while applying acoustic energy to fragment the occlusion. For example, the extractor may be a cage-like effector to hold the occlusion in place. The end effector may also assist in removing the occlusion fragments after therapy as the catheter is retracted from the body pathways (e.g., the urinary tract).

[0023] In another aspect, the occlusion treatment catheter may be a part of an occlusion treatment system (e.g., a ureteral stone treatment system) which includes a controller configured to control the operation of the catheter. The controller includes a user interface having a display and user input devices, sensor and transducer interfaces and a power supply for powering the sensor(s) and the acoustic energy transducer. The controller is configured to generate and display to the user data and/or images from the sensor signals. The controller is also configured to control and power the acoustic wave energy for the acoustic energy transducer. In another aspect, the system is configured to generate acoustic wave energy of varying parameters, including but not limited, a focused high (0.5-3Mhz) ultrasound frequency of continuous multiple pulses delivered at a varying duty cycle, or an

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alternating or modulating high (0.5-3Mhz) ultrasound frequency of multiple continuous pulses at a varying duty cycle.

[0024] In another aspect, the system may be configured maintain the energy amplitude or intensity of the ultrasound or shockwave described above at a low or high level

5 depending on the focal size of the acoustic energy transducer. The high (positive)-pressure amplitude could range from 2MPa to 7MPa, and the low (negative)-pressure amplitude could range from -2MPa to -7MPa.

[0025] In another aspect, the controller is also configured to control the acoustic wave parameters to optimize the effectiveness in fragmenting an occlusion and/or to increase the efficacy rate of the therapy. The system is programmable to accommodate the acoustic wave parameters and change the signature of the wave energy that is best suitable for effectively fragmenting the occlusion, including one or more of: the focal size of the acoustic transducer, the pressure amplitudes, ultrasound or shockwave frequency, duty cycle (duration of positive wave vs negative wave), successive delivery of energy waves and the pulse rate frequency.

[0026] In another aspect, the occlusion stone treatment catheter may be configured to fragment a stone within the ureter from a greater distance, such as from within the bladder, or within the ureter and more than 5 mm from the stone. In such case, the catheter is configured to be deployed through a cystoscope or similar device with a camera and working channel to access the bladder via the urethra. The ureteral stone treatment catheter is deployed through the working channel of the cystoscope to position the acoustic energy transducer proximate the bladder-end of the ureter, or within the ureter more than 5 mm from the stone. The sensor(s) on the catheter may be used to detect the exact location of the stone in the ureter in order to direct the acoustic energy transducer towards the stone. The sensor(s) can also detect any movement of the patient and adjust accordingly to compensate for the movement to ensure the therapy is delivered to the appropriate location of the stone.

[0027] Another example described herein is directed to a first method of using the occlusion treatment catheter to treat an occlusion within a human body. The treatment catheter is inserted into a body of a patient in a minimally-invasive technique (such as through a natural body opening or small incision) to access a natural body pathways. The catheter is advanced through the body pathways to position the acoustic energy transducer in close proximity to the occlusion. The detection sensor(s) may provide feedback, i.e., the sensor data, such as images, location data, proximity data, and the like, to the clinician

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which the clinician uses to assist in navigating the catheter through the body pathways, positioning the acoustic energy transducer proximate the occlusion, and verifying the proximity of the acoustic energy transducer to the occlusion. In another aspect, the proximity is preferably less than 5 mm.

5 [0028] Optionally, in another aspect, the location of the occlusion be accessed by the catheter using a guidewire system. The guidewire is inserted into the human body (e.g., as described above for the catheter) and is advanced through the body pathways to the location of the occlusion. The guidewire may be further advanced around and beyond the occlusion, if necessary. The guidewire may include a sensor that detects impedance, or it may have an
10 OCT, ultrasound or other imaging to provide visualization for navigating the guidewire through the body pathways. The guidewire may also include a sheath around it to prevent damaging or injury to the body tissue forming the body pathways.

[0029] Once the guidewire is positioned, the catheter is deployed as an over-the-wire catheter via the guidewire. For example, the catheter may have a guidewire lumen which
15 extends along the entire length, or substantially entire length, of the catheter, or a rapid-exchange lumen which extends through only a distal portion of the catheter. The catheter is advanced over the guidewire through the body pathways into the bladder and into the ureter. As without the guidewire, the clinician may use feedback from the detection sensor(s), i.e., the sensor data, such as images, location data, proximity data, and the like, to assist in
20 navigating the catheter through the body pathways, positioning the acoustic energy transducer proximate the occlusion, and verifying the proximity of the acoustic energy transducer to the occlusion (e.g., preferably less than 5 mm).

[0030] Once the catheter is positioned with the acoustic transducer in close proximity to the occlusion, the acoustic energy transducer delivers acoustic energy to the stone to break
25 the occlusion into smaller pieces or even dust. As used herein, the terms “break,” “broken,” “break up” and “broken up,” with respect to an occlusion, includes fragmenting an occlusion into smaller particles or pieces, pulverizing or dusting an occlusion into dust or tiny particles, unless otherwise stated. In another aspect of the method, the occlusion is broken into particles having a diameter less than or equal to about 3 mm (or in another
30 aspect, less than or equal to about 2 mm). As used herein, the term “about” means within plus or minus 15%. In still another aspect, the clinician can confirm the size of the particles using one or more of the detection sensor(s), such as by imaging the particles, detecting the size of the particles, etc.

[0031] In still another aspect of the first method, the catheter may be used to irrigate the area of the occlusion with an irrigation fluid, such as saline, to inhibit any trauma or damage to the anatomical feature in which the occlusion is formed and other surrounding tissues and organs that could be caused by the acoustic energy. In another aspect, in the case that the catheter includes the proximal balloon or proximal balloon portion, the proximal balloon or proximal balloon portion may be used to provide an irrigation channel to irrigate the proximal side of the occlusion.

[0032] In another aspect of the first method, the catheter may include the distal balloon or distal balloon portion, and/or the proximal balloon or proximal balloon portion. In such case, the catheter is deployed with the balloon(s) in the uninflated state, and the catheter is positioned relative to the occlusion with the distal balloon (or distal balloon portion) distal to the occlusion and the proximal balloon (or proximal balloon portion). The balloon(s) are then inflated to stabilize the occlusion in place while the acoustic energy transducer breaks up the occlusion. In still another aspect of the method, the balloon is used to contain the occlusion in position during therapy to prevent the occlusion fragments from moving around. In still another aspect, the proximal balloon portion is used to assist in removing the occlusion fragments by applying irrigation proximal to the stone fragments to flush out the fragments. In yet another aspect, the distal balloon or distal balloon portion is used to assist in pulling out the occlusion fragments as the catheter is retracted from the body pathways and out of the body.

[0033] In still another aspect of the first method, the treatment catheter includes the end effector disposed on the distal end of the tubular member. The end effector is actuated to hold the occlusion in place while applying acoustic energy to fragment the occlusion. The end effector is also used to capture the occlusion fragments to assist in removing the occlusion fragments as the catheter is retracted from the body pathways.

[0034] In still another example of the first method, the controller generates and displays data and/or images from the sensor signals. The controller also controls and powers the acoustic wave energy for the acoustic energy transducer. In another aspect, the controller generates acoustic wave energy of varying parameters, including but not limited, a focused high (0.5-3Mhz) ultrasound frequency of continuous multiple pulses delivered at a varying duty cycle, or an alternating or modulating high (0.5-3Mhz) ultrasound frequency of multiple continuous pulses at a varying duty cycle.

[0035] In another aspect, the system may be configured to maintain the energy amplitude or intensity of the ultrasound or shockwave described above at a low or high level depending on the focal size of the acoustic energy transducer. The high (positive)-pressure amplitude could range from 2MPa to 7MPa, and the low (negative)-pressure amplitude could range from -2MPa to -7MPa.

[0036] In still another aspect of the method, the controller controls the acoustic wave parameters of the acoustic energy transducer to optimize the effectiveness in fragmenting a stone and/or to increase the efficacy rate of the therapy. The controller is programmed to accommodate the acoustic wave parameters and change the signature of the wave energy that is best suitable for effectively fragmenting the stone, including one or more of: the focal size of the acoustic transducer, the pressure amplitudes, ultrasound or shockwave frequency, duty cycle (duration of positive wave vs negative wave), successive delivery of energy waves and the pulse rate frequency.

[0037] In additional aspects of the method, the ureteral stone treatment catheter may have any of the features and aspects described herein, and the method may include any of the functions and processes performed by such features and aspects.

[0038] Another example described herein is directed to a second method of using the occlusion treatment catheter to treat an occlusion. The second method utilizes the occlusion treatment catheter configured to break up an occlusion within an anatomical feature from a greater distance than in the first method, such as from than 5 mm from the occlusion. As described above, a cystoscope, or similar device, having a camera. The camera may be used to capture images of the body pathways leading to the anatomical features to assist in navigating the cystoscope to a location within the anatomical feature to position a distal end of the cystoscope in proximity to the occlusion and more than 5 mm from the occlusion.

[0039] The catheter is then deployed through the working channel of the cystoscope to position the acoustic energy transducer proximate the occlusion and more than 5 mm from the stone. The detection sensor(s) may provide feedback, i.e., the sensor data, such as images, location data, proximity data, and the like, to the clinician which the clinician uses to assist in navigating the catheter through the body pathways, positioning the acoustic energy transducer within the body pathways, verifying the proximity of the acoustic energy transducer to the occlusion, and/or detecting the exact location of the occlusion in the body pathways in order to direct the acoustic energy transducer towards the occlusion. The detection sensor(s) may also detect any movement of the patient and adjust accordingly to

compensate for the movement to ensure the therapy is delivered to the appropriate location of the stone.

[0040] Once the catheter is positioned with the acoustic transducer at the desired location and oriented to direct the acoustic energy towards the occlusion, the acoustic energy transducer delivers acoustic energy to the occlusion to break the occlusion. The second method may also include any of combination of one or more of the other applicable aspects and features of the first method. For instance, the second method may include, without limitation, the use of a guidewire, the means of irrigation, the means of stabilization, means of extracting the broken up occlusion, and/or the functions of the controller controlling the acoustic energy delivered by the acoustic energy transducer.

[0041] Additional aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0042] The foregoing and other aspects of examples are described in further detail with reference to the accompanying drawings, wherein like reference numerals refer to like elements (e.g., elements having the same number are considered like elements such as 50a and 50b) and the description for like elements shall be applicable for all described examples wherever relevant:

[0043] FIGS. 1A-1D are partial cross-sectional views showing an example of a ureteral stone treatment catheter and a method for using the same to break a stone in the ureter of a urinary tract of a patient.

[0044] FIGS. 2A-2C are partial cross-sectional views showing another example of a ureteral stone treatment catheter and a method for using the same to break a stone in the ureter of a urinary tract of a patient.

[0045] FIGS. 3A-3D are partial cross-sectional views showing yet another example of a ureteral stone treatment catheter and a method for using the same to break a stone in the ureter of a urinary tract of a patient.

[0046] FIG. 4 is a front, perspective view of an exemplary ureteral stone treatment system, which includes any of the ureteral stone treatment catheters disclosed herein.

[0047] FIGS 5-7 are front, enlarged, perspective views of examples of acoustic energy transducers for use in the occlusion treatment catheters, including the ureteral stone treatment catheters.

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DETAILED DESCRIPTION

[0048] Specific examples of an anatomical occlusion treatment catheter will now be described. The specific examples are directed to treating a kidney stone (referred to as a “stone”) within the urinary tract, with the understanding that the disclosed occlusion treatment catheter and its use may also be adapted for use in treating any occlusions within an anatomical feature accessible by natural body pathways using a minimally invasive approach, such as treating gallstones in the digestive system, treating clots and plaque occlusions in the circulatory system, etc.

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[0049] Referring to the drawings, FIGS. 1A-1D depict an example of a ureteral stone treatment catheter 100 (also referred to as “catheter 100”) for treating a ureteral stone 102 and a method of using the catheter 100 to treat the stone 102 in the ureter 106 of the urinary tract 104 of a patient. FIG. 1A shows the stone 102 to be treated within the ureter 106 of the urinary tract 104.

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[0050] Turning to FIG. 1B, the occlusion treatment catheter 100 (also referred to as “ureteral stone occlusion treatment catheter 100” or “treatment catheter 100”) comprises an elongated, flexible, tubular member 116. The tubular member 116 has a proximal end 115 and a distal portion 117. The tubular member 116 has a diameter and flexibility compatible with advancing the tubular member 116 into the ureter 106 via the patient’s urethra 112 and bladder 110. Accordingly, the tubular member preferably has a diameter of 15 Fr or less. Alternatively, the tubular member may have a diameter of 9 Fr or less. The tubular member 116 may be formed of any suitable material which provides sufficient flexibility to navigate the urinary tract 104, such as suitable polymeric materials, metals and/or alloys, such as polyethylene, stainless steel or other suitable biocompatible materials or combinations thereof.

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[0051] The catheter 100 has an acoustic energy transducer 120 disposed on the distal portion 117 of the tubular member 116. The acoustic energy transducer 120 may be any suitable acoustic transducer, such as a piezoelectric transducer, capacitive based transducer, electrohydraulic transducer, electromechanical transducer, capacitive micromachined ultrasonic transducer (CMUT), piezoelectric micromachined ultrasonic transducer (PMUT),

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optical micromachined ultrasonic transducer (OMUT), other ultrasound transducer, or similar transducer which generates an acoustic wave in an acoustic medium. Typically, the acoustic energy transducer 120 is oriented laterally (i.e., side-facing) to transmit acoustic energy waves radially from the tubular member 116, or even at an angle between forward-facing and side-facing in order to direct acoustic energy in both a radial and forward direction. This allows the acoustic energy transducer 120 to have a size The acoustic energy transducer 120 may be oriented distally (i.e., forward-facing) to transmit acoustic energy waves distally beyond the distal end of the tubular member 116 and substantially along the longitudinal axis of the tubular member 116. For instance, the acoustic energy transducer 120 may be mounted on the very distal end of the tubular member 116, or within the tubular member 116 and directed to transmit acoustic energy waves out of the distal end of the tubular member 116. The acoustic energy transducer 120 is configured to transmit acoustic energy waves at the stone 102 from a distance of about five mm or less of the stone 102 in order to break up the stone 102.

[0052] The acoustic impedance of the acoustic energy transducer 120 is designed to match the acoustic impedance of a typical stone 102 within +/- 20% difference for maximum energy transfer to the stone 102, and to reduce any off-target effects to the surrounding tissue, muscles or organs. For other types of occlusion treatment catheters (such as a gallstone treatment catheter, clot treatment catheter, plaque treatment catheter), the acoustic energy transducer is designed to match the impedance of the particular occlusion matter (e.g., kidney stone, gallstone, calcium/calcified plaque, soft plaque, clot, etc.) within +/- 20% difference.

[0053] As shown in Figs. 5-7, the acoustic energy transducer 120 may have different shapes configured to effect the acoustic wave energy transmitted by the transducer 120.

Fig. 5 illustrates a cylindrical shaped acoustic energy transducer 120a. Fig. 6 illustrates an acoustic energy transducer 120b having a rectangular shape having one or more convex sides. Fig. 7 shows an acoustic energy transducer 120c having a rectangular shape having one or more concave sides. Each acoustic energy transducer 120 has a height "h" which is the length of a side of the transducer 120 from which the transducer 120 transmits acoustic wave energy, as depicted in Figs. 5-7, and a thickness "t" which is the length of the transducer 120 transverse to the height. The acoustic energy transducer 120 has one or more acoustic matching layers 121 on the transducer material (e.g., on a piezoelectric transducer) to configure the transducer 120 such that the acoustic impedance of the acoustic energy

transducer matches the particular type of occlusion, such as the stone 102. In order to produce sufficient focusing to break the stone 102, or other occlusion as the case may be, the acoustic energy transducer 120 has a thickness of less than 3 mm (or in certain examples, less than 2 mm) and one of the shapes of transducers 120a, 120b or 120c.

5 [0054] In addition, in order to produce sufficient energy to break the stone 102, or other occlusion as the case may be, the height “h” of the acoustic energy transducer is at least 50% that of the size of the stone 102 (or other occlusion). The size of the stone 102 (or other occlusion) is the longest dimension of the stone 102, such as the diameter of an approximately spherical shaped stone 102, length of the longest side of an approximately rectangular shaped occlusion, the major diameter of an approximately elliptical shaped stone 102, etc. To account for the different occlusion types, as well as different occlusions of the same type have varying shapes, multiple configurations of catheters 100 may be available that meet the at least 50% coverage requirement of the occlusion.

10 [0055] The ureteral stone treatment catheter 100 has one or more detection sensor(s) 118 disposed on the distal portion 117 of the tubular member 116. The example of the catheter 100 depicted in FIGS. 1B-1D has a single detection sensor 118, but additional detection sensors 118 may be similarly utilized. Similar to the acoustic energy transducer 120, the detection sensor 118 may be forward-facing in the distal direction to detect in the distal direction, side facing (laterally facing) to detect in a radial direction, or at an angle therebetween to detect in both a radial and forward direction. The detection sensor 118 is configured to perform any one or more of various functions, including: assisting in navigation of the catheter 100 through the urinary tract 104; detecting the location of the stone 102 within the ureter 106; determine the proximity of the acoustic energy transducer 120 to the stone 102; determine the size of the stone 102; and/or determine the size of the stone fragments after breaking the stone 102. The detection sensor 118 may be of any suitable type which can provide a sensor signal for performing the above functions, a detection and/or imaging transducer, including but not limited to camera, pressure, impedance, optical coherence tomograph (OCT), doppler, regular ultrasound, radio frequency, temperature, or combination of the foregoing.

25 [0056] The detection sensor 118 is a part of a detection system which includes the sensor 118 and a sensor signal processing system 168 (see FIG. 4) within a controller 160 (see FIG. 4). The sensor signal processing system 168 is configured to receive the sensor signals from the sensor 118 and to generate sensor data that can be used by a clinician in

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operating the ureteral stone treatment catheter 100. In various examples, the sensor signal processing system 168 may use the sensor signals to generate images, distance information, location information and the like, which indicates and/or shows one or more of: features of the urinary tract 104 as catheter is navigated through the urinary tract 104, the location of the stone 102; the location of the catheter 102, the proximity of the acoustic energy transducer 120 to the stone 102; the size of the stone 102; the size of the stone fragments after fragmenting with acoustic energy, etc.

[0057] In addition, the detection sensor(s) 118 may be fixed relative to the tubular member 116. Alternatively, the detection sensor(s) 118 may be rotational in all directions to detect (e.g., image) the entire urinary tract surrounding the catheter 100. This allows the detection sensor(s) 118 to more accurately perform the functions of the detection sensor(s) 118, as described herein.

[0058] The acoustic energy transducer 120 and/or any one or more of the detection sensor(s) 118 may be integrated into a single transducer having dual modes (or multiple modes in the case of 3 or more integrated transducers) including detection for performing the function of the detection sensor(s) 118 and an acoustic wave mode for performing the function of the acoustic energy transducer 120. An example of a single, dual mode transducer 120a is shown in FIGS. 3A-3D.

[0059] Optionally, the ureteral stone treatment catheter 100 may also have a working channel or lumen 119 (referred to collectively as a “working channel 119”) which for provides access to the distal end of the catheter 100 from the proximal end of the catheter 100. The working channel 119 may comprise the lumen 119 of the tubular member 116. Alternatively, the working lumen 119 may be an additional channel or lumen disposed on the outer surface of the tubular member 116. The working channel may be used to deploy imaging catheter or other detection catheter to the distal portion of the catheter 100 to assist in detecting the location of the stone 102 within the urinary tract 104 and/or assisting in navigation of the catheter 102 through the urinary tract 104, similar to the detection sensor(s) 118 described above. Additionally, the working channel 119 can be used to direct irrigation fluid to the area of the stone 102 to inhibit any trauma or damage to the ureter 106 which could be caused by the acoustic energy applied to break up the stone 102, and/or to remove the stone fragments after the stone 102 has been broken up by the acoustic energy.

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[0060] The working channel 119 may also function as a guidewire lumen 119 which extends along the entire length, or substantially entire length, of the catheter 100.

Alternatively, the catheter 100 may have a rapid-exchange lumen (not shown) which extends along only a distal portion of the catheter 100.

5 [0061] The ureteral stone treatment catheter 100 may be a part of a ureteral stone treatment system 160 as depicted in FIG. 4. The ureteral stone treatment system 160 includes the catheter 100 and a controller 161. The catheter 100 is operably coupled to the controller 161, such as by connectors and/or a wireless communication system. The controller 161 is configured to control the operation of the catheter 100. The controller 161
10 includes a user interface having a display 166 for displaying images and other data, including images and data generated by the detection system. The controller 161 also has user input devices 162 configured to allow the user to operate and control the treatment system 160. The controller 161 has sensor interface(s) for receiving sensor signals from the sensor(s) 118. The controller also has transducer interfaces and a power generator 170 for
15 supplying power to drive the acoustic energy transducer 120. The controller 161 is also configured to control the acoustic wave energy transmitted by the acoustic energy transducer 120.

[0062] The controller 161, in combination with the acoustic energy transducer 120, is configured to generate acoustic wave energy of varying parameters, including but not
20 limited, a focused high (0.5-3Mhz) ultrasound frequency of continuous multiple pulses delivered at a varying duty cycle, or an alternating or modulating high (0.5-3Mhz) ultrasound frequency of multiple continuous pulses at a varying duty cycle.

[0063] The controller 161 is also configured to maintain the energy amplitude or intensity of the ultrasound or shockwave generated by the acoustic energy transducer 120 at
25 a low or high level depending on a focal size of the acoustic energy transducer 120. The controller 161 can provide high (positive)-pressure amplitude could range from 2MPa to 7MPa, and the low (negative)-pressure amplitude could range from -2MPa to -7MPa.

[0064] The controller 161 is also configured to control the acoustic wave parameters of the acoustic energy transducer 120 to optimize the effectiveness in fragmenting the
30 stone 120 and/or to increase the efficacy rate of the ureteral stone therapy. To this end, the controller 161 is programmable to accommodate the acoustic wave parameters and change the signature of the wave energy that is best suitable for effectively fragmenting the stone 120, including one or more of: the focal size of the acoustic energy transducer 120,

the pressure amplitudes, ultrasound or shockwave frequency, duty cycle (duration of positive wave vs negative wave), successive delivery of energy waves and the pulse rate frequency.

[0065] With reference to FIGS. 1A-1D, a method will be described for using the ureteral stone treatment catheter 100 to treat the ureteral stone 102 - in other words, to break the stone 102 and remove it from the urinary tract 104. It is understood that the disclosed method may also be adapted to treat any occlusions within an anatomical feature accessible by natural body pathways using a minimally invasive approach, such as treating gallstones in the digestive system, treating clots and plaque occlusions in the circulatory system, etc.

[0066] The treatment catheter 100 is advanced, via the urethra 112 and the bladder 110, into the ureter 106 to position the acoustic energy transducer 120 in close proximity to the stone 102. This may be accomplished using a guidewire 114, as shown in FIGS. 1B-1D, or without a guidewire, such as with the use of cystoscope or other similar device, or by inserting the standalone catheter 100.

[0067] If a guidewire 114 is utilized, the guidewire 114 is inserted into the urethra 112 and is advanced through the urethra 112 into the bladder 110, and then into the ureter 106. The guidewire 114 may have a sheath (not shown) around it to prevent damaging or injury to the ureter 112. The guidewire 114 is further advanced in the ureter 106 towards the stone 102 to be treated. As shown in FIGS. 1B-1D, the guidewire 114 may be advanced around and beyond the stone 102 towards the kidney 108. The guidewire 114 may include a sensor (same or similar to the sensor 118) that detects impedance, or it may have an OCT, ultrasound or other imaging to provide visualization for navigating the guidewire 114 through the urinary tract 104.

[0068] After the guidewire 114 is positioned as shown in FIG. 1B, the catheter 100 is deployed as an over-the-wire catheter 100 via the guidewire 114. The guidewire lumen, e.g., working lumen 119 or other guidewire lumen as described above, receives the guidewire 114 and the catheter 100 is advanced over the guidewire 114 through the urethra 112 into the bladder 110 and into the ureter 106. The catheter is advanced over the guidewire 114 to position the acoustic energy transducer 120 proximate the stone 102. As without the guidewire, the clinician may use feedback from the detection sensor(s), i.e., the sensor data, such as images, location data, proximity data, and the like, to assist in navigating the catheter through the urinary tract, positioning the acoustic energy transducer

120 proximate the stone 102, and verifying the proximity of the acoustic energy transducer to the stone (e.g., preferably less than 5 mm).

[0069] In the case of a cystoscope instead of a guidewire 114, the cystoscope is first deployed in the urinary tract 104 similarly to the guidewire 114, and may have a camera or other sensor to assist in navigating the cystoscope. The catheter 100 is then deployed through a working channel of the cystoscope to position the acoustic energy transducer 120 proximate the stone 102.

[0070] With or without the use of a guidewire 114 or cystoscope, the detection sensor 118 is used to assist the clinician in navigating the catheter through the urinary tract, positioning the acoustic energy transducer 120 proximate the stone 102, and verifying the proximity of the acoustic energy transducer 120 to the stone 102 (preferably less than 5 mm).

[0071] As shown in FIGS. 1B and 1C, when the catheter 100 is positioned with the acoustic energy transducer 120 in close proximity to the stone 102, the acoustic energy transducer 120 delivers acoustic wave energy to the stone 102 to break the stone 102 into smaller pieces or even dust. The acoustic energy transducer 120 is powered and controlled by the power generator 170 of the controller 160, according to the acoustic wave parameters described above. Optionally, while the acoustic energy transducer 120 is delivering acoustic wave energy to break the stone 102, the area of the stone 102 within the ureter 106 is irrigated with an irrigation fluid, such as saline, delivered via the working lumen 119, to inhibit any trauma or damage to the ureter and other surrounding tissues and organs that could be caused by the acoustic energy.

[0072] Typically, the goal is to break the stone 102 (or other occlusion) into particles having a diameter less than or equal to about 3 mm, or even less than 2 mm. The detection sensor 118 is used to detect and confirm the size of the particles of the broken up stone 102. The area of the broken up stone 102 may also be irrigated with the irrigation fluid delivered via the working lumen 119, to flush the broken up stone 102 from the urinary tract 104.

[0073] After the stone 102 is broken up, and the stone fragments are extracted from the urinary tract 104, the catheter 100 and/or the guidewire 114 and/or cystoscope are withdrawn and removed from the urinary tract 104.

[0074] Turning now to FIGS. 2A-2B, another exemplary ureteral stone treatment catheter 140 (also referred to as “catheter 140” or “treatment catheter 140”) for treating a ureteral stone 102 and a method of using the catheter 140 to treat the stone 102 in the

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ureter 106 of the urinary tract 104 of a patient, is illustrated. The treatment catheter 140 is substantially similar to the catheter 100, except that catheter 140 is configured to break up the stone 120 within the ureter 102 from a greater distance than catheter 100, including with the acoustic energy transducer 120 positioned within the bladder 110, or within the ureter 106 and more than 5 mm from the stone 102. Typically, as catheter 140 does not have to be advanced all the way into the ureter 106, the catheter 140 is configured to be deployed through a cystoscope or similar device with a camera and working channel to access the bladder 110 via the urethra 112. Nevertheless, the catheter 140 may be deployed without or without a guidewire 114, or as a standalone device, in the same manner of deployment as the catheter 100, as described herein.

[0075] The catheter 140 may be a part of a ureteral stone treatment system 160 as depicted in FIG. 4, same as described with respect to the catheter 100.

[0076] With reference to FIGS. 2A-2B, a method for using the ureteral stone treatment catheter 140 to treat the ureteral stone 102 will now be described. The ureteral stone treatment catheter 140 is advanced through the urethra 112, into the bladder to position the acoustic energy transducer 120 proximate the bladder-end 107 of the ureter 106.

Alternatively, the catheter 140 may be further advanced into the ureter 106 to position the acoustic energy transducer 120 within the ureter 106 more than 5 mm from the stone 120.

The catheter 140 may be deployed in the urinary tract 104 by any of the methods described above, such as with or without a guidewire, or with use of a cystoscope or similar device. In the typical method using a cystoscope, the cystoscope is first deployed within the urinary tract 104 by advancing the cystoscope through the urethra 112, and into the bladder 110 with a distal end of the cystoscope positioned proximate the bladder-end 107 of the ureter 106. The camera on the cystoscope is used to capture images of urinary tract 104 to assist in navigating the cystoscope. The catheter 140 is then deployed through the working channel of the cystoscope through the urethra 112 into the bladder, to position the acoustic energy transducer 120 proximate the bladder-end of the ureter 106.

[0077] In any of the methods of deploying the catheter 140, the detection sensor(s) 118 on the catheter 120 may be used to assist in navigating the catheter 140, to detect the exact location of the stone 102 in the ureter 106 in order to direct the acoustic energy transducer 120 towards the stone 102, and/or perform any of the other functions of the detection sensor(s) described herein. The sensor(s) 118 can also detect any movement of

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the patient and adjust accordingly to compensate for the movement to ensure the therapy is delivered to the appropriate location of the stone 102.

[0078] With the catheter 140 positioned with the acoustic transducer at the desired location and oriented to direct the acoustic energy towards the stone 102, the acoustic energy transducer 120 delivers acoustic energy to the stone 102 to break the stone 102. The delivery of acoustic energy is performed in the same manner as for the method for using catheter 120. The method of using the catheter 140 to treat the stone 102 may include irrigation for inhibiting damage and/or removing the broken up stone, as describe for the method of using the catheter 120, described above.

[0079] After the stone 102 is broken up, and the stone fragments are extracted from the urinary tract 104, the catheter 140 and/or the guidewire 114 and/or cystoscope are withdrawn and removed from the urinary tract 104.

[0080] Turning to FIGS. 3A-3D, still another example of a ureteral stone treatment catheter 150 (also referred to as “catheter 150” or “treatment catheter 150”) for treating a ureteral stone 102 and a method of using the catheter 150 to treat the stone 102 in the ureter 106 of the urinary tract 104 of a patient, is illustrated. The catheter 150 is similar to the catheter 100, except that it also includes one or more balloons 152, and/or an end-effector (not shown) disposed on the disposed on the distal portion 117 of the tubular member 116. The acoustic energy transducer 120 and detection sensor 118 in the catheter 150 are depicted as the single, dual mode transducer, as described herein. Of course, the catheter 120 may comprise a separate acoustic energy transducer 120 and detection sensor 118. Again, the catheter 150 and method of using the same may be adapted for use in treating any type of occlusions within an anatomical feature accessible by natural body pathways using a minimally invasive approach, such as treating gallstones in the digestive system, treating clots and plaque occlusions in the circulatory system, etc.

[0081] As best shown in FIGS. 3B and 3D, the catheter 150 includes a distal balloon 152a disposed on the distal portion 117 of the tubular member 116 and positioned distal to the acoustic energy transducer 120, and a proximal balloon 152b disposed on the distal portion 117 of the tubular member 116 and positioned proximal to the acoustic energy transducer 120. FIG. 3B shows the balloons 152a, 152b in an uninflated state, and FIG. 3D shows the balloons 152a, 152b in an inflated state. The balloons 152a, 152b may be separate balloons or a single balloon having a distal balloon portion positioned distal to the acoustic

energy transducer 120, and a proximal balloon portion positioned proximal to the acoustic energy transducer 120.

[0082] As depicted in FIGS. 3A and 3B, the balloons 152a, 152b are deployed in an uninflated state to the target location proximate the stone 102 for applying the acoustic energy, and are then inflated as shown in FIGS. 3C and 3D. When the balloons 152a, 152b are inflated around the stone 102, the balloons 152a, 152b stabilize the distal portion of the catheter 150, including the acoustic energy transducer 120, while the acoustic energy transducer 120 applies acoustic wave energy to the break the stone 102. In addition, the balloons 152a, 152b may contain the stone 102 and the stone fragments after the stone 102 is broken up in position to prevent stone and stone fragments from moving around. The balloons 152a, 152b can also assist in irrigating the area of the stone 102 while breaking up the stone 102, and assist in removing the broken up stone 102 from the urinary tract 104. For instance, the proximal balloon 152b, or proximal balloon portion, may be inflated in the position proximal to the stone 102 to assist in irrigating the area of the stone while delivering acoustic wave energy to the stone 102, and removing the stone fragments by applying irrigation proximal to the stone fragments to flush out the fragments. The distal balloon 152a, or distal balloon portion, can be inflated distal to the stone 102 such that it can be used assist in pulling out the stone fragments as the catheter 150 is retracted from the urinary tract 104.

[0083] Alternative to, or in addition to, the balloons 152, the catheter 150 may have an end effector (not shown) disposed on the distal portion 117 of the tubular member 116. The end effector is configured to the stone 102 in place while applying acoustic energy to fragment stone 102. As one non-limiting example, the extractor may be a cage-like effector configured to hold the stone 102 in place. The end effector may also be used to assist in removing the stone fragments after therapy as the catheter 150 is retracted and removed from the urinary tract 104.

[0084] The catheter 150 may be a part of a ureteral stone treatment system 160 as depicted in FIG. 4, same as described with respect to the catheter 100.

[0085] FIGS. 3A-3D also illustrate a method for using the ureteral stone treatment catheter 150 to treat the ureteral stone 102. The method of using the catheter 150 is very similar to the method of using the catheter 100, except for the added functions of the balloons 152a, 152b, and/or the end effector. Accordingly, the catheter 150, with the balloons 152a, 152b in the uninflated state, is deployed into the urinary tract 104 by any of

the methods described for deploying the catheter 100 into the urinary tract 104. The treatment catheter 150 is advanced, via the urethra 112 and the bladder 110, into the ureter 106 to position the acoustic energy transducer 120 in close proximity to the stone 102 (preferably less than 5 mm), with the distal balloon 152a position distal to the stone 102 and the proximal balloon 152b positioned proximal to the stone 102, within the ureter 106. As shown in FIGS. 3C and 3D, with the catheter 150 positioned with the acoustic energy transducer 120 in close proximity to the stone 102, the balloons 152a and 152b are inflated. The balloons 152a, 152b bear against the wall of the ureter 106 thereby stabilizing the distal portion of the catheter 150, and containing the stone 102 in place.

[0086] Alternatively, if the catheter 150 has an end effector, the end effector is positioned around the stone 102, and the end effector is actuated to hold the stone 102.

[0087] The acoustic energy transducer 120 is actuated and controlled by the power generator 170 of the controller 160, to break the stone 102, as described for the method of using catheter 100. Optionally, while the acoustic energy transducer 120 is delivering acoustic wave energy to break the stone 102, the area of the stone 102 within the ureter 106 is irrigated with an irrigation fluid via the working channel 119, wherein the proximal balloon 152b acts to channel the irrigation fluid around the proximal side of the stone 102. Additional irrigation fluid may be used to flush the fluid path formed by the proximal balloon 152b to flush out the fragments from the ureter 106.

[0088] After the stone 102 is broken up, and the stone fragments are extracted from the urinary tract 104, the catheter 140 and/or the guidewire 114 and/or cystoscope are withdrawn and removed from the urinary tract 104. The catheter 140 may be retracted with the distal balloon 152a and/or the proximal balloon 152b fully or partially inflated (e.g., by partially deflating the balloons 152a, 152b) to help pull any remaining fragments out of the ureter 106.

[0089] Accordingly, the ureteral stone treatment catheters 100, 140 and 150, and methods of using the same, provide a number of advantages over the current procedural interventions offered in the treatment of ureteral stones. The advantages include a minimally-invasive intracorporeal approach in an office setting that utilizes acoustic wave energy delivered in close proximity to the stone to fragment or dust the stones into small particles and have a stone-free efficacy rate after 30 days equivalent to or greater than URS, considered to be the current gold standard. Current stone procedures are usually performed in an operating room, and the high demand for hospital operating rooms (ORs) are

responsible for the typical delay of 7-21 days treatment of kidney stones. Furthermore, these OR-based procedures require general anesthesia which carries inherent risk, particularly for elderly patients.

[0090] Additional examples are directed to a gallstone treatment catheter, gallstone treatment system, and methods of using the same. The gallstone treatment catheter is substantially similar to the ureteral stone treatment catheters 100, 140 and 150. Trans-catheter gallstone ablation using the gallstone treatment catheter can serve as a non-operative alternative for the treatment of cholelithiasis in patients with symptomatic cholelithiasis and biliary colic, cholecystitis, gallstone pancreatitis, and choledocholithiasis.

Similar to the ureteral stone treatment catheters 100, 140 and 150, the gallstone treatment catheter is delivered either percutaneously and/or through the working channel of an endoscope to position the acoustic energy transducer 120 proximate a gallstone to be broken up. The gallstone is then broken up using acoustic energy waves and removed from the body same or similar to breaking up and removing a ureteral stone 102, as described herein.

[0091] Additionally, the system inhibits damage or trauma to the inner lining of the ureter, belying the need to place a post-procedural ureteral stent. Examples include the two different approaches herein for treating ureteral stones. The system or components that can be administered through the ureter are optionally flexible and small enough in size to inhibit ureteral injury, such as perforation, and inhibit pain and discomfort to the patient when delivered under local anesthesia in an office-based environment. The therapy parameters are optionally chosen to be of low energy in order to minimize damage to the urinary system and be tolerated by the patient during the delivery of therapy under local anesthesia in a non-OR setting.

[0092] While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the appended claims.

What is claimed is:

1. A catheter for treating an occlusion in an anatomical feature of a patient, the catheter comprising:

an elongated, flexible, tubular member having a proximal end and a distal portion,
5 the tubular member configured to be inserted through a body pathway of a patient; and
an acoustic energy transducer disposed on a distal portion of the tubular member and
configured to deliver acoustic wave energy to break the occlusion, the acoustic energy
transducer having an acoustic impedance matched to an acoustic impedance of the
occlusion within $\pm 20\%$.

2. The catheter of claim 1, wherein the combined tubular member and acoustic
energy transducer are configured to be advanced into the body pathway wherein the
acoustic energy transducer is positioned within 5 mm of the stone.

3. The catheter of claim 1, wherein the acoustic energy transducer has a
thickness of less than 3 mm.

4. The catheter of claim 3, wherein the acoustic energy transducer has one or
more matching layers for matching the acoustic impedance of the acoustic energy
20 transducer to within $\pm 20\%$ of the acoustic impedance of the occlusion.

5. The catheter of claim 4, wherein a height of the acoustic energy transducer is
at least 50% of the size of the occlusion.

6. The catheter of any of claims 1-5, further comprising:
a detection sensor disposed on the distal portion of the tubular member and
configured to provide a sensor signal for detecting at least one of the following: a location
of the stone within the ureter; a location of the catheter within the urinary tract; a size of the
stone, a proximity of the acoustic energy transducer to the stone; a size of stone fragments
30 of the stone after it is broken using the acoustic energy transducer.

7. The catheter of claim 6, wherein the detection sensor is a transducer selected
from the group consisting of: camera, pressure, impedance, optical coherence tomograph

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(OCT), doppler, regular ultrasound, radio frequency, temperature, or combination of the foregoing., which can provide a signal for detecting the location of a stone and/or the catheter within the urinary tract.

5 8. The catheter of claim 6, wherein the acoustic energy transducer and the detection sensor are integrated into a single, dual mode transducer.

 9. The catheter of claim 6, further comprising:
 a working channel extending from the proximal end to the distal portion of the
10 tubular member.

 10. The catheter of claim 6, further comprising:
 a distal balloon disposed on the tubular member distal to the acoustic energy
transducer and having an uninflated state and an inflated state; and
15 a proximal balloon disposed on the tubular member proximal to the acoustic energy
transducer and having an uninflated state and an inflated state;
 wherein the distal balloon and proximal balloon are configured to stabilize the distal
portion of the tubular member within the ureter when in their respective inflated states.

20 11. The catheter of claim 6, further comprising:
 an end effector disposed on the distal portion of the tubular member for holding the
stone in place while applying acoustic energy from the acoustic energy transducer to break
the stone.

25 12. The catheter of claim 11, wherein the end effector is a cage-like effector.

 13. The catheter of claim 6, wherein the acoustic energy transducer has one of
the following shapes: an approximately cylinder shape; an approximately rectangular shape
with one or more convex sides; and an approximately rectangular shape with one or more
30 concave sides.

 14. A system for treating an occlusion in an anatomical feature of a patient; the
system comprising:

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a catheter for treating the occlusion, comprising:

an elongated, flexible, tubular member having a proximal end and a distal portion, the tubular member configured to be inserted through a body pathway a patient; and

5 an acoustic energy transducer disposed on a distal portion of the tubular member and configured to deliver acoustic wave energy to break the occlusion, the acoustic energy transducer having an acoustic impedance matched to an acoustic impedance of the occlusion within +/- 20%; and

10 a controller configured to control the operation of the catheter, including controlling and powering the acoustic energy transducer to deliver acoustic wave energy to the occlusion.

15 The system of claim 14, wherein:
the catheter further comprises:

15 a detection sensor disposed on the distal portion of the tubular member and configured to provide a sensor signal for detecting at least one of the following: a location of the occlusion within the anatomical feature; a location of the catheter within the anatomical feature; a size of the occlusion, a proximity of the acoustic energy transducer to the occlusion; a size of occlusion fragments of the occlusion after it is broken using the
20 acoustic energy transducer; and

a working channel extending from the proximal end to the distal portion of the tubular member;

a distal balloon disposed on the tubular member distal to the acoustic energy transducer and having an uninflated state and an inflated state; and

25 a proximal balloon disposed on the tubular member proximal to the acoustic energy transducer and having an uninflated state and an inflated state; and

wherein the distal balloon and proximal balloon are configured to stabilize the distal portion of the tubular member within the anatomical feature when in their respective inflated states; and

30 the controller comprises:

a sensor interface to interface with the detection sensor;

a transducer interface to interface with the acoustic energy transducer;

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a sensor signal processing system configured to receive sensor signals from the detection and to generate images and sensor data from the sensor signals;

a user interface having a display to display the images generated by the sensor signal processing system; and

5 a power supply for powering the acoustic energy transducer.

16. The system of claim 15, wherein the controller is programmable to configure varying parameters of an acoustic wave energy delivered by the acoustic energy transducer to break the stone.

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17. The system of claim 16, wherein the controller is programmed to include each of the following varying parameters: a focused high (0.5-3Mhz) ultrasound frequency of continuous multiple pulses delivered at a varying duty cycle, or an alternating or modulating high (0.5-3Mhz) ultrasound frequency of multiple continuous pulses at a
15 varying duty cycle.

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18. The system of any of claims 14-17, wherein the controller is programmed to maintain the energy amplitude or intensity of the ultrasound or shockwave described above at a low or high level depending on the focal size of the acoustic energy transducer, and the
20 high (positive)-pressure amplitude ranges from 2MPa to 7MPa, and the low (negative)-pressure amplitude could range from -2MPa to -7MPa.

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19. The system of claim 18, wherein the controller is configured to control the parameters to optimize the effectiveness in fragmenting the stone or to increase the efficacy
25 rate of breaking the occlusion using the acoustic energy transducer.

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20. A method of using the catheter of claim 1 to treat an occlusion in an anatomical feature of a patient, the method comprising:

advancing the catheter into the anatomical feature via natural body pathways to
30 position the acoustic energy transducer proximate the occlusion;

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the acoustic energy transducer delivering acoustic wave energy to the occlusion to break the occlusion into occlusion fragments.

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21. The method of claim 20, wherein the catheter is advanced into the natural body pathway over a guidewire previously deployed in the body pathway.

22. The method of claim 18, further comprising:

5 irrigating an area surrounding the occlusion with irrigation fluid while delivering the acoustic wave energy to break the occlusion.

23. A method of using the catheter of claim 10 to treat an occlusion in an anatomical feature of a patient, the method comprising:

10 advancing the catheter with the distal balloon and the proximal balloon in their uninflated states into the anatomical feature via a natural body pathway to position the acoustic energy transducer proximate the occlusion, wherein the catheter is advanced using the detection sensor to assist in navigating the catheter in the body pathway;

inflating the distal balloon and the proximal balloon into their inflated states wherein
15 the distal balloon and proximal balloon stabilize the distal portion of the tubular member within the anatomical feature; and

the acoustic energy transducer delivering acoustic wave energy to the occlusion to break the occlusion into occlusion fragments.

24. The method of claim 23, further comprising:

20 using the detection sensor to determine a proximity of the acoustic energy transducer to the occlusion.

25. The method of claim 23, wherein the inflated proximal balloon forms an

25 irrigation channel around a proximal side of the stone; and the method further comprises:

irrigating an area surrounding the stone including with irrigation fluid while delivering the acoustic wave energy to break the stone.

26. The method of claim 23, further comprising:

30 determining a size of the stone fragments using the detection sensor; and

confirming that the stone fragments have a maximum diameter small enough to be removed from the ureter without damaging the ureter.

- 30 -

27. The method of claim 26, wherein the maximum diameter is less than or equal to about 3 mm.

28. The method of claim 27, further comprising:
5 after breaking the stone using the acoustic energy transducer, irrigating the area around the stone to remove the stone fragments from the ureter.

29. The method of claim 28, further comprising:
one or more of the proximal balloon and distal balloon pulling out stone fragments
10 from the ureter as the catheter is retracted from the urinary tract.

30. The method of claim 29, further comprising:
retracting the catheter from the urinary tract to remove the catheter from the urinary tract.

15

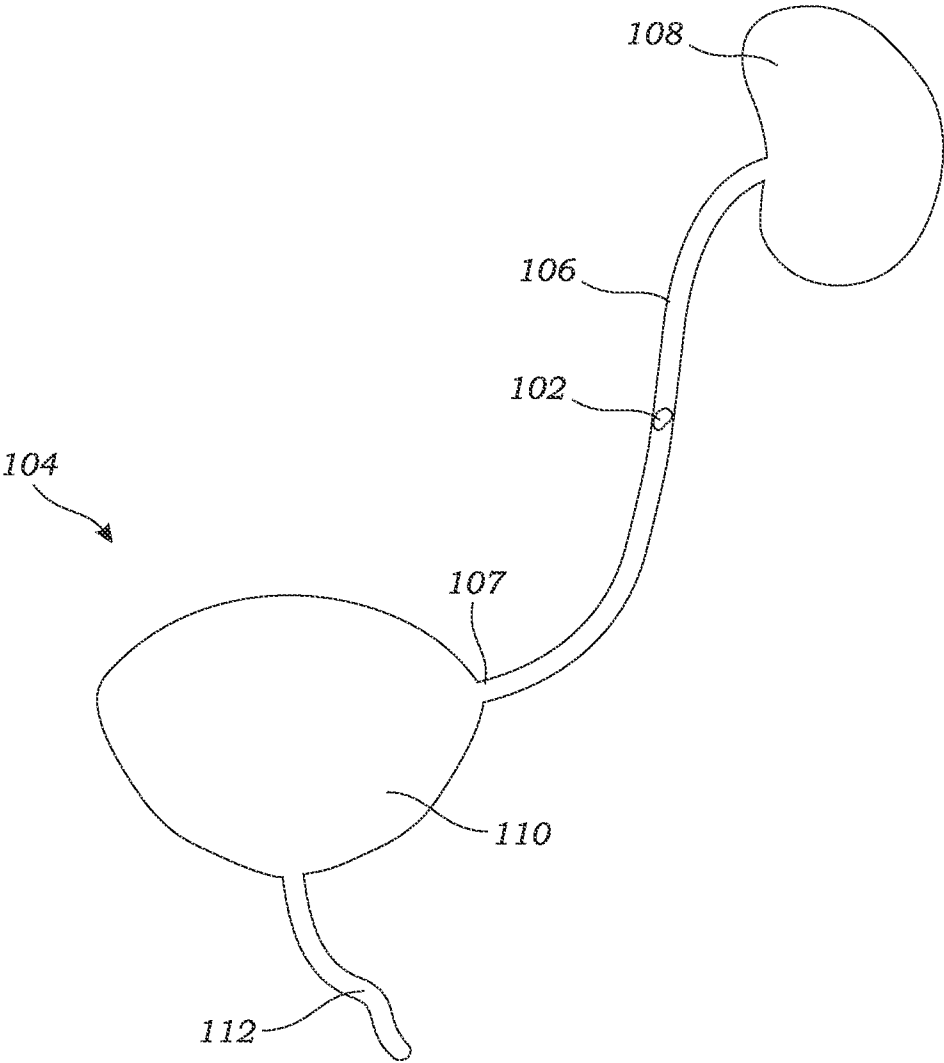


Fig. 1A

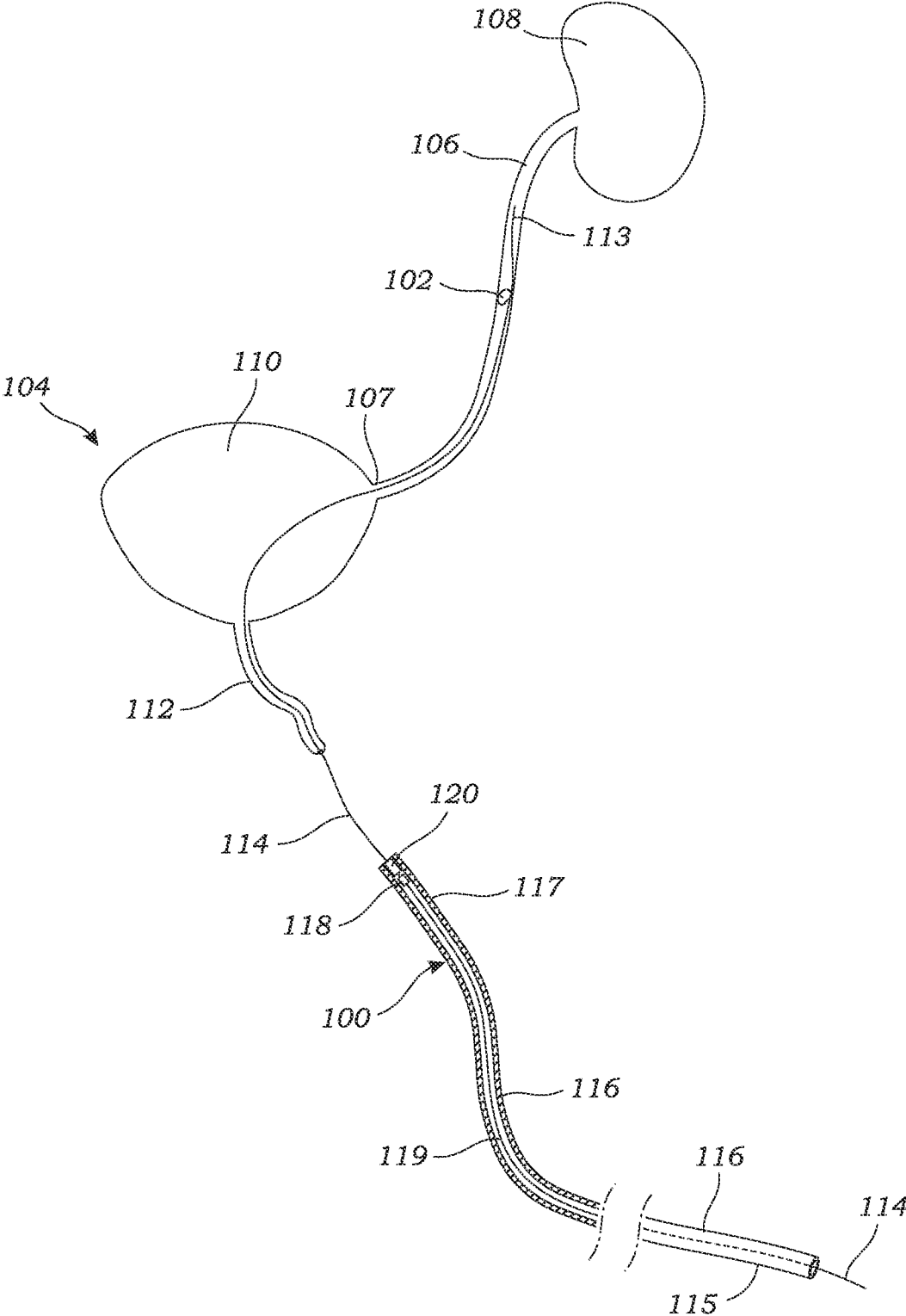


Fig. 1B

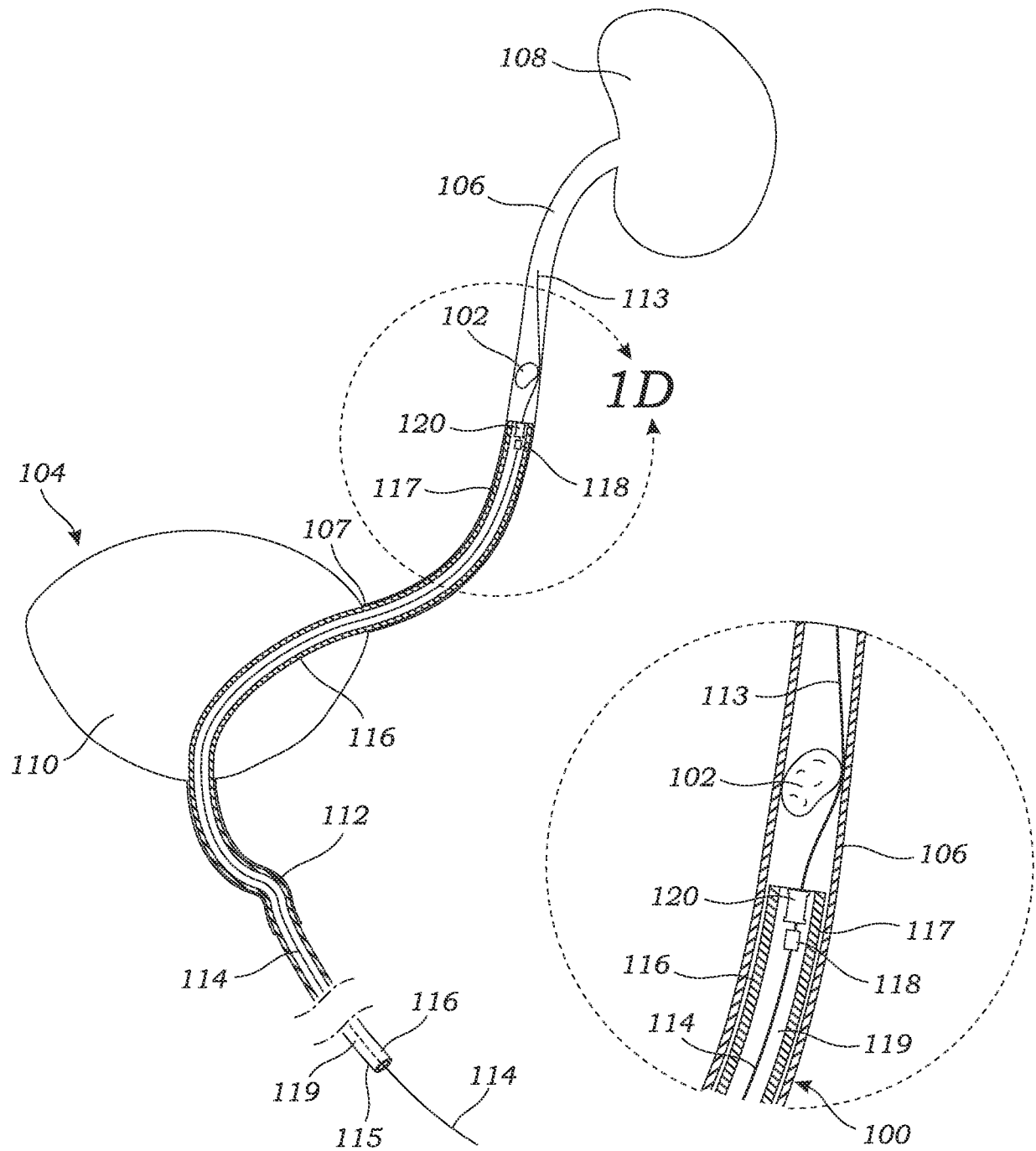
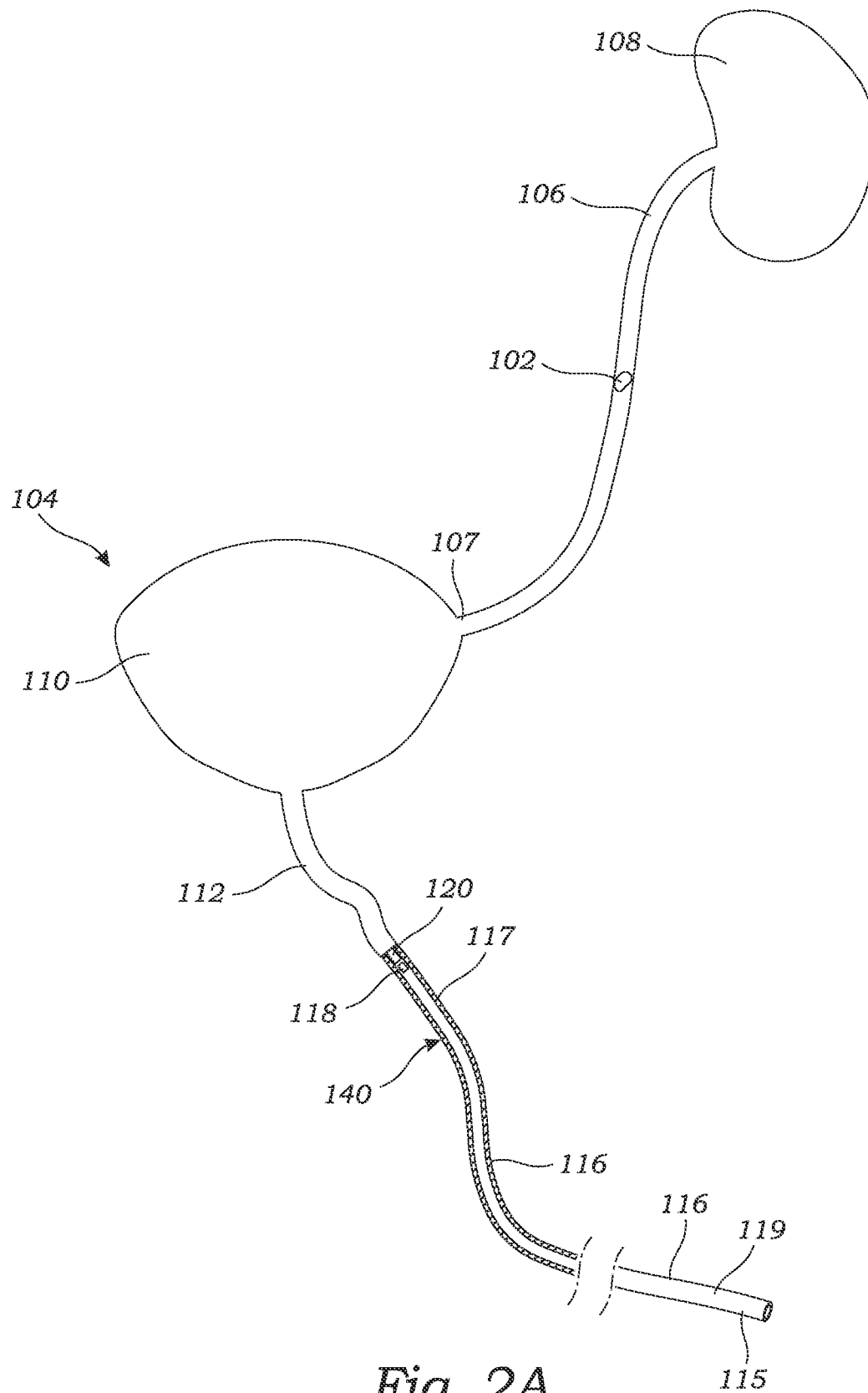


Fig. 1C

Fig. 1D

*Fig. 2A*

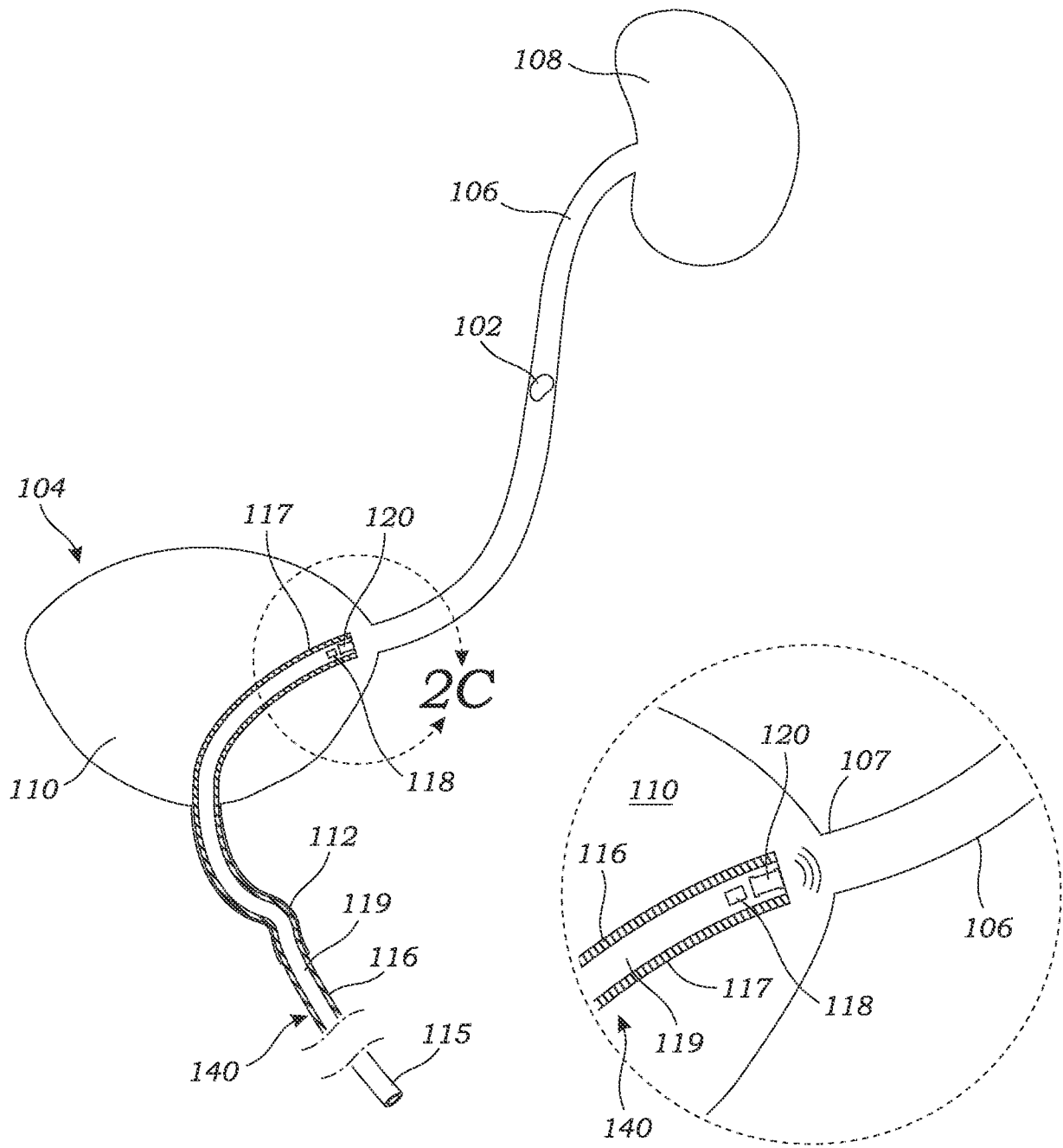
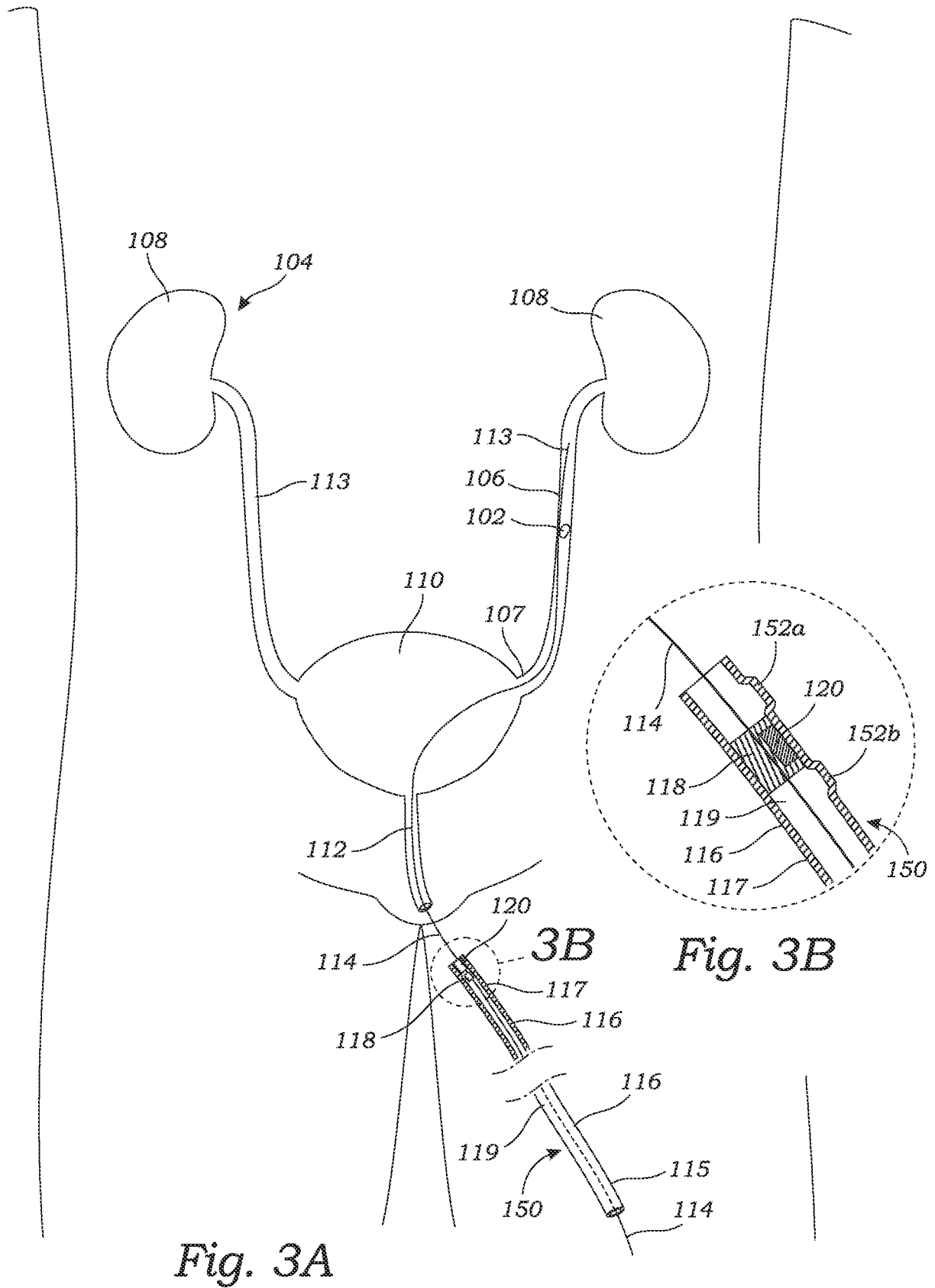


Fig. 2B

Fig. 2C



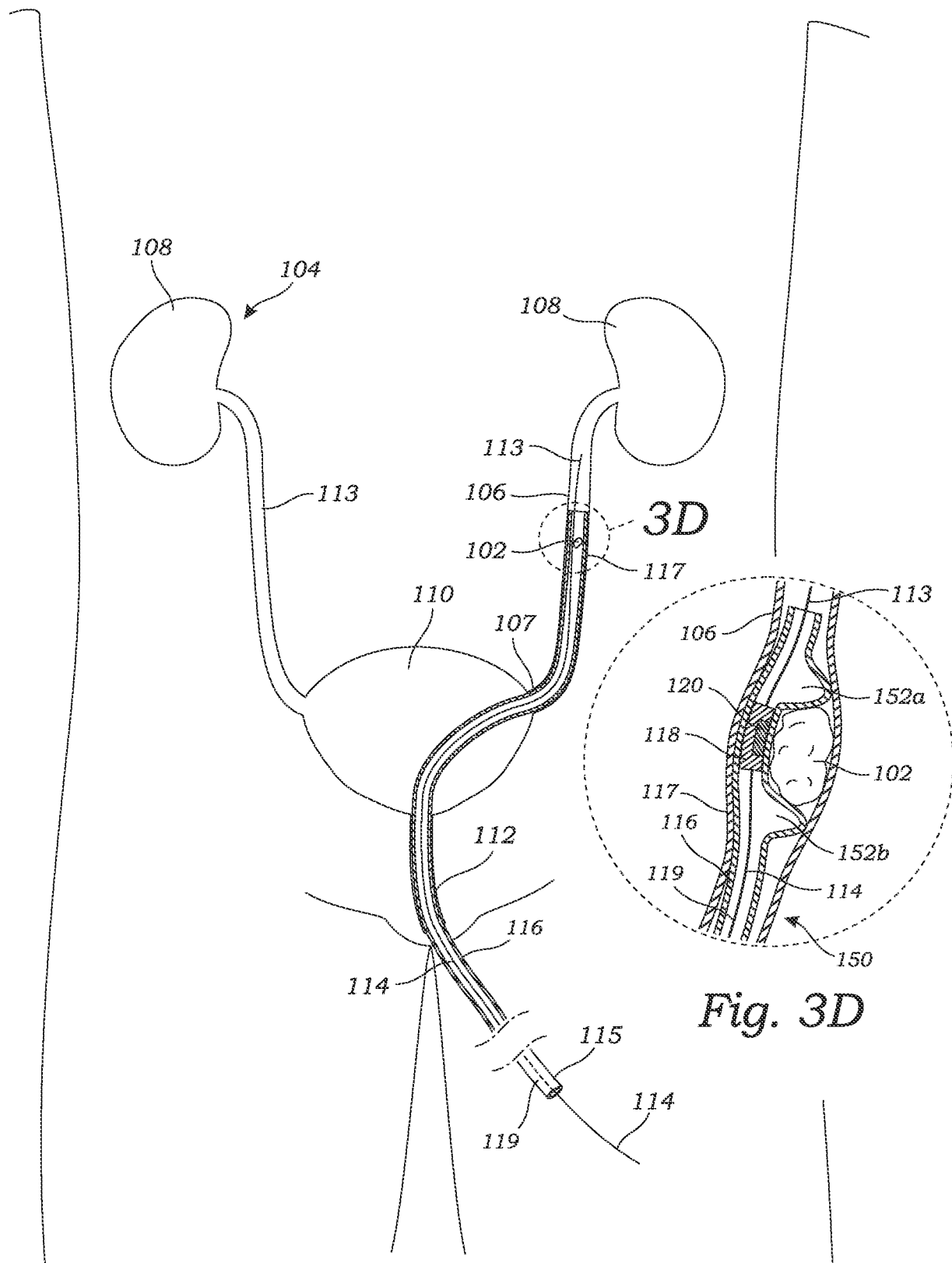
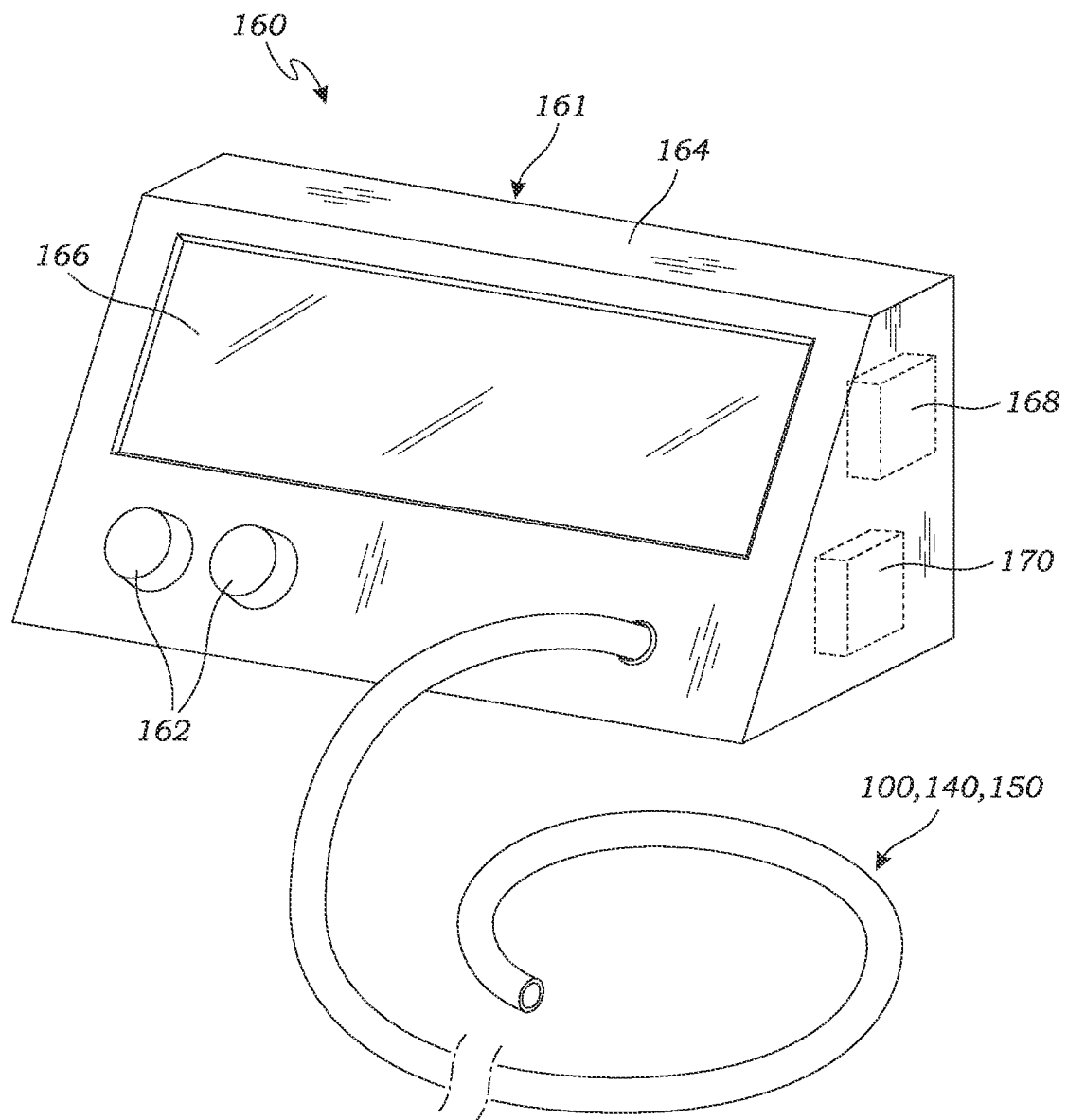


Fig. 3D

*Fig. 4*

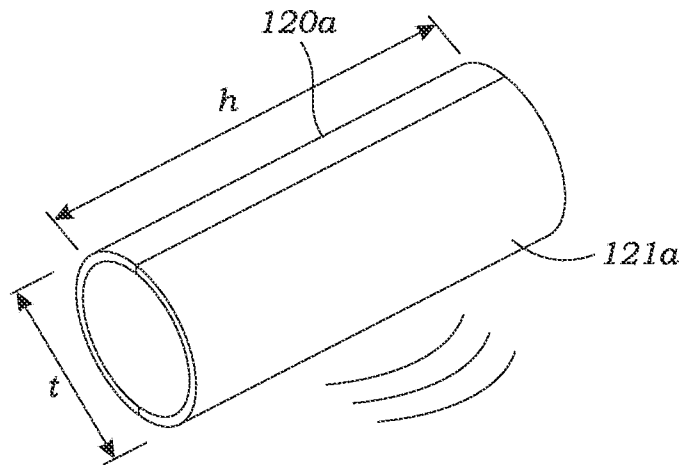


Fig. 5

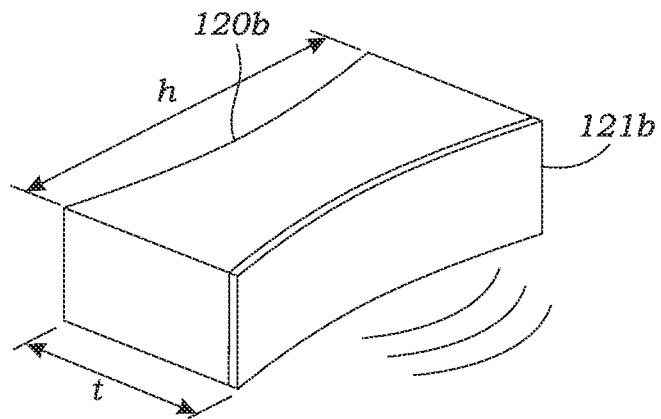


Fig. 6

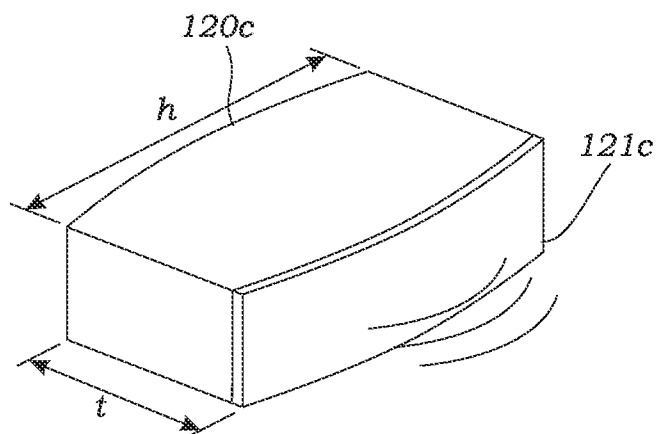


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2022/022404

A. CLASSIFICATION OF SUBJECT MATTER		
A61B 17/22(2006.01)i		
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) A61B 17/22(2006.01); A61B 18/00(2006.01); A61B 5/055(2006.01); A61B 8/12(2006.01); A61M 25/10(2006.01); A61M 31/00(2006.01); A61N 7/02(2006.01)		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Korean utility models and applications for utility models Japanese utility models and applications for utility models		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) eKOMPASS(KIPO internal) & Keywords: catheter, acoustic, energy, transducer, occlusion, impedance, match		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2020-0107843 A1 (SUNNYBROOK RESEARCH INSTITUTE) 09 April 2020 (2020-04-09) paragraphs [10], [33]-[87]; claims 1, 18, 20, 25, 39; figure 3A	1-9,11-14
Y		10,15-19
Y	WO 2019-193591 A1 (VENSICA MEDICAL LTD.) 10 October 2019 (2019-10-10) claim 1; figures 1A,1B	10,15-19
A	US 2019-0117242 A1 (MEDTRONIC VASCULAR, INC.) 25 April 2019 (2019-04-25) whole document	1-19
A	US 2016-0008636 A1 (GUIDED INTERVENTIONS, INC.) 14 January 2016 (2016-01-14) whole document	1-19
A	EP 1100385 B1 (EKOS CORPORATION) 18 January 2006 (2006-01-18) whole document	1-19
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "D" document cited by the applicant in the international application "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 25 July 2022		Date of mailing of the international search report 25 July 2022
Name and mailing address of the ISA/KR Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon 35208, Republic of Korea Facsimile No. +82-42-481-8578		Authorized officer PARK, Hye Lyun Telephone No. +82-42-481-3463

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2022/022404

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **20-30**
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 20-30 pertain to a method for treatment of the human body by surgery methods, and thus relate to a subject matter which this International Searching Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/US2022/022404

Patent document cited in search report			Publication date (day/month/year)	Patent family member(s)			Publication date (day/month/year)
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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

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