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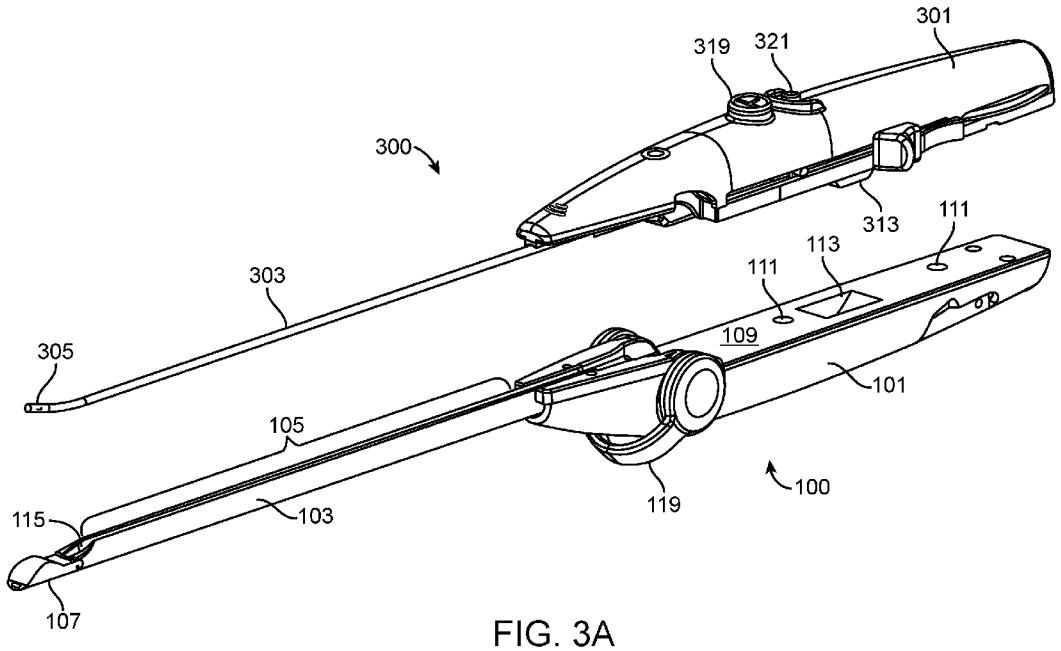

FIG. 3A

(57) Abstract: An imaging component comprises shaft and a cavity extending across the shaft from its proximal end towards its distal end. The cavity removably receives at least one of a plurality of different instruments. A wall of the cavity comprises an elongated opening in communication with an exterior of the shaft at least partially along the shaft. An imaging transducer is coupled to the distal end of the shaft. The imaging component is advanced to a target site either alone or with a first instrument coupled thereto. A therapeutic or diagnostic procedure is performed with the first instrument. The first instrument is then retracted and removed from the imaging component while the imaging component stays at the target site. A second instrument is then coupled to the imaging component and advanced to the target site to perform a further therapeutic or diagnostic procedure.

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METHODS AND SYSTEMS FOR IN SITU EXCHANGE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Provisional Application No. 62/674,479 filed May 21, 2018, the full contents of which are incorporated herein by reference.

BACKGROUND

[0002] The present disclosure relates to medical systems, devices, and methods. More particularly, the present disclosure relates to imaging components in use with therapeutic and diagnostic instruments.

[0003] Current systems, devices, and methods for imaging may be less than ideal in at least some respects. For example, many current devices may have limited flexibility for use in a variety of diagnostic and therapeutic procedures. For example, many current devices may not interface well with other therapeutic or diagnostic instruments. For example, many current devices may be expensive and/or difficult to clean. For example, many current devices may risk injuring a patient during insertion and/or removal.

[0004] Additionally or alternatively, current systems, devices, and methods for diagnosing and providing therapy may be less than ideal in at least some other respects. For example, in procedures where more than one instrument may be required, multiple instruments may need to be inserted or removed from a patient lumen, and these additional steps of insertion and removal may increase injury risk for the patient. Additionally or alternatively, many current methods may require removal of an imaging component many times during a single procedure, and the removal of the imaging component may limit the ability to continually and steadily view the surgical field during the procedure.

[0005] In light of the above, improved systems, devices, and methods for imaging a surgical field are desired. Such systems, devices, and methods would address at least some of the drawbacks above and would, for example, be less expensive, easier to clean, and/or able to be used for a greater variety of therapeutic and diagnostic procedures.

SUMMARY

[0006] The present disclosure relates to imaging components in use with therapeutic and diagnostic instruments. In particular, the imaging components disclosed herein may be positioned *in situ* to capture images of the surgical field while a variety of therapeutic and/or diagnostic instruments may be exchanged at least partially through the imaging component. The imaging components disclosed herein may be used alone, in combination with only one

instrument, or with multiple instruments. An exemplary imaging component may comprise a shaft and a cavity extending across the shaft from its proximal end towards its distal end. The cavity may removably receive at least one of a plurality of different instruments. A wall of the cavity may comprise an elongated opening in communication with an exterior of the shaft at least partially along the shaft. An imaging transducer may be coupled to the distal end of the shaft to continually image the surgical field when the imaging component is positioned *in situ*. The imaging component may be advanced to a target site either alone for imaging or with a first instrument coupled thereto. A first instrument may be inserted into the shaft of the imaging component *in situ*. A therapeutic or diagnostic procedure may be performed with the first instrument. The first instrument may then be retracted and removed from the imaging component. The imaging component may continually and steadily capture images of the surgical field before, during, and after retraction and removal of the first or other instrument(s). A second instrument can then be coupled to the imaging component and advanced to the target site to perform a further therapeutic or diagnostic procedure, without interrupting the imaging of the surgical field. The first instrument can be a diagnostic instrument to perform a diagnostic procedure, and the second instrument can be a therapeutic instrument to perform a therapeutic procedure as informed by the diagnostic procedure (or vice versa, or both the first and second instruments may be diagnostic instruments, or both the first and second instruments may be therapeutic instruments). Additional instruments may be coupled to the imaging transducer after removal and retraction of a second instrument. For example, a diagnostic procedure may be repeated in order to review therapeutic efficacy. In some cases, the imaging transducer may be used alone. In some cases, one or more disposable tubes may be coupled to the cavity to serve as a sterile, and optionally disposable, adapter for the different instruments to be coupled to and advanced along the imaging component.

[0007] Aspects of the present disclosure provide imaging components. An exemplary imaging component may comprise a shaft comprising a proximal end, a distal end, and a cavity extending across the shaft from the proximal end towards the distal end. The cavity may be configured to removably receive at least one of a plurality of different instruments. A wall of the cavity may comprise an elongated opening in communication with an exterior of the shaft at least partially along the shaft. The exemplary imaging component may further comprise an imaging transducer coupled to the distal end of the shaft.

[0008] The cavity may be defined by an exterior surface of the shaft. The exterior surface of the shaft may comprise only atraumatic edges. An edge of the elongated opening may be bent towards an interior of the cavity. The cavity may be configured to slidably receive the

instrument. A distal portion of the cavity may be angled axially relative to the shaft. The distal portion of the cavity may be angled at about 3 to 45 degrees axially relative to the shaft.

[0009] At least one of the plurality of instruments may comprises a tube. The tube may be aligned to be in parallel with the shaft of the imaging component. The tube may be rotatable relative to the shaft while the shaft remains stationary. The tube may comprise a lumen configured to slidably receive a second instrument of the plurality of instruments. The tube may be configured to slidably receive the second instrument after the second instrument is aligned to be in parallel with the shaft of the imaging component. The second instrument may be rotatable relative to the shaft while the shaft remains stationary. The tube may be disposable. The second instrument may comprise a tissue collector. The tissue collector may comprise a biopsy needle. The second instrument may comprise a tissue ablation element. The tissue ablation element may comprise one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element. The second instrument may comprise a resection tool. The second instrument may comprise an instrument for implantation of a device such as radiopaque markers, drug-eluting wireform, fertility/contraception treatment, anchoring system, herniation mesh, stent, or other devices. The second instrument may comprise instrumentation for providing detailed mapping of anatomy such as laser, x-ray, secondary ultrasound, or other devices. The first and second instruments may be any diagnostic or therapeutic device or may be a tube for receiving additional instruments.

[0010] At least one of the plurality of different instruments comprises a therapeutic or diagnostic instrument. The therapeutic or diagnostic instrument may comprise a tissue collector, a biopsy needle, a tissue ablation element, an optical scope, implantation device, and/or therapy electrodes. The tissue ablation element may comprise one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

[0011] The shaft may be flexible. The shaft may be controllably flexed along a longitudinal axis thereof via a flex mechanism.

[0012] The imaging transducer may comprise an ultrasound transducer. The imaging transducer may comprise a light emitting diode (LED) or a camera.

[0013] The cavity may define a circular cross sectional area. The cavity may comprise a substantially uniform cross sectional area along the shaft. The cavity may comprise an asymmetrical cross sectional area. The cavity may extend across the shaft from the proximal end to the distal end.

[0014] Aspects of the present disclosure may provide imaging systems. An exemplary imaging system may comprise any of the imaging components described herein and a disposable tube slidably received within the cavity of the imaging component. The system may further comprise a second instrument removably received within a lumen of the disposable tube. The second instrument may be a diagnostic or therapeutic instrument, a tissue collector, a biopsy needle, an optical scope, implantation device, and/or a tissue ablation element. The tissue ablation element comprises one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, a cryoablation element, etc.

[0015] Aspects of the present disclosure may provide methods of performing therapy or diagnosis at a target site. In an exemplary method, any of the imaging components described herein may be inserted into the subject. With the imaging component in situ, at least one of the plurality of instruments may be inserted into the cavity towards the target site, therapy or diagnosis may be performed using the instrument(s) at the target site, and the instrument(s) may then be removed from the cavity.

[0016] At least one of the plurality of instruments comprises a tissue collector, a biopsy needle, and/or tissue ablation element. The tissue ablation element may comprise one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element. The instrument(s) may comprise a therapeutic or diagnostic instrument such as an optical scope, implantation device, or therapy electrodes.

[0017] The exemplary method may comprise steps of inserting a second instrument into the cavity towards the target site, performing therapy or diagnosis using the second instrument at the target site, and removing the second instrument from the cavity. The second instrument may be different from the at least one of the plurality of instruments. The method may be performed in laparoscopic surgery, non-invasively, and/or in minimally invasive surgery.

[0018] The second instrument may comprise a tissue collector, a biopsy needle, and/or tissue ablation element. The tissue ablation element may comprise one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element. The second instrument may comprise a therapeutic or diagnostic instrument such as an optical scope, implantation device, or therapy electrodes.

[0019] Aspects of the present disclosure may provide methods of performing image guided ablation therapy. In an exemplary method, any of the imaging components as described herein may be inserted into a subject. With the imaging component in situ, a biopsy needle may be inserted into the cavity, pathology samples may be collected using the biopsy needle, the biopsy needle may be removed from the cavity, radiofrequency (RF) ablation elements may be inserted

into the cavity, tissue may be ablated using the RF ablation elements, the RF ablation elements may be removed from the cavity, an optical scope may be inserted into the cavity, completion of the image guided ablation therapy may be confirmed using the optical scope, and the optical scope may be removed from the cavity. The method may be performed in laparoscopic surgery, non-invasively, and/or in minimally invasive surgery.

[0020] Aspects of the present disclosure may provide methods of coupling instruments. An imaging component may be advanced to within a surgical space. The imaging component may comprise a shaft comprising a proximal end and a distal end. A first instrument may be coupled to the imaging component for use in the surgical space. The first instrument may be a therapeutic or diagnostic instrument. The first instrument may be uncoupled from the imaging component while the imaging component remains within the surgical space. A second instrument may be coupled to the imaging component for use in the surgical space while the imaging component remains within the surgical space. The second instrument may be a therapeutic or diagnostic instrument different from the first instrument. The imaging component may comprise an imaging transducer comprising an ultrasound transducer. The method may be performed in laparoscopic surgery, non-invasively, and/or in minimally invasive surgery.

[0021] The coupling of the first instrument may occur while the imaging component remains within the surgical space. Alternatively or in combination, the coupling the first instrument may occur while the imaging component is outside of the surgical space.

[0022] The method may further comprise steps of collecting a tissue sample from the surgical space with the first instrument and/or ablating a region within the surgical space with the second instrument.

[0023] The method may further comprise performing therapy or diagnosis with the first instrument. The second instrument may be selected based on data gathered from said performing therapy or diagnosis with the first instrument. A parameter of therapy or diagnosis performed with the second instrument may be adjusted based on data gathered from said performing therapy or diagnosis with the first instrument. The data gathered may comprise image data, and the parameter may be adjusted by adjusting an ablation zone for the second instrument.

[0024] The imaging component may further comprise a cavity extending across the shaft from the proximal end towards the distal end. A wall of the cavity may comprise an elongated opening in communication with an exterior of the shaft at least partially along the shaft. The cavity may be defined by an exterior surface of the shaft. The exterior surface of the shaft may comprise only atraumatic edges. An edge of the elongated opening may be bent towards an interior of the cavity. The cavity may be configured to slidably receive the first instrument or the

second instrument. A distal portion of the cavity may be angled axially relative to the shaft. The distal portion of the cavity may be angled at about 3 to 45 degrees axially relative to the shaft. A tube may be advanced to within the cavity. The tube may be aligned to be in parallel with the shaft of the imaging component. The tube may be rotatable relative to the shaft while the shaft remains stationary. The tube may comprise a lumen configured to slidably receive the first instrument or the second instrument. The tube may be configured to slidably receive the first instrument or the second instrument after the first or second instrument is aligned to be in parallel with the shaft of the imaging component. The first or second instrument may be rotatable relative to the shaft while the shaft remains stationary. The tube may be disposable.

[0025] The first or second instrument may comprise a tissue collector, a biopsy needle, a tissue ablation element, an optical scope, implantation device, and/or therapy electrodes. The tissue ablation element may comprise one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

[0026] The shaft may be flexible. The shaft may be controllably flexed along its longitudinal axis via a flex mechanism.

[0027] The imaging component may comprise an imaging transducer comprising a light emitting diode (LED) or a camera. The cavity may define a circular cross sectional area. The cavity may comprise a substantially uniform cross sectional area along the shaft. The cavity may comprise an asymmetrical cross sectional area. The cavity may extend across the shaft from the proximal end to the distal end.

[0028] The 1) imaging component and 2) the first instrument or the second instrument may be coupled axially. The 1) imaging component and 2) the first instrument or the second instrument may be coupled laterally. The 1) the imaging component and 2) the first instrument or second instrument may be coupled with aid of magnets or indents.

[0029] Aspects of the present disclosure provide systems for performing therapy and/or diagnosis at a target site within a patient. An exemplary system may comprise a first therapeutic or diagnostic instrument, a second therapeutic or diagnostic instrument different from the first therapeutic or diagnostic instrument, and an imaging component configured to be removably coupled to both the first and second therapeutic or diagnostic instruments, either simultaneously or individually. The imaging component may be configured to be deliverable to the target site within the patient both (i) separately from the first and second therapeutic or diagnostic instruments, and (ii) coupled with the first and/or second therapeutic or diagnostic instruments. The imaging component may be configured to be removably coupled to both the first and second therapeutic or diagnostic instruments, either simultaneously or individually, after the imaging

component is delivered to the target site within the patient. The imaging device may be used alone, in combination with only one instrument, or with multiple instruments.

[0030] The first and second therapeutic or diagnostic instruments may comprise two of the following: a tissue collector, a tissue ablation element, an optical scope, or therapy electrodes. The tissue collector may comprise a biopsy needle. The tissue ablation element may comprise one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

[0031] The imaging component may comprise a shaft comprising a proximal end, a distal end, and a cavity extending across the shaft from the proximal end towards the distal end. A wall of the cavity may comprise an elongated opening in communication with an exterior of the shaft at least partially along the shaft. The cavity may be defined by an exterior surface of the shaft. The exterior surface of the shaft may comprise only atraumatic edges. An edge of the elongated opening may be bent towards an interior of the cavity. The cavity may be configured to slidably receive the instrument. A distal portion of the cavity may be angled axially relative to the shaft. The distal portion of the cavity may be angled at about 3 to 45 degrees axially relative to the shaft.

[0032] The system may further comprise a tube. The tube may be aligned to be in parallel with the shaft of the imaging component. The tube may be rotatable relative to the shaft while the shaft remains stationary. The tube may comprise a lumen configured to slidably receive the first or second instrument. The tube may be configured to slidably receive the first or second instrument after the first or second instrument is aligned to be in parallel with the shaft of the imaging component. The first or second instrument may be rotatable relative to the shaft while the shaft remains stationary. The tube may be disposable.

[0033] The shaft of the imaging component may be flexible. The shaft may be controllably flexed along its longitudinal axis via a flex mechanism.

[0034] The imaging component may comprise an imaging transducer comprising a light emitting diode (LED) or a camera. The cavity may define a circular cross sectional area. The cavity may comprise a substantially uniform cross sectional area along the shaft. The cavity may comprise an asymmetrical cross sectional area. The cavity may extend across the shaft from the proximal end to the distal end. The imaging transducer may comprise an ultrasound transducer.

[0035] Aspects of the present disclosure provide methods of performing therapy or diagnosis at a target site. An imaging component may be advanced to the target site. The imaging component may comprise 1) a shaft comprising a proximal end, a distal end, and a cavity extending across the shaft from the proximal end towards the distal end, wherein a wall of the

cavity comprises an elongated opening in communication with an exterior of the shaft at least partially along the shaft, and 2) an imaging transducer coupled to the distal end of the shaft. Therapy or diagnosis may be performed using a first instrument inserted into the cavity and advanced to the target site.

[0036] The method may further comprise a step of inserting the first instrument into the cavity before advancing the imaging component to the target site. The first instrument may be inserted into the cavity after advancing the imaging component to the target site. The first instrument may be removed from the cavity while the imaging component remains at the target site. A second instrument may be inserted into the cavity and the second instrument may be advanced to the target site. Therapy or diagnosis may be performed using the second instrument.

[0037] The cavity of the imaging component may be defined by an exterior surface of the shaft. The exterior surface of the shaft may comprise only atraumatic edges. An edge of the elongated opening may be bent towards an interior of the cavity. The cavity may be configured to slidably receive the instrument.

[0038] The distal portion of the cavity may be angled axially relative to the shaft. The distal portion of the cavity may be angled at about 3 to 45 degrees axially relative to the shaft.

[0039] The imaging component may further comprise a tube. The tube may be aligned to be in parallel with the shaft of the imaging component. The tube may be rotatable relative to the shaft while the shaft remains stationary. The tube may comprise a lumen configured to slidably receive the first instrument. The tube may be configured to slidably receive the first instrument after the second instrument is aligned to be in parallel with the shaft of the imaging component. The first instrument may be rotatable relative to the shaft while the shaft remains stationary. The tube may be disposable.

[0040] The first instrument may comprise a tissue collector. The tissue collector may comprise a biopsy needle. Alternatively or in combination, the first instrument may comprise a tissue ablation element. The tissue ablation element may comprise one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element. The instrument may comprise an optical scope. The instrument may comprise therapy electrodes.

[0041] The shaft of the imaging component may be flexible. The shaft may be controllably flexed along its longitudinal axis via a flex mechanism.

[0042] The imaging transducer may comprise a light emitting diode (LED) or a camera.

[0043] The cavity may define a circular cross sectional area. The cavity may comprise a substantially uniform cross sectional area along the shaft. The cavity may comprise an

asymmetrical cross sectional area. The cavity may extend across the shaft from the proximal end to the distal end. The imaging transducer may comprise an ultrasound transducer.

[0044] Additional aspects and advantages of the present disclosure will become readily apparent to those skilled in this art from the following detailed description, wherein only illustrative embodiments of the present disclosure are shown and described. As will be realized, the present disclosure is capable of other and different embodiments, and its several details are capable of modifications in various obvious respects, all without departing from the disclosure. Accordingly, the drawings and description are to be regarded as illustrative in nature, and not as restrictive.

INCORPORATION BY REFERENCE

[0045] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0046] The novel features of the present disclosure are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present disclosure will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the present disclosure are utilized, and the accompanying drawings of which:

[0047] FIG. 1A shows a perspective view of an imaging component, in accordance with some embodiments.

[0048] FIG. 1B shows a side, cross-sectional view of the imaging component of FIG. 1A, in accordance with some embodiments.

[0049] FIG. 1C shows a magnified, perspective view of a distal end of the imaging component of FIG. 1A comprising a cavity, in accordance with some embodiments.

[0050] FIG. 2A shows a magnified, perspective view of a distal end of the imaging component of FIG. 1A with a tissue collector instrument disposed within the shaft of the imaging component, in accordance with some embodiments.

[0051] FIG. 2B shows a side, cross-sectional view of the imaging component of FIG. 1A with a biopsy instrument disposed within the shaft of the imaging component, in accordance with some embodiments.

[0052] FIG. 2C shows a magnified, perspective view of a distal end of the imaging component of FIG. 1A with a radiofrequency ablation instrument disposed within the shaft of the imaging component, in accordance with some embodiments.

[0053] FIG. 2D shows a top view of the imaging component of FIG. 1A with a drug delivery instrument disposed within the shaft of the imaging component, in accordance with some embodiments.

[0054] FIG. 2E shows a side, cross-sectional view of the imaging component of FIG. 1A with a needle disposed within the shaft of the imaging component, in accordance with some embodiments.

[0055] FIG. 3A shows an assembly view of an imaging system comprising the imaging component of FIG. 1A and an optical scope instrument, in accordance with some embodiments.

[0056] FIG. 3B shows an assembly view of the imaging system of FIG. 3A illustrating an attachment mechanism of the system, in accordance with some embodiments.

[0057] FIG. 4 shows a magnified, perspective view of a shaft of the imaging component of FIG. 1A wherein the shaft of the imaging component is flexible, in accordance with some embodiments.

[0058] FIG. 5A illustrates a perspective view of a system for diagnosing and/or providing therapy, including an imaging component configured to be removably coupled to multiple therapeutic and/or diagnostic instruments, in accordance with some embodiments. FIG. 5A shows the imaging component and the therapeutic and/or diagnostic instrument being separated.

[0059] FIG. 5B illustrates a perspective view of the system of FIG. 5A, with the therapeutic and/or diagnostic instrument being in a ready position to be removably coupled to the imaging component, in accordance with some embodiments.

[0060] FIG. 5C illustrates a perspective view of the system of FIG. 5A, with the therapeutic and/or diagnostic instrument being removably coupled to the imaging component, in accordance with some embodiments.

[0061] FIG. 6 shows a schematic of an imaging system comprising a digital processing device and a display visible to a user, in accordance with some embodiments.

[0062] FIG. 7A shows a schematic of the imaging component of FIG. 1A positioned within a uterus to image tissue thereof, in accordance with some embodiments.

[0063] FIG. 7B shows a surgical field image captured as in FIG. 7A that would be visible on a display, showing safety and treatment boundaries, in accordance with some embodiments.

[0064] FIG. 7C shows a surgical field image combining both a virtual image showing safety and treatment boundaries and the physical presence of a treatment needle, in accordance with some embodiments.

[0065] FIG. 7D shows a surgical field image combining both a virtual image showing safety and treatment boundaries as well as the physical presence of treatment needle and tines, in accordance with some embodiments.

[0066] FIG. 8 is a flow chart showing an exemplary method of performing therapy or diagnosis at a target site, in accordance with some embodiments.

[0067] FIG. 9 is a flow chart showing an exemplary method of performing image guided ablation therapy, in accordance with some embodiments.

[0068] FIG. 10 illustrates a schematic of an exemplary digital processing device programmed or otherwise configured with an imaging component, in accordance with some embodiments.

[0069] FIG. 11A shows a side, cross-section view of an imaging component having a shaft with a circular cross-section, in accordance with some embodiments.

[0070] FIG. 11B shows a side, cross-sectional view of an imaging component with edges bent inward towards the interior of the cavity, in accordance with some embodiments.

[0071] FIG. 12A illustrates a system for diagnosing and/or providing therapy, which includes an imaging component configured to be removably coupled to multiple therapeutic and/or diagnostic instruments *in situ*, in accordance with some embodiments. FIG. 12A shows the imaging component in use separate from the therapeutic and/or diagnostic instrument.

[0072] FIG. 12B illustrates the system of FIG. 12A, with the therapeutic and/or diagnostic instrument in a ready position to be removably coupled to the imaging component *in situ*, in accordance with some embodiments.

[0073] FIG. 12C illustrates the system of FIG. 12A, with the therapeutic and/or diagnostic instrument and the imaging component being removably coupled to one another *in situ* to be able to perform therapeutic and/or diagnostic procedure(s) *in situ*, in accordance with some embodiments.

DETAILED DESCRIPTION

[0074] Embodiments of the present disclosure provide an imaging component comprising a cavity extending across (e.g., along) the length of a shaft, wherein the cavity may be configured to removably receive at least one of a plurality of different instruments. In some embodiments, the cavity of the imaging component may be partially open to an exterior of the shaft. The imaging component may comprise an imaging transducer at the distal end of the shaft. Additionally, the shaft of the imaging component may be configured such that additional

therapeutic and/or diagnostic instruments/attachments may be removed and/or received and/or inserted during a medical procedure without disturbing the imaging component. Additionally or alternatively, the imaging component may remain *in situ* while the therapeutic and/or diagnostic instrument is received and/or removed. In some embodiments, the imaging component may be used without an additional therapeutic and/or diagnostic instrument coupled thereto. In some embodiments, the imaging component may be inserted and/or removed from a patient lumen without the presence of a therapeutic and/or diagnostic instrument. Such an imaging component may be used during a medical procedure such as, for example, non-invasive, minimally invasive, and/or laproscopic surgery.

[0075] Embodiments of the present disclosure may improve upon existing methods for imaging and treating a lesion in a tissue tract for procedures where multiple instruments may be required to diagnose and/or provide therapy during a single procedure. For example, an imaging component may be used for diagnosis; then a biopsy attachment may be inserted for a pathology sample; then an ablation attachment may be inserted for ablating any lesions; and then a further attachment or instrument may be inserted to perform additional procedures such a deliver drugs, implants, and/or therapeutic and/or diagnostic agents. The imaging component of the present disclosure may facilitate the insertion and removal of medical instruments by providing a shaft with atraumatic edges and a cavity configured to receive a plurality of different instruments. Additionally or alternatively, the imaging component may be used independently of an additional instrument or attachment. In such embodiments, the edges of the cavity may be smooth or rounded such that the edges may not catch on the patient tissue when used alone.

[0076] The cavity of an imaging component may improve upon existing methods for imaging and treatment by providing a cavity of an imaging component which may be easier to clean than a component with a closed cavity or lumen. The cavity of an imaging component may improve on existing methods for imaging and treatment by facilitating manufacture of the imaging component. Embodiments of the present disclosure may lower treatment cost by providing an imaging component with a disposable tube. Embodiments of the present disclosure may lower treatment costs by providing a reusable imaging component with a cavity into which disposable instruments may be inserted. Embodiments of the imaging component may provide a shaft which aligns the instrument with the ultrasound image at all times. Embodiments of the present disclosure may accommodate various instruments with different sizes and shapes. Embodiments of the present disclosure may provide a scale or position information to assist insertion of an instrument.

[0077] The systems and methods of the present disclosure may be particularly useful in the treatment of fibroids in a patient uterus. The imaging component may be deployed transvaginally and transcervically into the uterus, or in other cases, laproscopically into and through an exterior of the uterus or other organ or tissue tract. The imaging component may be used in conjunction with an additional instrument such as a biopsy needle; a tissue ablation element, such as for example a radiofrequency ablation element, an ultrasonic ablation element, a heat-based ablation element, a cryoablation element, etc.; and/or other instrument suitable to be disposed within the cavity of the imaging component. Additionally or alternatively, the additional instrument may be used to deliver drugs, implants, or other therapeutic agents to the tissue to be treated. Additionally or alternatively, the tissue ablation element may comprise embodiments or variations of the needle/tine assemblies of commonly assigned U.S. Patent Nos. 8,206,300, 8,262,574, and 8,992,427, the contents of which are incorporated herein by references.

[0078] Embodiments of the present disclosure may improve upon at least some of the systems and methods of the commonly assigned references by providing a shaft of an imaging component with atraumatic edges to enable use of the imaging component alone. In some embodiments, embodiments of the present disclosure may improve upon the ability to remove and/or receive an additional instrument by providing an imaging system without an attachment mechanism located in at least the portion of the system to be positioned *in situ*. In such an embodiment, the imaging component shaft may be non-cylindrically symmetric (e.g., oval or rectangular in cross-section) in order to reference the rotation of the additional instrument relative to the imaging component shaft. In some embodiments, the present disclosure may additionally or alternatively provide a shaft of an imaging component with a small angled portion to minimize damage risk to a surface of an imaging transducer surface by an instrument. Additionally or alternatively, the imaging component may comprise a disposable tube inserted within the cavity to provide, among many possible purposes, a working channel for inserting additional instruments with different diameters and making the system easier to clean.

[0079] The imaging components described herein may be used in a surgical procedure to provide a real time image of a target structure to be treated, including projecting safety and treatment boundaries as described in commonly assigned U.S. Patent Nos. 8,088,072 and 8,262,577, the contents of which are incorporated by reference. The imaging components described herein may be useful for both imaging and treating uterine fibroids as described in commonly assigned U.S. Patent No. 7,918,795, which is incorporated herein by reference. Other commonly assigned patents and published applications describing probes useful for treating

uterine fibroids which may be used with the imaging components described herein include U.S. Patent Nos. 7,815,571, 7,874,986, 8,506,485, 9,357,977, and 9,517,047, which are incorporated herein by references. Additional, commonly assigned patent applications describing systems for establishing and adjusting displayed safety and treatment zone boundaries which may be used in conjunction with the imaging components described herein include: U.S. Pat. Pub. No. 2014/0073910 , US. Pat. No. 8,992,427, U.S. Pat. App. No. 15/811,520, and P.C.T. App. No. US2017/060674, which are each incorporated herein by reference. Commonly assigned patent application P.C.T. App. No. PCT/US2017/060674, describes mapping and planning system which may be used in conjunction with the imaging components described herein, is also incorporated herein by reference.

[0080] In some embodiments, the systems and methods of the present disclosure may provide an imaging component to be used in a variety of diagnostic and therapeutic procedures. Some embodiments may provide methods and systems to perform therapy or diagnosis on a volume of tissue. A volume of tissue may comprise a patient organ. A patient organ or bodily cavity may comprise for example: muscles, tendons, a mouth, a tongue, a pharynx, an esophagus, a stomach, an intestine, an anus, a liver, a gallbladder, a pancreas, a nose, a larynx, a trachea, lungs, a kidneys, a bladder, a urethra, a uterus, a vagina, an ovary, testes, a prostate, a heart, an artery, a vein, a spleen, a gland, a brain, a spinal cord, a nerve, etc. Some embodiments provide systems and methods suitable for laparoscopic surgery. Some embodiments provide systems and methods suitable for non-invasive surgery. Some embodiments provide systems and methods suitable for minimally invasive surgery. Some embodiments provide systems and methods suitable for robotic or robot assisted surgery.

[0081] Reference will now be made in detail to various embodiments, examples of which are illustrated in the accompanying drawings. In the following detailed description, numerous specific details are set forth in order to provide a thorough understanding of the invention and the described embodiments. However, the invention is optionally practiced without these specific details. In other instances, well-known methods, procedures, components, and circuits have not been described in detail so as not to unnecessarily obscure aspects of the embodiments.

[0082] It will be understood that, although the terms "first," "second," etc. are optionally used herein to describe various elements, these elements should not be limited by these terms. These terms are only used to distinguish one element from another. For example, a first instrument could be termed an instrument sensor, and, similarly, a second instrument could be termed a first instrument, without changing the meaning of the description, so long as all occurrences of the "first instrument" are renamed consistently and all occurrences of the second instrument are

renamed consistently. The first instrument and the second instrument are both instruments, but they are not the same instrument.

[0083] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the claims. As used in the description of the embodiments and the appended claims, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will also be understood that the term "and/or" as used herein refers to and encompasses any and all possible combinations of one or more of the associated listed items. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof.

[0084] As used herein, the term "if" is optionally construed to mean "when" or "upon" or "in response to determining" or "in accordance with a determination" or "in response to detecting," that a stated condition precedent is true, depending on the context. Similarly, the phrase "if it is determined [that a stated condition precedent is true]" or "if [a stated condition precedent is true]" or "when [a stated condition precedent is true]" is optionally construed to mean "upon determining" or "in response to determining" or "in accordance with a determination" or "upon detecting" or "in response to detecting" that the stated condition precedent is true, depending on the context.

[0085] For ease of explanation, the figures and corresponding description below may be described below with reference to uterine imaging, specifically, in conjunction with the diagnosis and ablation and/or treatment of uterine fibroids. However, one of skill in the art will recognize that a similar imaging component may be used with similar instruments in other therapeutic applications for example: instruments for tissue biopsy, for drug delivery, for fluid infusion and/or aspiration, and for the treatment of cancers, tumors, fibroids, and other masses, malignant or benign, in any suitable bodily lumen.

[0086] **FIG. 1A** shows an illustration of an imaging component **100**, in accordance with some embodiments. Imaging component **100** may comprise a handle portion **101** connected to an imaging shaft **103**. At the distal end of imaging shaft **103** may be coupled an imaging transducer **107**. The imaging shaft may comprise a proximal end and a distal end with a cavity **105** extending across the length of the shaft from the proximal end towards the distal end. The cavity **105** may be at least partially open to the exterior of the shaft. For example, a side, or wall of the cavity may comprise an elongated opening in communication with the exterior of the shaft. The

elongated opening may be in communication with the exterior of the shaft at least partially along the length of the shaft. In some embodiments, an edge of the elongated opening may be bent towards an interior of the cavity of the shaft (for example, see **FIG. 11B** further described below). The length of the shaft may be sufficiently long to fully access the uterus of a patient while the handle portion **101** remains exterior to the patient. Additionally or alternatively, the shaft may comprise a length significantly longer than the distance sufficient to fully access a patient uterus. The side opening may be open along the full length of the shaft or it may be open only partially along the length of the shaft. The side opening may be open, for example, for greater than three-fourths the length of the shaft, for greater than half the length of the shaft, or for greater than one quarter the length of the shaft. The cavity **105** may be configured to receive at least one of a plurality of different additional instruments or attachments, such that a first instrument may be received by the cavity, the first instrument may be removed from the cavity, and a second instrument may be received by the cavity.

[0087] The handle portion **101** may be one part of a two-part handle such that when a first instrument or a second instrument is received the two handle portions may combine to form a single handle. The inside of the handle portion **109** may comprise alignment elements **111** such that a first part and a second part may be reproducibly aligned with respect to one another after changing instruments. The alignment elements may be configured such that a first part and a second part may be sufficiently secured with respect to one another to use the two handle portions as a single handle. In some embodiments, the alignment elements may comprise magnets. I n other embodiments, alignment elements may comprise for example: latches, hooks, or any other mechanism suitable to removably combine a two-part handle. The handle portion may additionally comprise a positioning element **113**, such as a slot to accommodate a complementary protrusion or other element on the opposite handle portion, in order to provide a more secure reference between parts of the two-part handle. The positioning element may comprise a mechanical feature to secure the instrument relative to the imaging component by limiting translation of the instrument on the axis of the shaft of the imaging component.

[0088] In other embodiments, imaging component **100** may be configured to be used with an instrument which does not have a handle portion. In such embodiments, the handle portion **101** of the imaging component **100** is sufficient to be used alone to guide the imaging component during a procedure. In some embodiments, imaging component **100** may have a scale or a guide on the inside of the handle portion **109** in order to gauge the insertion depth of an instrument. In other embodiments, the imaging component may be used without an instrument. In some embodiments, a scale may facilitate embodiments where the instrument does not have a handle.

In other embodiments, a scale may facilitate the insertion of a component of the instrument in embodiments where the instrument has a handle.

[0089] **FIG. 1B** shows a cross-sectional view of an imaging component **100**, in accordance with some embodiments. The body of the shaft may comprise internal structure in order to carry electronics or other associated components to control the imaging transducer. The shaft may also comprise a wire system or other flex mechanism in order to allow the shaft to controllably bend, flex, or deflect the distal end of the shaft. The shaft may comprise a channel or duct to direct fluid (e.g., water, saline, etc.) to a distal end of the shaft and onto a tissue surface. Imaging shaft **103** may be round in cross-section or take a shape with sufficiently softened, chamfered, rounded, or beveled edges such that the edges may be atraumatic to a patient opening during insertion or removal of an imaging component with or without an instrument. Shaft **103** may additionally comprise a smooth exterior surface. Shaft **103** may be made of a material such that the surface may be deformable to allow the shaft to bend or adapt to the shape of a bodily lumen.

[0090] The cavity **105** of imaging shaft **103** may be configured to slidably receive one or more of a plurality of instruments. In some embodiments, the cavity may be defined by an exterior surface of the shaft. In some embodiments, the cavity may be partially open along a wall, such that the cavity may be in communication with the exterior of the shaft. The opening may be sufficiently closed to provide structural support such that when the imaging component may be inserted into a patient bodily lumen, the opening of the lumen may not be significantly disturbed by the insertion or removal of an instrument. Optionally, the exterior surface of the shaft may comprise only atraumatic edges. The cavity **105** of imaging shaft **103** may be sufficiently open such that when instruments of different sizes may be received or inserted into the cavity, the cavity may allow some distortion of the cavity opening. The cavity may facilitate cleaning of the imaging component.

[0091] **FIG. 11A** shows a cross-section view of an imaging component having a shaft with a circular cross-section, in accordance with some embodiments. The imaging component of **FIG. 11A** may be sufficiently circular in cross-section such that the imaging component may be rotated without disturbing a patient lumen. **FIG. 11B** shows a cross-sectional view of an imaging component with edges bent inward towards the interior of the cavity, in accordance with some embodiments. The inward bent edges **1111** of a cavity may serve to support the opening of a bodily lumen such that the shaft may be inserted or removed atraumatically from a bodily lumen with or without an instrument.

[0092] While the cavity of the shaft in the illustrated example may define a circular cross sectional area, in other embodiments the cavity may be elliptical or any other geometric shape with sufficiently softened, rounded, or beveled edges and corners such that insertion or removal of the shaft may not damage the patient bodily lumen. In some embodiments, the cavity may be non-cylindrically symmetric. In some embodiments, the cavity may be asymmetrical to provide an axis for alignment of the instrument within. The cavity may be open for less than three-quarters its perimeter in cross-section, additionally or alternatively, the cavity may be open for less than half its perimeter, less than a quarter its perimeter, and less than one eighth its perimeter. In other embodiments, the cavity of the shaft of the imaging component may be closed to the exterior of the shaft, and an instrument may be slidably inserted fully interior to the shaft of the imaging component.

[0093] In some embodiments, the cavity may comprise a substantially uniform cross sectional area along the shaft. In other embodiments, a portion of the length of the shaft may have a different cross section than another portion of the length of the shaft. In an example, the proximal portion of the shaft may be asymmetric to provide an axis for alignment of an instrument and the distal portion of the shaft may have a circular cross sectional area. In another embodiment, the cavity tapers toward the end of the shaft. In such an example, the taper may facilitate feeding an instrument into the cavity. In some embodiments, the cross sectional area of the cavity may narrow in diameter to allow greater flexibility of the distal end of the shaft.

[0094] In some embodiments, imaging shaft **103** may additionally comprise a tube **115** to be positioned at the cavity **105** of imaging shaft **103**. Tube **115** may comprise a lumen. The lumen of tube **115** may be configured to slidably receive one or more of a plurality of instruments. Tube **115** may be aligned in parallel with the shaft of the imaging component, such that an additional instrument/attachment may be slidably received by the tube. Subsequently, the tube **115** may slidably receive the additional instrument/attachment after it has been aligned to be in parallel with the shaft of the imaging component. In some embodiments, the tube **115** may be disposable. In some embodiments, the tube **115** may be reusable such as by being un-coupled from the imaging shaft **103**, washed, and autoclaved. Tube **115** may have an exterior surface wherein the surface is substantially in contact with the inner wall of cavity **105**. Tube **115** may have an interior surface of a different geometry to the outer surface configured to receive one or more of a plurality of instruments. In some embodiments, a second tube may be removably inserted into the first tube and the second tube may have a different inner lumen geometry than the first, thereby aiding in the insertion of one or more of a plurality of instruments. In some embodiments, the tube **115** may be rotated relative to the imaging component. In some

embodiments, the tube **115** may fully rotate relative to the imaging component in either direction under the control of a user within the shaft of the imaging component. In some embodiments, the tube **115** may be internally or externally lubricated to facilitate insertion or removal of an instrument.

[0095] The tube **115** may be inserted into the bodily lumen *in situ* with the imaging component yet advanced therein. Additionally or alternatively, the tube **115** may be inserted into the shaft of the imaging component prior to insertion of the imaging component into the bodily lumen. The tube **115** may have sufficient structural integrity to support a bodily lumen during insertion of the imaging component without an instrument. When an additional instrument is inserted into the tube **115** or the tube **115** is inserted into the imaging component *in situ*, disruption to the bodily lumen may be minimized. The tube **115** may be made of a material that can be sterilized. The tube **115** may be made of a material that may be of low enough cost that it may be disposed of after a single use. Exemplary materials for a disposable tube may comprise polyimide, PTFE, Urethanes and thermoplastics like Pebax or Nylon, etc. Tube **115** may be made of a material comprising sufficient elasticity in order to adapt to an instrument of a size somewhat larger or smaller than the perimeter of the tube. In embodiments where the cavity is not circular, the tube may take the shape of the cavity or it may take another shape.

[0096] The tube **115** may lower treatment costs by facilitating insertion and/or removal of an additional instrument into the cavity of the imaging component **100** and thereby preventing damage to the surface of the cavity **105** of the imaging component **100**. The tube **115** may lower cost by facilitating cleaning of the cavity **105** of the imaging component **100**. The tube **115** may lower cost of treatment by providing an inexpensive component which may act as an adapter for a variety of different therapeutic and/or diagnostic instruments/attachments, such as being provided in a variety of different inner geometries suitable for the different instruments/attachments but having a uniform outer geometry to be removably coupled to the same single imaging component **100**. For example, a disposable tube with a smaller inner diameter may facilitate the insertion and control of a needle with a smaller outer diameter than the inner diameter of the shaft of the imaging component.

[0097] **FIG. 1C** shows a magnified view of a distal end of the imaging component comprising a cavity, in accordance with some embodiments. The distal end of the imaging component may comprise an imaging transducer **107**. The imaging transducer may comprise an ultrasound transducer and/or a plurality of ultrasound transducers. The ultrasound transducer may operate at a frequency of 500 kHz, 1 MHz, 5 MHz, 10 MHz, 20 MHz, 100 MHz, or a range defined by

any two of the preceding values. Some embodiments of the ultrasound transducer may comprise specifications of other transducers from the commonly assigned references incorporated herein.

[0098] In some embodiments, the distal end of the imaging transducer **117** may additionally comprise a light emitting diode and/or a camera in order to provide images to a user. In such embodiments, the imaging component may serve as an optical scope as well as an ultrasound imaging platform. The distal end of the imaging transducer may comprise optical components, such as an optic fiber, a relay lens, an objective lens, etc.

[0099] The imaging transducer **107** may be configured to be deflectable. The imaging transducer may be configured to deflect relative to the longitudinal axis of the shaft of the imaging component. In some embodiments, the distal end of an imaging component comprises a hinge to facilitate deflection of an imaging transducer. The deflection of the imaging transducer may be controlled by a deflection lever **119** on the handle portion **101** of the imaging component. The one or a plurality of imaging transducers may be oriented by the deflection of the imaging transducer. The one or a plurality of imaging transducers may be oriented by the deflection of the imaging transducer in order to facilitate maintaining the field of view of an image during a treatment. Additionally or alternatively, the ultrasound transducers may be aligned radially and/or axially to image multiple views simultaneously. Deflection of the imaging transducer may be induced in order to avoid obstruction of an instrument. Additionally or alternatively, deflection of the imaging transducer may be used to deflect a flexible instrument within the cavity. The distal end of the shaft may comprise an interlock system, similar to those in the incorporated references, in order to prevent the imaging transducer from obstructing an instrument or being damaged by sharp edges of an instrument. Actuation of the deflection lever may function in a manner similar to that described in U.S. Patent No. 8,992,427, incorporated herein by reference. The deflection lever **119** may deflect the imaging transducer by less than 45 degrees and additionally or alternatively, for example, less than 120 degrees, less than 90 degrees, less than 60 degrees, less than 30 degrees, less than 15 degrees, and less than 5 degrees.

[0100] The distal end of the imaging component may comprise atraumatic edges in order to facilitate insertion of the imaging component with or without an instrument in the cavity. The distal end of the cavity of the imaging component may additionally or alternatively comprise a portion angled axially relative to the shaft, such that a distal end of an instrument may be deflected upward as it is pushed out the distal end of the cavity. The distal end of the cavity of the imaging component may comprise an angled portion with an angle of 3 to 45 degrees. The distal end of the cavity of the imaging component may comprise an angled portion with an angle

at less than 45 degrees and additionally or alternatively, for example, less than 90 degrees, less than 60 degrees, less than 30 degrees, less than 15 degrees, and less than 5 degrees.

[0101] The cavity of the imaging component may be configured to slidably receive one or more of a plurality of instruments. In some embodiments, the imaging component may be configured to receive one or a plurality of therapeutic or diagnostic instruments. In some embodiments, at least one of the plurality of different instrument may be a therapeutic or diagnostic instrument. In some embodiments, the instrument may comprise an instrument such as a biopsy needle; an optical scope; implantation device; therapy electrodes; a tissue ablation element, such as for example a radiofrequency ablation element, an ultrasonic ablation element, a heat-based ablation element, a cryoablation element, etc.; and/or other instrument suitable to be disposed within the cavity of the imaging component. Additionally or alternatively, the instrument may be used to deliver drugs or other therapeutic agents to the tissue to be treated. **FIGS. 2A-2E** show instruments which may be slidably received by the imaging component. One of ordinary skill in the art will recognize that many instruments, including those disclosed in the following figures, may be used with the imaging component disclosed herein.

[0102] **FIG. 2A** shows a magnified view of a distal end of the imaging component with a tissue collector instrument **210** disposed within the shaft **105** of the imaging component **100**, in accordance with some embodiments. The tissue collector element may be used to extract tissue and/or cell pathology samples for examination by a medical professional to determine the extent of a disease. In some embodiments, the tissue collector may comprise a biopsy needle. Tissue collector **210** may comprise a shaft of a tissue collector **211**, which has a distal end and a proximal end. The shaft of tissue collector **211** may be configured to detach from a handle component of the instrument or may be configured to be used without a handle component such that the tissue collector **210** may be disposable.

[0103] The shaft of tissue collector **211** may be made of a pliable and/or flexible material such that it may be deflected by the imaging transducer and/or an angled portion within the cavity of the shaft. In the illustrated example, a distal end of a shaft of a tissue collector is deflected upward by an angled portion within the cavity of the shaft. The distal end of a shaft of a tissue collector may be deflected up in order to avoid damage of the imaging transducer, among other possible purposes. The distal end of the cavity of the imaging component may comprise a portion angled axially relative to the shaft, such that a distal end of an instrument may be deflected upward as it is pushed out the distal end of the cavity. The distal end of the cavity of the imaging component may comprise an angled portion angled at less than 45 degrees and

additionally or alternatively, for example, less than 90 degrees, less than 60 degrees, less than 30 degrees, less than 15 degrees, and less than 5 degrees.

[0104] Additionally or alternatively, the shaft of the imaging collector may comprise a wire system or other means to deflect the distal end of the tissue collector such that a distal end of a tissue collector does not damage the imaging transducer. The distal end of the tissue collector instrument may comprise a slot or opening **213** into which tissue may be collected. In some embodiments, the tissue collector may rotate relative to the shaft. In some embodiments, the tissue collector may fully rotate relative to the shaft in either direction under the control of a user within the shaft of the imaging component while the shaft remains stationary, such that the slot **213** may scrape, scoop, or otherwise collect tissue.

[0105] The shaft of the tissue collector may be longer than the shaft of the imaging transducer such that the slot or opening may collect tissue from deep inside the uterus or other body cavity. In some embodiments, the shaft of the tissue collector may be two inches longer than the shaft of the imaging transducer. Additionally or alternatively for example, the shaft may be six inches longer, may be four inches longer, may be two inches longer, may be the same length, or may be within a range of any two of the preceding values.

[0106] **FIG. 2B** shows a cross-sectional view of an imaging component with a tissue collector instrument **211** disposed within the shaft of the imaging component, in accordance with some embodiments. Tissue collector **211** may be disposed within a tube **115** disposed within the cavity **105** of the imaging component. Additionally or alternatively, tissue collector **211** may be disposed within the cavity of the imaging component without the use of a tube. While the shaft of the collector instrument in the illustrated example may be circular, in other embodiments, the shaft of the collector instrument may be elliptical any other geometric shape such that the shaft may be inserted or removed from the cavity of the imaging component. In some embodiments, the shaft of the collector may be asymmetrical to provide an axis for alignment of the instrument within the cavity of the imaging component. In some embodiments, the cavity comprises a substantially uniform cross sectional area along the length of the shaft. In other embodiments, the cross sectional area changes along the length of the shaft such as, for example, the proximal end of the shaft may be asymmetric to provide an axis for alignment while the distal end of the shaft may be circular.

[0107] **FIG. 2C** shows a magnified view of a distal end of the imaging component with an ablation instrument **230** disposed within the shaft of the imaging component, in accordance with some embodiments. The ablation instrument **230** may contain a needle assembly comprising needle **235** and, optionally, tines **233**. The shaft of the ablation instrument **231** may be deployed

from the shaft of an imaging component **103**. Additionally or alternatively, the needle may be deployed from a lumen of a tube **115**. The ablation instrument may comprise one or more of, for example, a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, a cryoablation element, and any other type of ablation elements known to one of ordinary skill in the art.

[0108] Ablation instrument **230** may be disposed within a tube **115** disposed within the cavity **105** of the imaging component. Additionally or alternatively, ablation instrument **230** may be disposed within the cavity of the imaging component without the use of a tube. While the shaft of the ablation instrument **231** in the illustrated example may be circular, in other embodiments, the shaft of the ablation instrument may be elliptical or any other geometric shape such that the shaft may be inserted or removed from the cavity of the imaging component. In some embodiments, the shaft of the ablation instrument may be asymmetrical to provide an axis for alignment of the instrument within the cavity of the imaging component.

[0109] The shaft of the ablation instrument **231** may be made of a pliable and/or flexible material such that it may be deflected by the imaging transducer and/or an angled portion within the cavity of the shaft. Additionally or alternatively, the shaft of the ablation instrument may comprise a wire system or other means to deflect the distal end of the ablation instrument such that a distal end of the ablation instrument does not damage the imaging transducer. In some embodiments, the ablation element may rotate relative to the imaging component. In some embodiments, the ablation instrument may fully rotate relative to the imaging component in either direction under the control of a user within the shaft of the imaging component while the shaft remains stationary, such that the tines may be optimally aligned.

[0110] The needle assembly may be constructed and controlled by a user, for example, as previously described in commonly owned U.S. Patent Nos. 8,206,300, 8,262,574, and 8,992,427, the full disclosures of which are incorporated herein by reference. The needle assembly may be integrated into an instrument handle such that the position and deployment of the needle and tines may be controlled by the user. The handle may be constructed, for example, as previously described in commonly owned U.S. Patent No. 8,992,427, the full disclosure of which is incorporated herein by reference. The needle assembly may be compatible with systems and methods for improved safety and treatment boundaries during the treatment of uterine fibroids as, for example, described in the incorporated references.

[0111] **FIG. 2D** shows a view of an imaging component with a drug delivery instrument **240** disposed within the shaft **105** of the imaging component **100**, in accordance with some embodiments. A drug delivery instrument may serve as a platform to inject therapeutic agents

into the tissue of a patient. Exemplary therapeutic agents may comprise analgesics, anesthetics, hemostatics, antibiotics, steroids, anticoagulants, anti-inflammatories, etc. Additionally or alternatively, the drug delivery instrument may be configured to deliver to target tissue, one or more drug eluting, drug releasing, or otherwise therapeutic and/or diagnostic seeds, pellets, or other implants. The drug delivery instrument may comprise needle **243** disposed inside a distal end of a shaft of a drug delivery instrument **241**. The shaft of a drug delivery instrument **241** may comprise a distal end and a proximal end. The shaft of the drug delivery instrument may be longer than the shaft of the imaging transducer such that the needle may inject agents deep inside the uterus. In some embodiments, the shaft of the drug delivery instrument may be two inches longer than the shaft of the imaging transducer. Additionally or alternatively, for example, the shaft may be six inches longer, may be four inches longer, may be two inches longer, may be the same length, or may be within a range of any two of the preceding values.

[0112] The shaft of drug delivery instrument **241** may be made of a pliable and/or flexible material such that it may be deflected by the imaging transducer and/or an angled portion within the cavity of the shaft. Additionally or alternatively, the shaft of the drug delivery instrument may comprise a wire system or other means to deflect the distal end of the drug delivery instrument such that a distal end of a drug delivery instrument does not damage the imaging transducer. In some embodiments, the drug delivery instrument may rotate relative to an imaging component. In some embodiments, the drug delivery instrument may fully rotate relative to an imaging component in either direction under the control of a user within the shaft of the imaging component while the shaft remains stationary.

[0113] The shaft of a drug delivery instrument may be detachable from a handle component of the instrument or maybe constructed without a handle component such that the drug delivery instrument may be disposable. In the illustrated embodiment, drug delivery instrument **240** does not have a handle portion. In such embodiments, the handle portion **101** of the imaging component **100** may be used to guide the drug delivery instrument during a procedure. Shown in **FIG. 2D** imaging component **100** may have a scale, a guide, or other indicia **245** on the inside face of the handle portion **109** in order to gauge the insertion depth of a needle **243** of a drug delivery instrument **240**.

[0114] **FIG. 2E** shows a cross-sectional view of the imaging component with a needle disposed within the shaft of the imaging component **103**, in accordance with some embodiments. The shaft of a drug delivery instrument **241** comprising a needle **243** may be disposed within a tube **115** disposed within the cavity **105** of the imaging component. Additionally or alternatively, the shaft of a drug delivery instrument **241** may be disposed within the cavity of the imaging

component without the use of a tube. While shaft of the drug delivery instrument in the illustrated example may be circular, in other embodiments the shaft of the drug delivery instrument may be elliptical any other geometric shape such that the shaft may be inserted or removed from the cavity of the imaging component. In some embodiments, the shaft of the drug delivery instrument may be asymmetrical to provide an axis for alignment of the instrument within the cavity of the imaging component. In some embodiments, the drug delivery instrument may rotate relative to the imaging component. In other embodiments, the drug delivery instrument may fully rotate relative to the imaging component in either direction under the control of a user within the tube of the shaft of the imaging component while the shaft remains stationary.

[0115] **FIGs. 2A** to **2E** illustrate exemplary instruments which may be disposed within the shaft of an imaging component, which examples are not intended to be limiting. Other examples may comprise a fluid infusion and/or aspiration instrument. A fluid infusion and/or aspiration instrument may comprise an instrument with a shaft comprising a lumen therein, configured to conduct a fluid to a tissue of a patient. A fluid infusion and/or aspiration instrument may deliver fluid to cool a tissue. Additionally or alternatively, a fluid infusion and/or aspiration instrument may deliver a fluid to clean a tissue. Additionally or alternatively, a fluid infusion and/or aspiration instrument may deliver a fluid to inflate a bodily cavity. A fluid infusion and/or aspiration instrument may deliver a solution and/or suspension comprising a therapeutic agent, such as an antiseptic, an anesthetic, an analgesic, an antibiotic, a steroid, etc. A fluid infusion and/or aspiration element may be integrated into any of the instruments described herein. Alternatively, a fluid infusion and/or aspiration element may comprise an instrument to be inserted and retracted as a step during a multi-instrument procedure.

[0116] **FIG. 3A** shows an assembly view of an imaging system comprising an imaging component **100** and an optical scope instrument **300**, in accordance with some embodiments. While an optical scope element may be shown in the illustrated embodiment, optical scope instrument **300** may be any other suitable instrument, for example, any of the instruments disclosed herein. Illustrated in **FIG. 3A**, the imaging system may slidably receive a disposable tube **115** within the cavity **105** of the imaging component. In some embodiments, the imaging system may comprise a disposable tube slidably received within the cavity of the imaging component. In such embodiments, an instrument may be removably received with a lumen of the disposable tube. Additionally or alternatively, the cavity of the imaging component may be configured to slidably receive one or more of a plurality of instruments, which instruments may comprise various therapeutic and/or diagnostic instruments.

[0117] In illustrative examples, the imaging component may removably receive an instrument such as a biopsy needle; a tissue collector instrument; an optical scope; implantation device; therapy electrodes; a tissue ablation element, such as for example a radiofrequency ablation element, an ultrasonic ablation element, a heat-based ablation element, a cryoablation element, etc.; and/or other instrument suitable to be disposed within the cavity of the imaging component. Additionally or alternatively, the instrument may be used to deliver drugs or other therapeutic agents to the tissue to be treated. Additionally or alternatively, with or without the use of a disposable tube, the imaging component may removably receive any of the instruments illustrated in **FIG. 2A-2E**.

[0118] In the illustrated embodiment, the distal end **305** of the optical scope instrument may comprise a light emitting diode and/or a camera in order to provide images to a user. In such embodiments, the optical scope instrument may serve as an endoscope. The distal end **305** of the optical scope element may comprise optical components, such as an optic fiber, a relay lens, an objective lens, etc. The optical scope instrument **300** may comprise a shaft of an optical scope instrument **303**, which has a distal end and a proximal end. The shaft of optical scope instrument **303** may be configured to detach from a handle component of the instrument or may be configured to be used without a handle component such that the optical scope instrument **300** may be disposable.

[0119] The shaft of optical scope instrument **303** may be made of a pliable and/or flexible material such that it may be deflected by the imaging transducer and/or an angled portion within the cavity of the shaft. Additionally or alternatively, the shaft of the optical scope instrument may comprise a (e.g., push, pull, and/or rotate/torque) wire system or other means to deflect the distal end of the optical scope instrument. Deflection of a distal end of an optical scope instrument may serve to prevent damage the imaging transducer and/or allow multiple image angles may be collected. In some embodiments, the optical scope element may rotate relative to the imaging component. In some embodiments, the optical scope instrument may fully rotate relative to the imaging component in either direction under the control of a user within the shaft of the imaging component while the shaft remains stationary, such that multiple image angles may be collected.

[0120] The shaft of the optical scope instrument may be longer than the shaft of the imaging transducer such images may be collected from deep inside the uterus. In some embodiments, the shaft of the optical scope instrument may be two inches longer than the shaft of the imaging transducer. Additionally or alternatively, for example, the shaft may be six inches longer, may

be four inches longer, may be two inches longer, may be the same length, or may be within a range of any two of the preceding values.

[0121] In the illustrated embodiment, the optical scope instrument comprises a handle portion **301**. While a handle portion **301** may be shown connected to an optical scope in the illustrated example similar handle portions may be connected to any suitable instrument, such as those disclosed herein. The handle portion **301** may be the second part of a two-part handle such that when an optical scope instrument may be slideably inserted into the imaging component the two handle portions may combine to form a single handle. The handle portion may additionally comprise a positioning element **313**, in order to provide a more secure reference between parts of the two-part handle. Positioning element **313** may mate with slot **113**. In such embodiments, the handle portion may comprise a release control **321**, which may be actuated by a user, to retract the positioning element into the handle and allow the two-handle to be separated.

[0122] The handle portion may additionally comprise one or a plurality of control elements **319**. Control elements **319** may allow a medical professional to control the distal end of an instrument. In one example, the control element controls a wire system which may reproducibly deflect or steer a distal end of an instrument. Additionally or alternatively, the control element may rotate a shaft of an instrument with the cavity of the imaging component or within the disposable tube. In another example, the control element scoops tissue in a tissue collector instrument. In another example, the control element deploys a needle assembly comprising optional tines in an ablation instrument. Additionally or alternatively, the control element begins the ablation procedure. In another example, the control element applies pressure to inject a chemical though a drug delivery instrument. In another example, the control element begins or ends image collection in an optical scope instrument.

[0123] **FIG. 3B** shows an assembly view of an imaging system illustrating an attachment mechanism of a system, in accordance with some embodiments. The inside of the handle portion **309** may comprise alignment elements **311**. Alignment elements **311** may be configured such that the optical scope instrument may be reproducibly aligned with respect the imaging component after changing instruments. Additionally or alternatively, the alignment elements may sufficiently secure the instrument and the imaging component with respect to one another to use the two handle portions as a single handle. In some embodiments, the alignment elements may comprise magnets. In other embodiments, the alignment elements may comprise for example: latches, hooks, or any other mechanism suitable to removably combine a two-part handle. The inside of the handle portion **309** may additionally comprise a positioning element **313**, in order to provide a more secure reference between parts of the two-part handle. In such

embodiments, the handle portion may comprise a release control **321**, which may be actuated by a user, to retract the positioning element into the handle and allow the two-handle to be separated.

[0124] In some embodiments, a method of detecting or sensing the identification of removable instruments is provided when coupling the imaging component and the removable instrument. The imaging component may include software to recognize the removable instrument and manage the interconnection between the imaging component and removable instrument. The sensor or mechanism may be, by way of non-limiting examples, optical, RF, magnetic, biometric, electronic and mechanical IDs and readers. The method will ensure only qualified removable devices are received on the imaging device to ensure that only compatible devices may be used with the imaging component.

[0125] **FIG. 4** illustrates a shaft of an imaging component wherein the shaft of the imaging component may be flexible, in accordance with some embodiments. In the illustrated embodiment, the shaft of the imaging component may comprise a flexible shaft portion **403**. The body of the flexible portion of the shaft may comprise internal structure in order to carry electronics or other associated components to control the imaging transducer. The imaging transducer may comprise a channel or duct to direct fluid (e.g., water, saline, etc.) to a distal end of the shaft and onto a tissue surface. The flexible portion may comprise a fraction of the length of the shaft of the imaging component. In some embodiments, the flexible portion comprises less than three-quarters the length of the shaft. Additionally or alternatively, the flexible portion may comprise less than a quarter the length of the shaft, and less than one eighth the length of the shaft, and the full length of the shaft.

[0126] The cross-section of the flexible portion of the shaft may continue the geometry of the shaft such that no gaps or traumatic edges may be created between the flexible portion of the shaft and the shaft. The flexible portion may be round in cross-section or take a shape with sufficiently softened, chamfered, rounded or beveled edges such that the edges may be atraumatic to a patient opening during insertion or removal of an imaging component with or without an instrument. The flexible portion may additionally comprise a smooth exterior surface. The flexible portion may be made of a material such that the surface may be deformable to allow the flexible portion to bend or adapt to the shape of a bodily lumen.

[0127] The cavity of the flexible portion may be configured to slidably receive one or more of a plurality of instruments. The cavity of the flexible shaft portion may be configured to continue the shape of the cavity of the shaft such that no gaps or traumatic edges may be created between the flexible portion of the shaft and the shaft. In some embodiments, the cavity of the flexible

portion may be partially open along a wall, such that a lumen of the cavity of the flexible portion may be in communication with the exterior of the shaft. The opening of the flexible portion may be sufficiently closed to provide structural support such that when the imaging component may be inserted into a patient bodily lumen, the opening of the lumen may not be significantly disturbed by the insertion or removal of an instrument. In some embodiments, the edges of a cavity of the flexible portion may bend inward towards the interior of the cavity, such as in the embodiment illustrated in **FIG. 11B**. The inward bent edges of a cavity of the flexible portion may serve to support the opening of a bodily lumen such that the shaft may be inserted or removed atraumatically from a bodily lumen with or without an instrument. The cavity of the flexible portion may be sufficiently open such that when instruments of different sizes may be received or inserted into the cavity, some distortion of the cavity opening may occur. The cavity may facilitate cleaning of the imaging component by providing access to the interior of the cavity from its exterior.

[0128] While the cavity of the flexible portion in the illustrated example defines a circular cross sectional area, in other embodiments the cavity of the flexible portion may be elliptical any other geometric shape with sufficiently softened, rounded, or beveled edges and corners such that insertion or removal of the shaft of the flexible portion does not damage the patient bodily lumen. In some embodiments, the cavity of the flexible portion may be asymmetrical to provide an axis for alignment of the instrument within. The cavity of the flexible portion may be open for less than three-quarters of its perimeter in cross-section, additionally or alternative, the cavity may be open for less than half its perimeter, less than a quarter its perimeter, and less than one eighth its perimeter. In other embodiments, the cavity of the flexible portion of the shaft of the flexible portion may be closed to the exterior of the shaft of the flexible portion, and an instrument may be slidably inserted fully interior to the shaft of the flexible portion.

[0129] In some embodiments, the flexible shaft portion may be constructed from a pliable and/or flexible material such that it may be flexed within a patient bodily lumen. In some embodiments, the shaft may be controllably flexed along its longitudinal axis via a flex mechanism. Additionally or alternatively, the flexible portion of the shaft may comprise a wire system or other flex mechanism in order to allow the flexible portion to controllably bend, flex, or deflect the distal end of the flexible portion. The flex mechanism may be controlled by a control element on a handle portion of the imaging component.

[0130] In the illustrated example, the flexible portion may be flexed axially to about a 90 degree angle with respect to the handle. Additionally or alternatively, the flexible portion may be flexed axially to, for example, less than 180 degrees, less than 120 degrees, less than 90

degrees, less than 45 degrees, less than 10 degrees, less than 1 degrees. Additionally or alternatively, the flexible portion may be flexed in an anterior-posterior axis relative to the handle of the imaging component. In some embodiments, the flexible portion may be flexed in an anterior-posterior axis to, for example, less than 180 degrees, less than 120 degrees, less than 90 degrees, less than 45 degrees, less than 10 degrees, less than 1 degrees. Additionally or alternatively, the flexible portion may be flexed in a medial-lateral axis relative the handle of the imaging component. In some embodiments, the flexible portion may be flexed in a medial-lateral axis to, for example, less than 180 degrees, less than 120 degrees, less than 90 degrees, less than 45 degrees, less than 10 degrees, less than 1 degrees.

[0131] **FIG. 5A** illustrates a system for diagnosing and/or providing therapy, which may be removably coupled to multiple therapeutic and/or diagnostic instruments, in accordance with some embodiments. A system for performing therapy and/or diagnosis may comprise a therapeutic or diagnostic instrument **510** and an imaging component **520**.An instrument **510** of the system for performing therapy and/or diagnosis may comprise a therapeutic or diagnostic instrument, such as, for example, any of the therapeutic or diagnostic instruments described herein. In some embodiments, the imaging component may be used in conjunction with an instrument such as a biopsy needle; a tissue collector, an optical scope; implantation device; therapy electrodes; a tissue ablation element, such as for example a radiofrequency ablation element, an ultrasonic ablation element, a heat-based ablation element, a cryoablation element, etc.; and/or any other instrument suitable to be disposed within the cavity of the imaging component. Additionally or alternatively, the instrument may be used to deliver drugs or other therapeutic agents to the tissue to be treated. **FIGS. 2A-2E** shows exemplary instruments which may be slidably received by the imaging component. In some embodiments, the system may comprise a first and a second therapeutic or diagnostic instrument. An imaging component **520** may comprise an imaging component, such as, for example, examples, embodiments, and variations on the imaging component described herein.

[0132] **FIG. 5B** illustrates a system for diagnosing and/or providing therapy with a therapeutic and/or diagnostic instrument being removably coupled to an imaging component, in accordance with some embodiments. As shown, the instrument **510** may be axially aligned with respect to the imaging component **520**. Additionally, the distal end of the shaft of the instrument **513** may be fed into the proximal end of the cavity **525** of the imaging component. Subsequently, the instrument may be advanced toward imaging component, such that the shaft of the instrument is slidably received by cavity of the imaging component. The instrument may be slidably removed from the imaging component by a similar procedure.

[0133] **FIG. 5C** illustrates a system for diagnosing and/or providing therapy with a therapeutic and/or diagnostic instrument removably coupled to an imaging component, in accordance with some embodiments. The system for diagnosing therapy may comprise retention elements such as hooks, latches, or the mechanical features described herein in order to secure the instrument **510** to the imaging component **520**. The system for diagnosing and/or providing therapy may be configured to couple to a plurality of instruments. For example, a first instrument may be coupled to an imaging component, and, subsequently, a second instrument may be coupled. The imaging component may be configured to be coupled to both the first and second therapeutic and/or diagnostic instrument either simultaneously or individually. For example, if the first instrument is a disposable tube, the second instrument may be slidably inserted within the first instrument. In some embodiments, the imaging component may be configured to be deliverable to the target site within the patient previously coupled with the first and/or second therapeutic or diagnostic instruments exterior to the target site. Additionally or alternatively, the imaging component may be configured to be removably coupled to both the first and second therapeutic or diagnostic instruments, either simultaneously or individually, after the imaging component is delivered to the target site within the patient (e.g., the instrument may be coupled *in situ*).

[0134] **FIG. 12A** illustrates a system for diagnosing and/or providing therapy, which may be removably coupled to multiple therapeutic and/or diagnostic instruments *in situ*, in accordance with some embodiments. FIG. 12A shows the imaging component in use separate from the therapeutic and/or diagnostic instrument, in accordance with some embodiments. A system for performing therapy and/or diagnosis may comprise a therapeutic or diagnostic instrument **1210** and an imaging component **1220**.An instrument **1210** of the system for performing therapy and/or diagnosis may comprise a therapeutic or diagnostic instrument, such as, for example, any of the therapeutic or diagnostic instruments described herein. In some embodiments, the imaging component may be used in conjunction with an instrument such as a biopsy needle; a tissue collector, an optical scope; implantation device; therapy electrodes; a tissue ablation element, such as for example a radiofrequency ablation element, an ultrasonic ablation element, a heat-based ablation element, a cryoablation element, etc.; and/or any other instrument suitable to be disposed within the cavity of the imaging component. Additionally or alternatively, the instrument may be used to deliver drugs or other therapeutic agents to the tissue to be treated. **FIGS. 2A-2E** show exemplary instruments which may be slidably received by the imaging component. In some embodiments, the system may comprise a first and a second therapeutic or diagnostic instrument. An imaging component **1220** may comprise an imaging component, such as, for example, examples, embodiments, and variations on the imaging component described

herein. As shown the illustrated embodiment, imaging component **1220** may disposed within a bodily lumen **L** of a patient without an additional therapeutic and/or diagnostic instrument positioned within the shaft of the imaging component. In some examples, the imaging component **1220** may be used without a therapeutic and/or diagnostic instrument.

[0135] **FIG. 12B** illustrates a system for diagnosing and/or providing therapy with a therapeutic and/or diagnostic instrument being removably coupled to an imaging component *in situ*, in accordance with some embodiments. As shown, the instrument **1210** may be axially aligned with respect to the imaging component **1220**, while the imaging component is disposed within the patient lumen. Additionally, the distal end of the shaft of the instrument **1213** may be fed into the proximal end of the cavity **1225** of the imaging component, while the imaging component remains *in situ*. Subsequently, the instrument may be advanced toward imaging component, such that the shaft of the instrument is slidably received by cavity of the imaging component *in situ*. The instrument may be slidably removed from the imaging component by a similar procedure. Instrument **1210** may be slidably inserted without displacing the distal end of the imaging component. Instrument **1210** may be slidably inserted without discontinuation or disruption of the imaging functionality of imaging component **1220**.

[0136] **FIG. 12C** illustrates a system for diagnosing and/or providing therapy with a therapeutic and/or diagnostic instrument removably coupled to an imaging component *in situ*, in accordance with some embodiments. The system for diagnosing therapy may comprise retention elements such as hooks, latches, or the mechanical features described herein in order to secure the instrument **1210** to the imaging component **1220**. The system for diagnosing and/or providing therapy may be configured to couple to a plurality of instruments. For example, a first instrument may be coupled to an imaging component, and, subsequently, a second instrument may be coupled. The imaging component may be configured to be coupled to both the first and second therapeutic and/or diagnostic instrument either simultaneously or individually. For example, if the first instrument is a disposable tube, the second instrument may be slidably inserted within the first instrument.

[0137] **FIG. 6** shows an imaging system **600** comprising a digital processing device **612** and a display visible to a user **614**, in accordance with some embodiments. As illustrated in **FIG. 6**, an imaging system **600** may additionally comprise an imaging component **100** and an instrument **300**. The digital processing device **612** may comprise one or more processors configured with instructions to set and record both treatment parameters and imaging parameters. The display **614** may be included in a common enclosure **618**; however, in other embodiments, the display **614** may be remote to a digital processing device and/or the imaging component **100**. The

imaging component **100** may be connected to the digital processing device **612** by an imaging cord **624** to provide the image(s) captured by to the digital processing device **612** to be displayed by the display **614**; however, additionally or alternatively, the imaging component may communicate with the digital processing device wirelessly. The instrument **300** may be connected to the digital processing device **612** by an instrument cord **622**; however, additionally or alternatively, the instrument may communicate with the digital processing device wirelessly. In embodiments where the imaging component and the instrument are connected by cords, the digital processing device may supply power to both components.

[0138] The instrument **300** may comprise a handle portion **301** having a slidably mounted control elements **319** on its upper surface. In some embodiments, the control elements **319** may control the positioning of internal stops within the handle which may monitored by the processor **612** in order to calculate the size and position of the boundaries of the targeting region and/or the safety region which are shown on the display **614**. In embodiments where instrument **300** is an ablation element, the stops may also serve to physically limit deployment of the needle and optionally tines.

[0139] Some embodiments of the methods and systems of the present disclosure may be integrated with systems and methods for establishing and adjusting displayed safety and treatment zone boundaries. Such embodiments may include systems and methods of the incorporated references including: U.S. Pat. Pub. No. 2014/0073910, US. Pat. No. 8,992,427, U.S. Pat. App. No. 15/811,520, and P.C.T. App. No. US2017/060674, the contents of which are incorporated herein by reference. Some embodiments of the methods and systems of the present disclosure may be integrated with systems and methods for mapping and planning systems. Such embodiments may include systems and methods of the incorporated references including P.C.T. App. No. PCT/US2017/060674.

[0140] **FIG. 7A** illustrates an imaging component which may be used to treat a fibroid **F** located in the myometrium **M** in a uterus **U** beneath a uterine wall **UW** (the endometrium) and surrounded by the serosal wall **SW**. The imaging component **100** can be introduced transvaginally and transcervically (or alternately laparoscopically) to the uterus, and the imaging transducer **107** deployed to image the fibroid within a field of view indicated by the broken lines.

[0141] **FIG. 7B** shows an image that would be visible on a display, showing safety and treatment boundaries, in accordance with some embodiments. In some embodiments, once the fibroid is located on the display **614**, the controls on the handle may be used to locate and size both a treatment boundary **TB** and a safety boundary **SB**. In some embodiments, initially, the virtual boundary lines **TB** and **SB** may neither be positioned over the fibroid nor properly sized

to treat the fibroid. Prior to beginning therapy, the physician may want to both position and size the boundaries **TB** and **SB** for proper treatment. As the imaging transducer **107** may be already positioned against the uterine wall **UW** the only way to advance the treatment and safety boundaries may be to move the boundaries forward by actuating the control element **319**. In some embodiments, this may cause the treatment and safety boundaries **TB** and **SB** to move forwardly along the axis line **AL** and thereby translate the area to be treated. This may cause the virtual boundaries on the real-time image display **614** to move over the image of the fibroid. Additionally or alternatively, the size of the treatment boundary **TB** may be enlarged or shrunk in order to mitigate the risk of affecting healthy and/or more sensitive tissue around the area of treatment.

[0142] In embodiments where the instrument is a tissue ablation element, while holding imaging component **100** steady, the physician may then advance a needle slide, causing the needle **235** to extend into the fibroid **F**, as shown in **Fig. 7C**. The illustration in **Fig. 7C** includes a representation of the imaging component **100**, which corresponds to the physical probe which is present in the patient. The remainder of **Fig. 7C** corresponds to the image present on the target display **614**.

[0143] After needle **235** has been fully deployed as limited by an optional physical or virtual needle stop housing in the instrument handle **301**, the tines **233** may be deployed by advancing a tine slide a target level of tine deployment is reached as indicated by engagement of the tine slide with an optional tine stop or visually on the display. Optionally, the imaging component **100** may be rotated about a central axis (typically aligned with the axis of the needle **235**) to confirm the treatment and safety boundaries in all planes of view about the fibroid. Display **614** will show the position of the treatment and safety boundaries in real time relative to the target fibroid and serosa. The tines are then configured as shown in **Fig. 7D**, and power can be supplied to the tines (and optionally the needle) in order to achieve treatment within the boundary depicted by the virtual treatment boundary **TB**. Again, **Fig. 7D** mixes both the virtual image which would be present on the display **614** as well as the physical presence of the imaging component **100.**

[0144] Embodiments of the present disclosure may provide a method of performing therapy or diagnosis at a target site. **FIG. 8** shows an exemplary method **800** of performing therapy or diagnosis at a target site, in accordance with some embodiments. At a step **810**, the imaging component may be inserted into the subject. At a step **820**, the instrument may be inserted into the cavity towards the target site. Alternatively, the imaging component may be inserted into the cavity with the additional therapeutic and/or diagnostic instrument previously inserted into the

cavity of the imaging component. At a step **830**, therapy or diagnosis may be performed using the instrument at the target site. At a step **840**, the instrument may be removed from the cavity.

[0145] In some embodiments, the method **800** may additionally comprise at least steps **850, 860, 870**. At a step **850**, the method may comprise inserting a second instrument into the cavity towards the target site. During a step **850**, the imaging component may remain *in situ*. At a step **860**, therapy or diagnosis may be performed using the second instrument at the target site. At a step **870**, the second instrument may be removed from the cavity, wherein the second instrument may be different from the first instrument. In some embodiments, steps **850**, **860** and **870** may be repeated using a third, forth, or more instruments.

[0146] Method **800** may represent a general method of use of an imaging component from which one of ordinary skill will recognize many variations and adaptations.

[0147] In some embodiments, the present disclosure may additionally provide a method of performing image guided ablation therapy. **FIG. 9** shows an exemplary method **900** of performing image guided ablation therapy, in accordance with some embodiments. At a step **905**, the imaging component may be inserted into a subject; with the imaging component *in situ*. At a step **910**, a biopsy needle may be inserted into the cavity. At a step **915**, pathology samples may be collected using the biopsy needle. At a step **920**, the biopsy needle may be removed from the cavity. Test results obtained from the biopsy sample may be used to inform later steps of a method of preforming a method of image guided ablation therapy. For example, one or more biopsies and/or further imaging may inform the surgeon whether and/or where tissue needs to be excised and/or ablated, where a therapeutic and/or diagnostic agent should be delivered, and/or where addition imaging should be performed. At a step **925**, radiofrequency (RF) ablation elements may be inserted into the cavity. At a step **930**, lesions may be ablated using the RF ablation elements. At a step **935**, the RF ablation elements may be removed from the cavity. At a step **940**, an optical scope may be inserted into the cavity. At a step **945**, completion of the image guided ablation therapy may be confirmed using the optical scope. At a step **950**, the optical scope may be removed from the cavity. Alternatively or additionally to confirming ablation with the optical scope, the RF ablation element may be swapped out for a drug delivery device to deliver analgesic(s), hemostatic agent(s), and/or other therapeutic agents after tissue ablation or other therapeutic and/or diagnostic step.

[0148] Other exemplary methods may comprise a method of coupling instruments, comprising: advancing an imaging component to within a surgical space, wherein the imaging component comprises a shaft comprising a proximal end and a distal end; coupling a first instrument to the imaging component for use in the surgical space, wherein the first instrument may be a

therapeutic or diagnostic instrument; uncoupling the first instrument from the imaging component while the imaging component remains within the surgical space; and coupling a second instrument to the imaging component for use in the surgical space while the imaging component remains within the surgical space, wherein the second instrument may be a therapeutic or diagnostic instrument different from the first instrument.

[0149] In some embodiments, a method of coupling instruments additionally comprises coupling the first instrument while the imaging component remains within the surgical space. In some embodiments, a method of coupling instruments additionally comprises coupling the first instrument while the imaging component is outside of the surgical space. In some embodiments, a method of coupling instruments additionally comprises collecting a tissue sample from the surgical space with the first instrument. In some embodiments, a method of coupling instruments additionally comprises ablating a region within the surgical space with the second instrument. In some embodiments, a method of coupling instruments additionally comprises performing therapy or diagnosis with the first instrument. In some embodiments, a method of coupling instruments additionally comprises selecting the second instrument based on data gathered from said performing therapy or diagnosis with the first instrument. In some embodiments, a method of coupling instruments additionally comprises adjusting a parameter of therapy or diagnosis performed with the second instrument based on data gathered from said performing therapy or diagnosis with the first instrument. In such embodiments, data gathered may comprise image data, and adjusting the parameter may comprise adjusting an ablation zone for the second instrument.

[0150] In another exemplary method, embodiments of the present disclosure may provide a method of performing therapy or diagnosis at a target site. A method of performing therapy may comprise: advancing an imaging component to the target site. A method of performing therapy may comprise an imaging component comprising: a shaft comprising a proximal end, a distal end, and a cavity extending across the shaft from the proximal end towards the distal end, wherein a wall of the cavity comprises an elongated opening in communication with an exterior of the shaft at least partially along the shaft. A method of performing therapy may comprise an imaging transducer coupled to the distal end of the shaft. A method of performing therapy may comprise performing therapy or diagnosis using an instrument inserted into the cavity and advanced to the target site.

[0151] In some embodiments, a method of performing therapy may additionally comprise inserting the first instrument into the cavity before advancing the imaging component to the target site. In some embodiments, a method of performing therapy may additionally comprise

inserting the first instrument into the cavity after advancing the imaging component to the target site. In some embodiments, a method of performing therapy may additionally comprise removing the first instrument from the cavity while the imaging component remains at the target site. In some embodiments, a method of performing therapy may additionally comprise inserting a second instrument into the cavity and advancing the second instrument to the target site. In some embodiments, a method of performing therapy may additionally comprise performing therapy or diagnosis using the second instrument.

[0152] Methods described herein may function to perform therapy or diagnosis on a volume of tissue (e.g., a patient uterus, another organ). In some embodiments, the methods described herein may be performed in laparoscopic surgery. In such an embodiment, the methods described herein may additionally comprise insertion of a trocar into a patient bodily lumen. During laparoscopic surgery, the imaging component may be inserted into the cannula of the trocar in order to perform a surgical procedure. In some embodiments, the method may be performed non-invasively. In such embodiments, the imaging component may be inserted into a pre-existing or naturally formed patient bodily lumen. Additionally or alternatively, the method may be performed in minimally invasive surgery. In such embodiments, a lumen may be formed in a patient, which may be of a minimal size to speed healing time and minimize operative trauma.

[0153] Methods described herein may be implemented, at least in part, by way of an embodiment, variation, and/or example of the instruments and, additionally or alternatively, the imaging component **100** described herein. Additionally or alternatively, methods described herein may be implemented using any other suitable imaging component and/or instrument, and as facilitated by any of the computational and/or processing components described further below. Methods described herein may be implemented by system **500** and/or **1200**. The imaging component may be used in conjunction with an instrument such as a biopsy needle; an optical scope; implantation device; therapy electrodes; a tissue ablation element, such as for example a radiofrequency ablation element, an ultrasonic ablation element, a heat-based ablation element, a cryoablation element, etc.; and/or other instrument suitable to be disposed within the cavity of the imaging component. Additionally or alternatively, the instrument may be used to deliver drugs or other therapeutic agents or implants to the tissue to be treated. **FIGS. 2A-2E** show exemplary instruments which may be slidably received by the imaging component.

[0154] A person of ordinary skill in the art will recognize many adaptations and variations on the methods described herein. Further, one or more steps described with respect to methods herein may be deleted or repeated, additional steps may be added, and the steps may be

performed in any order. Steps described with respect to one method may be added or combined with another. For example, steps of method **900** may be added to method **800**.

[0155] In some embodiments, imaging components, systems, and methods described herein include a digital processing device, or use of the same. In further embodiments, the digital processing device includes one or more hardware central processing units (CPUs), general purpose graphics processing units (GPGPUs), or field programmable gate arrays (FPGAs) that carry out the device's functions. In still further embodiments, the digital processing device further comprises an operating system configured to perform executable instructions. In some embodiments, the digital processing device may be optionally connected a computer network. In further embodiments, the digital processing device is optionally connected to the internet such that it accesses the World Wide Web. In still further embodiments, the digital processing device is optionally connected to a cloud computing infrastructure. In other embodiments, the digital processing device is optionally connected to an intranet. In other embodiments, the digital processing device is optionally connected to a data storage device.

[0156] In accordance with the description herein, suitable digital processing devices include, by way of non-limiting examples, server computers, desktop computers, laptop computers, notebook computers, sub-notebook computers, netbook computers, netpad computers, set-top computers, media streaming devices, handheld computers, internet appliances, mobile smartphones, tablet computers, personal digital assistants, video game consoles, and vehicles. Those of skill in the art will recognize that many smartphones are suitable for use in the system described herein. Those of skill in the art will also recognize that select televisions, video players, and digital music players with optional computer network connectivity are suitable for use in the system described herein. Suitable tablet computers include those with booklet, slate, and convertible configurations, known to those of skill in the art.

[0157] In some embodiments, the digital processing device includes an operating system configured to perform executable instructions. The operating system is, for example, software, including programs and data, which manages the device's hardware and provides services for execution of applications. Those of skill in the art will recognize that suitable server operating systems include, by way of non-limiting examples, FreeBSD, OpenBSD, NetBSD®, Linux, Apple® Mac OS X Server®, Oracle® Solaris®, Windows Server®, and Novell® NetWare®. Those of skill in the art will recognize that suitable personal computer operating systems include, by way of non-limiting examples, Microsoft® Windows®, Apple® Mac OS X®, UNIX®, and UNIX-like operating systems such as GNU/Linux®. In some embodiments, the operating system is provided by cloud computing. Those of skill in the art will also recognize that suitable mobile

smart phone operating systems include, by way of non-limiting examples, Nokia® Symbian® OS, Apple® iOS®, Research In Motion® BlackBerry OS®, Google® Android®, Microsoft® Windows Phone® OS, Microsoft® Windows Mobile® OS, Linux®, and Palm® WebOS®. Those of skill in the art will also recognize that suitable media streaming device operating systems include, by way of non-limiting examples, Apple TV®, Roku®, Boxee®, Google TV®, Google Chromecast®, Amazon Fire®, and Samsung® HomeSync®. Those of skill in the art will also recognize that suitable video game console operating systems include, by way of non-limiting examples, Sony® PS3®, Sony® PS4®, Microsoft® Xbox 360®, Microsoft Xbox One, Nintendo® Wii®, Nintendo® Wii U®, and Ouya®.

[0158] In some embodiments, the device includes a storage and/or memory device. The storage and/or memory device is one or more physical apparatuses used to store data or programs on a temporary or permanent basis. In some embodiments, the device is volatile memory and requires power to maintain stored information. In some embodiments, the device is non-volatile memory and retains stored information when the digital processing device is not powered. In further embodiments, the non-volatile memory comprises flash memory. In some embodiments, the non-volatile memory comprises dynamic random-access memory (DRAM). In some embodiments, the non-volatile memory comprises ferroelectric random access memory (FRAM). In some embodiments, the non-volatile memory comprises phase-change random access memory (PRAM). In other embodiments, the device is a storage device including, by way of non-limiting examples, CD-ROMs, DVDs, flash memory devices, magnetic disk drives, magnetic tapes drives, optical disk drives, and cloud computing based storage. In further embodiments, the storage and/or memory device is a combination of devices such as those disclosed herein.

[0159] In some embodiments, the digital processing device includes a display to send visual information to a user. In some embodiments, the display is a cathode ray tube (CRT). In some embodiments, the display is a liquid crystal display (LCD). In further embodiments, the display is a thin film transistor liquid crystal display (TFT-LCD). In some embodiments, the display is an organic light emitting diode (OLED) display. In various further embodiments, on OLED display is a passive-matrix OLED (PMOLED) or active-matrix OLED (AMOLED) display. In some embodiments, the display is a plasma display. In other embodiments, the display is a video projector. In still further embodiments, the display is a combination of devices such as those disclosed herein.

[0160] In some embodiments, the digital processing device includes an input device to receive information from a user. In some embodiments, the input device is a keyboard. In some embodiments, the input device is a pointing device including, by way of non-limiting examples,

a mouse, trackball, track pad, joystick, game controller, or stylus. In some embodiments, the input device is a touch screen or a multi-touch screen. In other embodiments, the input device is a microphone to capture voice or other sound input. In other embodiments, the input device is a video camera or other sensor to capture motion or visual input. In further embodiments, the input device is a Kinect, Leap Motion, or the like. In still further embodiments, the input device is a combination of devices such as those disclosed herein.

[0161] Referring to **FIG. 10**, in a particular embodiment, an exemplary digital processing device **612** is programmed or otherwise configured control to an imaging component and/or instruments as described herein. The device **612** may regulate various aspects of the imaging component and/or instruments of the present disclosure, such as, for example, performing processing steps. In this embodiment, the digital processing device **612** includes a central processing unit (CPU, also "processor" and "computer processor" herein) **1005**, which may be a single core or multi core processor, or a plurality of processors for parallel processing. The digital processing device **612** also includes memory or memory location **1010** (e.g., random-access memory, read-only memory, flash memory), electronic storage unit **1015** (e.g., hard disk), communication interface **1020** (e.g., network adapter) for communicating with one or more other systems, and peripheral devices **1025**, such as cache, other memory, data storage and/or electronic display adapters. The memory **1010**, storage unit **1015**, interface **1020** and peripheral devices **1025** are in communication with the CPU **1005** through a communication bus (solid lines), such as a motherboard. The storage unit **1015** may be a data storage unit (or data repository) for storing data. The digital processing device **612** can be operatively coupled to a computer network ("network") **1030** with the aid of the communication interface **1020**. The network **1030** can be the Internet, an internet and/or extranet, or an intranet and/or extranet that is in communication with the Internet. The network **1030** in some cases is a telecommunication and/or data network. The network **1030** can include one or more computer servers, which can enable distributed computing, such as cloud computing. The network **1030**, in some cases with the aid of the device **612**, can implement a peer-to-peer network, which may enable devices coupled to the device **612** to behave as a client or a server.

[0162] Continuing to refer to **FIG. 10**, the CPU **1005** can execute a sequence of machine-readable instructions, which can be embodied in a program or software. The instructions may be stored in a memory location, such as the memory **1010**. The instructions can be directed to the CPU **1005**, which can subsequently program or otherwise configure the CPU **1005** to implement methods of the present disclosure. Examples of operations performed by the CPU **1005** can include fetch, decode, execute, and write back. The CPU **1005** can be part of a circuit, such as

an integrated circuit. One or more other components of the device **612** can be included in the circuit. In some cases, the circuit is an application specific integrated circuit (ASIC) or a field programmable gate array (FPGA).

[0163] Continuing to refer to **FIG. 10**, the storage unit **1015** can store files, such as drivers, libraries and saved programs. The storage unit **1015** can store user data, e.g., user preferences and user programs. The digital processing device **612** in some cases can include one or more additional data storage units that are external, such as located on a remote server that is in communication through an intranet or the Internet. The digital processing device **612** can communicate with one or more remote computer systems through the network **1030**. For instance, the device **612** can communicate with a remote computer system of a user.

[0164] Examples of remote computer systems include personal computers (e.g., portable PC), slate or tablet PCs (e.g., Apple® iPad, Samsung® Galaxy Tab), telephones, Smart phones (e.g., Apple® iPhone, Android-enabled device, Blackberry®), or personal digital assistants.

[0165] Methods as described herein can be implemented by way of machine (e.g., computer processor) executable code stored on an electronic storage location of the digital processing device **612**, such as, for example, on the memory **1010** or electronic storage unit **1015**. The machine executable or machine readable code can be provided in the form of software. During use, the code can be executed by the processor **1005**. In some cases, the code can be retrieved from the storage unit 1**015** and stored on the memory **1010** for ready access by the processor **1005**. In some situations, the electronic storage unit **1015** can be precluded, and machine-executable instructions are stored on memory **1010**.

[0166] The digital processing device **612** can include or be in communication with an electronic display **614** that comprises a user interface (UI) **1040**. Examples of UI's include, without limitation, a graphical user interface (GUI) and web-based user interface. In some cases, electronic display **614** may be connected to the computer system **612** via a network, e.g., via network **1030**.

[0167] In some embodiments, the platforms, systems, media, and methods disclosed herein include one or more non-transitory computer readable storage media encoded with a program including instructions executable by the operating system of an optionally networked digital processing device. In further embodiments, a computer readable storage medium is a tangible component of a digital processing device. In still further embodiments, a computer readable storage medium is optionally removable from a digital processing device. In some embodiments, a computer readable storage medium includes, by way of non-limiting examples, CD-ROMs, DVDs, flash memory devices, solid state memory, magnetic disk drives, magnetic

tape drives, optical disk drives, cloud computing systems and services, and the like. In some cases, the program and instructions are permanently, substantially permanently, semi-permanently, or non-transitorily encoded on the media.

[0168] In some embodiments, the platforms, systems, media, and methods disclosed herein include at least one computer program, or use of the same. A computer program includes a sequence of instructions, executable in the digital processing device's CPU, written to perform a specified task. Computer readable instructions may be implemented as program modules, such as functions, objects, Application Programming Interfaces (APIs), data structures, and the like, that perform particular tasks or implement particular abstract data types. In light of the disclosure provided herein, those of skill in the art will recognize that a computer program may be written in various versions of various languages.

[0169] The functionality of the computer readable instructions may be combined or distributed as desired in various environments. In some embodiments, a computer program comprises one sequence of instructions. In some embodiments, a computer program comprises a plurality of sequences of instructions. In some embodiments, a computer program is provided from one location. In other embodiments, a computer program is provided from a plurality of locations. In various embodiments, a computer program includes one or more software modules. In various embodiments, a computer program includes, in part or in whole, one or more web applications, one or more mobile applications, one or more standalone applications, one or more web browser plug-ins, extensions, add-ins, or add-ons, or combinations thereof.

[0170] In some embodiments, a computer program includes a web application. In light of the disclosure provided herein, those of skill in the art will recognize that a web application, in various embodiments, utilizes one or more software frameworks and one or more database systems. In some embodiments, a web application is created upon a software framework such as Microsoft® .NET or Ruby on Rails (RoR). In some embodiments, a web application utilizes one or more database systems including, by way of non-limiting examples, relational, non-relational, object oriented, associative, and XML database systems. In further embodiments, suitable relational database systems include, by way of non-limiting examples, Microsoft® SQL Server, mySQL™, and Oracle®. Those of skill in the art will also recognize that a web application, in various embodiments, is written in one or more versions of one or more languages. A web application may be written in one or more markup languages, presentation definition languages, client-side scripting languages, server-side coding languages, database query languages, or combinations thereof. In some embodiments, a web application is written to some extent in a markup language such as Hypertext Markup Language (HTML), Extensible Hypertext Markup

Language (XHTML), or eXtensible Markup Language (XML). In some embodiments, a web application is written to some extent in a presentation definition language such as Cascading Style Sheets (CSS). In some embodiments, a web application is written to some extent in a client-side scripting language such as Asynchronous Javascript and XML (AJAX), Flash® Actionscript, Javascript, or Silverlight®. In some embodiments, a web application is written to some extent in a server-side coding language such as Active Server Pages (ASP), ColdFusion®, Perl, Java™, JavaServer Pages (JSP), Hypertext Preprocessor (PHP), Python™, Ruby, Tcl, Smalltalk, WebDNA®, or Groovy. In some embodiments, a web application is written to some extent in a database query language such as Structured Query Language (SQL). In some embodiments, a web application integrates enterprise server products such as IBM® Lotus Domino®. In some embodiments, a web application includes a media player element. In various further embodiments, a media player element utilizes one or more of many suitable multimedia technologies including, by way of non-limiting examples, Adobe® Flash®, HTML 5, Apple® QuickTime®, Microsoft® Silverlight®, Java™, and Unity®.

[0171] In some embodiments, a computer program includes a mobile application provided to a mobile digital processing device. In some embodiments, the mobile application is provided to a mobile digital processing device at the time it is manufactured. In other embodiments, the mobile application is provided to a mobile digital processing device via the computer network described herein.

[0172] In view of the disclosure provided herein, a mobile application is created by techniques known to those of skill in the art using hardware, languages, and development environments known to the art. Those of skill in the art will recognize that mobile applications are written in several languages. Suitable programming languages include, by way of non-limiting examples, C, C++, C#, Objective-C, Java™, Javascript, Pascal, Object Pascal, Python™, Ruby, VB.NET, WML, and XHTML/HTML with or without CSS, or combinations thereof.

[0173] Suitable mobile application development environments are available from several sources. Commercially available development environments include, by way of non-limiting examples, AirplaySDK, alcheMo, Appcelerator®, Celsius, Bedrock, Flash Lite, .NET Compact Framework, Rhomobile, and WorkLight Mobile Platform. Other development environments are available without cost including, by way of non-limiting examples, Lazarus, MobiFlex, MoSync, and Phonegap. Also, mobile device manufacturers distribute software developer kits including, by way of non-limiting examples, iPhone and iPad (iOS) SDK, Android™ SDK, BlackBerry® SDK, BREW SDK, Palm® OS SDK, Symbian SDK, webOS SDK, and Windows® Mobile SDK.

[0174] Those of skill in the art will recognize that several commercial forums are available for distribution of mobile applications including, by way of non-limiting examples, Apple® App Store, Google® Play, Chrome WebStore, BlackBerry® App World, App Store for Palm devices, App Catalog for webOS, Windows® Marketplace for Mobile, Ovi Store for Nokia® devices, Samsung® Apps, and Nintendo® DSi Shop.

[0175] In some embodiments, a computer program includes a standalone application, which is a program that is run as an independent computer process, not an add-on to an existing process, e.g., not a plug-in. Those of skill in the art will recognize that standalone applications are often compiled. A compiler is a computer program(s) that transforms source code written in a programming language into binary object code such as assembly language or machine code. Suitable compiled programming languages include, by way of non-limiting examples, C, C++, Objective-C, COBOL, Delphi, Eiffel, Java™, Lisp, Python™, Visual Basic, and VB .NET, or combinations thereof. Compilation is often performed, at least in part, to create an executable program. In some embodiments, a computer program includes one or more executable complied applications.

[0176] In some embodiments, the computer program includes a web browser plug-in (e.g., extension, etc.). In computing, a plug-in is one or more software components that add specific functionality to a larger software application. Makers of software applications support plug-ins to enable third-party developers to create abilities which extend an application, to support easily adding new features, and to reduce the size of an application. When supported, plug-ins enable customizing the functionality of a software application. For example, plug-ins are commonly used in web browsers to play video, generate interactivity, scan for viruses, and display particular file types. Those of skill in the art will be familiar with several web browser plug-ins including, Adobe® Flash® Player, Microsoft® Silverlight®, and Apple® QuickTime®. In some embodiments, the toolbar comprises one or more web browser extensions, add-ins, or add-ons. In some embodiments, the toolbar comprises one or more explorer bars, tool bands, or desk bands.

[0177] In view of the disclosure provided herein, those of skill in the art will recognize that several plug-in frameworks are available that enable development of plug-ins in various programming languages, including, by way of non-limiting examples, C++, Delphi, Java™, PHP, Python™, and VB .NET, or combinations thereof.

[0178] Web browsers (also called Internet browsers) are software applications, designed for use with network-connected digital processing devices, for retrieving, presenting, and traversing information resources on the World Wide Web. Suitable web browsers include, by way of non-

limiting examples, Microsoft® Internet Explorer®, Mozilla® Firefox®, Google® Chrome, Apple® Safari®, Opera Software® Opera®, and KDE Konqueror. In some embodiments, the web browser is a mobile web browser. Mobile web browsers (also called mircrobrowsers, mini-browsers, and wireless browsers) are designed for use on mobile digital processing devices including, by way of non-limiting examples, handheld computers, tablet computers, netbook computers, subnotebook computers, smartphones, music players, personal digital assistants (PDAs), and handheld video game systems. Suitable mobile web browsers include, by way of non-limiting examples, Google® Android® browser, RIM BlackBerry® Browser, Apple® Safari®, Palm® Blazer, Palm® WebOS® Browser, Mozilla® Firefox® for mobile, Microsoft® Internet Explorer® Mobile, Amazon® Kindle® Basic Web, Nokia® Browser, Opera Software® Opera® Mobile, and Sony® PSP™ browser.

Software modules

[0179] In some embodiments, the platforms, systems, media, and methods disclosed herein include software, server, and/or database modules, or use of the same. In view of the disclosure provided herein, software modules are created by techniques known to those of skill in the art using machines, software, and languages known to the art. The software modules disclosed herein are implemented in a multitude of ways. In various embodiments, a software module comprises a file, a section of code, a programming object, a programming structure, or combinations thereof. In further various embodiments, a software module comprises a plurality of files, a plurality of sections of code, a plurality of programming objects, a plurality of programming structures, or combinations thereof. In various embodiments, the one or more software modules comprise, by way of non-limiting examples, a web application, a mobile application, and a standalone application. In some embodiments, software modules are in one computer program or application. In other embodiments, software modules are in more than one computer program or application. In some embodiments, software modules are hosted on one machine. In other embodiments, software modules are hosted on more than one machine. In further embodiments, software modules are hosted on cloud computing platforms. In some embodiments, software modules are hosted on one or more machines in one location. In other embodiments, software modules are hosted on one or more machines in more than one location.

[0180] In some embodiments, the platforms, systems, media, and methods disclosed herein include one or more databases, or use of the same. In view of the disclosure provided herein, those of skill in the art will recognize that many databases are suitable for storage and retrieval of information. In various embodiments, suitable databases include, by way of non-limiting examples, relational databases, non-relational databases, object oriented databases, object

databases, entity-relationship model databases, associative databases, and XML databases. Further non-limiting examples include SQL, PostgreSQL, MySQL, Oracle, DB2, and Sybase. In some embodiments, a database is internet-based. In further embodiments, a database is web-based. In still further embodiments, a database is cloud computing-based. In other embodiments, a database is based on one or more local computer storage devices.

[0181] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

WHAT IS CLAIMED IS:

1. An imaging component comprising:

a shaft comprising a proximal end, a distal end, and a cavity extending across the shaft from the proximal end towards the distal end,

wherein the cavity is configured to removably receive at least one of a plurality of different instruments, and

wherein a wall of the cavity comprises an elongated opening in communication with an exterior of the shaft at least partially along the shaft; and

an imaging transducer coupled to the distal end of the shaft.

2. The component of claim 1, wherein the cavity is defined by an exterior surface of the shaft.

3. The component of claim 2, wherein the exterior surface of the shaft comprises only atraumatic edges.

4. The component of claim 2, wherein an edge of the elongated opening is bent towards an interior of the cavity.

5. The component of claim 1, wherein the cavity is configured to slidably receive the instrument.

6. The component of claim 1, wherein a distal portion of the cavity is angled axially relative to the shaft.

7. The component of claim 6, wherein the distal portion of the cavity is angled at about 3 to 45 degrees axially relative to the shaft.

8. The component of claim 1, wherein the at least one of the plurality of instruments comprises a tube.

9. The component of claim 8, wherein the tube is aligned to be in parallel with the shaft of the imaging component.

10. The component of claim 9, wherein the tube is rotatable relative to the shaft while the shaft remains stationary.

11. The component of claim 8, wherein the tube comprises a lumen configured to slidably receive a second instrument of the plurality of instruments.

12. The component of claim 11, wherein the tube is configured to slidably receive the second instrument after the second instrument is aligned to be in parallel with the shaft of the imaging component.

13. The component of claim 12, wherein the second instrument is rotatable relative to the shaft while the shaft remains stationary.

14. The component of claim 1, wherein the tube is disposable.

15. The component of claim 1, wherein the second instrument comprises a tissue collector.

16. The component of claim 15, wherein the tissue collector comprises a biopsy needle.

17. The component of claim 1, wherein the second instrument comprises a tissue ablation element.

18. The component of claim 17, wherein tissue ablation element comprises one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

19. The component of claim 1, wherein the at least one of the plurality of different instruments comprises a therapeutic or diagnostic instrument.

20. The component of claim 19, wherein the therapeutic or diagnostic instrument comprises a tissue collector.

21. The component of claim 20, wherein the therapeutic or diagnostic instrument comprises a biopsy needle.

22. The component of claim 19, wherein the therapeutic or diagnostic instrument comprises a tissue ablation element.

23. The component of claim 22, wherein the tissue ablation element comprises one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

24. The component of claim 19, wherein the therapeutic or diagnostic instrument comprises an optical scope.

25. The component of claim 19, wherein the therapeutic or diagnostic instrument comprises therapy electrodes.

26. The component of claim 19, wherein the therapeutic diagnostic instrument comprises an implantation device.

27. The component of claim 19, wherein the therapeutic or diagnostic instrument comprises instrumentation for providing detailed mapping of anatomy.

28. The component of claim 27, wherein the anatomy to be mapped is a uterus.

29. The component of claim 1, wherein the shaft is flexible.

30. The component of claim 29, wherein the shaft is controllably flexed along a longitudinal axis thereof via a flex mechanism.

31. The component of claim 1, wherein the imaging transducer comprises an ultrasound transducer.

32. The component of claim 1, wherein the imaging transducer comprises a light emitting diode (LED) or a camera.

33. The component of claim 1, wherein the cavity defines a circular cross sectional area.

34. The component of claim 1, wherein the cavity comprises a substantially uniform cross sectional area along the shaft.

35. The component of claim 1, wherein the cavity comprises an asymmetrical cross sectional area.

36. The component of claim 1, wherein the cavity extends across the shaft from the proximal end to the distal end.

37. An imaging system comprising: the imaging component of any one of claims 1-36; and

a disposable tube slidably received within the cavity of the imaging component.

38. The imaging system of claim 37, further comprising a second instrument removably received within a lumen of the disposable tube.

39. The imaging system of claim 38, wherein the second instrument is a diagnostic or therapeutic instrument.

40. The imaging system of claim 38, wherein the second instrument is a tissue collector.

41. The imaging system of claim 38, wherein the second instrument is a biopsy needle.

42. The imaging system of claim 38, wherein the second instrument is an optical scope.

43. The imaging system of claim 38, wherein the second instrument is an implantation device.

44. The imaging system of claim 38, wherein the second instrument comprises instrumentation for providing detailed mapping of anatomy.

45. The imaging system of claim 44, wherein the anatomy mapped is a uterus.

46. The imaging system of claim 38, wherein second instrument comprises a tissue ablation element.

47. The imaging system of claim 46, wherein the tissue ablation element comprises one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

48. A method of performing therapy or diagnosis at a target site, comprising:

inserting the imaging component of any one of claims 1-36 into the subject;

with the imaging component in situ,

inserting the at least one of the plurality of instruments into the cavity towards the target site;

performing therapy or diagnosis using the at least one of the plurality of instruments at the target site; and

removing the at least one of the plurality of instruments from the cavity.

49. The method of claim 48, wherein the at least one of the plurality of instruments comprises a tissue collector.

50. The method of claim 49, wherein the tissue collector comprises a biopsy needle.

51. The method of claim 48, wherein the at least one of the plurality of instruments comprises a tissue ablation element.

52. The method of claim 48, wherein tissue ablation element comprises one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

53. The method of claim 48, wherein the at least one of the plurality of different instruments comprises a therapeutic or diagnostic instrument.

54. The method of claim 48, wherein the therapeutic or diagnostic instrument comprises an optical scope.

55. The method of claim 48, wherein the therapeutic or diagnostic instrument comprises an implantation device.

56. The method of claim 48, wherein the therapeutic or diagnostic instrument comprises instrumentation for providing detailed mapping of anatomy.

57. The method of claim 56, wherein the anatomy mapped is a uterus.

58. The method of claim 48, wherein the therapeutic or diagnostic instrument comprises therapy electrodes.

59. The method of claim 48, further comprising:

inserting a second instrument into the cavity towards the target site;

performing therapy or diagnosis using the second instrument at the target site; and

removing the second instrument from the cavity,

wherein the second instrument is different from the at least one of the plurality of instruments.

60. The method of claim 48, wherein the method is performed in laparoscopic surgery.

61. The method of claim 48, wherein the method is performed non-invasively.

62. The method of claim 48, wherein the method is performed in minimally invasive surgery.

63. The method of claim 48, wherein the second instrument comprises a tissue collector.

64. The method of claim 63, wherein the tissue collector comprises a biopsy needle.

65. The method of claim 48, wherein the second instrument comprises a tissue ablation element.

66. The method of claim 65, wherein tissue ablation element comprises one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

67. The method of claim 48, wherein the second instrument comprises an optical scope.

68. The method of claim 48, wherein the second instrument comprises an implantation device.

69. The method of claim 48, wherein the second instrument comprises instrumentation for providing detailed mapping of anatomy.

70. The method of claim 69, wherein the anatomy to be mapped is a uterus.

71. The method of claim 48, wherein the second instrument comprises therapy electrodes.

72. A method of performing image guided ablation therapy comprising:

inserting the imaging component of any one of claims 1-36 into a subject;

with the imaging component in situ,

inserting a biopsy needle into the cavity;

collecting pathology samples using the biopsy needle;

removing the biopsy needle from the cavity;

inserting radiofrequency (RF) ablation elements into the cavity;

ablating tissue using the RF ablation elements;

removing the RF ablation elements from the cavity;

inserting an optical scope into the cavity;

confirming completion of the image guided ablation therapy using the optical scope; and

removing the optical scope from the cavity.

73. The method of claim 72, wherein the method is performed in laparoscopic surgery.

74. The method of claim 72, wherein the method is performed non-invasively.

75. The method of claim 72, wherein the method is performed in minimally invasive surgery.

76. A method of coupling instruments, comprising:

advancing an imaging component to within a surgical space, wherein the imaging component comprises a shaft comprising a proximal end and a distal end;

coupling a first instrument to the imaging component for use in the surgical space, wherein the first instrument is a therapeutic or diagnostic instrument;

uncoupling the first instrument from the imaging component while the imaging component remains within the surgical space; and

coupling a second instrument to the imaging component for use in the surgical space while the imaging component remains within the surgical space, wherein the second instrument is a therapeutic or diagnostic instrument different from the first instrument.

77. The method of claim 76, wherein the imaging component comprises an imaging transducer comprising an ultrasound transducer.

78. The method of claim 76, wherein the method is performed in laparoscopic surgery.

79. The method of claim 76, wherein the method is performed non-invasively.

80. The method of claim 76, wherein the method is performed in minimally invasive surgery.

81. The method of claim 76, wherein said coupling the first instrument occurs while the imaging component remains within the surgical space.

82. The method of claim 76, wherein said coupling the first instrument occurs while the imaging component is outside of the surgical space.

83. The method of claim 76, further comprising collecting a tissue sample from the surgical space with the first instrument.

84. The method of claim 76, further comprising ablating a region within the surgical space with the second instrument.

85. The method of claim 76, further comprising performing therapy or diagnosis with the first instrument.

86. The method of claim 85, further comprising selecting the second instrument based on data gathered from said performing therapy or diagnosis with the first instrument.

87. The method of claim 85, further comprising adjusting a parameter of therapy or diagnosis performed with the second instrument based on data gathered from said performing therapy or diagnosis with the first instrument.

88. The method of claim 87, wherein the data gathered comprises image data, and adjusting the parameter comprises adjusting an ablation zone for the second instrument.

89. The method of claim 76, wherein the imaging component further comprises a cavity extending across the shaft from the proximal end towards the distal end, wherein a wall of the cavity comprises an elongated opening in communication with an exterior of the shaft at least partially along the shaft.

90. The method of claim 89, wherein the cavity is defined by an exterior surface of the shaft.

91. The method of claim 90, wherein the exterior surface of the shaft comprises only atraumatic edges.

92. The method of claim 89, wherein an edge of the elongated opening is bent towards an interior of the cavity.

93. The method of claim 89, wherein the cavity is configured to slidably receive the first instrument or the second instrument.

94. The method of claim 89, wherein a distal portion of the cavity is angled axially relative to the shaft.

95. The method of claim 94, wherein the distal portion of the cavity is angled at about 3 to 45 degrees axially relative to the shaft.

96. The method of claim 89, further comprising advancing a tube to within the cavity.

97. The method of claim 96, wherein the tube is aligned to be in parallel with the shaft of the imaging component.

98. The method of claim 96, wherein the tube is rotatable relative to the shaft while the shaft remains stationary.

99. The method of claim 96, wherein the tube comprises a lumen configured to slidably receive the first instrument or the second instrument.

100. The method of claim 99, wherein the tube is configured to slidably receive the first instrument or the second instrument after the first or second instrument is aligned to be in parallel with the shaft of the imaging component.

101. The method of claim 99, wherein the first or second instrument is rotatable relative to the shaft while the shaft remains stationary.

102. The method of claim 96, wherein the tube is disposable.

103. The method of claim 76, wherein the first or second instrument comprises a tissue collector.

104. The method of claim 103, wherein the tissue collector comprises a biopsy needle.

105. The method of claim 76, wherein the first or second instrument comprises a tissue ablation element.

106. The method of claim 105, wherein tissue ablation element comprises one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

107. The method of claim 76, wherein the first or second instrument comprises an optical scope.

108. The method of claim 76, wherein the first or second instrument comprises an implantation device.

109. The method of claim 76, wherein the first or second instrument comprises instrumentation for providing detailed mapping of anatomy.

110. The method of claim 109, wherein the anatomy to be mapped is a uterus.

111. The method of claim 76, wherein the first or second instrument comprises therapy electrodes.

112. The method of claim 76, wherein the shaft is flexible.

113. The method of claim 112, wherein the shaft is controllably flexed along its longitudinal axis via a flex mechanism.

114. The method of claim 76, wherein the imaging component comprises an imaging transducer comprising a light emitting diode (LED) or a camera.

115. The method of claim 89, wherein the cavity defines a circular cross sectional area.

116. The method of claim 89, wherein the cavity comprises a substantially uniform cross sectional area along the shaft.

117. The method of claim 89, wherein the cavity comprises an asymmetrical cross sectional area.

118. The method of claim 89, wherein the cavity extends across the shaft from the proximal end to the distal end.

119. The method of claim 76, wherein 1) the imaging component, and 2) the first instrument or the second instrument are coupled axially.

120. The method of claim 76, wherein 1) the imaging component, and 2) the first instrument or the second instrument are coupled laterally.

121. The method of claim 76, wherein 1) the imaging component, and 2) the first instrument or second instrument are coupled with aid of magnets or indents.

122. A system for performing therapy and/or diagnosis at a target site within a patient, comprising:

a first therapeutic or diagnostic instrument;

a second therapeutic or diagnostic instrument different from the first therapeutic or diagnostic instrument; and

an imaging component configured to be removably coupled to both the first and second therapeutic or diagnostic instruments, either simultaneously or individually;

wherein the imaging component is configured to be deliverable to the target site within the patient both (i) separately from the first and second therapeutic or diagnostic instruments, and (ii) coupled with the first and/or second therapeutic or diagnostic instruments, and

wherein the imaging component is configured to be removably coupled to both the first and second therapeutic or diagnostic instruments, either simultaneously or individually, after the imaging component is delivered to the target site within the patient.

123. The system of claim 122, wherein the first and second therapeutic or diagnostic instruments comprise two of the following: a tissue collector, a tissue ablation element, an optical scope, or therapy electrodes.

124. The system of claim 123, wherein the tissue collector comprises a biopsy needle.

125. The system of claim 123, wherein the tissue ablation element comprises one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

126. The system of claim 122, wherein the imaging component comprises a shaft comprising a proximal end, a distal end, and a cavity extending across the shaft from the proximal end towards the distal end, wherein a wall of the cavity comprises an elongated opening in communication with an exterior of the shaft at least partially along the shaft.

127. The system of claim 126, wherein the cavity is defined by an exterior surface of the shaft.

128. The system of claim 127, wherein the exterior surface of the shaft comprises only atraumatic edges.

129. The system of claim 126, wherein an edge of the elongated opening is bent towards an interior of the cavity.

130. The system of claim 126, wherein the cavity is configured to slidably receive the instrument.

131. The system of claim 126, wherein a distal portion of the cavity is angled axially relative to the shaft.

132. The system of claim 131, wherein the distal portion of the cavity is angled at about 3 to 45 degrees axially relative to the shaft.

133. The system of claim 132, further comprising a tube.

134. The system of claim 133, wherein the tube is aligned to be in parallel with the shaft of the imaging component.

135. The system of claim 134, wherein the tube is rotatable relative to the shaft while the shaft remains stationary.

136. The system of claim 133, wherein the tube comprises a lumen configured to slidably receive the first or second instrument.

137. The system of claim 136, wherein the tube is configured to slidably receive the first or second instrument after the first or second instrument is aligned to be in parallel with the shaft of the imaging component.

138. The system of claim 137, wherein the first or second instrument is rotatable relative to the shaft while the shaft remains stationary.

139. The system of claim 133, wherein the tube is disposable.

140. The system of claim 126, wherein the shaft is flexible.

141. The system of claim 140, wherein the shaft is controllably flexed along its longitudinal axis via a flex mechanism.

142. The system of claim 122, wherein the imaging component comprises an imaging transducer comprising a light emitting diode (LED) or a camera.

143. The system of claim 126, wherein the cavity defines a circular cross sectional area.

144. The system of claim 126, wherein the cavity comprises a substantially uniform cross sectional area along the shaft.

145. The system of claim 126, wherein the cavity comprises an asymmetrical cross sectional area.

146. The system of claim 126, wherein the cavity extends across the shaft from the proximal end to the distal end.

147. The system of claim 126, wherein the imaging transducer comprises an ultrasound transducer.

148. A method of performing therapy or diagnosis at a target site, comprising:

advancing an imaging component to the target site, the imaging component comprising:

a shaft comprising a proximal end, a distal end, and a cavity extending across the shaft from the proximal end towards the distal end,

wherein a wall of the cavity comprises an elongated opening in communication with an exterior of the shaft at least partially along the shaft; and

an imaging transducer coupled to the distal end of the shaft; and

performing therapy or diagnosis using a first instrument inserted into the cavity and advanced to the target site.

149. The method of claim 148, comprising inserting the first instrument into the cavity before advancing the imaging component to the target site.

150. The method of claim 148, comprising inserting the first instrument into the cavity after advancing the imaging component to the target site.

151. The method of claim 148, further comprising removing the first instrument from the cavity while the imaging component remains at the target site.

152. The method of claim 151, further comprising inserting a second instrument into the cavity and advancing the second instrument to the target site.

153. The method of claim 152, further comprising performing therapy or diagnosis using the second instrument.

154. The method of claim 151, wherein the cavity is defined by an exterior surface of the shaft.

155. The method of claim 154, wherein the exterior surface of the shaft comprises only atraumatic edges.

156. The method of claim 154, wherein an edge of the elongated opening is bent towards an interior of the cavity.

157. The method of claim 148, wherein the cavity is configured to slidably receive the instrument.

158. The method of claim 148, wherein a distal portion of the cavity is angled axially relative to the shaft.

159. The method of claim 158, wherein the distal portion of the cavity is angled at about 3 to 45 degrees axially relative to the shaft.

160. The method of claim 148, wherein the imaging component further comprises a tube.

161. The method of claim 160, wherein the tube is aligned to be in parallel with the shaft of the imaging component.

162. The method of claim 161, wherein the tube is rotatable relative to the shaft while the shaft remains stationary.

163. The method of claim 160, wherein the tube comprises a lumen configured to slidably receive the first instrument.

164. The method of claim 163, wherein the tube is configured to slidably receive the first instrument after the second instrument is aligned to be in parallel with the shaft of the imaging component.

165. The method of claim 164, wherein the first instrument is rotatable relative to the shaft while the shaft remains stationary.

166. The method of claim 160, wherein the tube is disposable.

167. The method of claim 148, wherein the first instrument comprises a tissue collector.

168. The method of claim 167, wherein the tissue collector comprises a biopsy needle.

169. The method of claim 148, wherein the first instrument comprises a tissue ablation element.

170. The method of claim 169, wherein tissue ablation element comprises one or more of a radiofrequency (RF) ablation element, an ultrasonic ablation element, a heat-based ablation element, or a cryoablation element.

171. The method of claim 148, wherein the instrument comprises an optical scope.

172. The method of claim 148, wherein the instrument comprises therapy electrodes.

173. The method of claim 148, wherein the shaft is flexible.

174. The method of claim 173, wherein the shaft is controllably flexed along its longitudinal axis via a flex mechanism.

175. The method of claim 148, wherein the imaging transducer comprises a light emitting diode (LED) or a camera.

176. The method of claim 148, wherein the cavity defines a circular cross sectional area.

177. The method of claim 148, wherein the cavity comprises a substantially uniform cross sectional area along the shaft.

178. The method of claim 148, wherein the cavity comprises an asymmetrical cross sectional area.

179. The method of claim 148, wherein the cavity extends across the shaft from the proximal end to the distal end.

180. The method of claim 148, wherein the imaging transducer comprises an ultrasound transducer.

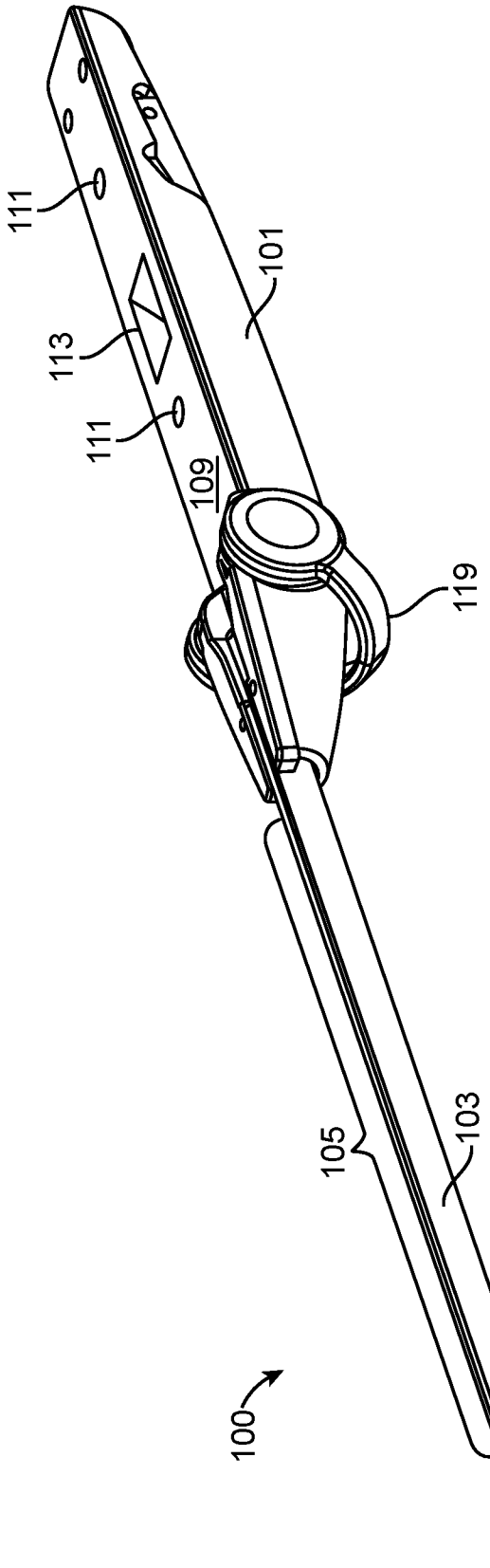


FIG. 1A

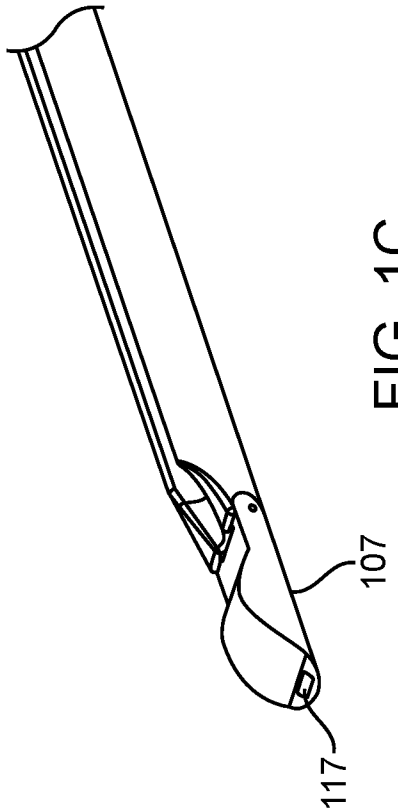


FIG. 1C

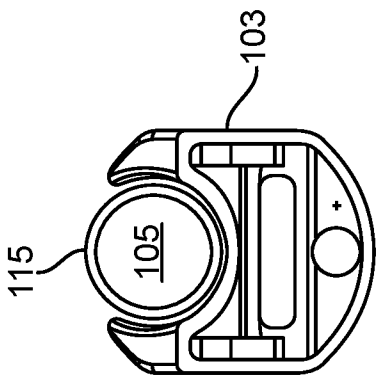


FIG. 1B

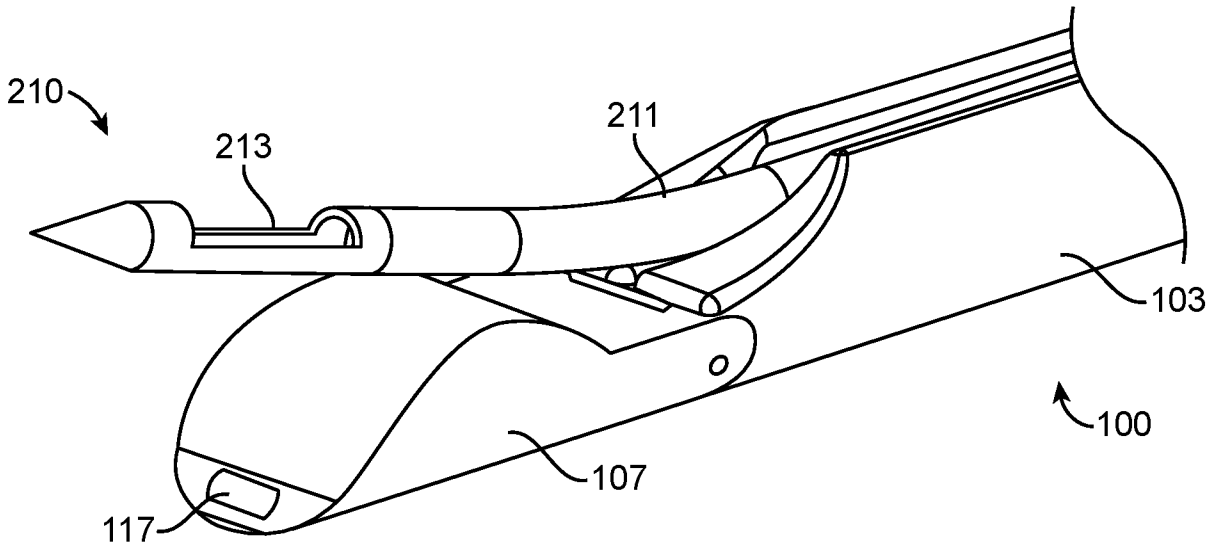


FIG. 2A

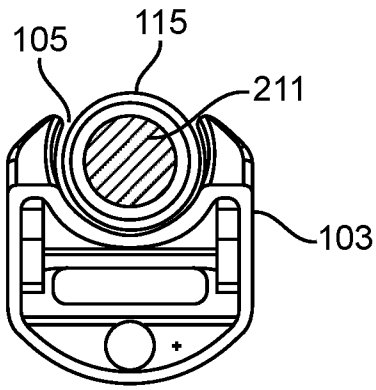


FIG. 2B

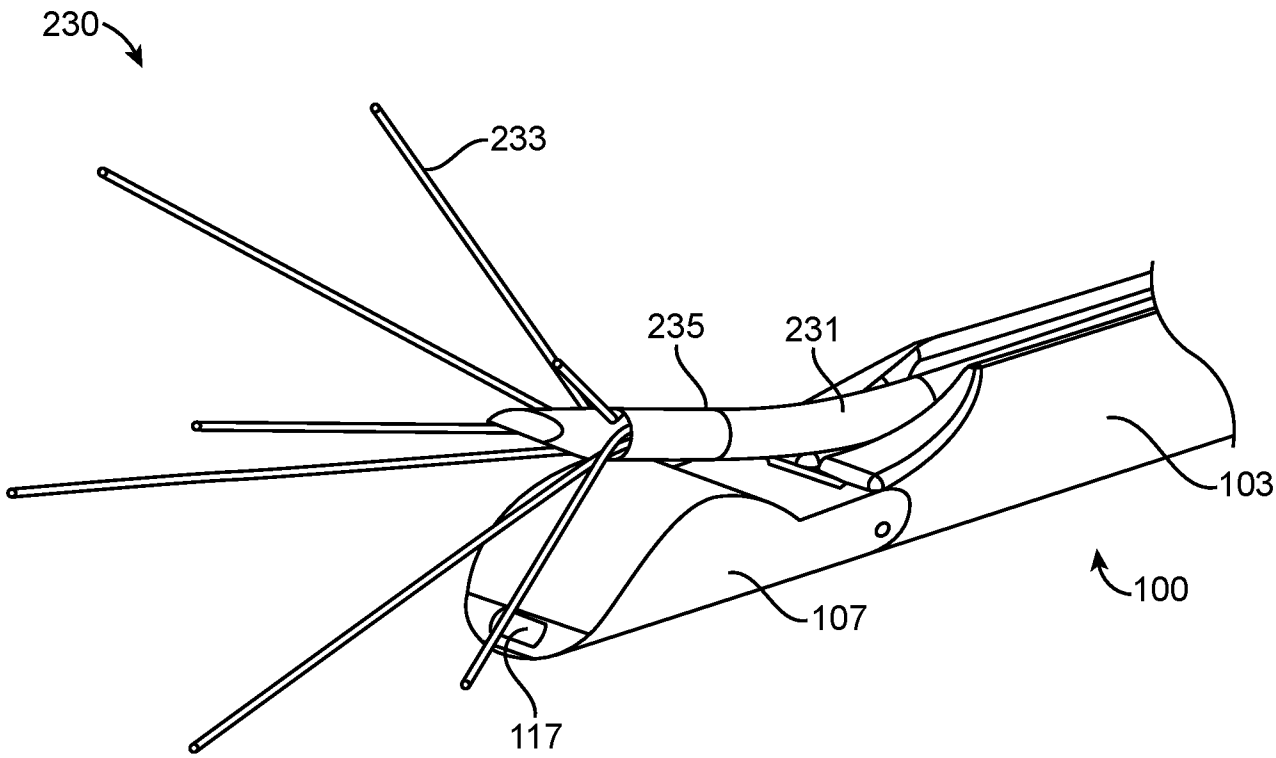


FIG. 2C

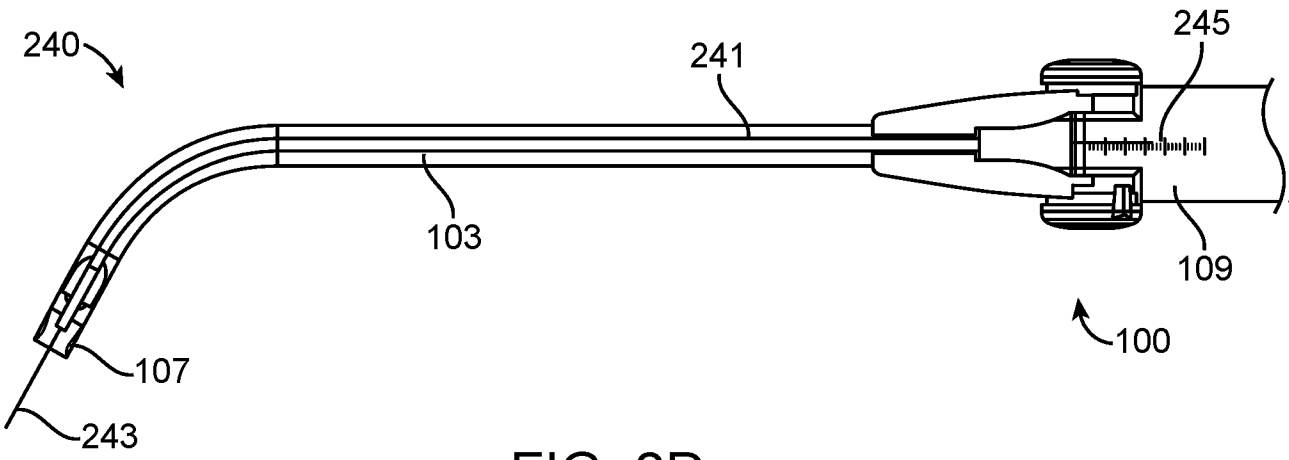


FIG. 2D

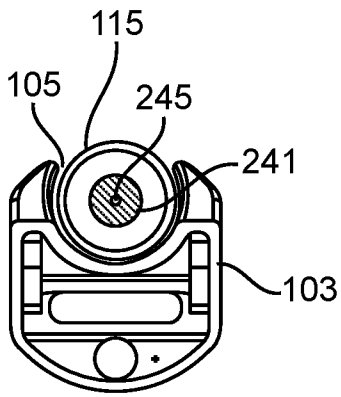
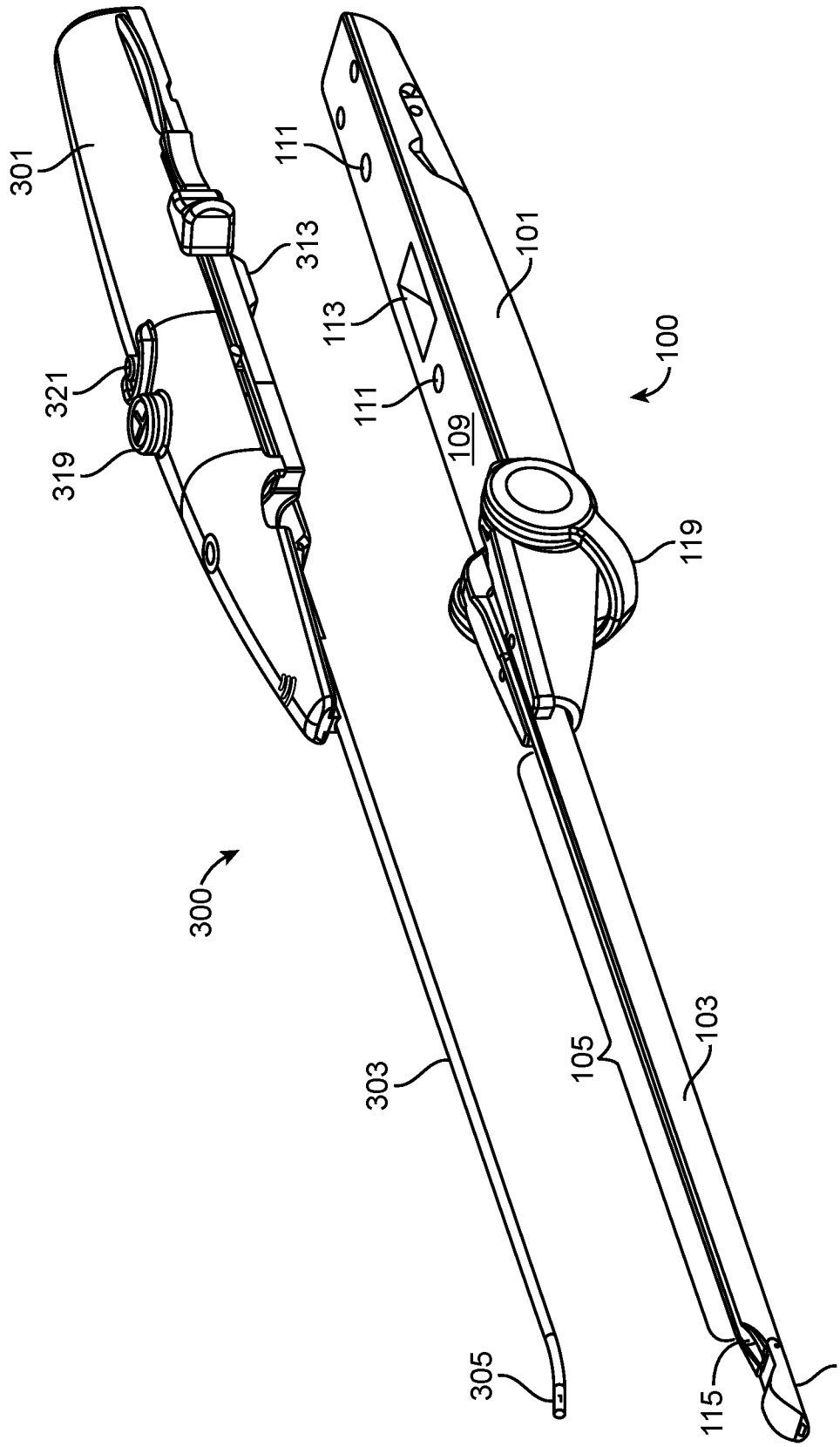


FIG. 2E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313
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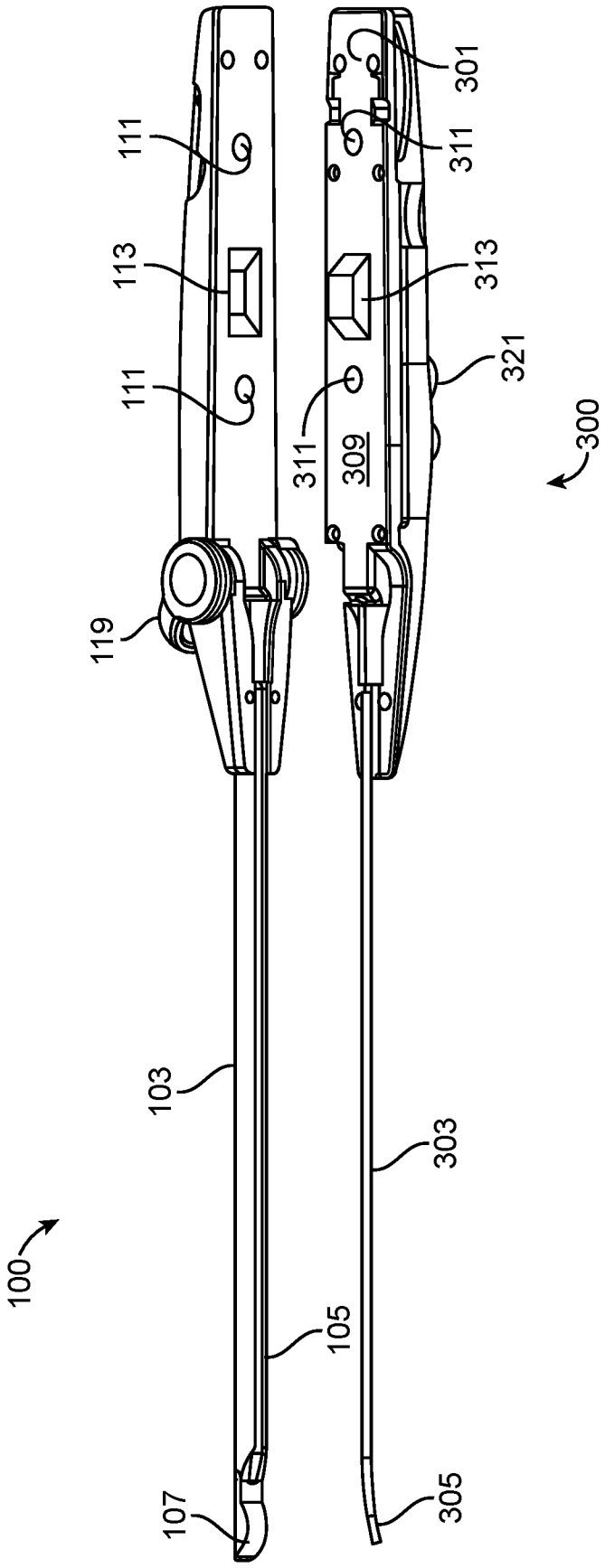
100
119
300
303
305
105
103
115
107

FIG. 3A


100
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105
107
111
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113
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303
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309
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311
313
321

FIG. 3B

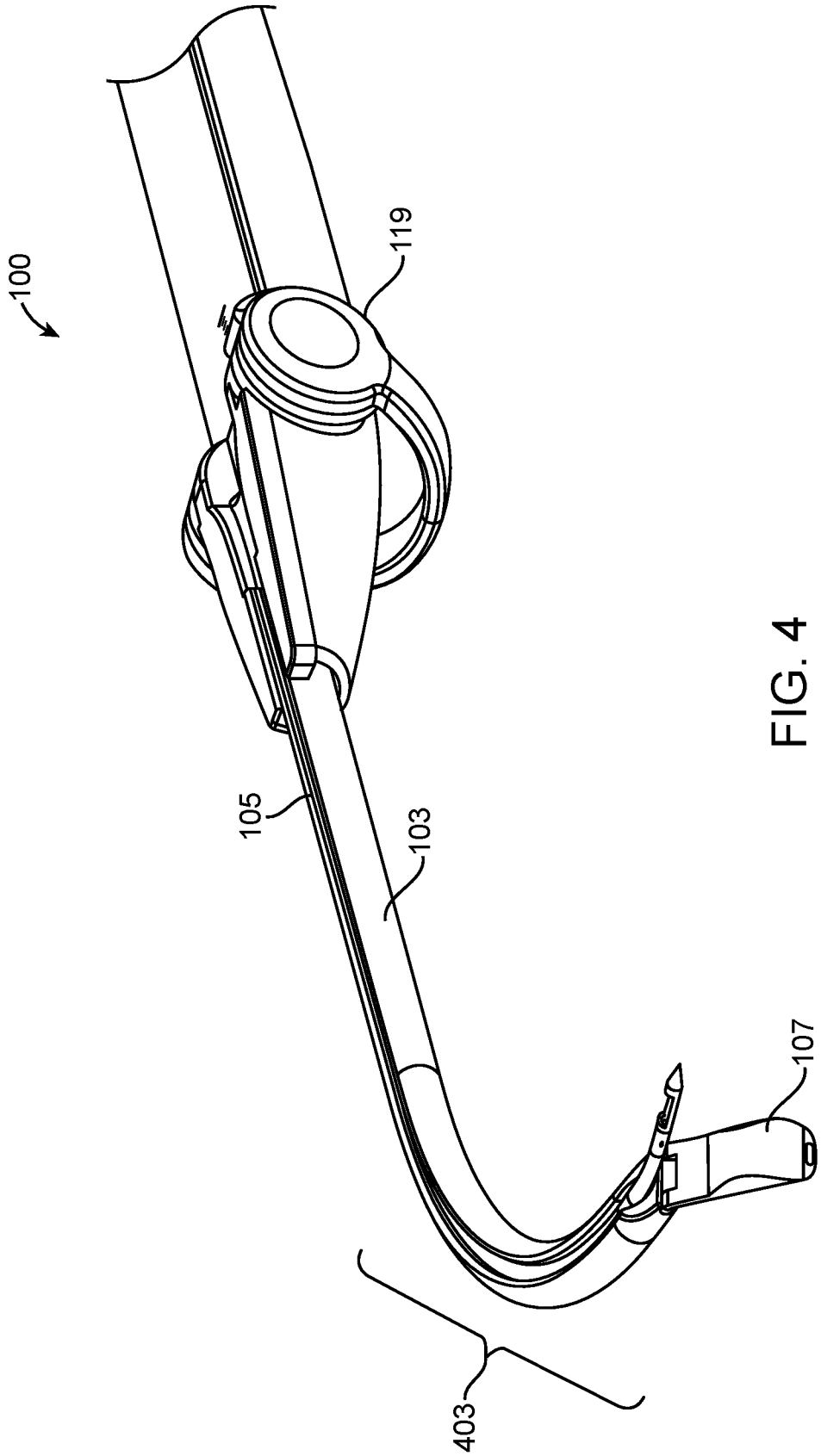


FIG. 4

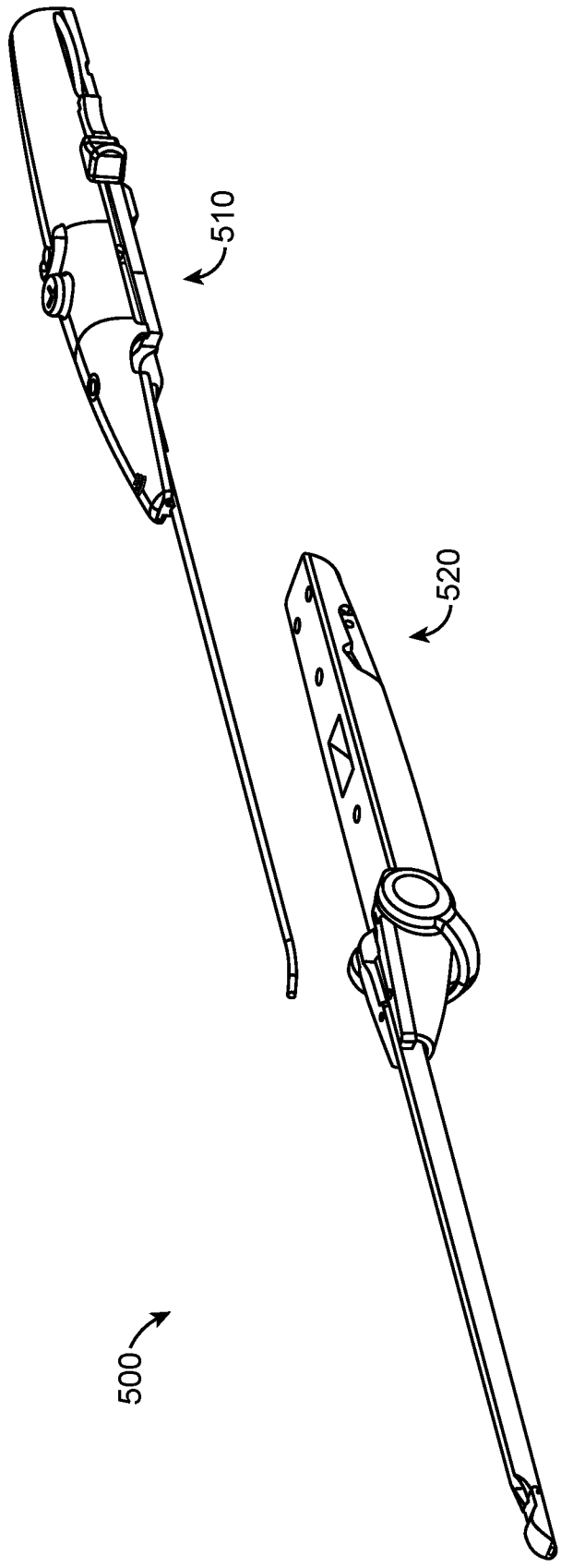


FIG. 5A

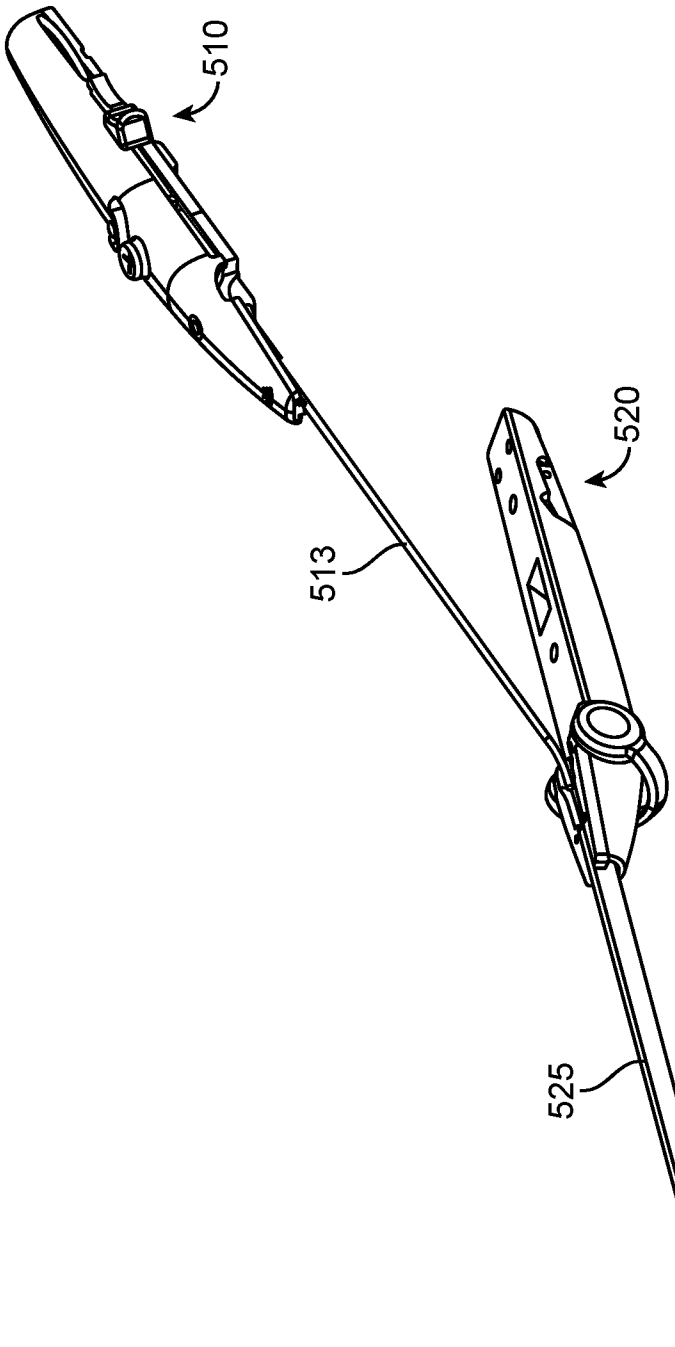


FIG. 5B

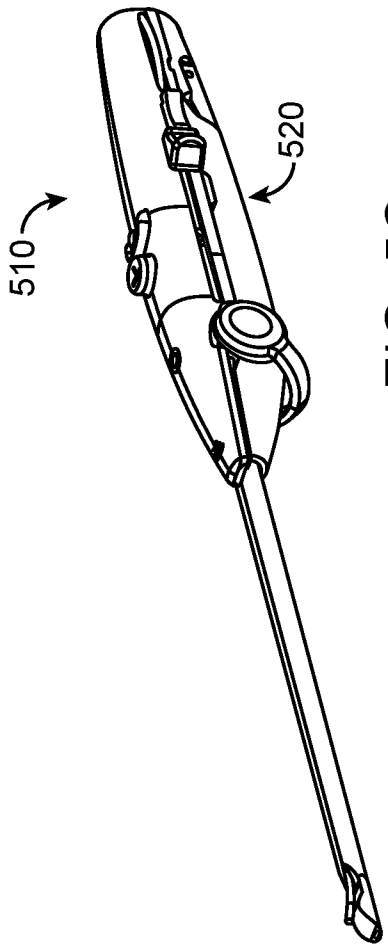


FIG. 5C

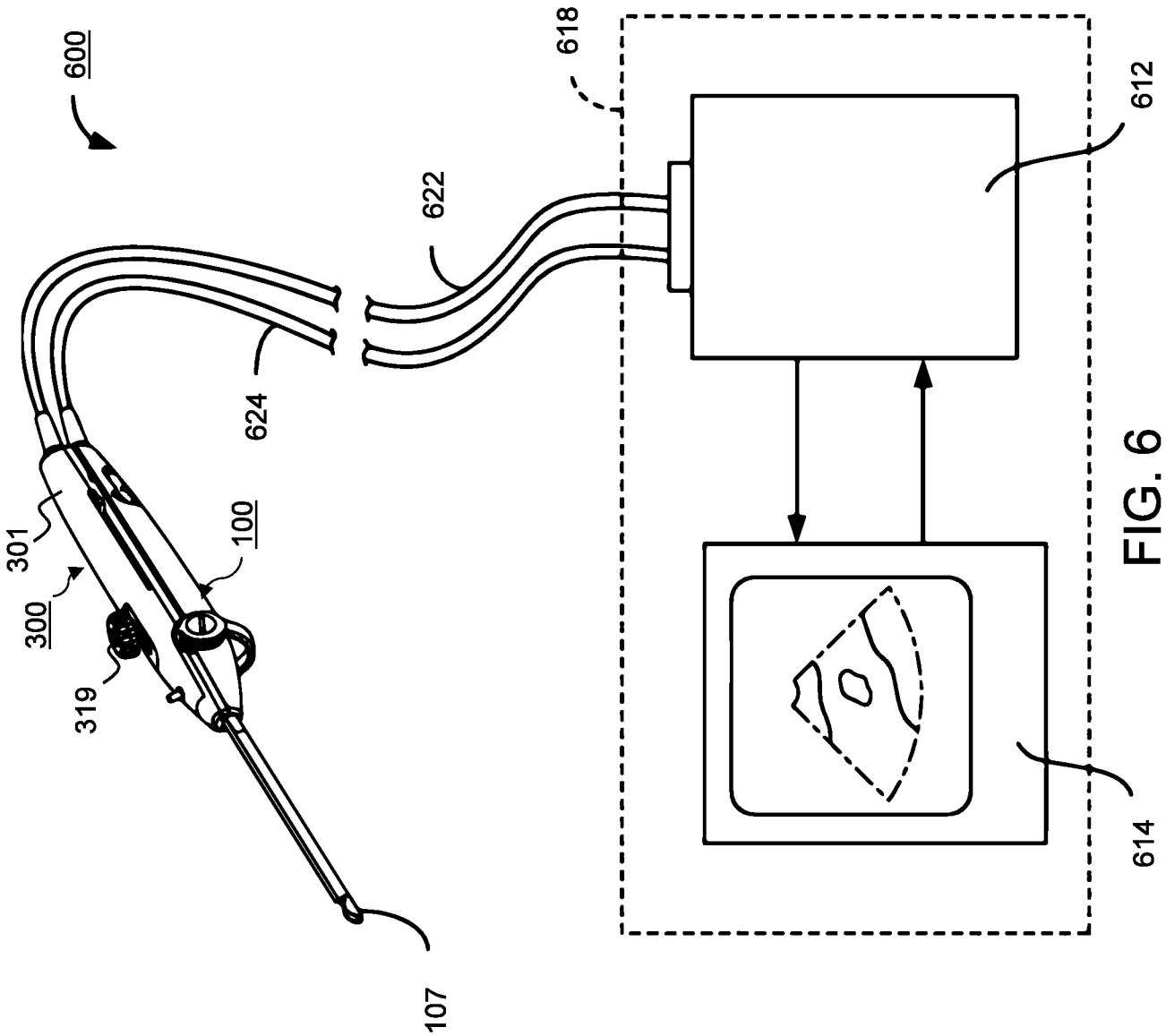


FIG. 6

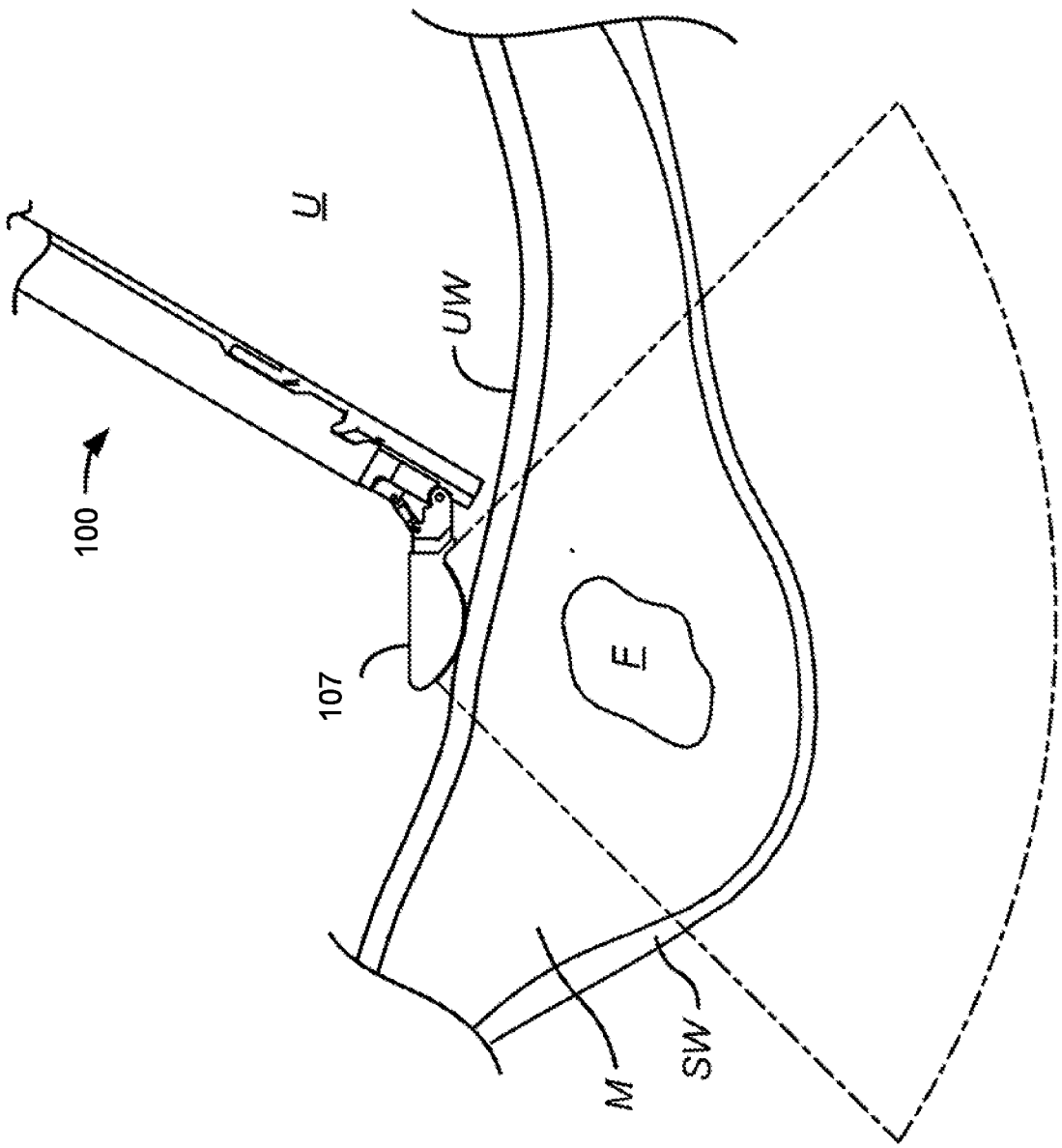


FIG. 7A

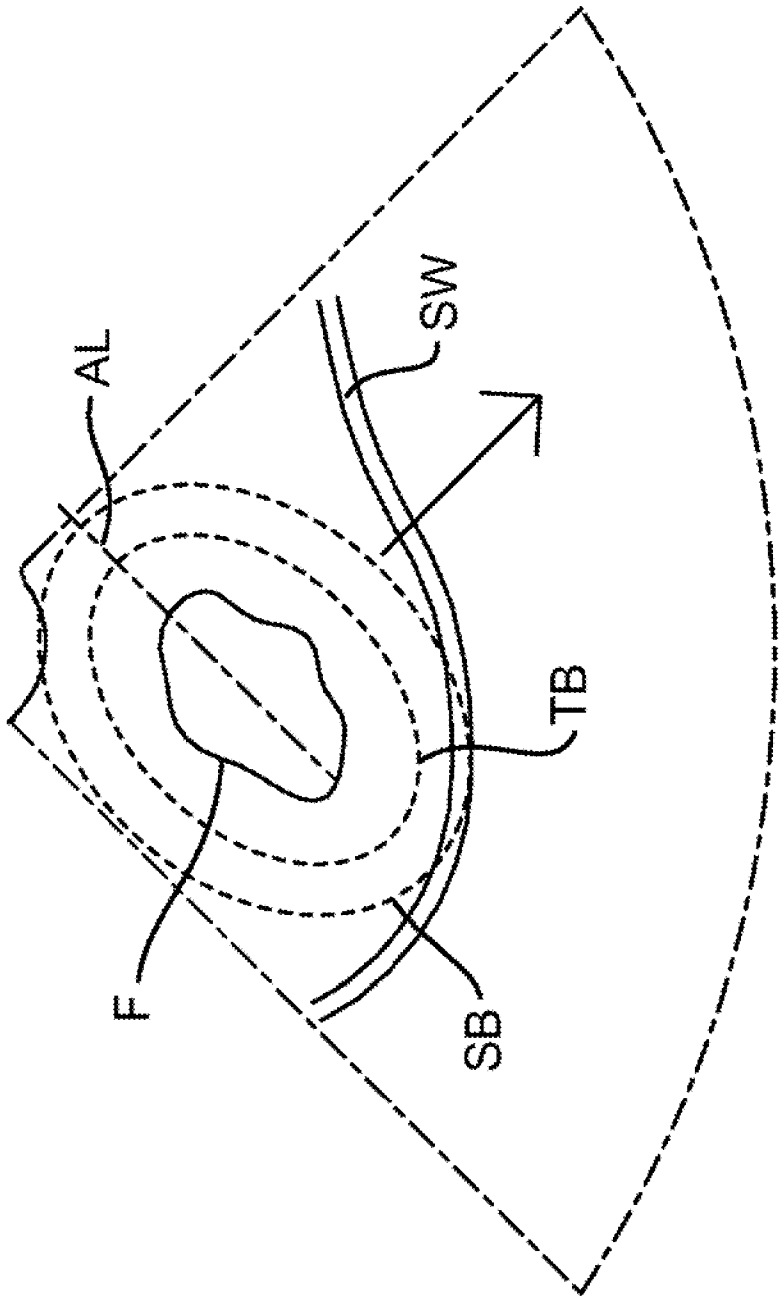


FIG. 7B

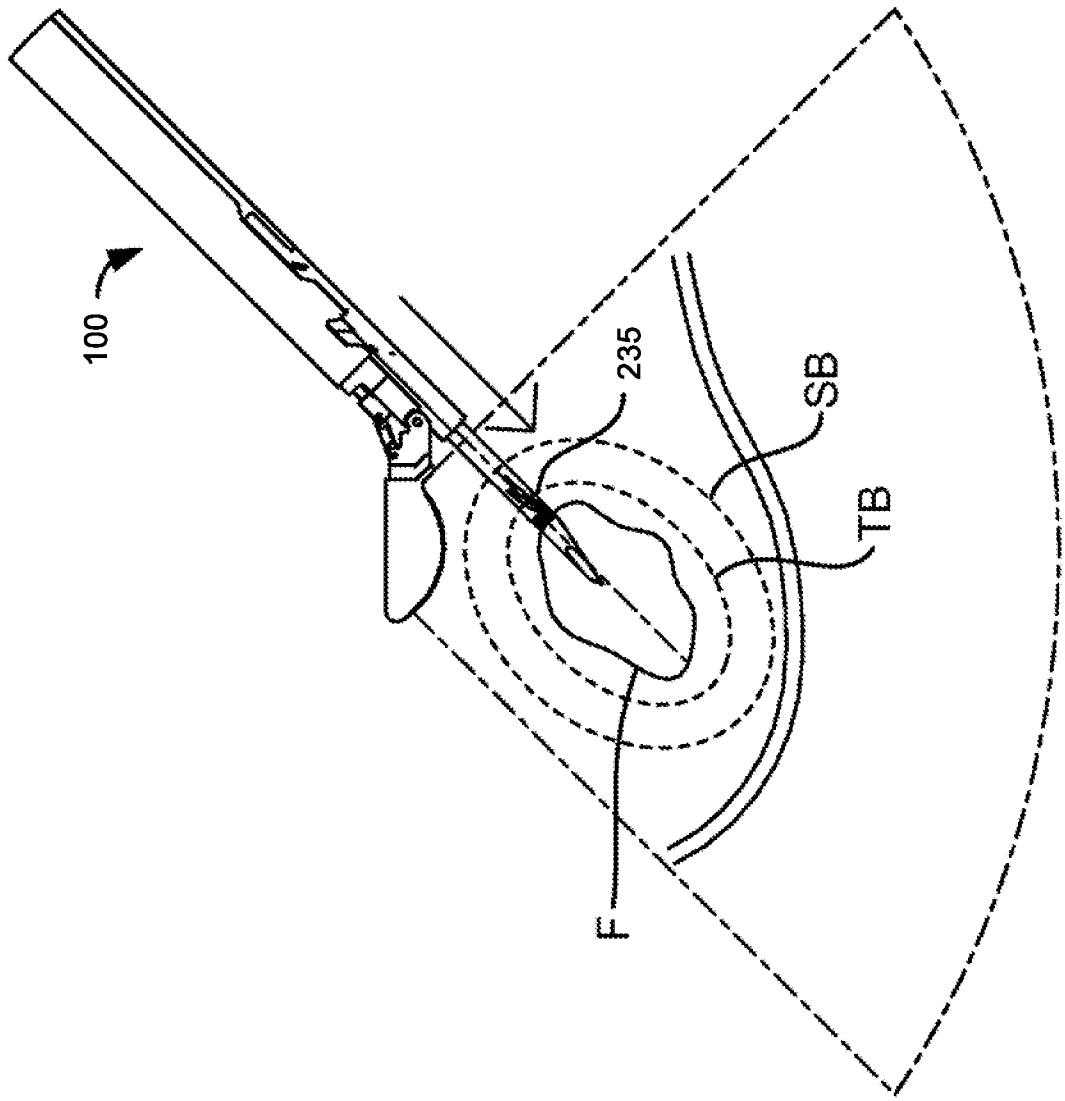


FIG. 7C

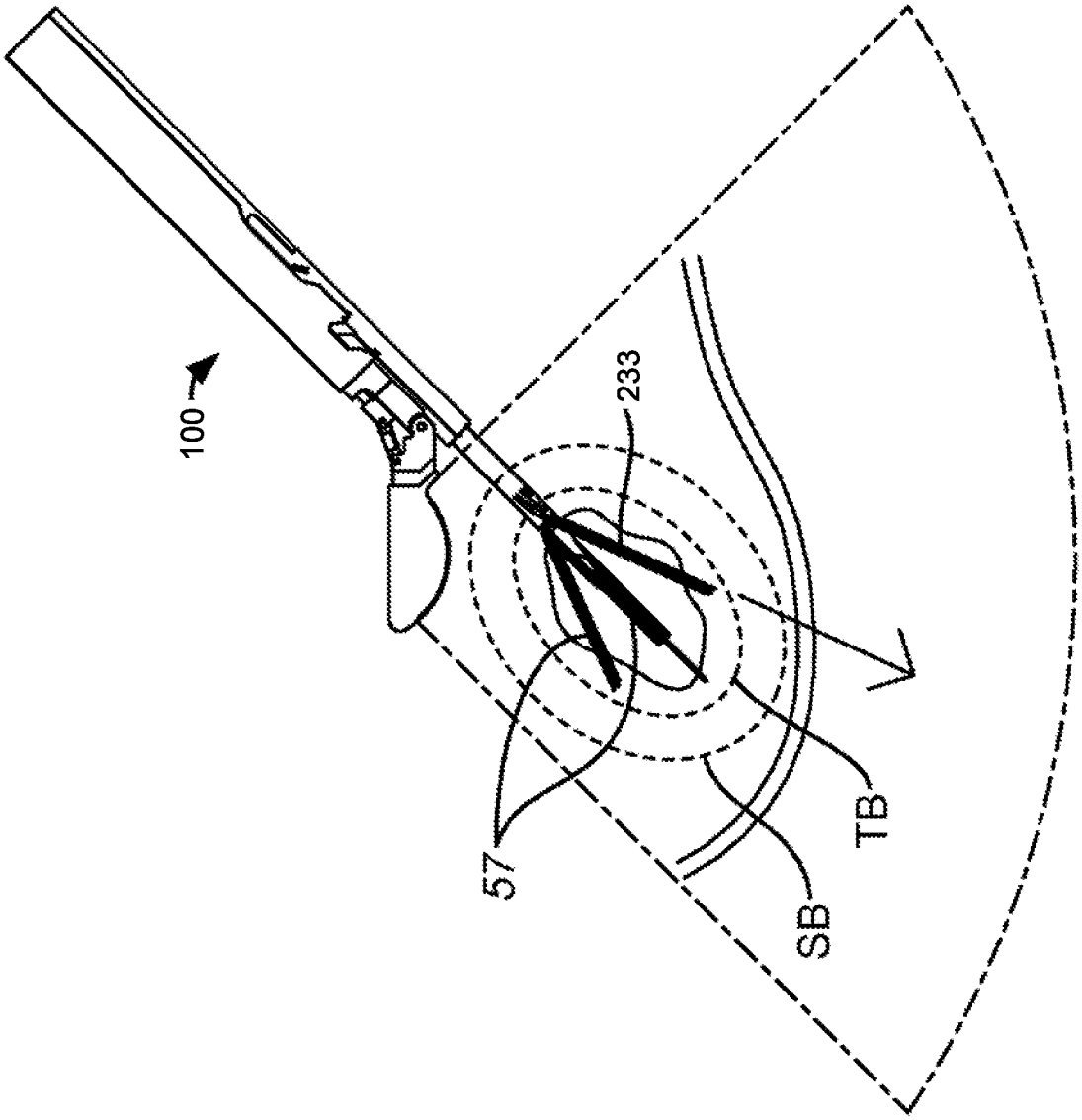


FIG. 7D

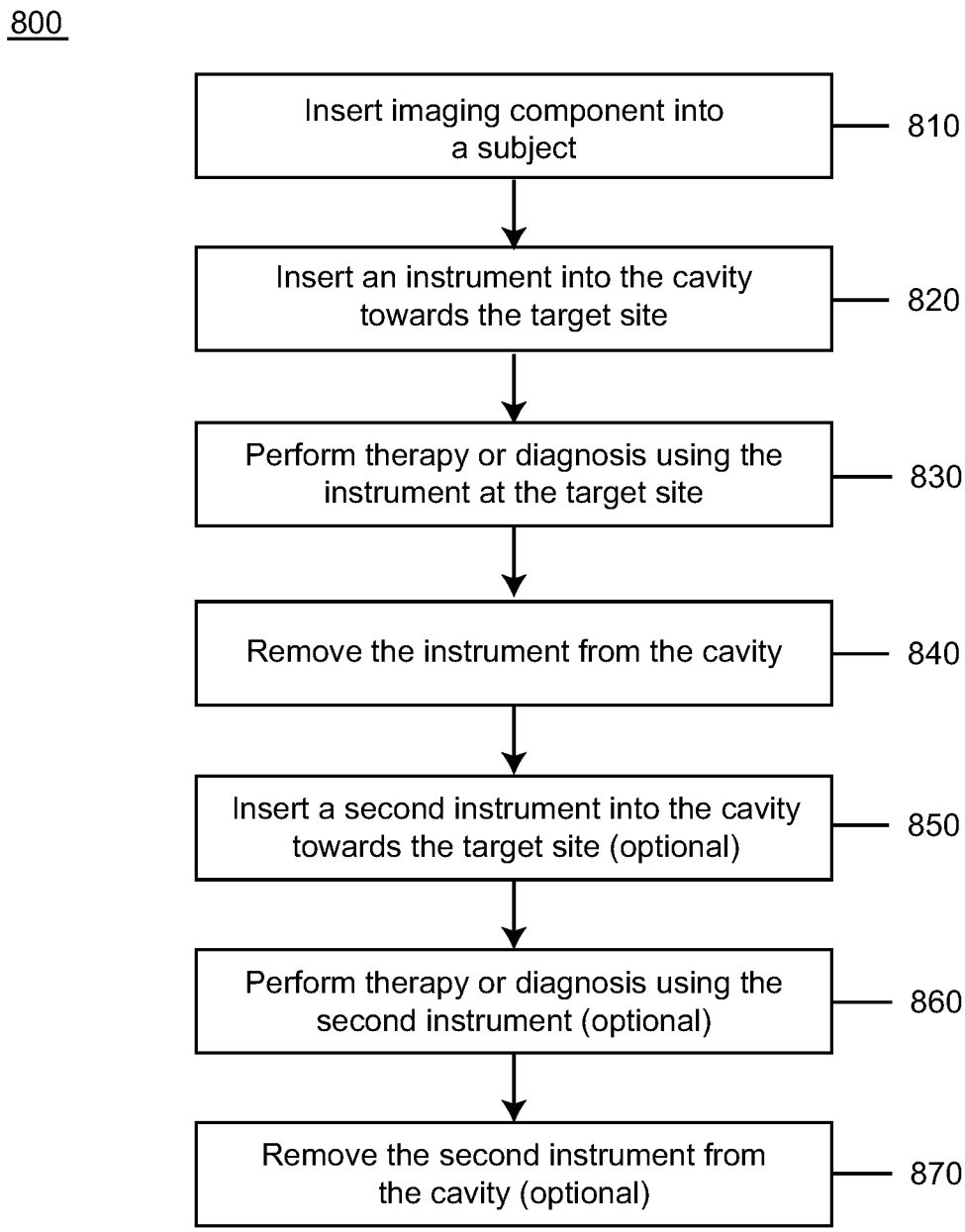
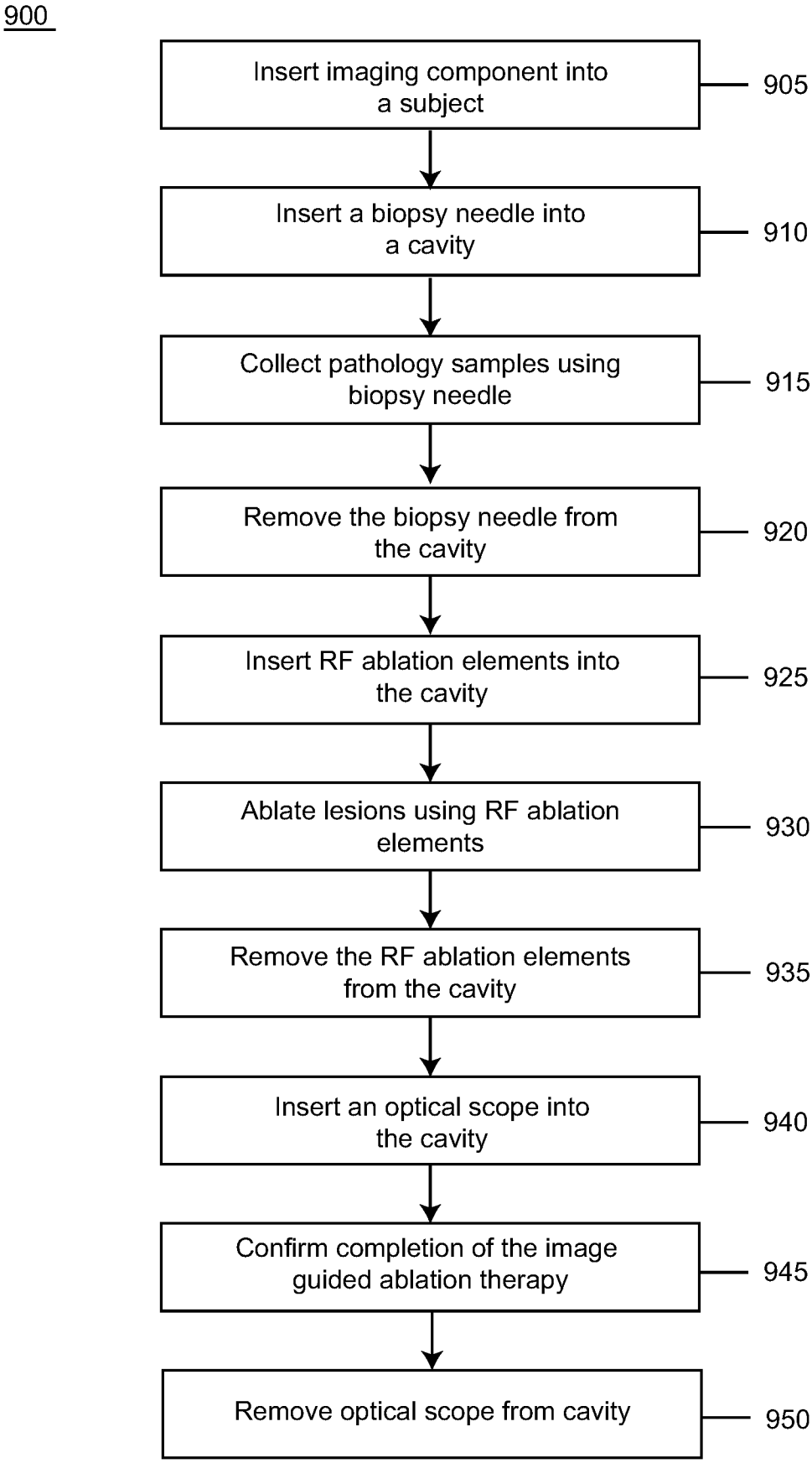

800
Insert imaging component into a subject
810
Insert an instrument into the cavity towards the target site
820
Perform therapy or diagnosis using the instrument at the target site
830
Remove the instrument from the cavity
840
Insert a second instrument into the cavity towards the target site (optional)
850
Perform therapy or diagnosis using the second instrument (optional)
860
Remove the second instrument from the cavity (optional)
870

FIG. 8


900
Insert imaging component into a subject
905
Insert a biopsy needle into a cavity
910
Collect pathology samples using biopsy needle
915
Remove the biopsy needle from the cavity
920
Insert RF ablation elements into the cavity
925
Ablate lesions using RF ablation elements
930
Remove the RF ablation elements from the cavity
935
Insert an optical scope into the cavity
940
Confirm completion of the image guided ablation therapy
945
Remove optical scope from cavity
950

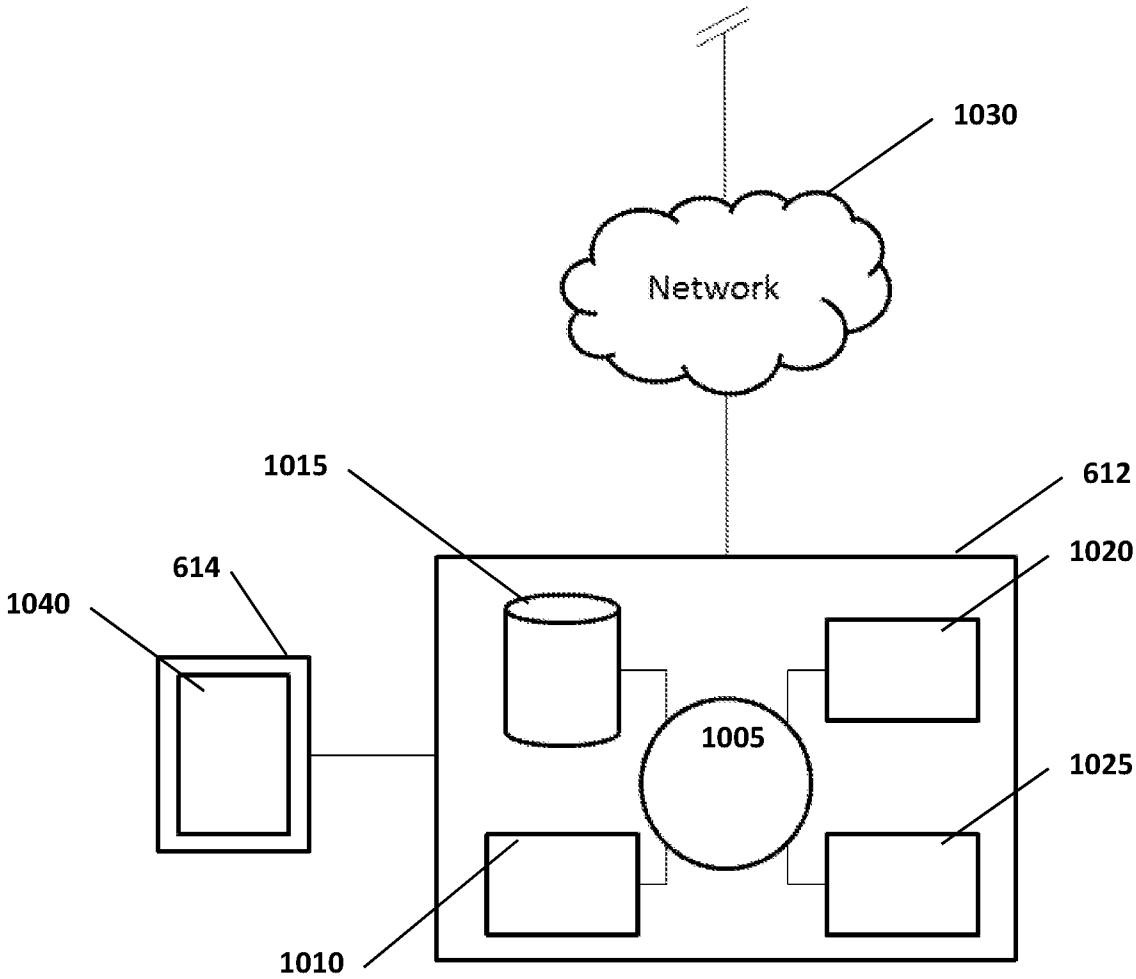


FIG. 10

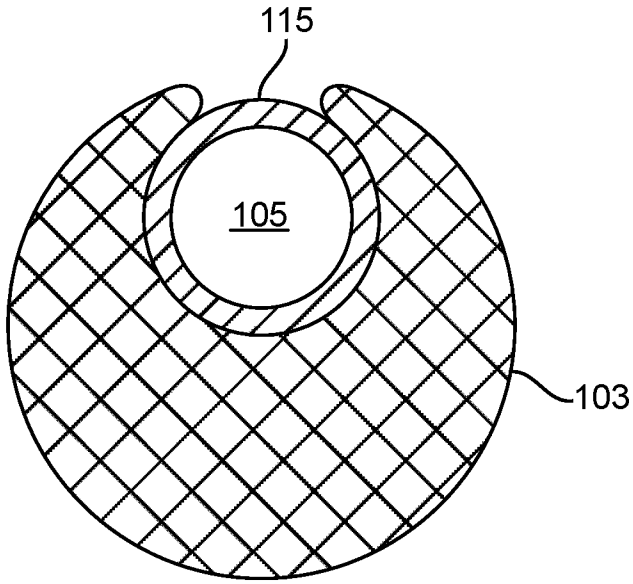


FIG. 11A

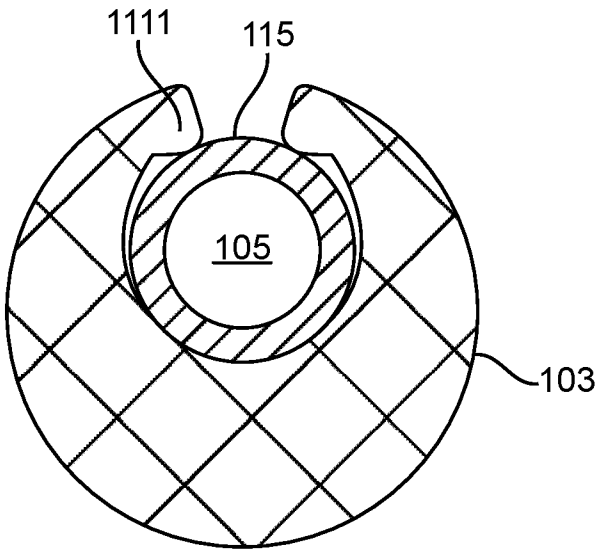


FIG. 11B

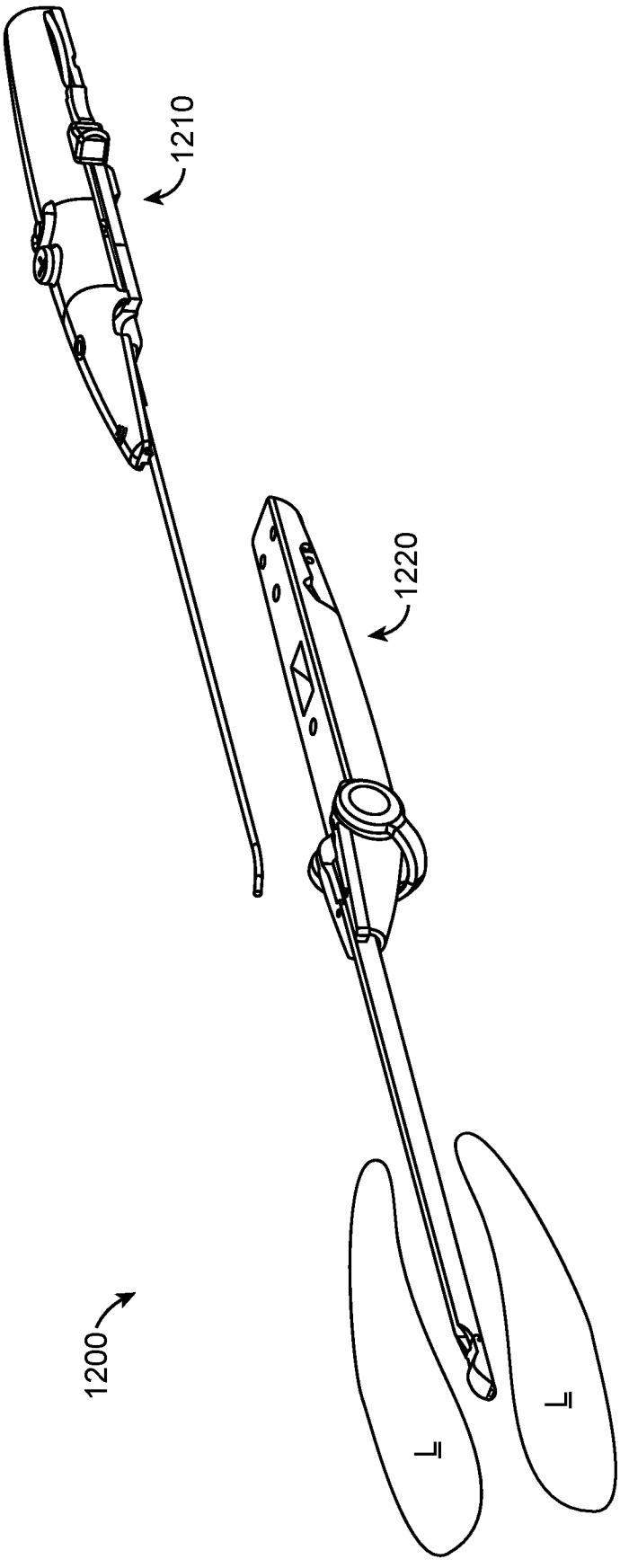


FIG. 12A

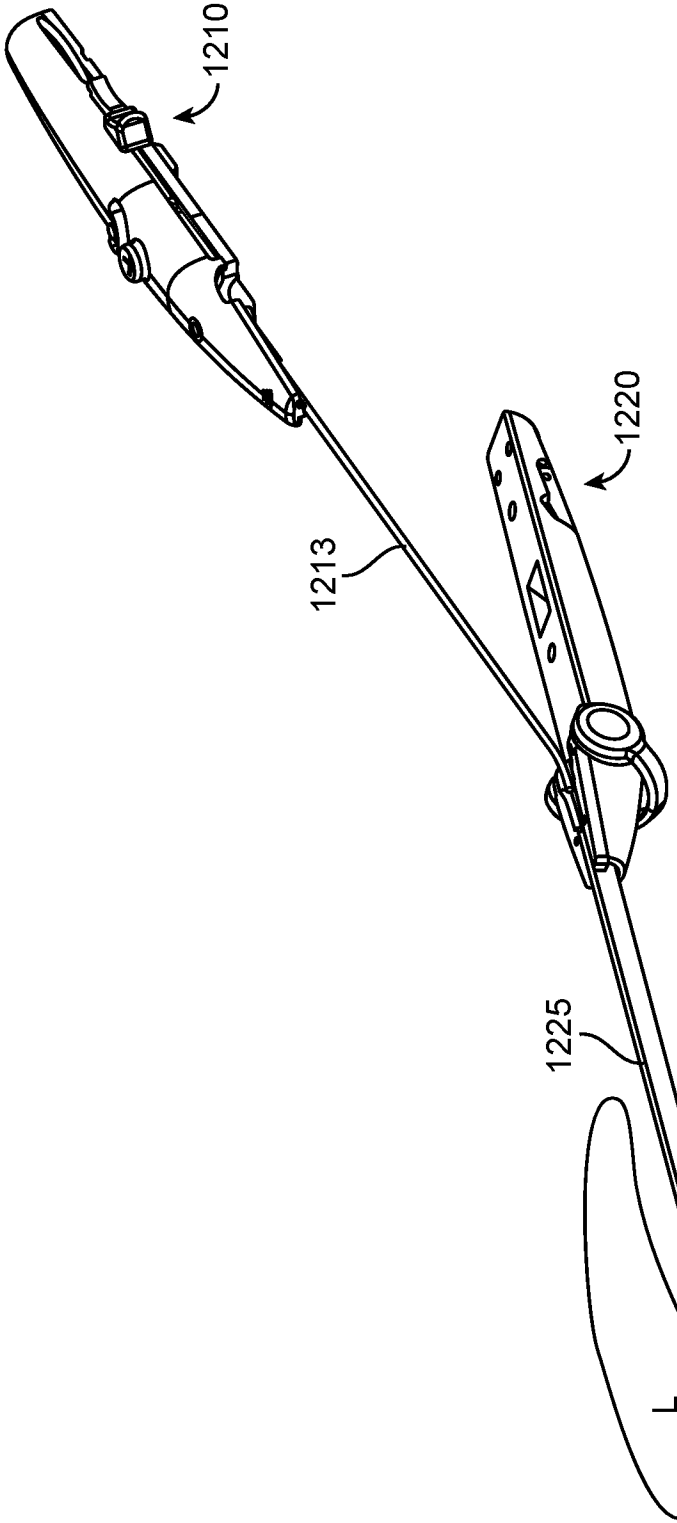


FIG. 12B

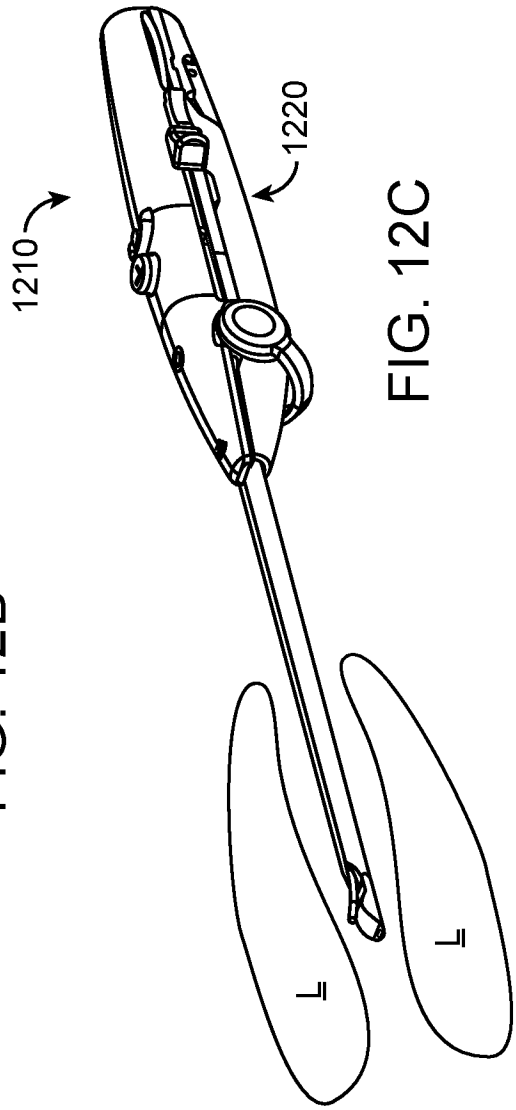


FIG. 12C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/32607

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 5/05, 8/12, 17/12; A61M 25/01 (2019.01)

CPC - A61B 5/05, 8/12, 17/12; A61M 25/01

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)
See Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/0014805 A1 (BURBANK F et al.) 16 August 2001; figures 5, 7; paragraphs [0057], [0063], [0067]-[0072], [0093]	1-5, 8-14, 17-19, 22, 23, 26, 29-31, 34, 36, 37/1-37/5, 37/8-37/14, 37/17-37/19, 37/22, 37/23, 37/26, 37/29-37/31, 37/34, 37/36, 38/37/1-38/37/5, 38/37/8-38/37/14, 38/37/17-38/37/19, 38/37/22, 38/37/23, 38/37/26, 38/37/29-38/37/31, 38/37/34, 38/37/36, 39/38/37/1-39/38/37/5, 39/38/37/8-39/38/37/14, 39/38/37/17-39/38/37/19, 39/38/37/22, 39/38/37/23, 39/38/37/26, 39/38/37/29-39/38/37/31, 39/38/37/34, 39/38/37/36, 48, 51-53, 55, 61, 65, 66, 68, 148, 150-157, 160-166, 169, 170, 173, 174, 177, 179, 180,

☒ 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	Date of mailing of the international search report
23 August 2019 (23.08.2019)	09 SEP 2019
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/32607

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
		38/37/1-38/37/5, 38/37/8-38/37/14, 38/37/17-38/37/19, 38/37/22, 38/37/23, 38/37/26, 38/37/29-38/37/31, 38/37/34, 38/37/36, 43/38/37/1-43/38/37/5, 43/38/37/8-43/38/37/14, 43/38/37/17-43/38/37/19, 43/38/37/22, 43/38/37/23, 43/38/37/26, 43/38/37/29-43/38/37/31, 43/38/37/34, 43/38/37/36, 44/38/37/1-44/38/37/5, 44/38/37/8-44/38/37/14, 44/38/37/17-44/38/37/19, 44/38/37/22, 44/38/37/23, 44/38/37/26, 44/38/37/29-44/38/37/31, 44/38/37/34, 44/38/37/36, 45/44/38/37/1-45/44/38/37/5, 45/44/38/37/8-45/44/38/37/14, 45/44/38/37/17-45/44/38/37/19, 45/44/38/37/22, 45/44/38/37/23, 45/44/38/37/26, 45/44/38/37/29-45/44/38/37/31, 45/44/38/37/34, 45/44/38/37/36, 48, 59, 38/37/1-38/37/5, 38/37/8-38/37/14, 38/37/17-38/37/19, 38/37/22, 38/37/23, 38/37/26, 38/37/29-38/37/31, 38/37/34, 38/37/36, 46/38/37/1-46/38/37/5, 46/38/37/8-46/38/37/14, 46/38/37/17-46/38/37/19, 46/38/37/22, 46/38/37/23, 46/38/37/26, 46/38/37/29-46/38/37/31, 46/38/37/34, 46/38/37/36 and 47/46/38/37/1-47/46/38/37/5, 47/46/38/37/8-47/46/38/37/14, 47/46/38/37/17-47/46/38/37/19, 47/46/38/37/22, 47/46/38/37/23, 47/46/38/37/26, 47/46/38/37/29-47/46/38/37/31, 47/46/38/37/34, 47/46/38/37/36
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
		40/38/37/16, 40/38/37/20, 40/38/37/21, 40/38/37/27, 40/38/37/28, 40/38/37/32, 40/38/37/33, 40/38/37/1-40/38/37/5, 40/38/37/8-40/38/37/14, 40/38/37/17-40/38/37/19, 40/38/37/22, 40/38/37/23, 40/38/37/26, 40/38/37/29-40/38/37/31, 40/38/37/34, 40/38/37/36, 41/38/37/15, 41/38/37/16, 41/38/37/20, 41/38/37/21, 41/38/37/27, 41/38/37/28, 41/38/37/32, 41/38/37/33, 41/38/37/1-41/38/37/5, 41/38/37/8-41/38/37/14, 41/38/37/17-41/38/37/19, 41/38/37/22, 41/38/37/23, 41/38/37/26, 41/38/37/29-41/38/37/31, 41/38/37/34, 41/38/37/36, 42/38/37/15, 42/38/37/16, 42/38/37/20, 42/38/37/21, 42/38/37/27, 42/38/37/28, 42/38/37/32, 42/38/37/33, 42/38/37/1-42/38/37/5, 42/38/37/8-42/38/37/14, 42/38/37/17-42/38/37/19, 42/38/37/22, 42/38/37/23, 42/38/37/26, 42/38/37/29-42/38/37/31, 42/38/37/34, 42/38/37/36, 49, 50, 54, 56, 57, 63, 64, 67, 69, 70, 167, 168, 171, 175, 176, 25, 37/25, 38/37/25, 39/38/37/25, 58, 60, 62, 71, 37/1, 37/6, 37/7, 37/19, 37/24, 37/35, 38/37/1, 38/37/6, 38/37/7, 38/37/19, 38/37/24, 38/37/35, 39/38/37/1, 39/38/37/6, 39/38/37/7, 39/38/37/19, 39/38/37/24, 39/38/37/35, 158, 159, 178, 38/37/1, 38/37/6, 38/37/7, 38/37/19, 38/37/24, 38/37/35, 43/38/37/1, 43/38/37/6, 43/38/37/7, 43/38/37/19, 43/38/37/24, 43/38/37/35, 44/38/37/1, 44/38/37/6, 44/38/37/7, 44/38/37/19, 44/38/37/24, 44/38/37/35, 45/44/38/37/1, 45/44/38/37/6, 45/44/38/37/7, 45/44/38/37/19, 45/44/38/37/24, 45/44/38/37/35, 38/37/1, 38/37/6, 38/37/7, 38/37/19, 38/37/24, 38/37/35, 46/38/37/1, 46/38/37/6, 46/38/37/7, 46/38/37/19, 46/38/37/24, 46/38/37/35, 47/46/38/37/1, 47/46/38/37/6, 47/46/38/37/7, 47/46/38/37/19, 47/46/38/37/24,

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
		46/38/37/35, 38/37/25, 43/38/25, 44/38/25, 45/44/38/25, 38/37/25, 46/38/37/25, 47/46/38/37/25, 38/37/15, 38/37/16, 38/37/20, 38/37/21, 38/37/27, 38/37/28, 38/37/32, 38/37/33, 43/38/37/15, 43/38/37/16, 43/38/37/20, 43/38/37/21, 43/38/37/27, 43/38/37/28, 43/38/37/32, 43/38/37/33, 44/38/37/15, 44/38/37/16, 44/38/37/20, 44/38/37/21, 44/38/37/27, 44/38/37/28, 44/38/37/32, 44/38/37/33, 45/44/38/37/15, 45/44/38/37/16, 45/44/38/37/20, 45/44/38/37/21, 45/44/38/37/27, 45/44/38/37/28, 45/44/38/37/32, 45/44/38/37/33, 38/37/15, 38/37/16, 38/37/20, 38/37/21, 38/37/27, 38/37/28, 38/37/32, 38/37/33, 46/38/37/15, 46/38/37/16, 46/38/37/20, 46/38/37/21, 46/38/37/27, 46/38/37/28, 46/38/37/32, 46/38/37/33, 46/38/37/15, 46/38/37/16, 46/38/37/20, 46/38/37/21, 46/38/37/27, 46/38/37/28, 46/38/37/32, 46/38/37/33, 40/38/37/1, 40/38/37/6, 40/38/37/7, 40/38/37/19, 40/38/37/24, 40/38/37/35, 41/38/37/1, 41/38/37/6, 41/38/37/7, 41/38/37/19, 41/38/37/24, 41/38/37/35, 42/38/37/1, 42/38/37/6, 42/38/37/7, 42/38/37/19, 42/38/37/24, 42/38/37/35, 40/38/37/25, 41/38/37/25, 42/38/37/25, 172
X --- Y	US 2013/0225995 A1 (OLYMPUS MEDICAL SYSTEMS CORP.) 29 August 2013; figure 1; paragraphs [0042]-[0044]	1, 6, 7, 19, 24, 35 --- 37/1, 37/6, 37/7, 37/19, 37/24, 37/35, 38/37/1, 38/37/6, 38/37/7, 38/37/19, 38/37/24, 38/37/35, 39/38/37/1, 39/38/37/6, 39/38/37/7, 39/38/37/19, 39/38/37/24, 39/38/37/35

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/0179380 A1 (GROSSMAN J) 2 August 2007; figure 1; paragraph 16	15, 16, 20, 21, 27, 28, 32, 33, 37/15, 37/16, 37/20, 37/21, 37/27, 37/28, 37/32, 37/33, 38/37/15, 38/37/16, 38/37/20, 38/37/21, 38/37/27, 38/37/28, 38/37/32, 38/37/33, 39/38/37/15, 39/38/37/16, 39/38/37/20, 39/38/37/21, 39/38/37/27, 39/38/37/28, 39/38/37/32, 39/38/37/33, 40/38/37/15, 40/38/37/16, 40/38/37/20, 40/38/37/21, 40/38/37/27, 40/38/37/28, 40/38/37/32, 40/38/37/33, 40/38/37/1-40/38/37/5, 40/38/37/8-40/38/37/14, 40/38/37/17-40/38/37/19, 40/38/37/22, 40/38/37/23, 40/38/37/26, 40/38/37/29-40/38/37/31, 40/38/37/34, 40/38/37/36, 41/38/37/15, 41/38/37/16, 41/38/37/20, 41/38/37/21, 41/38/37/27, 41/38/37/28, 41/38/37/32, 41/38/37/33, 41/38/37/1-41/38/37/5, 41/38/37/8-41/38/37/14, 41/38/37/17-41/38/37/19, 41/38/37/22, 41/38/37/23, 41/38/37/26, 41/38/37/29-41/38/37/31, 41/38/37/34, 41/38/37/36, 42/38/37/15, 42/38/37/16, 42/38/37/20, 42/38/37/21, 42/38/37/27, 42/38/37/28, 42/38/37/32, 42/38/37/33, 42/38/37/1-42/38/37/5, 42/38/37/8-42/38/37/14, 42/38/37/17-42/38/37/19, 42/38/37/22, 42/38/37/23, 42/38/37/26, 42/38/37/29-42/38/37/31, 42/38/37/34, 42/38/37/36, 49, 50, 54, 56, 57, 63, 64, 67, 69, 70, 167, 168, 171, 175 and 176
Y	US 2015/0094712 A1 (GYRUS ACMI INC.) 2 April 2015; paragraphs [0005], [0037]	25, 37/25, 38/37/25, 39/38/37/25, 58, 60, 62, 71
A	US 2012/0289858 A1 (OUYANG X et al.) 15 November 2012; entire document	1-75, 148-180
A	WO 2006/086234 A2 (BOSTON SCIENTIFIC SCIMED, INC.) 17 August 2006; entire document	1-75, 148-180
A	US 2009/0287081 A1 (GROSSMAN J et al.) 19 November 2009; entire document	1-75, 148-180

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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.:
because they relate to subject matter not required to be searched by this Authority, namely:

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).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

-***-Continued Within the Next Supplemental Box-***-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Group I: Claims 1-75, 148-180

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

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-***-Continued from Box No. III Observations where unity of invention is lacking-***-

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-75, 148-180 are directed toward: an imaging component and a method of performing therapy or diagnosis at a target site, comprising: a cavity extending across the shaft.

Group II: Claims 76-147 are directed toward: a method of coupling instruments and a system for performing therapy and/or diagnosis at a target site within a patient, comprising: advancing an imaging component to within a surgical space.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical features of Group I include: an imaging component and a method of performing therapy or diagnosis at a target site, comprising: a cavity extending across the shaft from the proximal end towards the distal end, wherein the cavity is configured to removably receive at least one of a plurality of different instruments, and wherein a wall of the cavity comprises an elongated opening in communication with an exterior of the shaft at least partially along the shaft; and an imaging transducer coupled to the distal end of the shaft; and performing therapy or diagnosis using a first instrument inserted into the cavity and advanced to the target site, which are not present in Group II.

The special technical features of Group II include: a method of coupling instruments and a system for performing therapy and/or diagnosis at a target site within a patient, comprising: advancing an imaging component to within a surgical space,; a first therapeutic or diagnostic instrument; a second therapeutic or diagnostic instrument different from the first therapeutic or diagnostic instrument; and the imaging component configured to be removably coupled to both the first and second therapeutic or diagnostic instruments, either simultaneously or individually; wherein the imaging component is configured to be deliverable to the target site within the patient both (i) separately from the first and second therapeutic or diagnostic instruments, and (ii) coupled with the first and/or second therapeutic or diagnostic instruments, and wherein the imaging component is configured to be removably coupled to both the first and second therapeutic or diagnostic instruments, either simultaneously or individually, after the imaging component is delivered to the target site within the patient, which are not present in Group I.

The common technical features of Groups I and II are: an imaging component comprising: a shaft comprising a proximal end and a distal end.

These common technical features are disclosed by US 2009/0287081 A1 (GROSSMAN). Grossman discloses an imaging component (200; figure 1A) comprising: a shaft (58) comprising a proximal end (end adjacent 40; figure 1A) and a distal end (end adjacent 14; figure 1A).

Since the common technical features are previously disclosed by the Grossman reference, the common features are not special and so Groups I and II lack unity.