(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 2 809 249 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
26.12.2018 Bulletin 2018/52

(21) Application number: **13743290.2**

(22) Date of filing: **28.01.2013**

(51) Int Cl.:
A61B 17/34 *(2006.01)* ***A61M 25/092*** *(2006.01)*
A61B 10/02 *(2006.01)* ***A61M 25/09*** *(2006.01)*

(86) International application number:
PCT/US2013/023398

(87) International publication number:
WO 2013/116140 (08.08.2013 Gazette 2013/32)

(54) STEERABLE FLEXIBLE NEEDLE WITH EMBEDDED SHAPE SENSING

STEUERBARE BIEGSAME NADEL MIT EINGEBETTETER FORMMESSUNG

AIGUILLE ORIENTABLE FLEXIBLE AVEC DÉTECTION DE LA FORME INTÉGRÉE

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **03.02.2012 US 201261594959 P**
15.02.2012 US 201261599015 P

(43) Date of publication of application:
10.12.2014 Bulletin 2014/50

(73) Proprietor: **Intuitive Surgical Operations, Inc.**
Sunnyvale, CA 94086 (US)

(72) Inventors:
- **DUINDAM, Vincent**
  Sunnyvale, CA 94086 (US)
- **PRISCO, Giuseppe Maria**
  56011 Calci (PI) (IT)
- **LARKIN, David, Q.**
  Menlo Park, CA 94025 (US)
- **DIMAIO, Simon**
  Sunnyvale, CA 94086 (US)
- **PANESCU, Dorin**
  San Jose, CA 95136 (US)
- **ZHAO, Tao**
  Sunnyvale, CA 94086 (US)

(74) Representative: **MacDougall, Alan John Shaw et al**
Mathys & Squire LLP
The Shard
32 London Bridge Street
London SE1 9SG (GB)

(56) References cited:
WO-A2-2008/131303
US-A1- 2005 228 274
US-A1- 2007 093 703
US-A1- 2007 293 721
US-A1- 2007 293 721
US-A1- 2010 249 507
US-A1- 2010 249 507
US-B2- 7 824 328
US-B2- 8 050 523

EP 2 809 249 B1

Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND

[0001] Aspects of this disclosure are related to shape sensing in a minimally invasive surgical instrument, and more particularly to the incorporation of shape sensing capabilities into a flexible needle.

[0002] Minimally invasive surgical procedures typically rely on some sort of instrument position monitoring to ensure proper access to, and behavior at, the target surgical location. Conventional minimally invasive surgical instruments are generally either formed from generally rigid, elongate elements (e.g., laparoscopic or robotic systems) or highly flexible systems designed to follow a predetermined anatomic path (e.g., angioplasty balloon catheters). In either case, position monitoring typically involves localized tracking.

[0003] For example, the overall shape of an instrument formed from rigid bodies can be determined via monitoring of just the extrema (e.g., the joints and ends) of those elements. For example, the shape of a rigid three-linkage robotic arm having two rotational joints (single degree of freedom for each joint) can be modeled using measurements from just the two rotational joints.

[0004] For catheter-based procedures, it is generally the catheter tip position that is critical, with the length of the catheter simply residing within a vessel in the body. For example, in an angioplasty procedure, the guidewire and/or balloon catheter tip must be positioned at the arterial blockage, and so the guidewire/balloon catheter tip is monitored (typically via direct visualization). The remaining guidewire/catheter length is not actively monitored, except in an incidental sense to the extent the remaining length is shown during fluoroscopic visualization of the tip advancement.

[0005] However, increasingly more complex minimally invasive surgical systems can require enhanced instrument position monitoring for safe and effective use. For example, the development of flexible, steerable needles provides an opportunity for procedures such as biopsy and/or therapeutic treatment, such as ablation treatments or radioactive seeds placement, at internal locations that would be problematic to access via a straight path - e.g., if it would be undesirable to puncture any intervening anatomy. Flexible, steerable needles can be delivered to the target site by direct penetration into the tissue, such as for example in the case of transcutaneous biopsy needles for the liver or other internal organs. Flexible, steerable needles can be delivered to the target site making use of the channel of an endoscope or a catheter, such as for example in the case of transluminal lung or stomach biopsy.

[0006] As used herein, steerable needles refer to a broad category of flexible needles with control inputs at the base (i.e., outside the body of the patient) and distal regions meant for piercing or puncturing target tissue. Depending on the shape and mechanical properties of the needle, interaction forces between the needle and the patient anatomy (i.e., the target tissue and/or any intervening anatomy between the surgical entry point and the target tissue) can cause the needle to deflect, such that steering can be provided by simply applying rotation to the base of the needle. Alternatively or additionally, a steerable needle can include active actuators to provide shaping and directionality. Steerable needles generally have a high axial stiffness and a tip shape that allows them to puncture or penetrate tissue with minimal axial compression, as compared to catheter-type devices that have a low axial stiffness and are not suited to penetrate or puncture.

[0007] Note that the term "flexible" in association with a steerable needle should be broadly construed. In essence, it means the needle can be bent without harm. For example, a flexible steerable needle may include a series of closely spaced components that are similar to "vertebrae" in a snake-like arrangement. In such an arrangement, each component is a short link in a kinematic chain, and movable mechanical constraints (e.g., pin hinge, cup and ball, and the like) between each link may allow one (e.g., pitch) or two (e.g., pitch and yaw) degrees of freedom (DOF) of relative movement between the links. As another example, a flexible steerable needle may be continuous, such as a closed bendable tube (e.g., nitinol, polymer, and the like) or other bendable piece (e.g., kerf-cut tube, helical coil, and the like).

[0008] At the same time, the use of a flexible needle in a minimally invasive fashion can be significantly more complicated than conventional robotic or laparoscopic procedures. Not only is the variability in the actual shape of a steerable needle much greater than that of a linkage of rigid elements, but the needle flexibility can greatly increase susceptibility to deviation from a target trajectory due to variations in tissue characteristics (e.g., scar tissue, or otherwise denser than expected tissue, may result in greater than expected curvature of the flexible needle).

[0009] Accordingly, it is desirable to provide a steerable needle system that can be effectively used in minimally invasive surgical procedures.

[0010] WO 2008/131303 discloses a medical instrument system which includes an elongate flexible instrument body with an optical fiber substantially encapsulated in a wall of the instrument body, the optical fiber including one or more fiber gratings. A detector is operatively coupled to the optical fiber and configured to detect respective light signals reflected by the one or more fiber gratings. A controller is operatively coupled to the detector, and configured to determine a twist of at least a portion of the instrument body based on detected reflected light signals. The instrument may be a guide catheter and may be robotically or manually controlled.

SUMMARY

[0011] Claim 1 defines the invention and the depend-

ent claims disclose the preferred embodiments. By incorporating a shape sensor into a flexible needle, the shape and/or surgical trajectory of such a needle can be effectively monitored and controlled to enable efficient and effective procedure performance. The present invention provides a flexible needle and a surgical system as set out in the appended claims.

[0012] As used herein, steerable needles refer to a broad category of flexible needles with control inputs at the base (i.e., outside the body of the patient) and distal regions meant for piercing or puncturing target tissue. The control inputs allow the needle to be guided along a desired surgical trajectory to a target location within the patient. In some embodiments, the needle may include a tip geometry that imparts a directional motion as the tip passes through tissue, such that the control inputs can simply be a handle(s) or other control to axially rotate the needle. In other embodiments, the needle may include wires, cables, or any other actuation mechanism to allow for more direct control over the shape and direction of travel of the needle. In such embodiments, the control inputs would be configured to provide the appropriate manipulation or actuation energy to the actuation mechanism(s) of the needle.

[0013] Depending on the shape and mechanical properties of the needle, interaction forces between the needle and the patient anatomy (i.e., the target tissue and/or any intervening anatomy between the surgical entry point and the target tissue) can cause the needle to deflect and move along curved trajectories. The shape and/or direction of these trajectories can be influenced through the control inputs. Steerable needles can be used in minimally invasive clinical procedures for diagnosis and treatment of difficult to reach targets, e.g., in prostate biopsy and brachytherapy.

[0014] In some embodiments, a steerable needle can be a highly flexible (e.g., nitinol) needle with an asymmetric beveled tip and control inputs for insertion and shaft rotation. As it is inserted into tissue, the needle moves approximately along a circular path in the direction of the bevel. Rotating the needle shaft causes the bevel direction to change, thereby causing the needle shape and/or trajectory direction to change as the needle is moved through the patient anatomy. In other embodiments, a steerable needle can be a highly flexible (e.g., nitinol) needle with a pre-bent tip section and control inputs for insertion and shaft rotation. In this case, the needle moves along an approximately circular trajectory in the direction of the pre-bent tip (the lowest-energy state of the needle), wherein shape and/or trajectory direction changes can be effected via needle shaft rotation. In yet other embodiments, a steerable needle can be a highly flexible needle with an asymmetric tip (either beveled or pre-bent) that is controlled from the base by shaft insertion, shaft rotation, and bending at the entry point to control shape and/or trajectory direction. In various other embodiments, a steerable needle can be a concentric-tube device in which several flexible pre-bent tubes are assembled concentrically. The external control inputs determine the relative orientation and sliding amount of the different flexible tubes. The tip position and orientation can be changed by sliding and rotating the pre-bent tubes using the control inputs, thereby enabling control over shape and/or trajectory direction in use.

[0015] In some embodiments, a steerable needle can be fitted with a shape sensor(s) that measures the continuous shape of the needle. The sensor can be placed in a separate lumen in the wall of the needle, tacked in place (optionally in grooves) on the inside or outside of the needle wall, be removably inserted into the lumen of the needle (e.g., as part of a stylet), or otherwise coupled to the flexible needle along at least a portion of its length. The use of the interior lumen of the needle beneficially avoids the requirement of extra wall thickness or size.

[0016] The information obtained from the shape sensor can be used in various ways. For example, from the measured shape the total insertion depth into the tissue as well as the tip position and orientation can be determined. These variables can be used in a servo-loop to precisely control the needle insertion and orientation - instead of measuring just the proximal insertion and rotation amounts on the control inputs and assuming perfect transfer to the tip, the shape sensor can be used to directly measure the distal insertion and rotation, independent from the torsional and axial flexibility of the needle and the effects of friction and normal forces between the needle and the tissue.

[0017] In another embodiment, the measured tip position and orientation (as computed from the shape information) can be used in planning algorithms that compute feasible paths from the current needle position to the target location. The shape sensor can be used to measure the needle pose in place of or in addition to (potentially imprecise and noise) imaging techniques.

[0018] In another embodiment, the shape sensor can be used to identify unknown model parameters in the biomechanical model of the tissue, as used in the planning software. For example, the bend radius of the trajectory of a steerable needle depends on the properties of the needle as well as the local properties of the surrounding tissue. These properties are hard to predict, but the shape sensor can be used to measure current actual bend radius of the trajectory to update model parameters.

[0019] In another embodiment, where one of the control inputs is bending the needle base near the entry point of the tissue, the shape sensor information, in conjunction with the needle material properties, can be used to estimate and locally update the kinematic mapping between needle base motions and needle tip motions. This mapping can be used to control the base of the needle for desired tip motion.

[0020] In another embodiment, the shape measurements can be used to detect undesired motions of the needle shaft, such as buckling and large deviations from the expected or allowed path. In conjunction with a mechanical model of the needle, the measured needle

shape can also be used to estimate forces applied along the needle shaft. This could be used to identify points where high force is being applied to tissue.

[0021] In another embodiment, the shape sensor can be used in conjunction with imaging techniques to improve registration of the needle relative to preoperative data. The base, or some other portion of the shape sensor, can be registered to the image coordinate space by attaching an image-able fiducial to a portion of the fiber, or docking a fixed reference point on the fiber to a visible fiducial feature on the patient, or similar. The intraoperative imaging would provide a means to adapt needle trajectory in response to tissue motion or deformation. The measured shape of the needle could be used to assist in detecting and localizing the needle in intraoperative images, such that its position/orientation with respect to anatomical targets could be measured.

[0022] In another embodiment, the shape sensor can be used, in conjunction with a driving mechanism, to provide input in order to manually or automatically control an actuator that steers the flexible needle during a medical procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023]

FIG. 1A is a block diagram of a minimally invasive surgical system that includes a steerable needle incorporating shape sensing.

FIG. 1B is a block diagram of a shape sensor processing system that can be part of the minimally invasive surgical system of FIG. 1A.

FIGS. 2A-2B are diagrams of steerable needle types usable with the minimally invasive surgical system of FIG. 1A.

FIGS. 3A-3F are various steerable needle/shape sensor combinations usable with the minimally invasive surgical system of FIG. 1A.

FIGS. 4-7 are operational flow diagrams for a minimally invasive surgical system incorporating a steerable needle with shape sensor.

DETAILED DESCRIPTION

[0024] By incorporating a shape sensor into a flexible needle, the shape and/or surgical trajectory of such a needle can be effectively monitored and controlled to enable efficient and effective procedure performance.

[0025] The embodiments below will describe various instruments and portions of instruments in terms of their state in three-dimensional space. As used herein, the term "position" refers to the location of an object or a portion of an object in a three-dimensional space (e.g., three degrees of translational freedom along Cartesian X, Y, Z coordinates). As used herein, the term "orientation" refers to the rotational placement of an object or a portion of an object (three degrees of rotational freedom - e.g., roll, pitch, and yaw). As used herein, the term "pose" refers to the position of an object or a portion of an object in at least one degree of translational freedom and to the orientation of that object or portion of the object in at least one degree of rotational freedom (up to six total degrees of freedom). As used herein, the term "shape" refers to a set of poses, positions, or orientations measured along an object.

[0026] FIG. 1 shows an exemplary minimally invasive surgical system 100 that includes a steerable needle 110 that can be manipulated during a surgical procedure by an actuator 130. As used herein, steerable needles refer to a broad category of flexible needles with control inputs (i.e., actuator 130) at the base (i.e., outside the body of the patient) and distal regions meant for piercing or puncturing target tissue. Such needles can be used for diagnosis and/or treatment of difficult to access targets in a patient, such as in prostate biopsy, lung biopsy, liver biopsy, and brachytherapy, among others. Note that in various embodiments, system 100 can include any number of steerable needles, as indicated by optional steerable needle 110-2 (along with any actuation, control, sensing, and/or processing elements required for the additional needles 110).

[0027] Actuator 130 can manipulate needle 110, for example, by steering needle 110 along a desired surgical trajectory to a target location within the patient, changing the shape of needle 110, and/or changing the orientation of needle 110. As described in greater detail below, in some embodiments, the needle may include a tip geometry that imparts a directional motion as the tip passes through tissue, such that the control inputs can simply be a handle(s) or other control to axially rotate the needle. In other embodiments, the needle may include wires, cables, or any other actuation mechanism to allow for more direct control over the shape and direction of travel of the needle. In such embodiments, the control inputs would be configured to provide the appropriate manipulation or actuation signals/energy to the actuation mechanism(s) of the needle.

[0028] System 100 further includes a continuous shape sensor 120 that is substantially aligned with at least a portion of steerable needle 110. Regardless of the specific steering mechanism provided for needle 110, usability of system 100 in a minimally invasive surgical procedure is enhanced by the inclusion of shape sensor 120. As described in greater detail below, the data read by shape sensor 120 is acquired and converted into usable shape information by a processor 140. The shape information can then be used to guide further manipulation of needle 110. A shape sensor is an elongate sensor that provides shape measurement over the length of the sensor. In contrast to a discrete position sensor, a shape sensor enables shape measurement via a single sensor. Note that a shape sensor may include a single continuous sensing region or multiple sensing regions distributed over the length of the sensor, so long as the data from the shape sensor as a whole can be used to determine

the measured shape. The integrated nature of a shape sensor can be particularly useful in delivering accurate shape measurement of needle 110. This in turn can enable more precise control and/or enhanced error correction to ensure that needle 110 accurately traverses a desired surgical trajectory.

[0029] Note that although shape sensor 120 is depicted and described as a single shape sensor for explanatory purposes, in various embodiments shape sensor 120 can include multiple shape sensors, where each shape sensor measures the shape of a continuous portion of the overall length of needle 110. Also, in various other embodiments, needle 110 can include multiple parallel shape sensors, as indicated by optional additional shape sensor(s) 120-2. Such multiple shape sensors can be used, for example, to provide for greater shape modeling precision or to compensate for temperature or other sensor-affecting factors. Various other usages will be readily apparent.

[0030] Shape sensor 120 can be coupled to needle 110 in a variety of ways. For example, FIG. 3A shows shape sensor 120 housed in a lumen 112A in a wall 110W of needle 110. Wall 110W further defines an interior needle lumen 111 for surgical use (e.g., material delivery or biopsy). In various embodiments, an optional securing feature 121A (e.g., a slot, ridge, threads, shoulder, or any other feature) can be provided on needle 110 (e.g., at the distal end region or anywhere along lumen 112A) to assist in securing, aligning, and/or orienting sensor 120 with needle 110. In such embodiments, shape sensor 120 can itself include a corresponding mating feature(s).

[0031] FIG. 3B shows another embodiment of needle 110 in which shape sensor 120 is attached to the outer surface of wall 110W. In some embodiments, wall 110W can include an optional outer groove 112B that can help to capture and/or align sensor 120 with needle 110. In various other embodiments, an optional securing feature 121B (e.g., a slot, ridge, threads, shoulder, or any other feature) can be provided on needle 110 (e.g., at the distal end region or anywhere along groove 112B) to assist in securing, aligning, and/or orienting sensor 120 with needle 110. In such embodiments, shape sensor 120 can itself include a corresponding mating feature(s).

[0032] FIG. 3C shows another embodiment of needle 110 in which shape sensor 120 is attached to the inner surface of wall 110W. In some embodiments, wall 110W can include an optional inner groove 112C that can help to capture and/or align sensor 120 with needle 110. In various other embodiments, an optional securing feature 121C (e.g., a slot, ridge, threads, shoulder, or any other feature) can be provided on needle 110 (e.g., at the distal end region or anywhere along groove 112C) to assist in securing, aligning, and/or orienting sensor 120 with needle 110. In such embodiments, shape sensor 120 can itself include a corresponding mating feature(s).

[0033] Note that in various other embodiments, multiple shape sensors 120 can be incorporated into needle 110. For example, and shown in FIG. 1A, an optional second shape sensor 120-2 can be affixed to needle 110 to provide additional shape measurement data for enhanced accuracy, error correction, temperature compensation, etc. Note that while both sensors are depicted as being positioned within inner lumen 111 of needle 110 for exemplary purposes, in various other embodiments, both shape sensors 120 can be on the outer surface of needle 110, or within wall 110W, or in any combination of inner surface, outer surface, and in-wall placements. Note further that any number of shape sensors 120 can be present, and in any relative arrangement along needle 110.

[0034] FIG. 3D shows another embodiment of needle 110 in which shape sensor 120 is positioned within needle lumen 111. This configuration allows shape measurements of needle 110 to be taken during insertion and navigation until the surgical target location is reached. Shape sensor 120 can then be removed, as shape and position information is no longer required, and the surgical procedure can be performed using the (now clear) needle lumen 111. In various embodiments, shape sensor 120 can be replaced within needle lumen 111 prior to removal of needle 110 from the patient. In some embodiments, shape sensor 120 can be part of a flexible stylet or guidewire sized to fit within needle lumen 111. The placement of shape sensor 120 within needle lumen 111 beneficially avoids impact to needle wall 110W and can allow for the use of larger diameter and potentially more accurate shape sensors 120.

[0035] Note further that the tip design for steerable needle 110 can take any form or shape as required for the particular procedural requirements of a surgical procedure. In some embodiments, needle 110 can include a bevel tip (e.g., Baker needle tip), as shown in FIGS. 3A-3D. In various other embodiments, alternative tip geometries can be used. For example, FIG. 3E shows needle 110 with a rounded tip (e.g., Tuohy needle tip), and FIG. 3F shows needle 110 with a solid tip (e.g., Sprotte needle tip). Various other tip designs will be readily apparent.

[0036] As further shown in FIG. 3F, in some embodiments needle 110 can include optional additional sensors 315 to provide further usage information. For example, sensor 315 can be a position sensor (e.g., EM sensor, accelerometer, etc.) providing localized position data that can be used with the shape data from shape sensor 120 to model the in-situ pose and/or shape of needle 110. Although depicted in the solid distal tip 311 of needle 110 in FIG. 3F for exemplary purposes, in various other embodiments, additional sensor(s) 315 can be located anywhere on needle 110, regardless of specific needle configuration.

[0037] Likewise, various mechanisms can be used to steer needle 110. For example, depending on the shape and mechanical properties of needle 110, interaction forces between needle 110 and the patient anatomy (i.e., the target tissue and/or any intervening anatomy between the surgical entry point and the target tissue) can

cause needle 110 to deflect as it is advanced through that patient anatomy. The mechanism may be actuated, manually or automatically, using information from the shape sensor as input.

[0038] For example, in various embodiments, needle 110 can be made from a highly flexible material (e.g., nitinol) and have an asymmetric bevel tip or pre-bent tip, such as shown in FIG. 1A. When inserted into tissue, the bevel tip will cause needle 110 to move in a curved trajectory in the direction of the bevel. Steerability is provided by rotating needle 110 axially to cause the bevel direction, and hence the needle trajectory, to change. In such cases, actuator 130 can be anything from a knob(s), handle(s), or other manual interface, to active drivers such as a servo motor, or combinations of manual and automated actuators.

[0039] In various other embodiments, needle 110 can be steered via more active mechanisms. For example, FIG. 2A shows an embodiment of needle 110 formed from multiple coaxial curved needle segments 210A, 210B, 210C, and 210D. Note that while four needle segments 210 are depicted for exemplary purposes, in various other embodiments needle 110 can include any number of segments. In use, actuator 130 can control the relative rotation and extension of segments 210A-210D, thereby determining the shape and orientation of needle 110. FIG. 2B shows another embodiment of needle 110 in which one or more control cables 215 are provided to which tension and/or extension forces can be applied to cause desired bending of needle 110. Cable(s) can be controlled via mechanical tensioners, motor actuators, or any other mechanism. For example, in some embodiments, cable(s) 215 can include material that responds to thermal changes, such as nitinol wire(s) configured to contract in response to electrical current-induced heating (such as described in "A Nitinol Wire Actuated Stewart Platform", by Dunlop et al. (Proc. 2002 Australasian Conference on Robotics and Automation, November 27-29, 2002)). Various other steering mechanisms will be readily apparent.

[0040] Regardless of the specific steering mechanism used with flexible needle 110, the usability of system 100 in a minimally invasive surgical procedure is enhanced by the inclusion of shape sensor 120 and the shape information provided therefrom. Furthermore, such benefit accrues regardless of the particular mode of control applied to needle 110. Specifically, in various embodiments, system 100 can be a purely manual system (e.g., an endoscopic instrument), in which actuator 130 is directly controlled by an optional manual controller 150, as shown in FIG. 1A. In some embodiments, optional manual controller 150 can be actuator 130 (e.g., a knob, handle, or grip for rotating needle 110), and in other embodiments optional manual controller can be a handle(s), trigger(s), lever(s), grip(s), and/or any other user interface for providing control inputs to actuator 130, either via direct mechanical attachment or linkage, via electrical/electronic control, or any combination of the above. In various other embodiments, system 100 can be a robotic system in which control over needle 110 is provided via a console or other remote interface of an optional robotic platform 160. In yet other embodiments, system 100 can incorporate elements of both direct control and robotic control (e.g., robotic system with manual override) and therefore include both optional manual controller 150 and optional robotic platform 160.

[0041] In robotically-assisted or telerobotic surgery, the surgeon typically operates a control device to control the motion of surgical instruments at the surgical site from a location that may be remote from the patient (e.g., across the operating room, in a different room or a completely different building from the patient) or immediately adjacent to the patient. Thus in some embodiments, robotic platform 160 can include one or more manually-operated input devices, such as joysticks, exoskeletal gloves or the like, which are coupled (directly or indirectly) to actuator 130 with servo motors or other drive mechanisms for steering needle 110 to the surgical site. During a procedure, robotic platform 160 can, in some embodiments, provide mechanical articulation and control of a variety of surgical instruments in addition to needle 110, such as tissue graspers, electrosurgical cautery probes, retractors, staplers, vessel sealers, endoscopes, scalpels, ultrasonic shears, suction/irrigation instruments, and the like, that each perform various functions for the surgeon, e.g., grasping a blood vessel, or dissecting, cauterizing or coagulating tissue.

[0042] Shape sensor 120 can be any type of shape sensor capable of measuring the curvature of flexible needle 110 during surgical use. For example, in various embodiments, shape sensor 120 can include a fiber optic shape sensor, such as described with respect to the systems and methods for monitoring the shape and relative position of a optical fiber in three dimensions described in U.S. patent application publication 2006013523, filed on Jul. 13, 2005; U.S. patent application publication 2008212082, filed on Jul. 16, 2004, and U.S. Pat. No. 6,389,187, filed on Jun. 17, 1998. In some embodiments, an optical fiber in shape sensor 120 can comprise one or more cores (either single- and/or multi-mode) contained within a single cladding. Multi-core constructions can be configured to provide sufficient distance and cladding separating the cores such that the light in each core does not interact significantly with the light carried in other cores. In other embodiments, shape sensor 120 can include any number of optical fibers with the same or varying numbers of cores. In other embodiments, one or more of the cores in the optical fiber can be used for illumination and/or ablation.

[0043] In certain embodiments, shape sensor 120 can be a fiber optic bend sensor that includes a backscatter mechanism such as fiber Bragg gratings (FBGs), such as in product from Luna Innovations, Inc. (Blacksburg, VA). In such embodiments, an array of FBGs can be provided within each core that comprises a series of modulations of the core's refractive index so as to generate a

spatial periodicity in the refraction index. The spacing may be chosen so that the partial reflections from each index change add coherently for a narrow band of wavelengths, and therefore reflect only this narrow band of wavelengths while passing through a much broader band. During fabrication of the FBGs, the modulations are spaced by a known distance, thereby causing reflection of a known band of wavelengths. However, when a strain is induced on the fiber core, the spacing of the modulations will change, depending on the amount of strain in the core.

[0044] To measure strain, light is sent down the fiber, and the reflected wavelength is a function of the strain on the fiber and its temperature. This FBG technology is commercially available from a variety of sources, such as Smart Fibres Ltd. of Bracknell, England. When applied to a multicore fiber, bending of the optical fiber induces strain on the cores that can be measured by monitoring the wavelength shifts in each core. By having two or more cores disposed off-axis in the fiber, bending of the fiber induces different strains on each of the cores. These strains are a function of the local degree of bending of the fiber. Regions of the cores containing FBGs, if located at points where the fiber is bent, can thereby be used to determine the amount of bending at those points. These data, combined with the known spacings of the FBG regions, can be used to reconstruct the shape of the fiber.

[0045] Note, however, that while the use of FBGs are described above for exemplary purposes, any mechanism for creating backscatter could be used in shape sensor 120, such as Rayleigh scattering, Raman scattering, Fluorescence scattering, and Brillouin scattering, among others. Typically, fiber optic shape sensors operate via optical time domain reflectometry (OTDR) or via optical frequency domain reflectometry (OFDR). The Kerr effect can also be used in shape sensor 120.

[0046] Note further that in various other embodiments, any flexible, elongate sensor or combination of sensors can be used as shape sensor 120. In various embodiments, shape sensor 120 can include a bend-enhanced fiber (BEF) sensor, such as ShapeTape from Measurand Inc. (Fredericton, New Brunswick, Canada), flexible piezoresistive sensor arrays or wire strain detectors (such as described in "ULTRA-SENSITIVE SHAPE SENSOR TEST STRUCTURES BASED ON PIEZO-RESISTIVE DOPED NANOCRYSTALLINE SILICON", Alpuim et al. (NanoSpain2008, April 14-18, 2008), and in "Electromechanical analysis of a piezoresistive pressure microsensor for low-pressure biomedical applications", Herrera-May et al. (REVISTA MEXICANA DE FI'SICA 55 (1) 14-24 February 2009)), a nitinol wire for resistive strain measurement, an unaltered polarization-maintaining (PM) optical fiber, and/or any other shape sensing technologies.

[0047] Processor 140 detects the shape and position of steerable needle 110 and processes that information to assist in surgical procedures. Processor 140 is configured to interface with the specific type of sensor(s) in shape sensor 120 (e.g., providing interferometry and/or reflectometry capabilities for use with optical fiber sensors, or providing a voltage and/or current meter for use with resistance-based sensors). FIG. 1B shows an exemplary embodiment of processor 140 for processing the measurement data from a fiber optic shape sensor 120. In view of this disclosure, instructions and modules used in any one of, or any combination of operations described with respect to processor 140 can be implemented in a wide variety of software and/or hardware architectures, such as software code modules running on dedicated processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), or any other logic implementation, alone or in any combination.

[0048] Processor 140 in FIG. 1B includes an interrogator 141, an input/output module 142, a processor module 143, and a shape data processing module 144. Interrogator 141 interrogates the optical fiber of shape sensor 120 and provides shape information to input/output module 142. Processor module 143 then processes the information from input/output module 142 using a shape data processing module 144 (e.g., stored in memory within processor 140). The generated shape information for needle 110 can then be used to model the in-situ pose and/or shape of needle 110. In some embodiments, known reference frame data (e.g., the position and orientation of actuator 130/proximal end region of needle 110) can be combined with the shape information for needle 110 to determine the in-situ pose and/or shape. In various other embodiments, positional measurements taken of needle 110 (e.g., via additional sensors on needle 110 or through visualization tracking) can be used with the shape data from shape sensor 120 to determine the in-situ pose and/or shape. More detailed description of an exemplary pose-determination process is provided in copending and commonly assigned U.S. patent application publications 2009324161 and 2011119023.

[0049] Note that in various embodiments, processor 140 (or system 100) can include optional additional processing modules to make use of the shape data provided by shape sensor 120. In some embodiments, an optional path planning module 145 can be included to identify an appropriate trajectory (or multiple trajectory options) for either fully- or semi-automated control or for providing guidance for manual control over system 100. In various other embodiments, if automated or semi-automated control is provided by system 100, an optional control planning module 146 can be included to generate the appropriate control signals for actuator 130, for example based on the output of path planning module 145.

[0050] In various other embodiments, an optional error detection module 147 can be included to compare measured shape, pose, and/or position data against expected values (e.g., desired values or values predicted from a mathematical model). For example, in some embodiments, the measured data can be compared against model data to validate and/or update the model data. In

other embodiments, the measured data can be compared to target data (e.g., comparing actual trajectory of needle 110 to a desired trajectory) to avoid excessive deviation from a desired behavior. In some embodiments, such error detection can provide notification to the surgeon via visual, aural, or tactile cues or reports. In various other embodiments, deviations can be presented graphically (e.g., on a video monitor, overlaying actual trajectory onto desired trajectory). In such embodiments, an optional graphics module 148 can also be included in processor 140 to provide the necessary graphical representation of the measurements of shape sensor 120. In other embodiments, graphics module 148 can be included simply to provide a visual representation of the shape data measured by shape sensor 120.

[0051] As noted above, a surgical procedure can be beneficially enhanced by measuring the shape of a steerable needle and then controlling the needle (e.g., adjusting the shape of the needle, changing the orientation of the needle (e.g., axial rotation), advancing/retracting the needle, etc.) based on that measured shape. Note that while the descriptions herein refer to the use of a steerable flexible needle with shape sensor in surgical applications for exemplary purposes, the same methods and procedures can be use in animals (e.g., veterinary use), cadavers, artificial anatomic replicas, and/or computer simulations of surgical procedures.

[0052] FIG. 4 shows an exemplary flow diagram for the use of shape sensing in such a procedure. In a Shape Measurement step 410, the shape of a steerable flexible needle (such as needle 110 described above) is measured. The measurement can be performed using any type of shape sensor capable of providing real time shape information for the flexible needle (such as shape sensor 120 described above). Then, in a Shape Modeling step 420, the measured data is used to model the actual shape of the flexible needle.

[0053] Note that depending on the requirements of the surgical system and procedure itself, the specific level of shape modeling in step 420 can vary. For example, in some embodiments, step 420 may simply involve determining the standalone shape of the needle - for example to determine if the needle has reached a desired deployed state. In some other embodiments, step 420 can involve determining the shape of the needle along with its orientation (e.g., using additional reference frame information from the proximal (attachment) region of the needle to the actuator (such as actuator 130, above), or from additional sensor data (such as sensor 315 above)). For example, FIG. 5 shows an embodiment of the flow diagram of FIG. 4 that includes an optional Pose Modeling step 522.

[0054] The continuous shape modeling of step 420 can provide a significant procedural advantage over approaches limited to the use of catheters having a single position sensor (or several discrete sensors at particular locations), which can only estimate shape and orientation by assuming perfect mechanical transfer between the inputs and the measured locations. The actual shape measurements of step 420 can allow total insertion depth of the needle to be accurately determined, along with distal tip position and orientation. This determination can be made regardless of the torsional and axial flexibility of the needle and any effects of friction and normal forces between the needle and the patient tissue, which would otherwise need to be precisely modeled to produce similar results using a discrete sensor system - an unwieldy and likely unmanageable approach for most surgical applications.

[0055] In some embodiments, step 420 can include the identification or refinement of model parameters in a biomechanical model of the tissue and/or kinematic model of the needle system, as indicated by optional Adjust Model Parameters step 523 in FIG. 5. For example, the actual behavior of the needle (e.g., bend radius) as it traverses a patient tissue or anatomical structure can be used to derive tissue density, changes in material (e.g., diseased or degenerative tissue regions exhibiting unexpected material properties, such as tumors, cysts, osteoporosis, etc.), or other difficult to predict and model anatomical aspects. In other embodiments, the actual needle trajectory can be used to estimate and update kinematic mapping between the actuator inputs and the actual needle movement (e.g., the tip and/or the shaft of the needle), thereby improving the responsiveness and accuracy of the needle control. In other embodiments, the actual needle trajectory can be used to calculate loading of the needle, at discrete locations or along its entire length, since the curvature(s) of the needle will be dependent at least in part on the local forces applied to the needle.

[0056] In some other embodiments, the pose information determinable in step 420 can be beneficially used to indicate or visualize the actual placement of the needle within a patient or the actual surgical trajectory being followed by the needle, as in an optional Path Modeling step 430. For example, step 430 can include using the needle shape information determined in step 420 to determine one or more target trajectories for the continuing advance of the needle (e.g., based on needle properties, anatomical model properties, needle behavior up to current location, supplemental anatomical information (e.g., visualization, enhanced material properties based on actuation force required by needle, etc.), and/or any other path-affecting information), as indicated by an optional Path Planning step 531 in FIG. 5.

[0057] In various other embodiments, steps 420 and/or 430 can include comparing the actual needle shape and/or trajectory with an expected or desired shape/trajectory. Any deviation from the desired shape/trajectory can be identified and/or used to provide feedback to the surgeon as to potential corrective actions, depending on the magnitude of the deviation. For example, FIG. 6 shows a flow diagram in which step 420 includes an optional Detect Shape Deviation step 621 in which the measured shape is compared to an expected shape. The

deviation can then be assessed in an Exceeds Threshold? step 622, where if the deviation is greater than some preset limit, a notification is provided in an Error State step 623. This notification can take any form, including a visual warning, an audible warning, an error message, a tactile indication, warning icon, and/or system freeze/recovery action, among others. In some embodiments, step 623 can result in procedure abort or restart, due to excessive needle deformation. In various other embodiments, if the shape deviation is less than a maximum deviation, a determination is made in an optional Correction Required? step 624, wherein if the deviation is small enough, no adjustment to the needle shape is made, and the process simply continues. However, if the deviation is determined to require correction, such correction can be calculated in a Determine Adjustment step 625. This adjustment can be provided to the surgeon as instructions, graphical representation, or any other means for conveying the information to the surgeon, or can be provided automatically to the system to cause automatic correction of the needle shape (e.g., providing appropriate control signals to the needle actuator).

[0058] In another example, FIG. 7 shows a flow diagram in which step 430 includes an optional Detect Path Deviation step 731 in which the measured needle trajectory is compared to an expected trajectory (e.g., a preoperatively determined trajectory or an intraoperatively modeled trajectory). The deviation can then be assessed in an Exceeds Threshold? step 732, where if the deviation is greater than some preset limit, a notification is provided in an Error State step 733. This notification can take any form, including a visual warning, an audible warning, an error message, a tactile indication, warning icon, and/or system freeze/recovery action, among others. In some embodiments, step 733 can result in procedure abort or restart, due to excessive trajectory deviation. In various other embodiments, if the trajectory deviation is less than a maximum deviation, a determination is made in an optional Correction Required? step 624, wherein if the deviation is small enough, no adjustment to the needle shape and/or actuation control inputs is made, and the process simply continues. However, if the deviation is determined to require correction, such correction can be calculated in a Determine Adjustment step 625. This adjustment can be provided to the surgeon as instructions, graphical representation, or any other means for conveying the information to the surgeon, or can be provided automatically to the system to cause automatic correction of the needle trajectory (e.g., providing appropriate control signals to the needle actuator).

[0059] In some other embodiments, the shape and/or position of the needle can also be adjusted in an optional Needle Control step 440. For example, the shape and/or path information derived from step 420 and optional step 430, respectively, can be used to determine the appropriate advancement/retraction and/or shape adjustment for the needle. For instance, if steps 420 and/or 420 indicate that the needle shape is sub-optimal for completion of the desired procedure, the needle can be adjusted towards a more optimized shape in step 440 (e.g., by actively changing the needle shape, by changing the needle orientation to cause the desired shape change during advancement/retraction, and/or by performing any other shape-affecting action). Similarly, if steps 420 and/or 430 indicate that the trajectory of the needle is sub-optimal for completion of the desire procedure, the needle can be adjusted towards a more optimized path in step 440 (e.g., by changing needle shape, by changing the needle orientation (e.g., rotation), retracting the needle, and/or any other trajectory-impacting action). In various embodiments, this shape and/or trajectory adjustment can be performed manually, in response to surgeon cues (e.g., visual indication of deviation, sounds, or tactile indications when a deviation from the desired path is detected), automatically, or any combination of the above. In some embodiments, the specific controls applied to the needle actuator can be determined based on the shape sensor data, as indicated by an optional Control Planning step 532 in FIG. 5.

[0060] All examples and illustrative references are non-limiting and should not be used to limit the claims to specific implementations and embodiments described herein and their equivalents. The headings are solely for formatting and should not be used to limit the subject matter in any way, because text under one heading may cross reference or apply to text under one or more headings. Finally, in view of this disclosure, particular features described in relation to one aspect or embodiment may be applied to other disclosed aspects or embodiments of the disclosure, even though not specifically shown in the drawings or described in the text.

Claims

1. A flexible needle (110) comprising:

a flexible elongate needle body with a needle lumen extending therein, the elongate needle body including a distal region configured to pierce or puncture target tissue;
a shape sensor (120) coupled to the elongate needle body; and
a connector adapted for connecting the shape sensor (120) to a processor (140) for determining the shape of the elongate flexible needle body based on data from the shape sensor (120).

2. The flexible needle (110) of claim 1 wherein the shape sensor (120) comprises at least one of an optical fiber with a fiber Bragg grating, a nitinol wire, and a piezoresistive element, or
wherein the flexible elongate needle body includes a wall (110 W) defining an interior lumen (112A), wherein the shape sensor (120) is removably insert-

able into the interior lumen (112A), or
wherein the flexible elongate needle body includes a wall (110 W) having an interior surface and an exterior surface, the interior surface defining an interior lumen (111),
wherein a second lumen (112A) is defined between the interior surface and the exterior surface, and
wherein the shape sensor (120) is positioned at least partially within the second lumen (112A), or
wherein the flexible elongate needle body includes a plurality of concentric curved segments (210 A-D), wherein each of the plurality of concentric curved segments (210 A-D) is independently rotatable and extendible and wherein a most distal segment of the plurality of concentric curved segments (210 A-D) includes the distal region configured to pierce or puncture target tissue, or
further comprising at least one control cable (215), wherein flexion of the flexible elongate needle body is controlled by the control cable (215), or
wherein the distal tip region comprises one of a bevel tip, a curved tip, and a solid tip that terminates at a point configured to pierce or puncture target tissue, or
further comprising a second shape sensor (120-2), at least a portion of the second shape sensor (120-2) being substantially parallel to at least a portion of the shape sensor (120), wherein the connector is further adapted for connecting the second shape sensor (120-2), to the processor (140) for determining the shape of the flexible needle (110) based on data from the shape sensor (120) and the second shape sensor (120-2), or
further comprising a position sensor (315), wherein the connector is further adapted for connecting the position sensor (315) to the processor (140) for determining a position of a section of the flexible needle (110) based on data from the position sensor (315).

3. The flexible needle (110) of claim 1 wherein the flexible elongate needle body includes a wall (110 W) defining the needle lumen, wherein the shape sensor (120) is attached to the wall (110W), and preferably wherein the shape sensor (120) is attached to an external surface of the wall (110W), and preferably wherein the shape sensor (120) is attached to an internal surface of the wall (110W).

4. The flexible needle (110) of Claim 3, wherein the wall (110 W) comprises a groove (112 B, C), and wherein the shape sensor (120) is at least partially positioned within the groove (112 B, C), and preferably
wherein the groove (112 B, C), comprises one or more positioning features (121A-C) mated with the shape sensor (120) and wherein the one or more positioning features (121A-C) prevents movement of the shape sensor (120) along the groove (112 B, C), and preferably
wherein the one or more positioning features (121A-C) comprises at least one of a slot, a ridge, and a threaded section.

5. A surgical system (100) comprising:

a flexible needle (110) according to any of claims 1 to 4; and
an actuator (130) for manipulating the flexible needle (110).

6. The surgical system of claim 5 further including the processor (140) for determining a shape of the flexible needle (110) based on data from the shape sensor (120).

7. The surgical system of Claim 5, wherein the flexible elongate needle body of the flexible needle comprises a wall (110 W) defining an interior lumen (112A) and wherein the shape sensor (120) is removably insertable into the interior lumen (112A) and wherein the shape sensor (120) comprises a stylet sized to fit within the interior lumen (112A).

8. The surgical system of Claim 5, wherein the flexible elongate needle body of the flexible needle (110) comprises a wall (110 W) defining the needle lumen of the flexible elongate needle body, and
wherein the shape sensor (120) is attached to the wall (110 W),
wherein the groove (112 B, C), comprises one or more positioning features (121A-C) mated with the shape sensor (120),
wherein the one or more positioning features (121A-C) prevents movement of the shape sensor (120) along the groove (112 B, C), and
wherein the one or more positioning features (121A-C) comprises at least one of a slot, a ridge, and a threaded section.

9. The surgical system of Claim 5, wherein the flexible needle (110) comprises a solid needle tip.

10. The surgical system of claim 5 further comprising a second shape sensor (120-2), at least a portion of the second shape sensor (120-2) being substantially parallel to at least a portion of the shape sensor (120), wherein the connector is further adapted for connecting the second shape sensor (120-2) to the processor (140) for determining the shape of the flexible needle (110) based on data from the shape sensor (120) and the second shape sensor (120-2), and wherein each of the shape sensor (120) and the second shape sensor (120) are attached to different concentric curved segments (210 A-D) of the flexible elongate needle body.

11. The surgical system of Claim 5, further comprising

a position sensor (315) attached to a section of the flexible needle (110), the processor (140) being configured to determine a position of the section based on data from the position sensor (315).

12. The surgical system of Claim 11, wherein the position sensor (315) is attached to a distal tip of the flexible needle (110).

13. The surgical system of Claim 12, further comprising a manual controller for allowing direct user control over the actuator (130).

14. The surgical system of Claim 5, further comprising a robotic surgical platform coupled to the actuator (130).

15. The surgical system of Claim 5 wherein the flexible needle (110) is a transcutaneous biopsy needle, or an endoscopic biopsy needle, or is adapted to deliver a tissue ablation device, or is adapted to deliver radioactive seeds.

Patentansprüche

1. Eine biegsame Nadel (110), die Folgendes beinhaltet:

einen biegsamen länglichen Nadelkörper mit einem sich darin erstreckenden Nadellumen, wobei der längliche Nadelkörper eine distale Region umfasst, die zum Durchbohren oder Durchstechen von Zielgewebe ausgelegt ist;
einen Formsensor (120), der mit dem länglichen Nadelkörper gekoppelt ist; und
ein Verbindungsstück, das dazu angepasst ist, den Formsensor (120) mit einem Prozessor (140) zu verbinden, um die Form des länglichen biegsamen Nadelkörpers auf der Grundlage der Daten von dem Formsensor (120) zu bestimmen.

2. Biegsame Nadel (110) nach Anspruch 1, wobei der Formsensor (120) mindestens eines von einer optischen Faser mit einem Bragg-Fasergitter, einem Nitinoldraht und einem piezoresistiven Element beinhaltet, oder
wobei der biegsame längliche Nadelkörper eine Wand (110W) umfasst, die ein Innenlumen (112A) definiert, wobei der Formsensor (120) entfernbar in das Innenlumen (112A) eingeführt werden kann, oder
wobei der biegsame längliche Nadelkörper eine Wand (110W) umfasst, die eine innere Oberfläche und eine äußere Oberfläche aufweist, wobei die innere Oberfläche ein Innenlumen (111) definiert,
wobei ein zweites Lumen (112A) zwischen der inneren Oberfläche und der äußeren Oberfläche definiert ist, und
wobei der Formsensor (120) mindestens teilweise innerhalb des zweiten Lumens (112A) positioniert ist, oder
wobei der biegsame längliche Nadelkörper eine Vielzahl von konzentrischen, gebogenen Segmenten (210A-D) umfasst, wobei jedes von der Vielzahl von konzentrischen, gebogenen Segmenten (210A-D) unabhängig drehbar und ausziehbar ist und wobei ein am distalsten gelegenes Segment von der Vielzahl von konzentrischen, gebogenen Segmenten (210 A-D) die distale Region, die zum Durchbohren oder Durchstechen von Zielgewebe ausgelegt ist, umfasst oder
ferner mindestens ein Steuerkabel (215) beinhaltet, wobei die Biegung des biegsamen länglichen Nadelkörpers durch das Steuerkabel (215) gesteuert wird, oder
wobei die distale Spitzenregion eine von einer schrägen Spitze, einer gebogenen Spitze und einer massiven Spitze beinhaltet, die an einem zugespitzten Punkt endet, der zum Durchbohren oder Durchstechen von Zielgewebe ausgelegt ist, oder
ferner einen zweiten Formsensor (120-2) beinhaltet, wobei mindestens ein Anteil des zweiten Formsensors (120-2) im Wesentlichen parallel zu mindestens einem Anteil des Formsensors (120) ist, wobei das Verbindungsstück ferner dazu angepasst ist, den zweiten Formsensor (120-2) mit dem Prozessor (140) zu verbinden, um die Form der biegsamen Nadel (110) auf der Grundlage der Daten von dem Formsensor (120) und dem zweiten Formsensor (120-2) zu bestimmen, oder
ferner einen Lagesensor (315) beinhaltet, wobei das Verbindungsstück ferner dazu angepasst ist, den Lagesensor (315) mit dem Prozessor (140) zu verbinden, um eine Lage eines Abschnitts der biegsamen Nadel (110) auf der Grundlage der Daten von dem Lagesensor (315) zu bestimmen.

3. Biegsame Nadel (110) nach Anspruch 1, wobei der biegsame längliche Nadelkörper eine Wand (110W) umfasst, die das Nadellumen definiert, wobei der Formsensor (120) an der Wand (110W) befestigt ist, und vorzugsweise
wobei der Formsensor (120) an einer äußeren Oberfläche der Wand (110W) befestigt ist, und vorzugsweise
wobei der Formsensor (120) an einer inneren Oberfläche der Wand (110W) befestigt ist.

4. Biegsame Nadel (110) nach Anspruch 3, wobei die Wand (110W) eine Kerbe (112B, C) beinhaltet und wobei der Formsensor (120) mindestens teilweise innerhalb der Kerbe (112B, C) positioniert ist und vorzugsweise
wobei die Kerbe (112B, C) ein oder mehrere Positi-

onierungsmerkmale (121A-C), die mit dem Formsensor (120) zusammenpassen, beinhaltet und wobei das eine oder die mehreren Positionierungsmerkmale (121A-C) die Bewegung des Formsensors (120) entlang der Kerbe (112B, C) verhindern und vorzugsweise
wobei das eine oder die mehreren Positionierungsmerkmale (121A-C) mindestens eines von einem Schlitz, einem Grat und einem Gewindeabschnitt beinhalten.

5. Ein chirurgisches System (100), das Folgendes beinhaltet:

eine biegsame Nadel (110) gemäß einem der Ansprüche 1 bis 4; und
einen Aktuator (130) zum Manipulieren der biegsamen Nadel (110).

6. Chirurgisches System nach Anspruch 5, das ferner den Prozessor (140) zum Bestimmen einer Form der biegsamen Nadel (110) auf der Grundlage der Daten von dem Formsensor (120) umfasst.

7. Chirurgisches System nach Anspruch 5, wobei der biegsame längliche Nadelkörper der biegsamen Nadel eine Wand (110W) beinhaltet, die ein Innenlumen (112A) definiert und wobei der Formsensor (120) entfernbar in das Innenlumen (112A) eingeführt werden kann und wobei der Formsensor (120) einen Mandrin beinhaltet, der so dimensioniert ist, dass er in das Innenlumen (112A) passt.

8. Chirurgisches System nach Anspruch 5, wobei der biegsame längliche Nadelkörper der biegsamen Nadel (110) eine Wand (110W) beinhaltet, die das Nadellumen des biegsamen länglichen Nadelkörpers definiert, und
wobei der Formsensor (120) an der Wand (110W) befestigt ist,
wobei die Kerbe (112B, C) ein oder mehrere Positionierungsmerkmale (121A-C) beinhaltet, die mit dem Formsensor (120) zusammenpassen,
wobei das eine oder die mehreren Positionierungsmerkmale (121A-C) die Bewegung des Formsensors (120) entlang der Kerbe (112B, C) verhindern und
wobei das eine oder die mehreren Positionierungsmerkmale (121A-C) mindestens eines von einem Schlitz, einem Grat und einem Gewindeabschnitt beinhalten.

9. Chirurgisches System nach Anspruch 5, wobei the biegsame Nadel (110) eine massive Nadelspitze beinhaltet.

10. Chirurgisches System nach Anspruch 5, das ferner einen zweiten Formsensor (120-2) beinhaltet, wobei mindestens ein Anteil des zweiten Formsensors (120-2) im Wesentlichen parallel zu mindestens einem Anteil des Formsensors (120) ist, wobei das Verbindungsstück ferner dazu angepasst ist, den zweiten Formsensor (120-2) mit dem Prozessor (140) zu verbinden, um die Form der biegsamen Nadel (110) auf der Grundlage der Daten von dem Formsensor (120) und dem zweiten Formsensor (120-2) zu bestimmen, und wobei jeder von dem Formsensor (120) und dem zweiten Formsensor (120) an verschiedenen konzentrischen, gebogenen Segmenten (210 A-D) des biegsamen länglichen Nadelkörpers befestigt ist.

11. Chirurgisches System nach Anspruch 5, das ferner einen Lagesensor (315) beinhaltet, der an einem Abschnitt der biegsamen Nadel (110) befestigt ist, wobei der Prozessor (140) dazu ausgelegt ist, eine Lage des Abschnitts auf der Grundlage der Daten von dem Lagesensor (315) zu bestimmen.

12. Chirurgisches System nach Anspruch 11, wobei der Lagesensor (315) an einer distalen Spitze der biegsamen Nadel (110) befestigt ist.

13. Chirurgisches System nach Anspruch 12, das ferner eine manuelle Steuereinrichtung beinhaltet, um direkte Kontrolle des Benutzers über den Aktuator (130) zu gestatten.

14. Chirurgisches System nach Anspruch 5, das ferner eine chirurgische Roboterplattform beinhaltet, die mit dem Aktuator (130) gekoppelt ist.

15. Chirurgisches System nach Anspruch 5, wobei die biegsame Nadel (110) eine transkutane Biopspienadel oder eine endoskopische Biopsienadel ist oder zur Zuführung einer Gewebeablationsvorrichtung angepasst ist oder zur Zuführung von radioaktiven Seeds angepasst ist.

Revendications

1. Aiguille flexible (110) comprenant :

un corps d'aiguille allongé flexible ayant une lumière d'aiguille s'étendant à l'intérieur de celui-ci, le corps d'aiguille allongé incluant une région distale configurée pour percer ou réaliser un trou dans un tissu cible ;
un capteur de forme (120) couplé au corps d'aiguille allongé ; et
un connecteur adapté pour connecter le capteur de forme (120) à un processeur (140) pour déterminer la forme du corps d'aiguille flexible allongé sur la base de données provenant du capteur de forme (120).

2. Aiguille flexible (110) selon la revendication 1, où le capteur de forme (120) comprend au moins l'un parmi une fibre optique ayant un réseau de Bragg sur fibre, un fil de nitinol, et un élément piézorésistif, ou où le corps d'aiguille allongé flexible inclut une paroi (110W) définissant une lumière intérieure (112A), où le capteur de forme (120) peut être inséré de manière amovible dans la lumière intérieure (112A), ou
où le corps d'aiguille allongé flexible inclut une paroi (110W) ayant une surface intérieure et une surface extérieure, la surface intérieure définissant une lumière intérieure (111),
où une seconde lumière (112A) est définie entre la surface intérieure et la surface extérieure, et
où le capteur de forme (120) est positionné au moins partiellement à l'intérieur de la seconde lumière (112A), ou
où le corps d'aiguille allongé flexible inclut une pluralité de segments incurvés concentriques (210A-D), où chacun des différents segments incurvés concentriques (210AD) peut indépendamment tourner et s'étendre et où un segment le plus distal des différents segments incurvés concentriques (210A-D) inclut la région distale configurée pour percer ou réaliser un trou dans un tissu cible, ou
comprenant en outre au moins un câble de commande (215), où une flexion du corps d'aiguille allongé flexible est commandée par le câble de commande (215), ou
où la région de pointe distale comprend l'une parmi une pointe conique, une pointe incurvée, et une pointe solide que se termine en un point configuré pour percer ou réaliser un trou dans un tissu cible, ou
comprenant en outre un second capteur de forme (120-2), au moins une partie du second capteur de forme (120-2) étant sensiblement parallèle à au moins une partie du capteur de forme (120), où le connecteur est en outre adapté pour connecter le second capteur de forme (120-2), au processeur (140) pour déterminer la forme de l'aiguille flexible (110) sur la base de données provenant du capteur de forme (120) et du second capteur de forme (120-2), ou
comprenant en outre un capteur de position (315), où le connecteur est en outre adapté pour connecter le capteur de position (315) au processeur (140) pour déterminer une position d'une section de l'aiguille flexible (110) sur la base de données provenant du capteur de position (315).

3. Aiguille flexible (110) selon la revendication 1, où le corps d'aiguille allongé flexible inclut une paroi (110W) définissant la lumière d'aiguille, où le capteur de forme (120) est fixé à la paroi (110W), et de préférence
où le capteur de forme (120) est fixé à une surface externe de la paroi (110W), et de préférence
où le capteur de forme (120) est fixé à une surface interne de la paroi (110W).

4. Aiguille flexible (110) selon la revendication 3, où la paroi (110W) comprend une rainure (112B, C), et où le capteur de forme (120) est au moins partiellement positionné à l'intérieur de la rainure (112B, C), et de préférence
où la rainure (112B, C) comprend une ou plusieurs caractéristiques de positionnement (121A-C) en correspondance avec le capteur de forme (120) et où la ou les caractéristiques de positionnement (121A-C) empêchent un mouvement du capteur de forme (120) le long de la rainure (112B, C), et de préférence où la ou les caractéristiques de positionnement (121A-C) comprennent au moins l'une parmi une fente, une crête, et une section filetée.

5. Système chirurgical (100) comprenant :

une aiguille flexible (110) selon l'une quelconque des revendications 1 à 4 ; et
un actionneur (130) pour manipuler l'aiguille flexible (110).

6. Système chirurgical selon la revendication 5, incluant en outre le processeur (140) pour déterminer une forme de l'aiguille flexible (110) sur la base de données provenant du capteur de forme (120).

7. Système chirurgical selon la revendication 5, où le corps d'aiguille allongé flexible de l'aiguille flexible comprend une paroi (110W) définissant une lumière intérieure (112A) et où le capteur de forme (120) peut être inséré de manière amovible dans la lumière intérieure (112A) et où le capteur de forme (120) comprend un stylet dont la taille est adaptée pour une insertion à l'intérieur de la lumière intérieure (112A).

8. Système chirurgical selon la revendication 5, où le corps d'aiguille allongé flexible de l'aiguille flexible (110) comprend une paroi (110W) définissant la lumière d'aiguille du corps d'aiguille allongé flexible, et où le capteur de forme (120) est fixé à la paroi (110W),
où la rainure (112B, C) comprend une ou plusieurs caractéristiques de positionnement (121A-C) en correspondance avec le capteur de forme (120),
où la ou les caractéristiques de positionnement (121A-C) empêchent un mouvement du capteur de forme (120) le long de la rainure (112B, C), et
où la ou les caractéristiques de positionnement (121A-C) comprennent au moins l'une parmi une fente, une crête, et une section filetée.

9. Système chirurgical selon la revendication 5, où l'aiguille flexible (110) comprend une pointe d'aiguille solide.

10. Système chirurgical selon la revendication 5, comprenant en outre un second capteur de forme (120-2), au moins une partie du second capteur de forme (120-2) étant sensiblement parallèle à au moins une partie du capteur de forme (120), où le connecteur est en outre adapté pour connecter le second capteur de forme (120-2) au processeur (140) pour déterminer la forme de l'aiguille flexible (110) sur la base de données provenant du capteur de forme (120) et du second capteur de forme (120-2), et où chacun du capteur de forme (120) et du second capteur de forme (120) est fixé à différents segments incurvés concentriques (210A-D) du corps d'aiguille allongé flexible.

11. Système chirurgical selon la revendication 5, comprenant en outre un capteur de position (315) fixé à une section de l'aiguille flexible (110), le processeur (140) étant configuré pour déterminer une position de la section sur la base de données provenant du capteur de position (315).

12. Système chirurgical selon la revendication 11, où le capteur de position (315) est fixé à une pointe distale de l'aiguille flexible (110).

13. Système chirurgical selon la revendication 12, comprenant en outre un dispositif de commande manuel permettant une commande directe par l'utilisateur sur l'actionneur (130).

14. Système chirurgical selon la revendication 5, comprenant en outre une plate-forme de chirurgie robotique couplée à l'actionneur (130).

15. Système chirurgical selon la revendication 5, où l'aiguille flexible (110) est une aiguille de biopsie transcutanée, ou une aiguille de biopsie endoscopique, ou est adaptée pour administrer un dispositif d'ablation de tissu, ou est adaptée pour administrer des grains radioactifs.

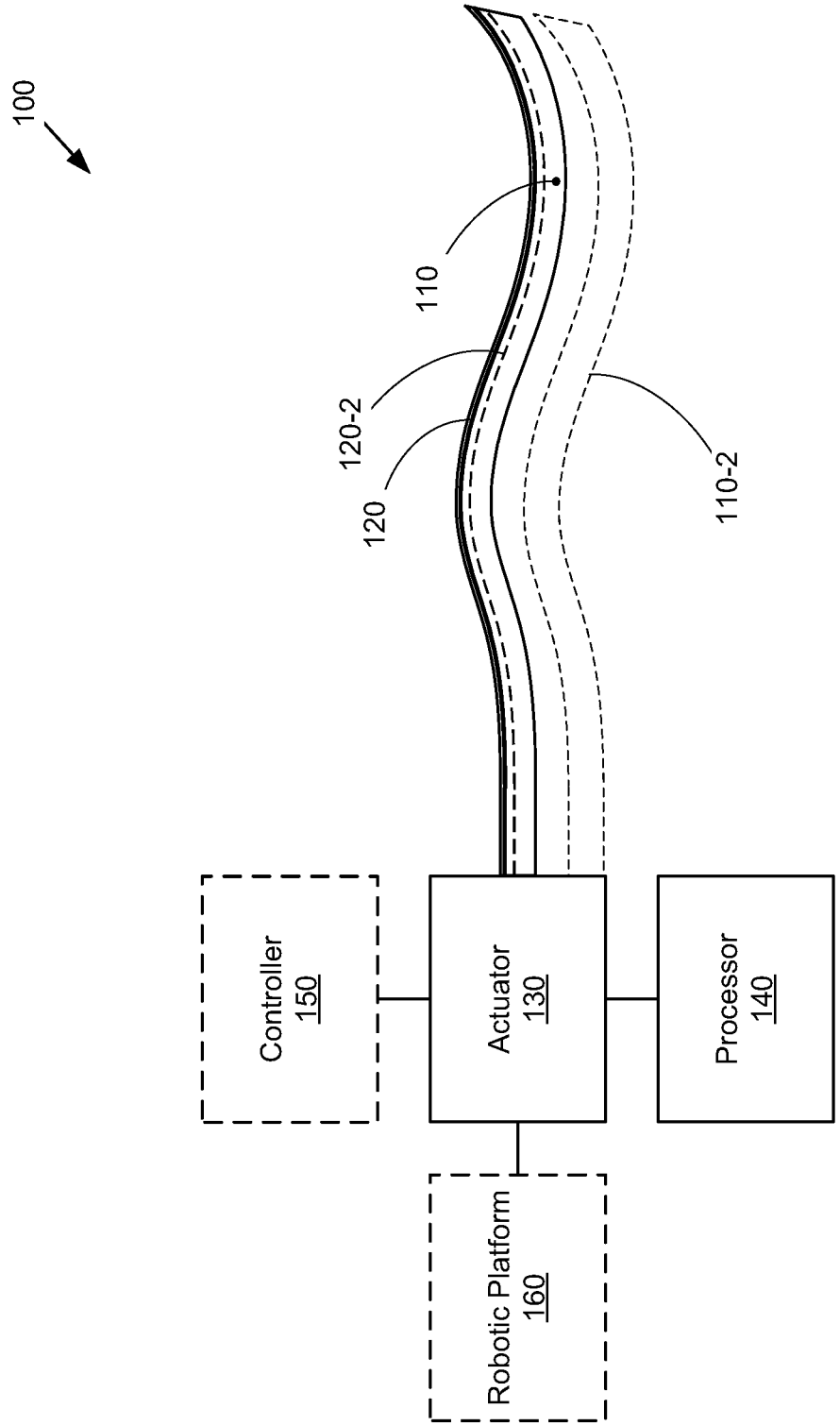

100
110
120-2
120
110-2
Controller
150
Actuator
130
Processor
140
Robotic Platform
160

FIG. 1A

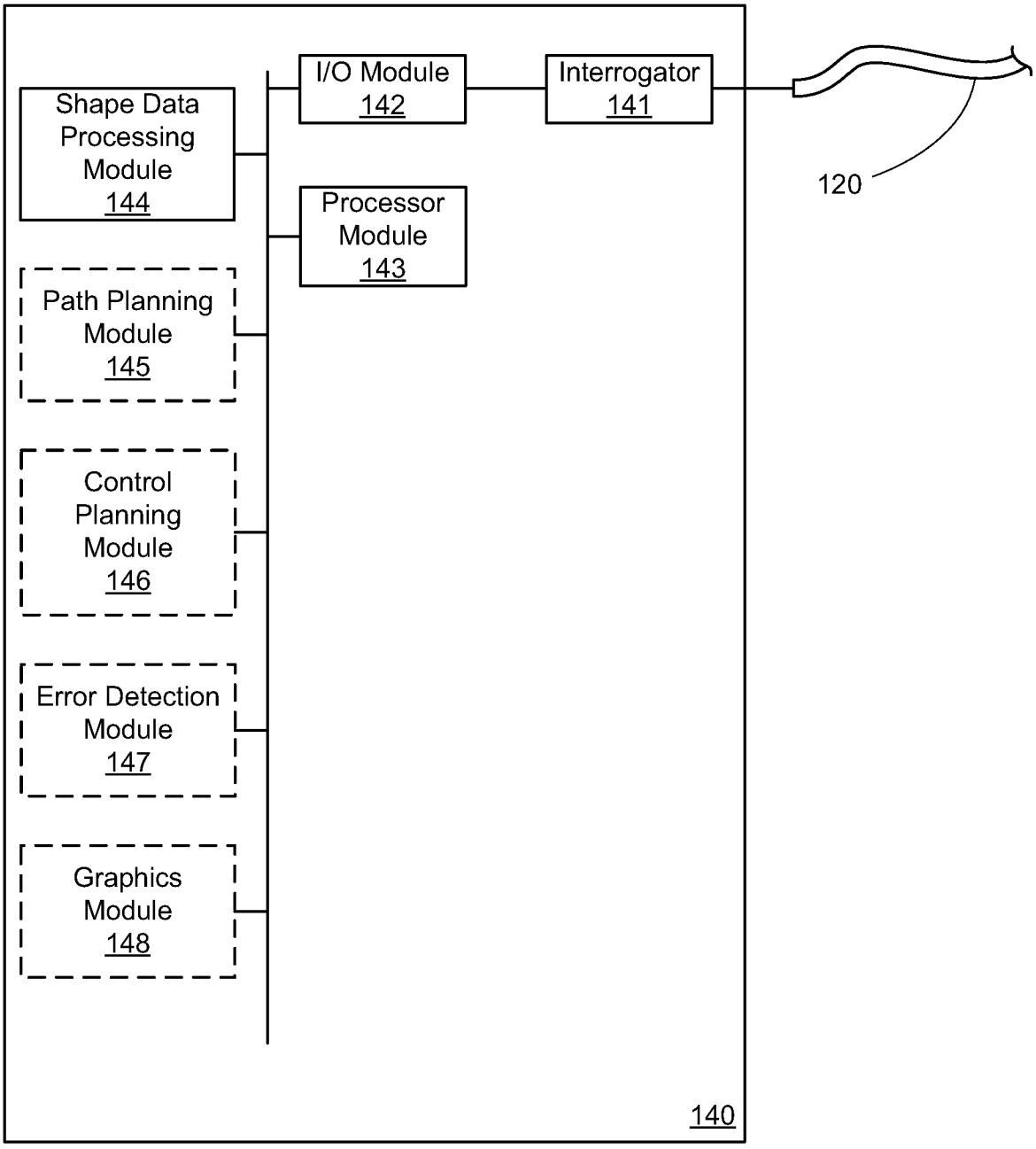

I/O Module
142
Interrogator
141
Shape Data
Processing
Module
144
120
Processor
Module
143
Path Planning
Module
145
Control
Planning
Module
146
Error Detection
Module
147
Graphics
Module
148
140

FIG. 1B

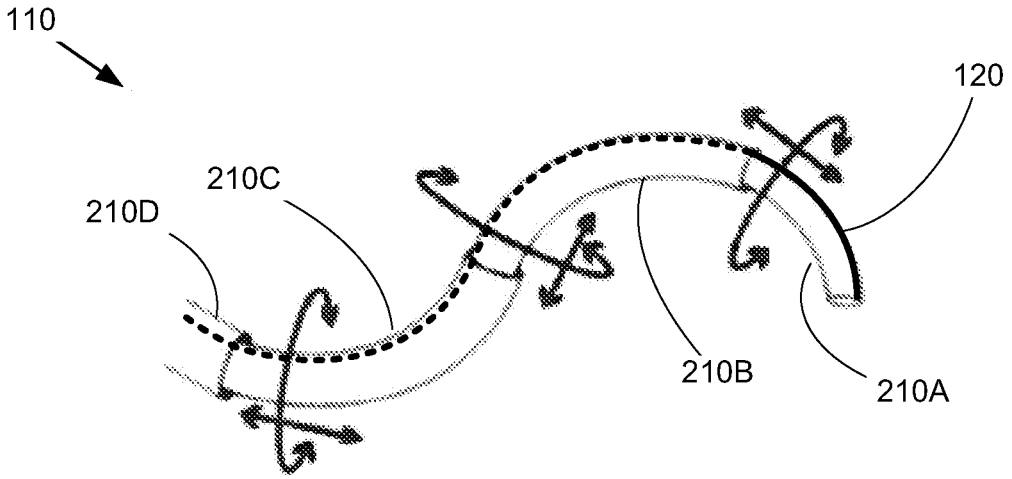


FIG. 2A

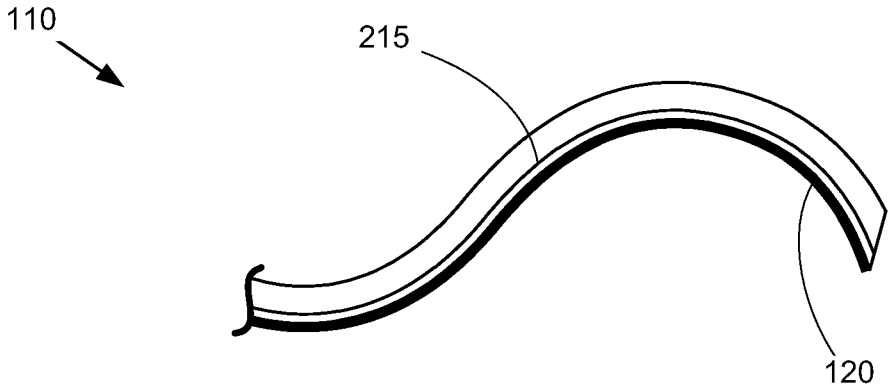
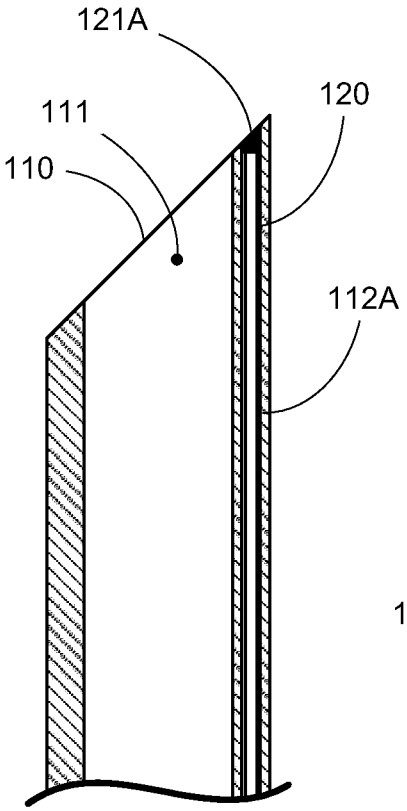
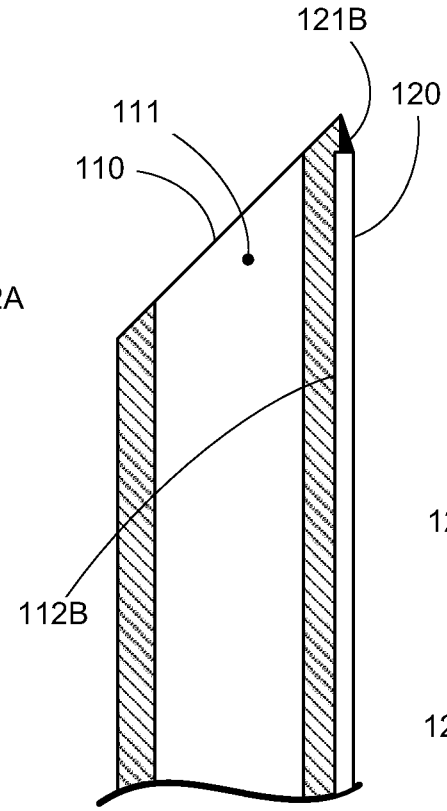
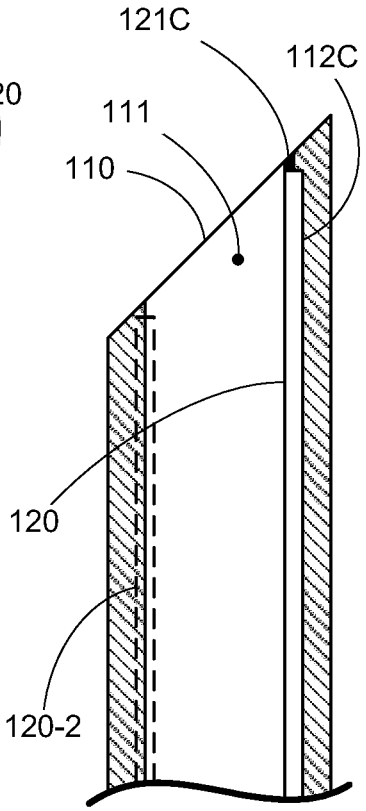
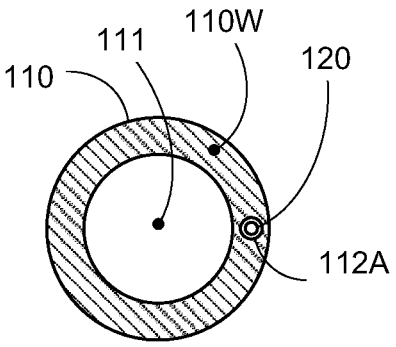


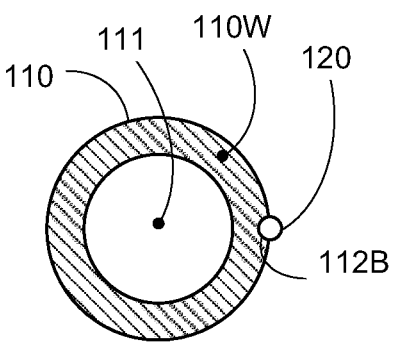
FIG. 2B











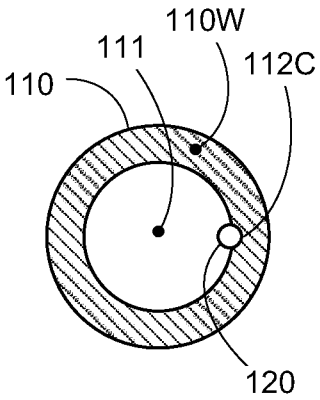


FIG. 3A

FIG. 3B

FIG. 3C

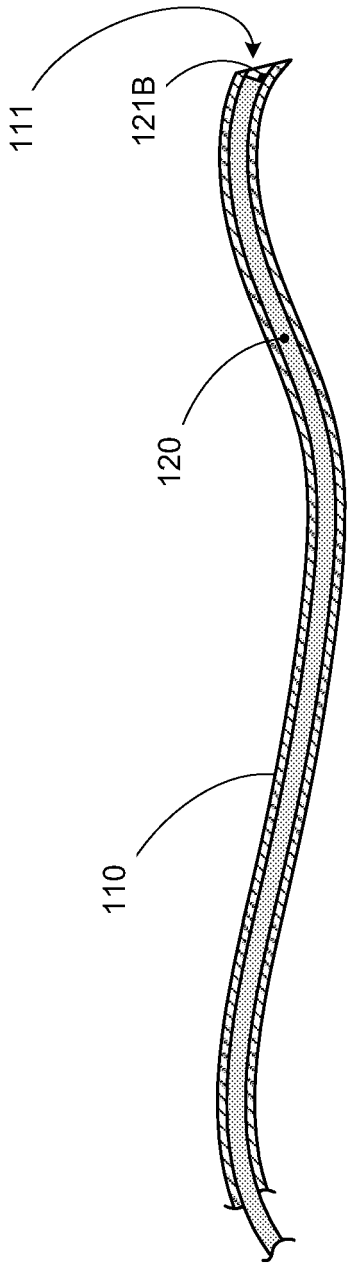


FIG. 3D

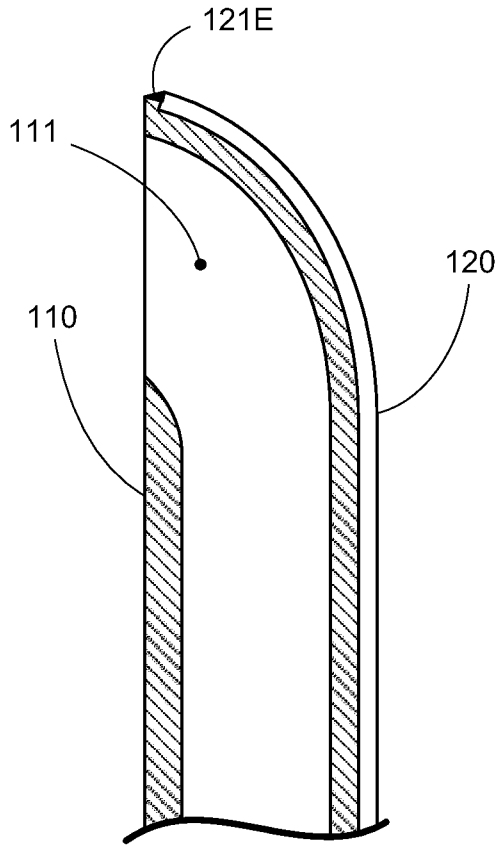


FIG. 3E

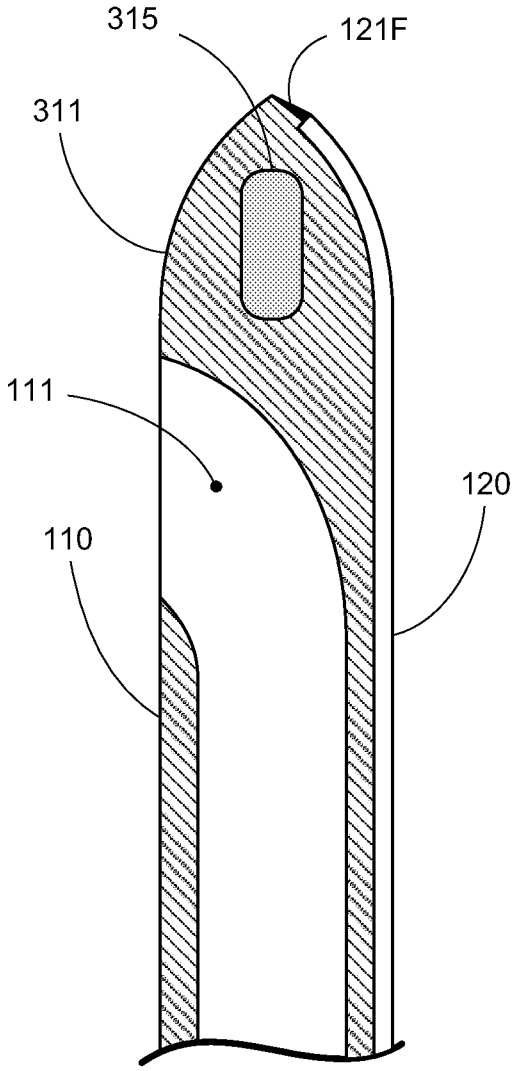


FIG. 3F

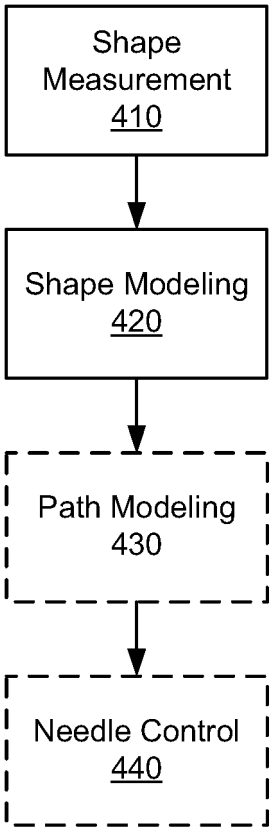

Shape Measurement 410
Shape Modeling 420
Path Modeling 430
Needle Control 440

FIG. 4

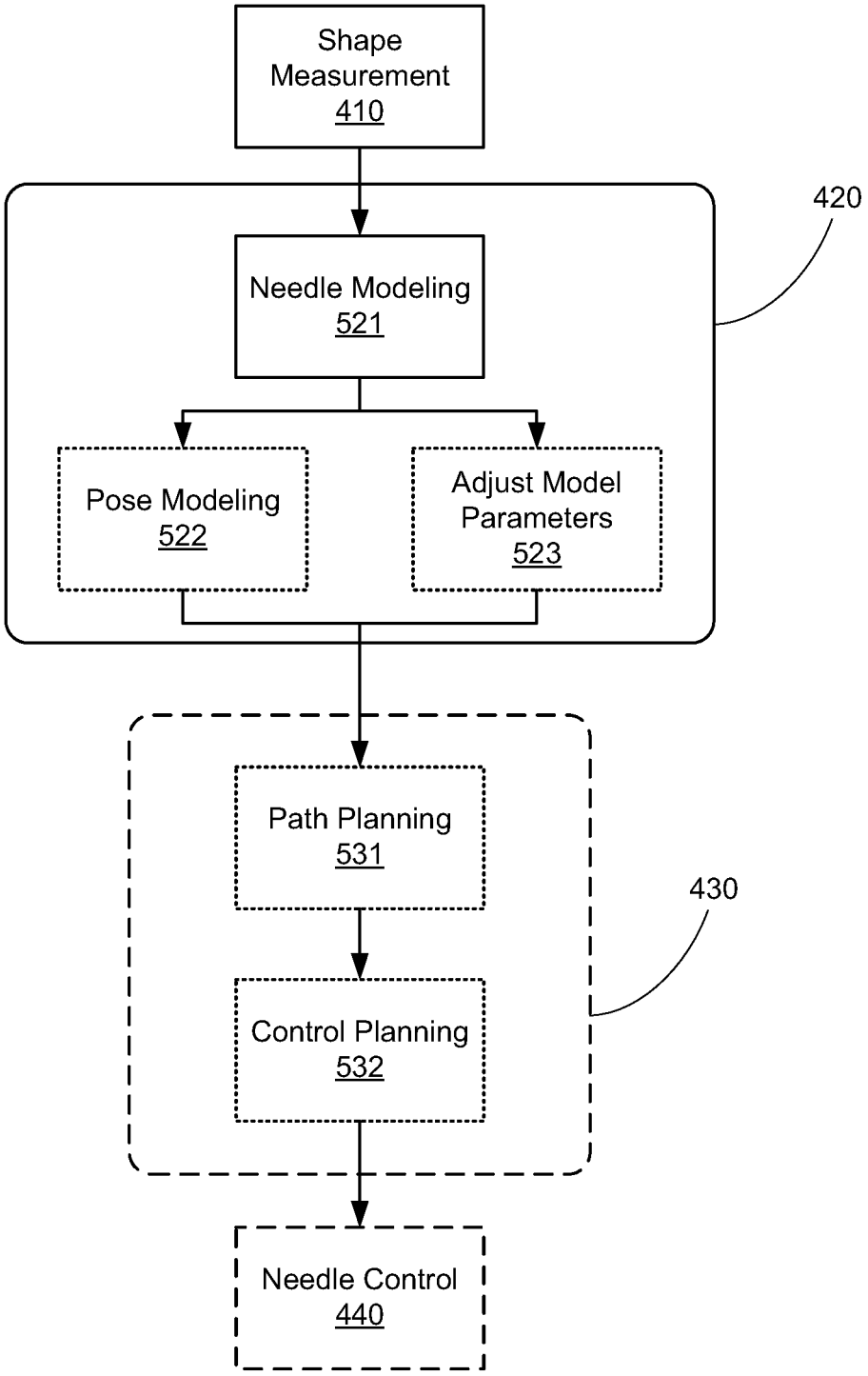

Shape Measurement 410
420
Needle Modeling 521
Pose Modeling 522
Adjust Model Parameters 523
430
Path Planning 531
Control Planning 532
Needle Control 440

FIG. 5

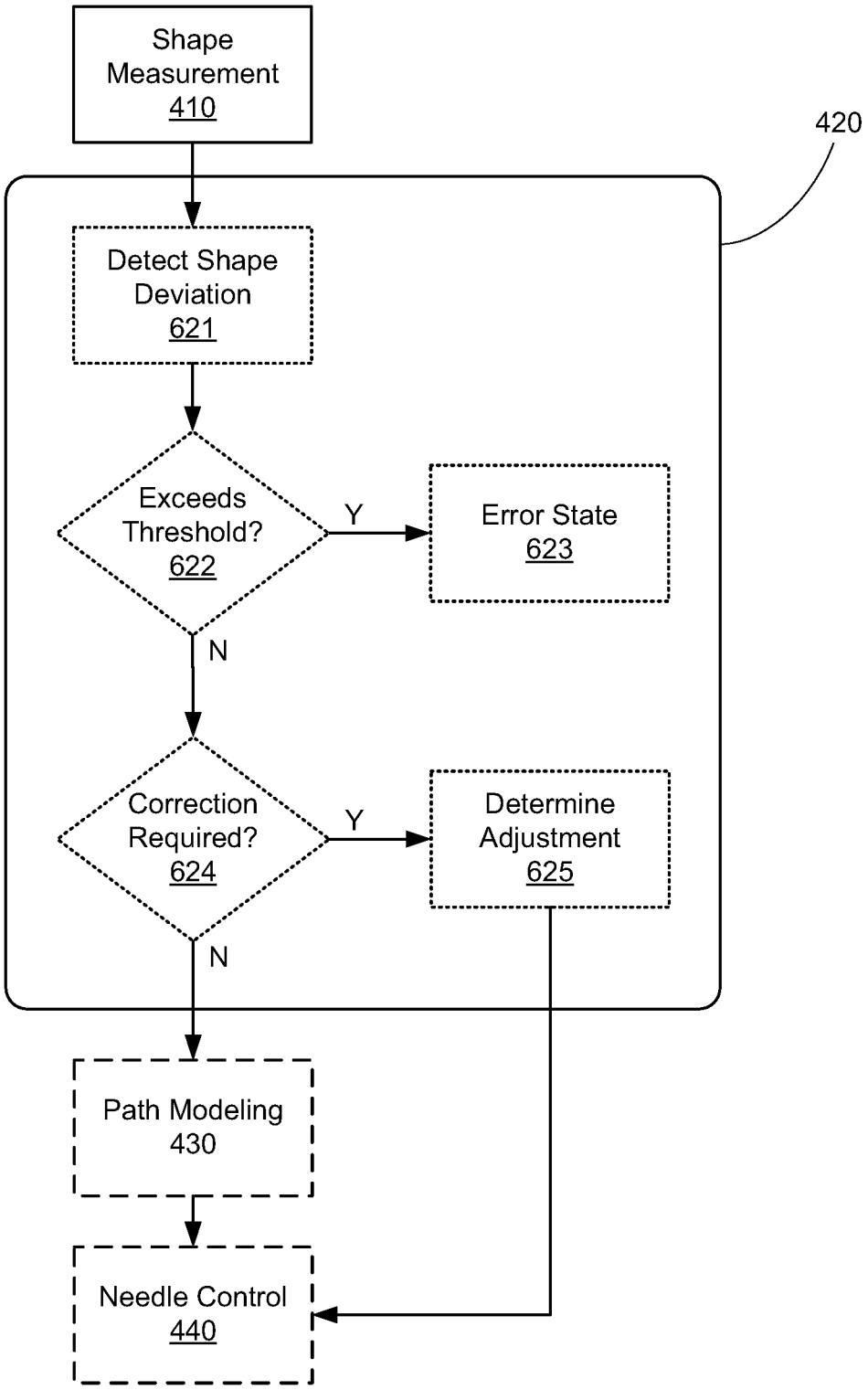

Shape Measurement 410
420
Detect Shape Deviation 621
Exceeds Threshold? 622
Y
Error State 623
N
Correction Required? 624
Y
Determine Adjustment 625
N
Path Modeling 430
Needle Control 440

FIG. 6

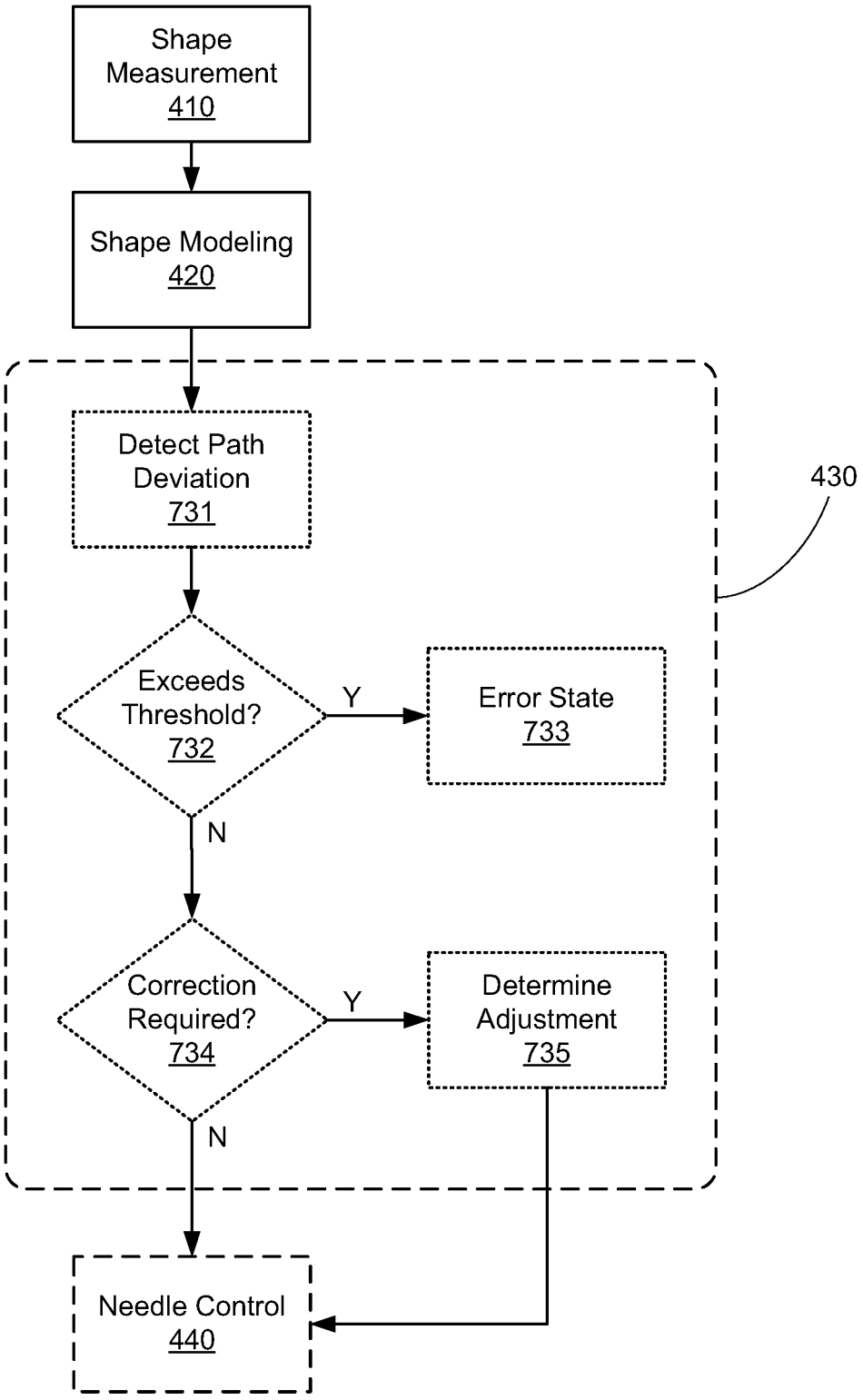

Shape Measurement 410
Shape Modeling 420
Detect Path Deviation 731
430
Exceeds Threshold? 732
Y
Error State 733
N
Correction Required? 734
Y
Determine Adjustment 735
N
Needle Control 440

FIG. 7

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- WO 2008131303 A **[0010]**
- US 2006013523 A **[0042]**
- US 2008212082 A **[0042]**
- US 6389187 B **[0042]**
- US 2009324161 A **[0048]**
- US 2011119023 A **[0048]**

Non-patent literature cited in the description

- **DUNLOP et al.** A Nitinol Wire Actuated Stewart Platform. *Proc. 2002 Australasian Conference on Robotics and Automation,* 27 November 2002 **[0039]**
- **ALPUIM et al.** ULTRA-SENSITIVE SHAPE SENSOR TEST STRUCTURES BASED ON PIEZO-RESISTIVE DOPED NANOCRYSTALLINE SILICON. *NanoSpain,* 14 April 2008 **[0046]**
- **HERRERA-MAY et al.** Electromechanical analysis of a piezoresistive pressure microsensor for low-pressure biomedical applications. *REVISTA MEXICANA DE FI'SICA,* 14 February 2009, vol. 55 (1 **[0046]**

专利名称(译)	带有嵌入式形状传感的可转向柔性针		
公开(公告)号	EP2809249A1	公开(公告)日	2014-12-10
申请号	EP2013743290	申请日	2013-01-28
[标]申请(专利权)人(译)	直观外科手术操作公司		
申请(专利权)人(译)	Intuitive Surgical公司运营，INC.		
当前申请(专利权)人(译)	Intuitive Surgical公司运营，INC.		
[标]发明人	DUINDAM VINCENT PRISCO GIUSEPPE MARIA LARKIN DAVID Q DIAMIO SIMON PANESCU DORIN		
发明人	DUINDAM, VINCENT PRISCO, GIUSEPPE, MARIA LARKIN, DAVID, Q. DIAMIO, SIMON PANESCU, DORIN		
IPC分类号	A61B17/34 A61M25/092 A61B10/02 A61M25/09		
CPC分类号	A61B10/0233 A61B17/3403 A61B17/3468 A61B2010/045 A61B2017/003 A61B2017/00331 A61B2017/00991 A61B2034/107 A61B2034/2051 A61B2034/2061 A61B5/062 A61B5/065 A61B17/3209 A61B34/20 A61B2017/00323 A61B2034/2059		
优先权	61/594959 2012-02-03 US 61/599015 2012-02-15 US		
其他公开文献	EP2809249B1 EP2809249A4		
外部链接	Espacenet		

摘要(译)

外科手术系统包括柔性可操纵针和用于测量针形状的形状传感器。手术系统可以是手动的（例如，腹腔镜），机器人或两者的任何组合。通过直接测量针的形状，可以避免针的复杂且可能不准确的建模以确定轨迹和插入深度，从而有利于更加稳健的直接测量和针形状和/或姿势的建模。