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(54) CATHETERS WITH CONTROL MODES FOR INTERCHANGEABLE PROBES

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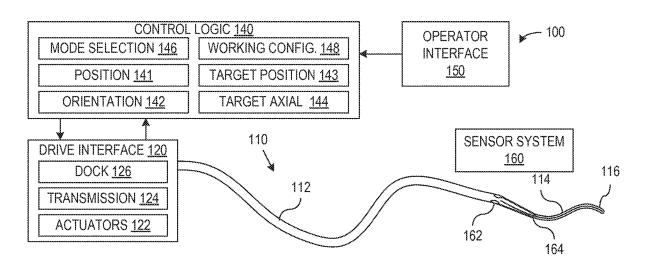
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(57) ABSTRACT

A medical system including a catheter, a sheath, and a control system. The catheter includes a lumen, a distal steerable segment, and a distal tip. The sheath is disposed within the lumen of the catheter and the sheath is extendable from the distal tip of the catheter. The control system is coupled to the catheter and includes a memory operable to store desired position coordinates and a plurality of modes including a stiffening mode in which the control system actively maintains the distal tip at the desired position coordinates.

19 Claims, 3 Drawing Sheets



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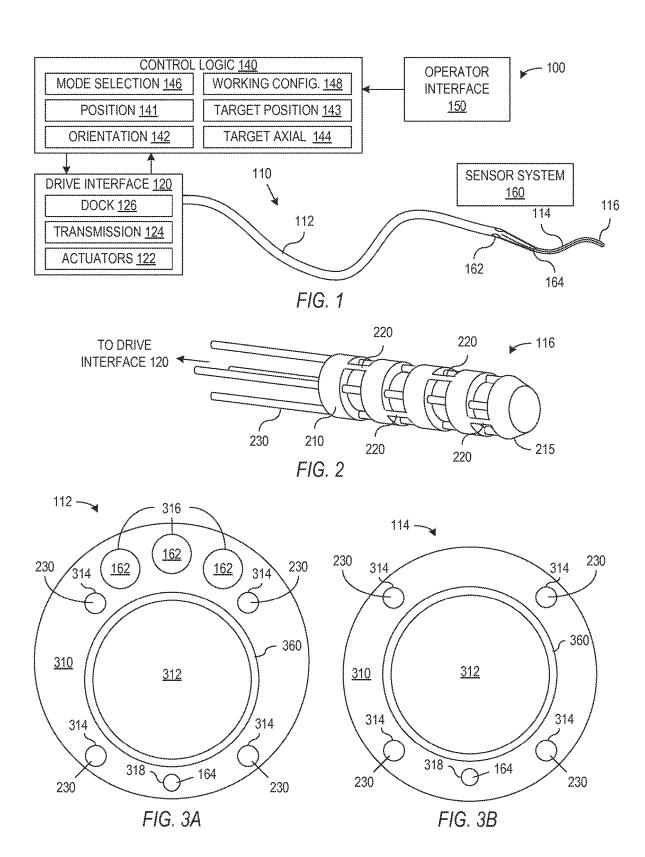
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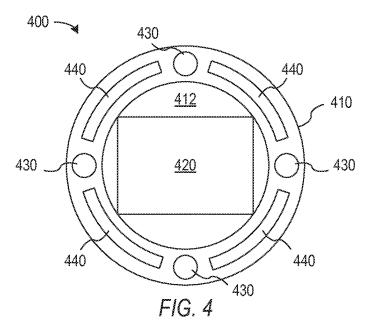
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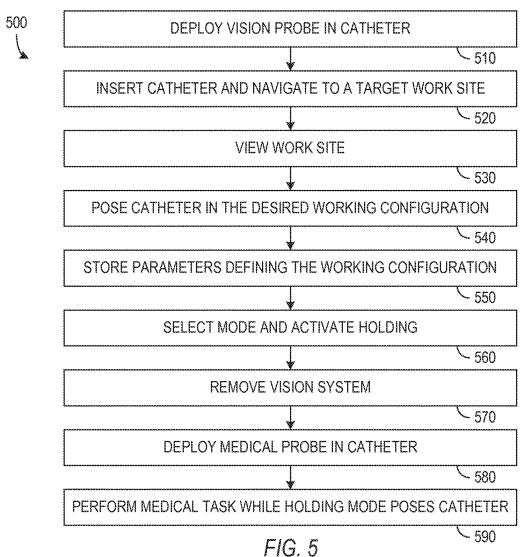
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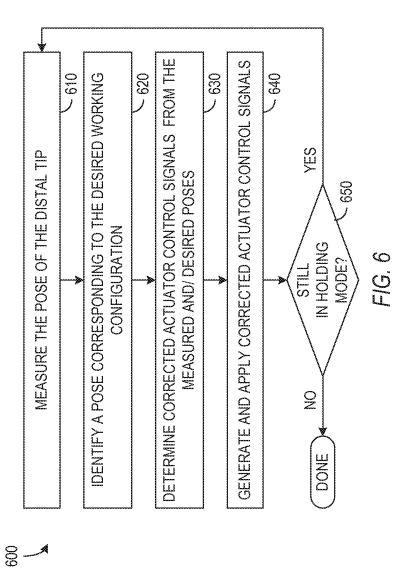
Aug. 19, 2025











CATHETERS WITH CONTROL MODES FOR INTERCHANGEABLE PROBES

CROSS-REFERENCE TO RELATED APPLICATIONS

This patent application is a continuation of U.S. patent application Ser. No. 16/283,039, filed Feb. 22, 2019, which is a continuation of U.S. patent application Ser. No. 13/274, 198, filed Oct. 14, 2011, both of which are incorporated by reference herein in their entireties. U.S. patent application Ser. No. 13/274,198 is related to and incorporates by reference the following patent applications: U.S. patent application Ser. No. 13/274,208; U.S. patent application Ser. No. 13/274,229; U.S. Pat. App. No. 13/274,237, all filed on Oct. 1514, 2011, which are also incorporated by reference herein in their entireties.

BACKGROUND

Medical devices that navigate body lumens need to be physically small enough to fit within the lumen. Lung catheters, for example, which may be used to perform minimally invasive lung biopsies or other medical procedures, may need to follow airways that decrease in size as 25 the catheter navigates branching passages. To reach a target location in a lung, a catheter may need to follow passages having diameters as small as 3 mm or less. Manufacturing a catheter that includes the mechanical structures suitable for remote or robotic operation and that has a diameter that is 30 sufficiently small to navigate such small lumens can be challenging. In particular, one desirable configuration for remotely operated catheter would provide a tool mounted on a flexible distal tip; tendons or pull wires that extend down the length of the catheter to an external drive system that 35 pulls on the tendons to actuate the tool or distal tip; lumens for suction and/or irrigation; a vision system for viewing of the target location; and sensors to identify the location of the instrument relative to a patient's body. Accommodating all of the desired features and elements of a lung catheter or 40 other device having a diameter about 3 mm or less can be difficult.

SUMMARY

In accordance with an aspect of the invention, a catheter control system has a control mode (sometimes referred to herein as a holding mode) that actively maintains the catheter in a working configuration desired for a medical procedure. This holding mode facilitates use of the catheter 50 system with interchangeable probes. In particular, a vision probe can be deployed in the catheter while the catheter navigates to a work site, to view the work site, or to assist in identifying the desired working configuration for the catheter during performance of a medical task. The catheter 55 control system can then switch into the holding mode, and the vision system can be removed. A medical probe can then be deployed through the catheter in place of the removed vision probe, and the control system maintains the working configuration and allows performance of a medical task 60 without the vision probe, while the desired working configuration is fixed and held. In one implementation, the control system actively keeps the catheter in the desired working configuration while the medical probe is inserted through the catheter, reaches the work site, and performs a 65 medical function. In an alternative implementation, the control system returns the catheter to the recorded working

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configuration before the medical function is performed. Since the catheter only needs to accommodate the vision or medical probe and not both, the diameter of the catheter may be smaller than might otherwise be possible for a convention system that provides similar functionality.

In accordance with another aspect of the invention, a feedback control method and system for a robotically controlled flexible device implements multiple different modes of closed-loop device actuation or stiffening for different applications and usage scenarios. The different stiffening modes can cause the device to respond in a desired way in case of externally applied forces, for example, tissue reaction forces as the device navigates through a clinical space or as the device interacts with tissue as part of a medical procedure. Details concerning feedback control methods and systems for robotically controlled flexible devices may be found in U.S. patent application Ser. No. 12/780,417 (filed May 14, 2010; disclosing "Drive Force Control in Medical Instrument Providing Position Measurements") and in U.S. 20 patent application Ser. No. 12/945,734 (filed Nov. 12, 2010; disclosing "Tension Control in Actuation of Multijoint Medical Instrument"), both of which are incorporated herein by reference.

In one embodiment, a flexible device such as a catheter uses real-time feedback from a sensor system in generation of signals for actuators attached to tendons that are used to articulate a distal portion of the device. For example, a catheter may include a flexible section at its distal tip that can bend in two directions (pitch and yaw). A fiber-optic shape sensor can measure the bending of the flexible section and return measurement data indicating the position and orientation of the distal tip relative to a base of the shape sensed. The position of the base may be determined, for example, using electromagnetic sensors that provide measurements of a position and orientation of the base relative to an external reference that may be attached to a patient. Multiple actuation tendons (e.g., pull wires or cables) attach to the distal tip and run along the length of the catheter to the actuators. Control logic that controls the actuators to pull the tendons and hence move the distal tip in any pitch/yaw direction can operate in different modes for different purposes. In particular, for a holding mode, the control logic can use the sensor data and fixed information on a target shape of the catheter to compute control signals for the actuators.

The control logic for a robotic catheter or other flexible system may have multiple modes of operation including one or more of the following: 1.) A position stiffness mode in which the control system controls actuators to minimize a difference between desired and measured positions of the distal tip of the catheter or probe; 2.) An orientation stiffness mode in which the control system controls the actuators to minimize a difference between desired and measured pointing directions of the distal tip; 3.) A target position stiffness mode in which the control system uses a combination of the measured tip position and pointing direction to control the distal tip to always point towards a specified target point; and 4.) A target axial motion stiffness mode in which the control system uses a combination of the measured tip position and pointing direction, together with sensor measurements from other parts of the device, and controls actuators to ensure that the distal tip is positioned on a specific line in space and has a pointing direction also along that line. The selection of which of the available modes the control system uses can be made through user selection, according to the type of probe being used (e.g. forceps, camera, laser, brush, or needle), or according to the action the catheter is performing (e.g., navigating or performing a

biopsy). Any of these modes can be used to hold the catheter for a medical procedure by fixing the desired location, direction, target point, or line.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a robotic catheter system in accordance with an embodiment of the invention having multiple control modes.

FIG. 2 shows an embodiment of an actuated distal tip that ¹⁰ can be employed in the system of FIG. 1.

FIGS. 3A and 3B show cross-sectional views of proximal and distal sections of a catheter in accordance with an embodiment of the invention.

FIG. 4 shows a cross-sectional view of a vision probe that may be deployed in the catheter of FIGS. 3A and 3B and swapped out for use of medical probes in the catheter shown in FIGS. 3A and 3B.

FIG. 5 is a flow diagram of a process for using the catheter system with a removable vision system and multiple control modes. 20

FIG. 6 is a flow diagram of a catheter control process in a steering mode.

Use of the same reference symbols in different figures 25 indicates similar or identical items.

DETAILED DESCRIPTION

A catheter system can employ a vision probe that is 30 interchangeable with one or more medical probes or tools. The vision probe can be removed and replaced with a medical probe used in a medical procedure. The interchanging of the vision and medical probes may permit the catheter system to have a smaller diameter and thus navigate smaller 35 passages than would a similar system that simultaneously accommodates both vision and medical systems. Alternatively, interchanging probes allow more space for vision and medical systems having greater functionality than might a catheter that must simultaneously accommodate both vision 40 and medical systems.

One method for using a catheter system includes steering a catheter along a body lumen for at least part of the path to a work site for a medical procedure. A vision system may then be deployed in the catheter during the steering and/or 45 used to view the work site reached when navigation is complete. The vision system can also be used to help identify a desired working configuration for the catheter and when manipulating the catheter into the desired working configuration. The control system of the catheter can then 50 record the working configuration and may be placed in a "holding" mode in which the pose of the catheter relative to a patient is monitored and the catheter is actuated to actively maintain or return to the recorded working configuration. The control system may provide different types of control 55 modes, which may be useful for different types of medical probes or different types of medical procedures. For example, if the medical probe includes a laser, a combination of the location and orientation of the distal tip of the catheter can be controlled so that the distal tip remains 60 targeted on a specific location in the patient. An alternative holding mode can maintain the location of the distal tip of the catheter while permitting the orientation of the distal tip to change or maintain a distal tip along a line.

FIG. 1 schematically illustrates a catheter system 100 in 65 accordance with one embodiment of the invention. In the illustrated embodiment, catheter system 100 includes a

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catheter 110, a drive interface 120, control logic 140, an operator interface 150, and a sensor system 160.

Catheter 110 is a generally flexible device having one or more lumens including a main lumen that can accommodate interchangeable probes such as described further below. Flexible catheters can be made using a braided structure such as a woven wire tube with inner or outer layers of a flexible or low friction material such as polytetrafluoroethylene (PTFE). In one embodiment, catheter 110 includes a bundle of lumens or tubes held together by a braided jacket and a reflowed (i.e., fused by melting) jacket of a material such as Polyether Block Amide (Pebax). An additional tip section (e.g., a metal structure such as shown in FIG. 2 and described further below) can be attached at the distal end of catheter 110. Alternatively, an extrusion of a material such as Pebax can similarly be used to form multiple lumens in catheter 110. Catheter 110 particularly includes a main lumen for interchangeable probe systems and smaller lumens for pull wires and sensor lines. In the illustrated embodiment, catheter 110 has a proximal section 112 attached to drive interface 120 and a distal section 114 that extends from the proximal section 112. Pull wires extend from drive system 120 through proximal section 112 and distal section 114 and connect to a steerable distal steerable segment 116.

The overall length of catheter 110 may be about 60 to 80 cm or longer with distal section 114 being about 15 cm long and steerable segment 116 being about 4 to 5 cm long. In accordance with an aspect of the invention, distal section 114 has a smaller diameter than does proximal section 112 and thus can navigate smaller natural lumens or passages. During a medical procedure, at least a portion of proximal section 112 and all of distal section 114 may be inserted along a natural lumen such as an airway of a patient. The smaller diameter of distal section 114 permits use of distal section 114 in lumens that may be too small for proximal section 112, but the larger diameter of distal section 114 facilitates inclusion of more or larger structures or devices such as electromagnetic (EM) sensors 162 that may not fit in distal section 114.

Steerable segment 116 is remotely controllable and particularly has a pitch and a yaw that can be controlled using pull wires. Steerable segment 116 may include all or part of distal section 114 and may be simply implemented as a multi-lumen tube of flexible material such as Pebax. In general, steerable segment 116 is more flexible than the remainder of catheter 110, which assists in isolating actuation or bending to steerable segment 116 when drive interface 120 pulls on actuating tendons. Catheter 110 can also employ additional features or structures such as use of Bowden cables for actuating tendons to prevent actuation from bending proximal section 112 (or bending any portion the section of 114 other than steerable segment 116) of catheter 110. FIG. 2 shows one specific embodiment in which steerable segment 116 is made from a tube 210 that in catheter 110 of FIG. 1 contains multiple tubes defining a main lumen for a probe system and smaller lumens for actuation tendons 230 and a shape sensor not shown in FIG. 2. In the illustrated embodiment, tendons 230 are placed 90° apart surrounding lumen 312 to facilitate steering catheter 110 in pitch and yaw directions defined by the locations of tendons 230. A reflowed jacket, which is not shown in FIG. 2 to better illustrate the internal structure of steerable segment 116, may also cover tube 210. As shown in FIG. 2, tube 210 is cut or formed to create a series of flexures 220. Tendons 230 connect to a distal tip 215 of steerable segment 116 and extend back to a drive interface 120. Tendons 230

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can be wires, cables, Bowden cables, hypotubes, or any other structures that are able to transfer force from drive interface 120 to distal tip 215 and limit bending of proximal section 112 when drive interface 120 pulls on tendons 230. In operation, pulling harder on any one of tendons 230 tends to cause steerable segment 116 to bend in the direction of that tendon 230. To accommodate repeated bending, tube 210 may be made of a material such as Nitinol, which is a metal alloy that can be repeatedly bent with little or no damage.

Drive interfaces 120 of FIG. 1, which pulls on tendons 230 to actuate distal steerable segment 116, includes a mechanical system or transmission 124 that converts the movement of actuators 122, e.g., electric motors, into movements of (or tensions in) tendons 230 that run through 15 catheter 110 and connect to distal steerable segment 116. (Push rods could conceivably be used in catheter 110 instead of pull wires but may not provide a desirable level of flexibility.) The movement and pose of distal steerable segment 116 can thus be controlled through selection of 20 drive signals for actuators 122 in drive interface 120. In addition to manipulating tendons 230, drive interface 120 may also be able to control other movement of catheter 110 such as range of motion in an insertion direction and rotation or roll of the proximal end of catheter 110, which may also 25 be powered through actuators 122 and transmission 124. Backend mechanisms or transmissions that are known for flexible-shaft instruments could in general be used or modified for drive interface 120. For example, some known drive systems for flexible instruments are described in U.S. Pat. 30 App. Pub. No. 2010/0331820, entitled "Compliant Surgical Device," which is hereby incorporated by reference in its entirety. Drive interface 120 in addition to actuating catheter 110 should allow removal and replacements of probes in catheter 110, so that the drive structure should be out of the 35 way during such operations.

A dock 126 in drive interface 120 can provide a mechanical coupling between drive interface 120 and catheter 110 and link actuation tendons to transmission 124. Dock 126 may additionally contain electronics for receiving and relaying sensor signals from portions of sensor system 160 in catheter 110 and an electronic or mechanical system for identifying the probe or the type of probe deployed in catheter 110.

Control logic 140 controls the actuators in drive interface 45 120 to selectively pull on the tendons as needed to actuate and steer distal steerable segment 116. In general, control logic 140 operates in response to commands from a user, e.g., a surgeon or other medical personnel using operator interface 150, and in response to measurement signals from sensor system 160. However, in holding modes as described further below, control logic 140 operates in response to measurement signals from sensor system 160 to maintain or acquire a previously identified working configuration. Control logic 140 may be implemented using a general purpose 55 computer with suitable software, firmware, and/or interface hardware to interpret signals from operator interface 150 and sensor system 160 and to generate control signals for drive interface 120.

In the illustrated embodiment, control logic 140 includes 60 multiple modules 141, 142, 143, and 144 that implement different processes for controlling the actuation of catheter 110. In particular, modules 141, 142, 143, and 144 respectively implement a position stiffening mode, an orientation stiffening mode, a target position mode, and a target axial 65 mode, which are described further below. A module 146 selects which control process will be used and may base the

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selection on user input, the type or status of the probe deployed in catheter 110, and the task being performed. Control logic 140 also includes memory storing parameters 148 of a working configuration of distal steerable segment 116 that is desired for a task, and each of the modules 141, 142, 143, and 144 can uses their different control processes to actively maintain or hold the desired working configuration.

Operator interface 150 may include standard input/output 10 hardware such as a display, a keyboard, a mouse, a joystick, or other pointing device or similar I/O hardware that may be customized or optimized for a surgical environment. In general, operator interface 150 provides information to the user and receives instructions from the user. For example, operator interface 150 may indicate the status of system 100 and provide the user with data including images and measurements made by system 100. One type of instruction that the user may provide through operator interface 150, e.g., using a joystick or similar controller, indicates the desired movement or position of distal steerable segment 116, and using such input, control logic 140 can generate control signals for actuators in drive interface 120. Other instructions from the user can select an operating mode of control logic 140.

Sensor system 160 generally measures a pose of distal steerable segment 116. In the illustrated embodiment, sensor system 160 includes EM sensors 162 and a shape sensor 164. EM sensors 162 include one or more conductive coils that may be subjected to an externally generated electromagnetic field. Each coil of EM sensors 162 then produces an induced electrical signal having characteristics that depend on the position and orientation of the coil relative to the externally generated electromagnetic field. In an exemplary embodiment, EM sensors 162 are configured and positioned to measure six degrees of freedom, e.g., three position coordinates X, Y, and Z and three orientation angles indicating pitch, yaw, and roll of a base point. The base point in system 100 is at or near the end of proximal section 112 and the start of distal section 114 of catheter 110. Shape sensor 164 in the exemplary embodiment of the invention includes a fiber grating that permits determination of the shape of a portion of catheter 110 extending from the base point, e.g., the shape of distal section 114 or distal steerable segment 116. Such shape sensors using fiber gratings are further described in U.S. Pat. No. 7,720,322, entitled "Fiber Optic Shape Sensor," which is hereby incorporated by reference in its entirety. An advantage of the illustrated type of sensor system 160 is that EM sensors 162 can provide measurements relative to the externally generated electrical field, which can be calibrated relative to a patient's body. Thus, system 160 can use EM sensors 162 to reliably measure the position and orientation of a base point for shape sensor 164, and shape sensor 164 need only provide shape measurement for a relatively short distance. Additionally, distal section 114 only contains shape sensor 164 and may have a diameter that is smaller than the diameter of proximal section 112. More generally, sensor system 160 need only be able to measure the pose of distal steerable segment 116, and other types of sensors could be employed.

FIGS. 3A and 3B respectively show cross-sections of the proximal and distal sections 112 and 114 of catheter 110 in one embodiment of the invention. FIG. 3A shows an embodiment of catheter 110 having a body 310 that includes a main lumen 312 for a vision or medical probe, lumens 314 containing tendons 230, lumens 316 containing EM sensors 162 or associated signal wires, and a lumen 318 containing a fiber shape sensor 164. Main lumen 312, wire lumens 314,

and a shape sensor lumen 318 extend into distal section 114 as shown in FIG. 3B, but lumens 316 for EM sensors 162 are not needed in distal section 114 because EM sensors 162 are only in proximal section 112. Accordingly, distal section 114 can be smaller than proximal section 112. In an exemplary 5 embodiment, body 310 in proximal section 112 has an outer diameter of about 4 mm (e.g., in a range from 3 to 6 mm) and provides main lumen 312 with a diameter of about 2 mm (e.g., in a range from 1 to 3 mm) and in distal section 114 has an outer diameter of about 3 mm (e.g., in a range from 10 2 to 4 mm) while maintaining the diameter of main lumen 312 at about 2 mm. A smooth taper (as shown in FIG. 1) or an abrupt step in body 310 can be used at the transition from the larger diameter of proximal section 112 to the smaller diameter of distal section 116.

The specific dimensions described in above are primarily for a catheter that accommodates probes having a diameter of about 2 mm, which is a standard size for existing medical tools such as lung biopsy probes. However, alternative embodiments of the invention could be made larger or smaller to accommodate medical probes with a larger or smaller diameter, e.g., 1 mm diameter probes. A particular advantage of such embodiments is that a high level of functionality is provided in a catheter with relative small outer diameter when compared to the size of probe used in 25 the catheter.

FIGS. 3A and 3B also show a sheath 360 that may be employed between catheter body 310 and a probe in main lumen 312. In one embodiment of catheter 110, sheath 360 is movable relative to body 310 can be extended beyond the 30 end of distal steerable segment 116. This may be advantageous in some medical procedures because sheath 360 is even smaller than distal section 114 and therefore may fit into smaller natural lumens or passages. For example, if catheter 110 reaches a branching of lumens that are too small 35 to accommodate distal steerable segment 116, distal steerable segment 116 may be pointed in the direction of the desired branch, so that sheath 360 can be pushed beyond the end of distal steerable segment 116 and into that branch. Sheath 360 could thus reliably guide a medical probe into 40 the desired branch. However, sheath 360 is passive in that it is not directly actuated or steerable. In contrast, distal section 116 accommodates pull wires 230 that connect to distal steerable segment 116 and can be manipulated to steer or pose distal steerable segment 116. In some medical 45 applications, the active control of distal steerable segment 116 is desirable or necessary during a medical procedure, and passive sheath 360 may not be used in some embodiments of the invention.

Main lumen 312 is sized to accommodate a variety of 50 medical probes. One specific probe is a vision probe 400 such as illustrated in FIG. 4. Vision probe 400 has a flexible body 410 with an outer diameter (e.g., about 2 mm) that fits within the main lumen of catheter 110 and with multiple inner lumens that contain the structures of vision probe 400. 55 Body 410 may be formed using an extruded flexible material such as Pebax, which allows creation of multiple lumens. In the illustrated embodiment, the structure of vision probe 400 includes a CMOS camera 420, which is at the distal end of the probe and connected through one or more signal wires 60 (not shown) that extend along the length of vision probe 400, e.g., to provide a video signal to control logic 140 or operator interface 150 as shown in FIG. 1. Vision probe 400 also includes illumination fibers 430 that provide light for imaging within a body lumen and fluid ports 326 for suction 65 and irrigation that may be useful, for example, for rinsing of a lens of camera 420. Additionally, vision probe 400 may

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include an electromagnetic sensor (not shown) embedded just proximally to camera 420 to provide additional pose information about the tip of vision probe 400.

Vision probe 400 is adapted to be inserted or removed from catheter 110 while catheter 110 is in use for a medical procedure. Accordingly, vision probe 400 is generally free to move relative to catheter 110. While movement relative to catheter 110 is necessary or desirable during insertion or removal of vision probe 400, the orientation of a vision probe 400 (and some medical probes) may need to be known for optimal or easier use. For example, a user viewing video from vision probe 400 and operating a controller similar to a joystick to steer catheter 110 generally expects the directions of movement of the controller to correspond to the response of distal steerable segment 116 and the resulting change in the image from vision probe 400. Operator interface 150 needs (or at least can use) information on the orientation of vision probe 400 relative to tendons 230 in order to provide a consistency in directions used in the user interface. In accordance with an aspect of the invention, a keying system (not shown) can fix vision probe 400 into a known orientation relative to catheter 110 and tendons 230. The keying system may, for example, include a spring, fixed protrusion, or latch on vision probe 400 or distal steerable segment 116 and a complementary notch or feature in distal steerable segment 116 or vision probe 400.

Vision probe 400 is only one example of a probe system that may be deployed in catheter 110 or guided through catheter 110 to a work site. Other probe systems that may be used include, but are not limited to, biopsy forceps, biopsy needles, biopsy brushes, ablation lasers, and radial ultrasound probes. In general, catheter 110 can be used with existing manual medical probes that are commercially available from medical companies such as Olympus Europa Holding GmbH.

The catheter system 100 of FIG. 1 can be used in procedures that swap a vision probe and a medical probe. FIG. 5 is a flow diagram of one embodiment of a process 500 for using the catheter system 100 of FIG. 1. In process 500, vision probe 400 is deployed in catheter 110 in step 510, and catheter 110 is inserted along a path including a natural lumen of a patient. For example, for a lung biopsy, distal steerable segment 116 of catheter 110 may be introduced through the mouth of a patient into the respiratory tract of the patient. Vision probe 400 when fully deployed in catheter 110 may fit into a keying structure that keeps vision probe 400 in a desired orientation at or even extending beyond distal steerable segment 116 to provide a good forward view from the distal steerable segment 116 of catheter 110. As noted above, distal steerable segment 116 of catheter 110 is steerable, and vision probe 320 can provide video of the respiratory tract that helps a user when navigating catheter 110 toward a target work site. However, use of vision probe 400 during navigation is not strictly necessary since navigation of catheter 110 may be possible using measurements of sensor system 160 or some other system with or without vision probe 400 being deployed or used in catheter 110. The path followed to the work site may be entirely within natural lumens such as the airways of the respiratory track or may pierce and pass through tissue at one or more points.

When steerable segment 116 reaches the target work site, vision probe 400 can be used to view the work site as in step 530 and to pose steerable segment 116 for performance of a task at the target work site as in step 540. Posing of steerable segment 116 may use images or visual information from vision probe 400 and measurements from sensor system 160

to characterize the work site and determine the desired working configuration. The desired working configuration may also depend on the type of tool that will be used or the next medical task. For example, reaching a desired working configuration of catheter 110 may bring the distal tip of 5 steerable segment 116 into contact with tissue to be treated, sampled, or removed with a medical tool that replaces vision probe 400 in catheter 110. Another type of working configuration may point steerable segment 116 at target tissue to be removed using an ablation laser. For example, tissue 10 could be targeted in one or more 2D camera views while vision probe 400 is still in place in catheter 110, or target tissue can be located on a virtual view of the work site using pre-operative 3D imaging data together with the position sensing relative to patient anatomy. Still another type of 15 working configuration may define a line for the insertion of a needle or other medical tool into tissue, and the working configuration includes poses in which the distal tip of steerable segment 116 is along the target line. In general, the desired working configuration defines constraints on the 20 position or the orientation of the distal tip of steerable segment 116, and the shape of more proximal sections of catheter 110 is not similarly constrained and may vary as necessary to accommodate the patient.

Step **550** stores in memory of the control logic parameters 25 that identify the desired working configuration. For example, the position of a distal tip or target tissue can be defined using three coordinates. A target line for a need can be defined using the coordinates of a point on the line and angles indicating the direction of the line from that point. In 30 general, control logic **120** uses the stored parameters that define the desired working configuration when operating in a holding mode that maintains distal steerable segment **116** of catheter **110** in the desired working configuration as described further below.

Step **560** selects and activates a holding mode of the catheter system after the desired working configuration has been established and recorded. Control logic **140** for catheter **110** of FIG. **1** may have one or more modules **141**, **142**, **143**, and **144** implementing multiple stiffening modes that 40 may be used as holding modes when the desired configuration of steerable segment **116** has fixed constraints. The available control modes may include one or more of the following.

- 1.) A position stiffness mode compares the position of the distal tip of steerable segment 116 as measured by sensor system 160 to a desired tip position and controls the actuators to minimize the difference in desired and measured tip positions. The position stiffness mode may particularly be suitable for general manipulation 50 tasks in which the user tries to precisely control the position of the tip and for situations where the distal tip contacts tissue.
- 2.) An orientation stiffness mode compares the measured orientation or pointing direction of the distal tip to a 55 desired pointing direction of the distal tip and controls the actuators to minimize the difference in desired and actual tip pointing direction. This orientation stiffening that may be suitable, e.g., when controlling an imaging device such as vision probe 400 attached steerable 60 segment 116, in which case the viewing direction is kept as desired, while the exact position of steerable segment 116 may be less important.
- 3.) A target position stiffness mode uses a combination of the measured tip position and pointing direction to 65 control catheter 110 to always point the distal tip of steerable segment 116 towards a specified target point

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some distance in front of steerable segment 116. In case of external disturbances, control logic 140 may control the actuators to implement this target position stiffening behavior, which may be suitable, e.g., when a medical probe inserted though the catheter contains an ablation laser that should always be aimed at a target ablation point in tissue.

4.) A target axial motion stiffness mode uses a combination of the measured tip position and pointing direction to ensure that the distal tip of steerable segment 116 is always on a line in space and has a pointing direction that is also along that line. This mode can be useful, e.g., when inserting a biopsy needle along a specified line into tissue. Tissue reaction forces could cause the flexible section of catheter 110 to bend while inserting the needle, but this control strategy would ensure that the needle is always along the right line.

The selection of a mode in step 560 could be made through manual selection by the user, based on the type of probe that is being used (e.g., grasper, camera, laser, or needle) in catheter 110, or based on the activity catheter 110 is performing. For example, when a laser is deployed in catheter 110, control logic 120 may operate in position stiffness mode when the laser deployed in catheter 110 is off and operate in target position stiffness mode to focus the laser on a desired target when the laser is on. When "holding" is activated, control logic 140 uses the stored parameters of the working configuration (instead of immediate input from operator interface 150) in generating control signals for drive interface 120.

The vision probe is removed from the catheter in step 570, which clears the main lumen of catheter 110 for the step 580 of inserting a medical probe or tool through catheter 110. For the specific step order shown in FIG. 5, control logic 140 35 operates in holding mode and maintains distal steerable segment 116 in the desired working configuration while the vision system is removed (step 570) and the medical probe is inserted (step 580). Accordingly, when the medical probe is fully deployed, e.g., reaches the end of distal steerable segment 116, the medical probe will be in the desired working configuration, and performance of the medical task as in step 590 can be then performed without further need or use of the removed vision probe. Once the medical task is completed, the catheter can be taken out of holding mode or otherwise relaxed so that the medical probe can be removed. The catheter can then be removed from the patient if the medical procedure is complete, or the vision or another probe can be inserted through the catheter if further medical tasks are desired.

In one alternative for the step order of process 500, catheter 110 may not be in a holding mode while the medical probe is inserted but can be switched to holding mode after the medical probe is fully deployed. Once holding mode is initiated, control logic 140 will control the drive interface 130 to return distal steerable segment 116 to the desired working configuration if distal steerable segment 116 has moved since being posed in the desired working configuration. Thereafter, control logic 140 monitors the pose of distal steerable segment 116 and actively maintains distal steerable segment 116 in the desired working configuration while the medical task is performed in step 590.

FIG. 6 shows a flow diagram of a process 600 of a holding mode that can be implemented in control logic 140 of FIG. 1. Process 600 begins in step 610 with receipt of measurement signals from sensor system 160. The particular measurements required depend on the type of holding mode being implemented, but as an example, the measurements

can indicate position coordinates, e.g., rectangular coordinates X, Y, and Z, of the distal tip of steerable segment 116 and orientation angles, e.g., angles θ_x , θ_y , and θ_z of a center axis of the distal tip of steerable segment 116 relative to coordinate axes X, Y, and Z. Other coordinate systems and 5 methods for representing the pose of steerable segment 116 could be used, and measurements of all coordinates and direction angles may not be necessary. However, in an exemplary embodiment, sensor system 160 is capable of measuring six degrees of freedom (DoF) of the distal tip of 10 can be implemented in a computer-readable media, e.g., a steerable segment 116 and of providing those measurements to control logic 140 in step 610.

Control logic 140 in step 620 determines a desired pose of distal steerable segment 116. For example, control logic 140 can determine desired position coordinates, e.g., X', Y', and 15 Z', of the end of distal steerable segment 116 and desired orientation angles, e.g., angles θ'_{X} , θ'_{Y} , and θ'_{Z} of the center axis of distal steerable segment 116 relative to coordinate axes X, Y, and Z. The holding modes described above generally provide fewer than six constraints on the desired 20 coordinates. For example, position stiffness operates to constrain three degrees of freedom, the position of the end of distal steerable segment 116 but not the orientation angles. In contrast, orientation stiffness mode constrains one or more orientation angles but not the position of end of 25 distal steerable segment 116. Target position stiffness mode constrains four degrees of freedom, and axial stiffness mode constrains five degrees of freedom. Control logic 610 can impose further constraints to select one of set of parameters, e.g., X', Y', and Z' and angles θ'_{X} , θ'_{Y} , and θ'_{Z} , that provides 30 the desired working configuration. Such further constraints include but are not limited to mechanical constraints required by the capabilities of distal steerable segment 116 and of catheter 110 generally and utilitarian constraints such as minimizing movement of distal steerable segment 116 or 35 providing desired operating characteristics such as smooth, non-oscillating, and predictable movement with controlled stress in catheter 110. Step 620 possibly includes just keeping a set pose distal steerable segment 116 by finding smallest movement from the measured pose to a pose 40 satisfying the constraints, e.g., finding the point on the target line closest to the measure position for axial motion stiffness or finding some suitable pose from registered pre-op data that is close to the current pose.

Control logic 140 in step 630 uses the desired and/or 45 measured poses to determine corrected control signals that will cause drive interface 120 to move distal steerable segment 116 to the desired pose. For example, the mechanics of catheter 110 and drive interface 120 may permit development of mappings from the desired coordinates X', 50 Y', and Z' and angles θ'_{X} , θ'_{Y} , and θ'_{Z} to actuator control signals that provide the desired pose. Other embodiments may use differences between the measured and desired pose to determine corrected control signals. In general, the control signals may be used not only to control actuators 55 connected through tendons to distal steerable segment 116 but may also control (to some degree) insertion or roll of catheter 110 as a whole.

A branch step 650 completes a feedback loop by causing process 600 to return to measurement step 610 after control 60 system 140 applies new control signals drive interface 120. The pose of distal tip is thus actively monitored and controlled according to fixed constraints as long as control system 120 remains in the holding mode. It may be noted, however, that some degrees of freedom of distal steerable 65 segment 116 may not require active control. For example, in orientation stiffness mode, feedback control could actively

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maintain pitch and yaw of distal steerable segment 116, while the mechanical torsional stiffness of catheter 110 is relied on to hold the roll angle fixed. However, catheter 110 in general may be subject to unpredictable external forces or patient movement that would otherwise cause catheter 110 to move relative to the work site, and active control as in process 600 is needed to maintain or hold the desired working configuration.

Some embodiments or elements of the above invention non-transient media, such as an optical or magnetic disk, a memory card, or other solid state storage containing instructions that a computing device can execute to perform specific processes that are described herein. Such media may further be or be contained in a server or other device connected to a network such as the Internet that provides for the downloading of data and executable instructions.

Although the invention has been described with reference to particular embodiments, the description is only an example of the invention's application and should not be taken as a limitation. Various adaptations and combinations of features of the embodiments disclosed are within the scope of the invention as defined by the following claims.

What is claimed is:

- 1. A medical system comprising:
- a catheter comprising a lumen, a distal steerable segment, and a distal tip;
- a sheath disposed within the lumen of the catheter; and a control system coupled to the catheter, wherein the control system includes:
 - a memory operable to store desired position coordinates; and
 - a plurality of modes including a stiffening mode in which the control system actively maintains the distal tip at the desired position coordinates, wherein the sheath is extendable from the distal tip of the catheter while the control system actively maintains the distal tip at the desired position coordinates in the stiffening mode.
- 2. The medical system of claim 1, further comprising at least one sensor operable to determine measured position coordinates of the distal tip.
- 3. The medical system of claim 2, wherein the at least one sensor includes at least one electromagnetic sensor.
- 4. The medical system of claim 2, wherein during operation in the stiffening mode, the control system is configured

receive the measured position coordinates of the distal tip; determine a difference between the measured position coordinates and the desired position coordinates; and

- without user input directing movement of the catheter, move the distal steerable segment to minimize a difference between the measured and desired position coordinates.
- 5. The medical system of claim 4, wherein during operation in the stiffening mode, the control system constrains three degrees of freedom of the distal tip.
- 6. The medical system of claim 4, wherein during operation in the stiffening mode, the control system constrains at least four degrees of freedom of the distal tip.
- 7. The medical system of claim 1, further comprising at least one sensor operable to determine a measured orientation angle of the distal tip.
- 8. The medical system of claim 7, wherein the at least one sensor includes an optical fiber shape sensor.
- 9. The medical system of claim 7, wherein the memory is further operable to store a desired orientation angle of the

distal tip, and wherein the control system is further operable to actively maintain the distal tip in the desired orientation angle during operation in the stiffening mode.

10. The medical system of claim 9, wherein during operation in the stiffening mode, the control system is 5 further configured to:

receive the measured orientation angle of the distal tip; determine a difference between the measured orientation angle and the desired orientation angle; and

rotate the distal steerable segment to minimize a difference between the measured and desired orientation angles.

- 11. The medical system of claim 9, wherein during operation in the stiffening mode, the control system constrains three or more degrees of freedom of the distal tip. 15
- 12. The medical system of claim 1, wherein the plurality of modes further includes a mode in which the control system steers the catheter in response to commands received from an operator interface.
- 13. The medical system of claim 1, wherein the sheath is sized for extension into a natural passage during operation in

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the stiffening mode, the natural passage having a diameter less than an outer diameter of the catheter.

- 14. The medical system of claim 1, wherein the sheath comprises a passive sheath.
- 15. The medical system of claim 1, wherein the control system is configured to:
 - steer the catheter to point in a direction of a natural passage, wherein the sheath is extendable into the natural passage after the catheter points in the direction of the natural passage.
- 16. The medical system of claim 1, further comprising at least one removable probe deployable through the lumen and the sheath.
- 17. The medical system of claim 16, wherein the at least one removable probe comprises a laser.
- **18**. The medical system of claim **16**, wherein the at least one removable probe comprises a biopsy needle.
- 19. The medical system of claim 16, wherein the at least one removable probe comprises a camera.

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