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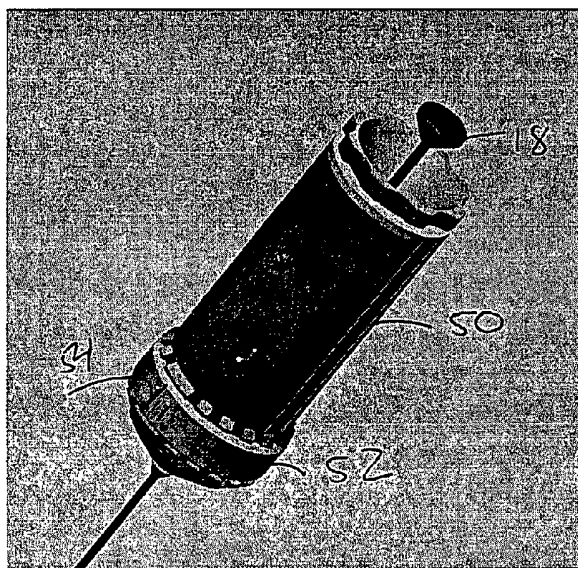
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: HANDLE FOR STEERABLE CATHETER



(57) Abstract: A handle for controlling a steerable catheter can be aligned so that the direction of movement of the catheter is aligned with the orientation of an image on a monitor. In one embodiment, the handle is axially symmetric, allowing a physician to grasp it such that the movement of the catheter is aligned with an image displayed. In another embodiment, the handle is a grip that is rotatable with respect to the controls of a steerable catheter in order to align the movement with the image displayed.

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HANDLE FOR STEERABLE CATHETER

FIELD OF THE INVENTION

The present invention relates to medical devices in general and to steerable
5 imaging devices in particular.

BACKGROUND OF THE INVENTION

On most handles for a steerable imaging device, the relationship between the
handle controls and the motion of the device is fixed. On some devices, however, the
"up" direction as viewed on the TV monitor will probably not be the same as the "up"
10 direction on a handle of the device. This occurs when the imaging device can rotate
relative to a surrounding catheter or within the patient's body. As a result, the physician
must move the controls to the left (for example) in order to steer the catheter in the "up"
direction on the TV monitor. If the imaging device rotates again, the physician must re-
determine which control direction corresponds to the "up" direction on the screen. This
15 process is not only cumbersome but increases the required time to complete an
examination.

SUMMARY OF THE INVENTION

To address the problems discussed above, the present invention is a handle
configuration and steering mechanism that can be rotated in the user's hand such that the
20 "up" direction on the handle can always be aligned with the "up" direction of images
produced on a screen. The handle may also include a rotating collar or other device to
indicate which direction on the handle corresponds to the "up" direction on the screen.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will
25 become more readily appreciated as the same become better understood by reference to
the following detailed description, when taken in conjunction with the accompanying
drawings, wherein:

FIGURE 1 illustrates a conventional 4-wire actuation handle for use in controlling
the direction of a steerable catheter;

30 FIGURE 2 is a handle for use with a steerable catheter according to an
embodiment of the present invention; and

FIGURE 3 is a rotatable grip for use with a steerable catheter in accordance with
another embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

As discussed above, the present invention is a handle that includes a steering mechanism for controlling the direction of a device to be inserted into a patient and that such device either produces images from within the body or whose position is imaged externally, such as by fluoroscopy, ultrasound, etc. The steering mechanism may be formed in a number of ways and be used with a variety of devices. In one embodiment, the steerable device is a multi-lumen catheter having one or more of the lumens dedicated to an imaging fiber and illumination fibers. The imaging and illumination fibers facilitate the transmittal of a visual image from inside the body to a physician or video camera. Alternatively, the catheter may include a solid state imaging sensor, such as a CCD or CMOS imaging chip. Another one or more of the lumens in the catheter are dedicated to pull wires that articulate the distal tip of the catheter. The pull wires have their distal ends secured at or adjacent the distal end of the catheter and their proximal ends connected to an actuator in the steering mechanism. Pulling one of the pull wires causes compression in one side of the catheter at the distal tip, which causes it to bend or articulate in that direction.

Utilizing four pull wires in four lumens allows four-way (left, right, up and down) motion. Some steerable catheters only utilize one pull wire and have only one direction of motion, while others utilize two wires for bi-directional motion. The present invention is most applicable to a four-wire system, but systems with fewer wires can also benefit.

One method of actuating the pull wires is shown in FIGURE 1. The steering mechanism includes a handle 20 with four pull wires 22, wherein proximal ends of the four pull wires are connected to the corners of an actuation plate 10. The steering mechanism includes a frame that supports a spherical ball and the attached actuation plate 10 so that the ball 12 can rotate between a front bearing 14 and a rear bearing 16, under direction of a lever arm 18. When the lever arm 18 is moved in a certain direction, the net result is that one or two of the four pull wires 22 are pulled. As is already known to those in the art, the resultant pull on the wires actuates the steerable tip of the catheter. This particular handle 20 is designed so that motion of the distal tip corresponds to the motion of the actuation lever – if the lever is moved down, then the distal tip of the catheter is also moved down.

The problem with the arrangement shown in FIGURE 1 is that the handle 20 remains fixed with respect to the orientation of the lever arm 18. If the imaging device

becomes rotated with respect to a catheter in which it is placed or the catheter is rotated with respect to a patient, movement of the lever arm in the "up" (or other) direction no longer corresponds to an "upward" (or other) movement of the image on a display. For example, the "up" direction of the visualization probe could be aligned with the "left" direction of the catheter. In this example, when the physician wants to steer the catheter towards the top of the video screen, he must actually move the control lever in a leftward direction. If the handle could be easily re-oriented such that "up" relative to the physician corresponds to "left" relative to the steering controls (which thus corresponded to "up" on the video screen), then the task of steering the tip of the catheter would be greatly simplified.

The present invention is a handle that controls a steerable catheter in a way that allows a user to easily re-orient the steering device such that movement of the pull wires in a direction produces movement of the image produced in a similar direction. Although the invention is described with respect to aligning an upward movement on a display with movement of the steering mechanism in a particular reference direction, it will be appreciated that movement in any direction can form a reference direction.

As shown in FIGURE 2, a handle 50 according to one embodiment of the invention contains the same lever arm 18 and catheter steering mechanism as shown in FIGURE 1, but has an exterior shape that is basically symmetric about a central axis and can be held in the user's hand in any orientation. The physician can grasp the outer diameter surface of the handle 50 with the palm and fingers in a substantially vertical orientation (like a water glass), then use the thumb to operate the lever arm 18. If the physician discovers (for example) that a leftward motion of the lever arm 18 is needed to create an upward motion of the distal tip, then he could grasp the handle 50 ninety degrees clockwise so that now an upward motion of the lever arm 18 will cause an upward motion of the tip of the catheter.

The handle 50 may also include a rotatable ring 52 that can spin around the handle body, but will remain in place due to friction or other means if it is left alone. This ring 52 could include a visual marker 54 that indicates which direction is "up". Thus once the physician finds out which direction on the handle 50 corresponds to "up" on the screen, he can rotate the ring 52 such that the visual marker 54 is aligned with the "up" direction. This facilitates keeping the handle 50 aligned in the proper orientation and

allows the user to put the handle down and pick it back up again without losing the proper orientation.

One particular application of the handle 50 of the present invention is for use with a fiber optic visualization catheter used in viewing the biliary tract. Such a catheter is normally introduced into the area of the biliary tract via a duodenoscope of the type well known in the art. A further improvement to the above handle would include a means for temporarily fastening the handle that actuates the catheter to the handle of the duodenoscope. Such a fastening means could include a velcro strap, a "C-clamp" and/or some kind of snap-fit component. The fastening means would allow the handle 50 to be rotated and aligned such that motion of the actuation lever could correspond with the motion of a catheter tip. The advantage of such a fastening means is that the physician can more easily operate the duodenoscope, the handle 50, and any auxiliary equipment required for the medical procedure. The physician would be able to release the catheter handle without it dropping towards the floor and without it losing rotational alignment.

In another embodiment, the handle may include an ergonomically shaped exterior grip 70 as shown in FIGURE 3. The grip 70 is rotatable around the steering mechanism such that a user can change the orientation of the grip 70 with respect to the lever arm 18 and associated steering mechanism. In use, the grip 70 is rotated so that movement of the lever arm 18 produces images that move in a desired direction on an image display. The grip 70 remains in its orientation by friction or may include a locking mechanism that allows the grip 70 to rotate when released.

As will be appreciated, the present invention enables the physician to always have the correct orientation between what is seen on the TV monitor and what direction to move the controls on the handle.

While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the scope of the invention. For example, the present invention can be used with any steerable device whose position is displayed on a screen. For example, catheters whose position is determined and displayed to a user using fluoroscopy or ultrasound can use the handle of the present invention in order to align movement of the catheter with a particular direction on the screen. It is therefore intended that the scope of the invention be determined from the following claims and equivalents thereof.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A steerable catheter, including:
 - a shaft having a proximal and a distal end and one or more lumens therein;
 - one or more pull wires having a distal end secured at or adjacent the distal end of the shaft and a proximal end secured to a steering mechanism that causes the one or more pull wires to be selectively tensioned or released in order to orient the catheter in a desired direction; and
 - a handle that allows a user to change the orientation of their hand, with respect to the steering mechanism, so that movement of the steering mechanism in a desired direction is aligned with an image of the catheter displayed for the user.
2. The steerable catheter of Claim 1, wherein the handle is axially symmetric and surrounds the steering mechanism so that a user can hold the handle at any position around the steering mechanism.
3. The steerable catheter of Claim 1, wherein the handle comprises a rotatable grip that is rotatable with respect to the steering mechanism.
4. The steerable catheter of Claim 3, wherein the grip is ergonomically shaped.
5. The steerable catheter of Claim 1, further comprising a movable indicator on the handle that indicates to the user the way in which the steering mechanism is to be activated in order to produce movement in a desired direction on the display.
6. The steerable catheter of Claim 5, wherein the movable indicator is a ring that is rotatable around the handle.
7. The steerable catheter of Claim 1, wherein the catheter includes an imaging mechanism that produces images of a patient's internal body cavity.
8. The steerable catheter of Claim 7, wherein the imaging mechanism includes fiber optic illumination and imaging bundles.

9. The steerable catheter of Claim 7, wherein the imaging mechanism includes a solid state imaging sensor.

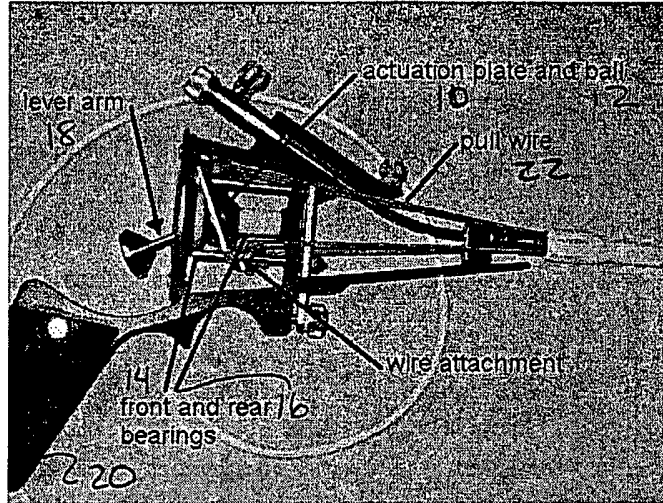


FIGURE 1 (Prior Art)

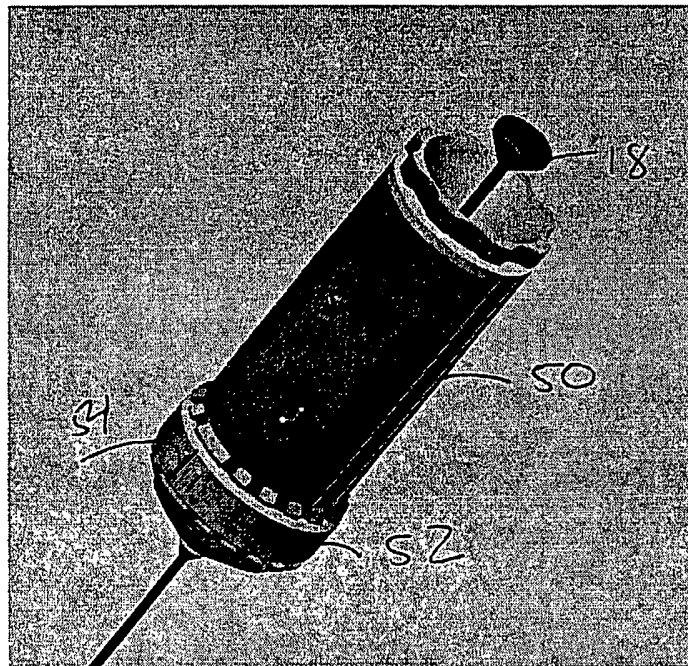
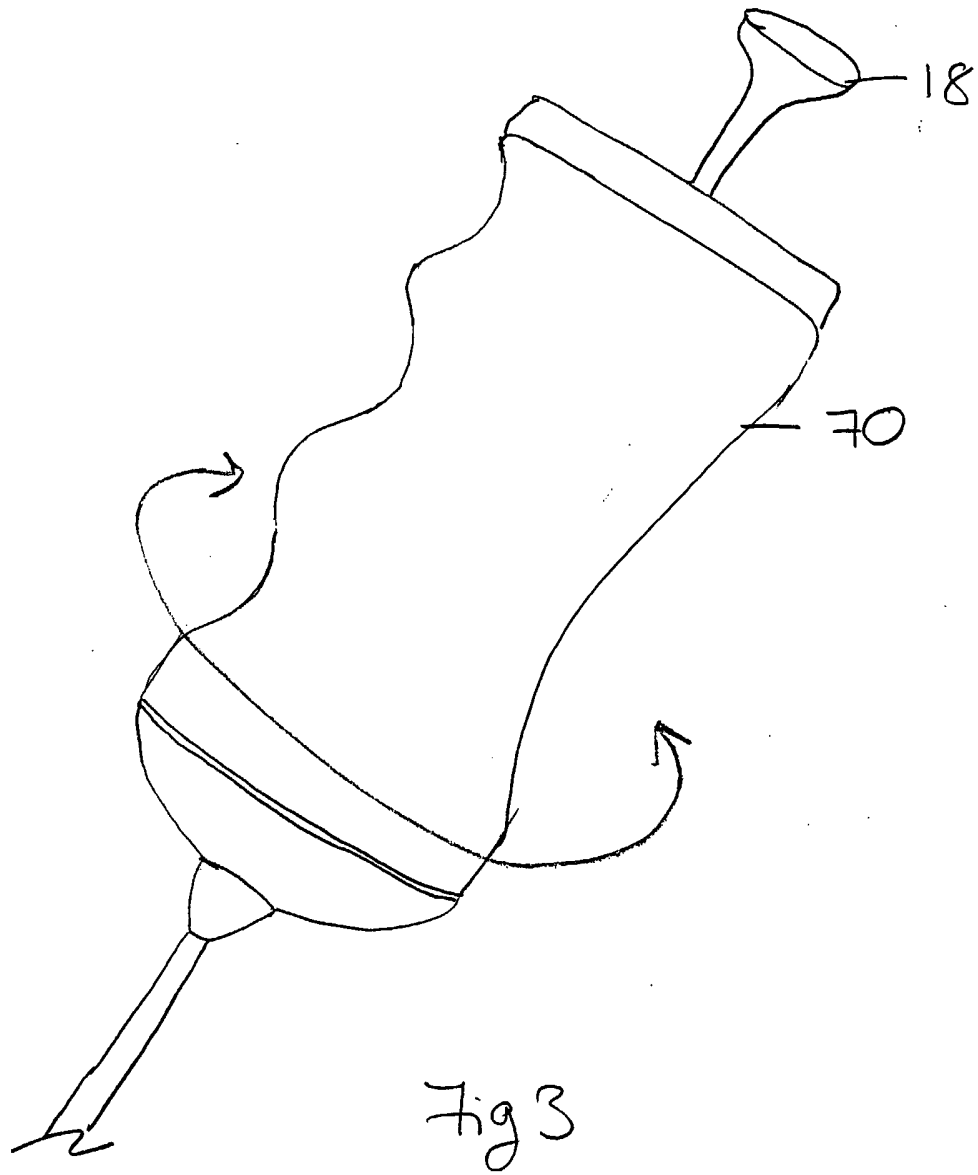


FIGURE 2



INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61M25/01		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	paragraphs '0033!', '0062!' - '0066!'; figures 12,13 -----	7-9
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Date of the actual completion of the international search <p style="text-align: center;">17 August 2005</p>	Date of mailing of the international search report <p style="text-align: center;">24/08/2005</p>	
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer <p style="text-align: center;">Cuiper, R</p>	

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
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