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(54) Title: ROTATIONAL SENSING CATHETER WITH SELF-SUPPORTING DRIVE SHAFT SECTION

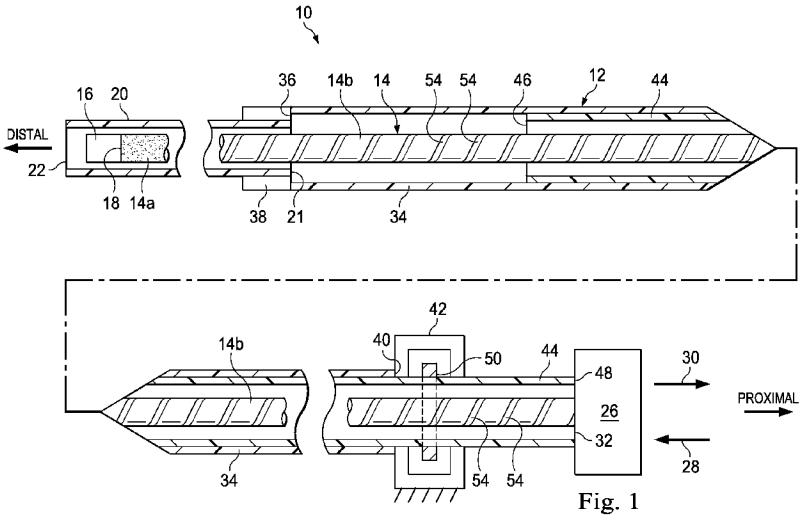

Fig. 1

(57) Abstract: An intravascular catheter has a telescope section including telescoped inner and outer tubular catheter members, a sheath having a proximal end anchored to an end of one of the inner and outer catheter members, and an elongated flexible drive member coaxially disposed within and being proximally and distally movable through the sheath. The drive member has a distal portion received in the sheath, and a second, unsheathed portion extending beyond the sheath into the interior of the telescope section. The unsheathed portion of the drive member has a stiffness greater than that of the sheath-disposed distal portion of the drive member and of a sufficient magnitude such that the unsheathed portion of the drive member is self-supporting within the telescope section.

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ROTATIONAL SENSING CATHETER WITH SELF-SUPPORTING DRIVE SHAFT SECTION

TECHNICAL FIELD

An embodiment of the present disclosure relates generally to the field of medical devices and, more particularly, to catheter apparatus used in internal vasculature diagnostic procedures.

BACKGROUND

Various techniques and systems have recently been developed to visualize the anatomy of vascular occlusions by using intravascular ultrasound (IVUS) imaging. IVUS techniques are catheter based and provide a real-time sectional image of the arterial lumen and the arterial wall. An IVUS catheter includes one or more ultrasound transducers at the distal tip of the catheter by which images containing cross-sectional information of the artery under investigation can be determined. IVUS imaging permits visualization of the configuration of the obstructing material and, in varying degrees, the boundaries of the intimal and medial layers of the arterial wall.

One common type of IVUS imaging catheter system typically includes an arrangement in which a single transducer at the distal end of the catheter is rotated at high speed (up to about 2000 rpm) to generate a rapid series of 360-degree ultrasound sweeps. Such speeds result in generation of up to about thirty images per second, effectively presenting a real-time image of the diseased artery.

The transducer is mounted on the end of a drive shaft or cable that is connected to a motor drive at the proximal end of the catheter. The rotating transducer is housed within a sheath that does not interfere with the ultrasound and protects the artery from the rapidly spinning drive shaft. Thus, an IVUS imaging (or "sensing") catheter may be advanced to the region of an occlusion using conventional angiographic techniques and then may be operated to provide real-time sectional images of the vascular lumen in the arterial wall, including the occluding material and intimal and medial layers of the artery wall. Other types of catheter-based systems for use in visualizing the internal anatomy of body portions implementing sheath-enclosed movable sensing/imaging elements disposed on elongated drive shaft structures are also known, including photo-acoustic, optical coherence tomography, phased array/multiple transducer, and spectroscopic systems.

Medical sensing catheters of these representative types comprise a tubing assembly through which the drive cable movably extends, the tubing assembly typically including a

sheath insertable into the patient and having a proximal end fixed to a telescope section which permits the drive cable, and thus the sensor, to be selectively moved though the patient's body via the interior of the inserted sheath which remains stationary in the patient's body. The telescope section comprises a tubular outer catheter or telescope member, to the distal end of which the proximal end of the sheath is anchored. The telescope section also has a tubular inner catheter or telescope member which telescopes into the interior of the outer telescope member through its proximal end and is movable through the interior of the outer telescope member between retracted and extended positions relative to the outer telescope member. The drive cable is secured to the inner telescope member for longitudinal movement therewith relative to the outer catheter member.

Distal movement of the inner telescope member toward its retracted position distally pushes the drive cable and the sensor through the sheath, and proximal movement of the inner telescope member toward its extended position pulls the drive cable and the sensor back through the sheath. When the inner telescope member is moved to its extended position a portion of the drive cable extending through the interior of the outer catheter member between the distal end of the outer telescope member and the distal end of the inner catheter member is substantially unsupported and unconstrained within the telescope section.

In response to a subsequent movement of the inner telescope member distally toward its retracted position the exposed, unsupported portion of the drive cable may undesirably be caused to buckle within the telescope section, thereby hindering a desired distal advancement of the drive cable through the sheath and potentially damaging the cable. A previously proposed solution to this potential drive cable buckling problem has been to position a separate reinforcing structure within the telescope section to support the portion of the drive cable extending through the telescope section when the inner telescope member is moved proximally away from its retracted position.

This previously proposed drive cable supporting technique, however, has proven to be less that wholly satisfactory because it requires the provision and installation in the overall catheter assembly of at least one additional component to support the otherwise unsupported section of the drive cable within the telescope section, thereby undesirably increasing the catheter assembly cost, complexity and manufacturing time. As may be readily seen from the foregoing, a need exists for an improved solution to the above-described catheter drive cable buckling problem. It is to this need that the present invention is primarily directed.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an enlarged scale longitudinally foreshortened schematic cross-sectional view through medical sensing catheter apparatus embodying principles of the present invention;

FIG. 2 is a longitudinally foreshortened schematic cross-sectional view through a telescope section of the catheter apparatus with an inner telescope portion of the section being in its fully retracted position; and

FIG. 3 is a view similar to that in FIG. 2 but with the inner telescope portion of the telescope section being in its fully extended position.

DETAILED DESCRIPTION

A catheter 10 embodying principles of the present invention is schematically depicted in FIGS. 1-3. By way of non-limiting example, the catheter apparatus 10 is a medical sensing catheter, and more specifically is an intravascular ultrasound (IVUS) imaging catheter. Catheter 10 includes an elongated flexible tubular assembly 12 that circumscribes an elongated flexible drive shaft or cable 14 having an ultrasound sensor 16 on its distal end 18.

The tubular assembly 12 that circumscribes the drive cable 14 and the sensor 16 includes a sheath 20 having a proximal end 21, and a distal end 22 insertable into the body of a patient, and a telescope section 24 (see FIGS. 2 and 3) that facilitates movement of the drive cable 14 distally and proximally through the sheath 20 while it remains stationary within the patient's body. Selective rotation and translation of the drive cable 14 relative to the sheath 20 is effected by a conventional, schematically depicted translational/rotational drive mechanism 26 (FIG. 1) that may be selectively translated in distal and proximal directions as respectively illustrated by arrows 28,30 in FIG. 1. The drive mechanism 26 is operatively coupled to the proximal end 32 of the drive cable 14 and functions in a conventional manner to translate and rotate the drive cable 14.

Telescope section 24 includes an elongated flexible tubular outer catheter or telescope member 34 having a distal end 36 fixedly secured to an annular coupling 38 that circumscribes and is fixedly secured to the proximal end of the sheath 20. The proximal end 40 of the outer telescope member 34 is anchored to a schematically depicted stationary support structure 42 distally positioned relative to the drive mechanism 26. The telescope section 24 further includes an elongated flexible tubular inner catheter or telescope member 44 which has distal and proximal ends 46,48 (see FIG. 1). Proximal end 48 is secured to the drive mechanism 26, and the inner telescope member 44 slidably extends through an O-ring

seal member 50 carried by the stationary support structure 42 which may be of a conventional construction and may be assembled around the O-ring 50.

According to a feature of the present invention the O-ring seal 50 is formed of a self-lubricating material, representatively a fluoroelastomeric material. The use of a self-lubricating seal member substantially facilitates and quickens the assembly of the support structure 42 by eliminating the necessity of lubricating the seal and one or more of the support structure parts prior to using the support structure 42.

As shown in FIGS. 1-3, the inner telescope member 44 is distally telescoped into the outer telescope member portion 34 of the overall tubular assembly 12 for translation relative thereto (by means of the drive mechanism 26) between a retracted position shown in FIG. 2 (in which the sensor 16 is distally advanced within the sheath 20) and an extended position shown in FIG. 3 (in which the sensor is proximally retracted within the sheath 20).

According to a further feature of the present invention, the flexible drive shaft 14 is not of a uniform construction along its length. Instead, a first portion 14a of the drive shaft 14 extending proximally away from the sensor 16 (see FIGS. 1 and 3) is of a conventional construction, representatively of a helically wound wire construction. Fixedly and coaxially secured to the proximal end of the drive shaft portion 14a (as, for example, by an end weld 52 as shown in FIG. 3), and extending proximally away therefrom, is a second representatively metal drive shaft portion 14b. The relative lengths of the drive shaft sections 14a,14b are sized in a manner such that when the inner telescope member 44 is in its FIG. 3 extended position the section 14b extends from the section 14a at least through essentially the entire interior length of the telescope section 24.

The flexible drive shaft section 14b has a stiffness sufficiently greater than that of the drive shaft portion 14a so as to be self-supporting during operation within the telescope section 24 when, as depicted in FIG. 3, the inner telescope member 44 is proximally moved away from its FIG. 2 retracted position toward or completely to its FIG. 3 extended position. By way of non-limiting example, the flexible drive shaft section 14b may be a tubular helically cut metal beam member with the representatively illustrated helical cut patterns 54 formed on its exterior surface. Although the illustrated embodiment shows the drive shaft section 14b as straight, it will be appreciated that the helical cuts 54 along the tubular metal beam allow the drive shaft section 14b to bend, if necessary, during operation and still rotate the sensor 16. However, the drive shaft section 14b could alternatively be of a variety of other materials and constructions without departing from principles of the present invention.

For example, a sufficiently rigid polymer tube may be selected as the drive shaft section 14b that can be joined to the shaft section 14a via a mechanical coupling.

For purposes of manufacturing efficiency, the relatively stiffer self-supporting flexible drive shaft section 14b may, as schematically depicted in FIG. 1, extend from its connection 52 at the drive shaft section 14a (see FIG. 3) to the drive mechanism 26. Alternatively, the length of the drive shaft section 14b may be somewhat shorter and connected at its proximal end to a terminal drive shaft section of a different construction such as, for example, the helically wound wire material used in the drive shaft section 14a, or a solid metal material.

The unique incorporation in the catheter 10 of the self-supporting flexible drive shaft section 14b desirably eliminates the previous necessity of shielding and supporting a drive shaft portion exposed within the telescope section by providing and installing a separate protective structure within the telescope section.

While the catheter 10 has been representatively illustrated as being an IVUS catheter, it will be readily appreciated by those of ordinary skill in this particular art that other types of catheter structures with flexible internal drive shafts or cables and associated telescope sections may advantageously incorporate the above-described type of self-supporting cable structure without departing from principles of the present invention. Such other types of catheter structures and sensing elements include, for example, photo-acoustic, optical coherence tomography (OCT), phased array/multiple transducer, and spectroscopic systems. Still further, while the outer telescope member 34 is shown fixed to the proximal end 21 of the sheath 20, and the inner telescope member 44 is fixed to the drive mechanism 26, these fixation locations of the inner and outer telescope members 44,34 may be reversed such that the drive shaft 14 moves with the outer telescope member 34.

WHAT IS CLAIMED IS

1. Catheter apparatus comprising:

a telescope section including telescoped inner and outer tubular catheter members;

a sheath having a proximal end anchored to an end of one of said outer or inner tubular catheter member; and

an elongated flexible drive member coaxially extending through said outer tubular catheter member and being proximally and distally movable through said sheath,

said elongated flexible drive member having a distal portion disposed within said sheath, and a second portion extending proximally beyond said sheath and having a stiffness greater than that of said distal portion of said elongated flexible drive member.

2. The catheter apparatus of Claim 1 wherein:

said second portion of said elongated flexible drive member is of a stiffness sufficient so as to be self-supporting within said telescope section.

3. The catheter apparatus of Claim 2 wherein:

said distal portion of said elongated flexible drive member is of a helically wound wire construction, and

said second portion of said elongated flexible drive member is of a helically cut metal beam construction.

4. The catheter apparatus of Claim 3 wherein:

said distal and second portions of said elongated flexible drive member are end-welded to one another.

5. The catheter apparatus of Claim 1 wherein:

said catheter apparatus is a medical sensing catheter including a sensing element secured to said distal portion of said elongated flexible drive member.

6. The catheter apparatus of Claim 5 wherein:

said medical sensing catheter is an IVUS catheter, and

said sensing element is a rotatable ultrasonic sensing element.

7. The catheter apparatus of Claim 1 wherein:

a portion of said inner tubular catheter member is slidingly supported within a self-lubricating O-ring seal member.

8. The catheter apparatus of Claim 7 wherein:

said outer tubular catheter member has a proximal end, and

said self-lubricating O-ring seal member is of a fluoroelastomeric material and is disposed proximally of said proximal end of said outer tubular catheter member.

9. Catheter apparatus comprising:

an elongated flexible tubing assembly having:

a telescope section including a tubular outer telescope member having proximal and distal ends, a tubular inner telescope member longitudinally movable through the interior of said outer telescope member toward and away from said distal end thereof between retracted and extended positions, and a sheath member having a proximal end anchored to said distal end of said outer telescope member; and

an elongated flexible drive member extending through said outer telescope member and being distally and proximally movable with said inner telescope member through said outer telescope member and said sheath, said elongated flexible drive member having a distal portion disposed within said sheath, and a second portion extending proximally from said distal portion, said second portion being moved into and exposed within said outer telescope member in response to movement of said inner telescope member to said extended position thereof,

said second portion of said elongated flexible drive member having a greater stiffness than that of said distal portion of said elongated flexible drive member.

10. The catheter apparatus of Claim 9 wherein:

said second portion of said elongated flexible drive member is of a self-supporting construction.

11. The catheter apparatus of Claim 10 wherein:

said second portion of said elongated flexible drive member is a tubular cut beam member.

12. The catheter apparatus of Claim 11 wherein:

said distal portion of said elongated flexible drive member is of a helically wound wire construction.

13. The catheter apparatus of Claim 12 wherein:

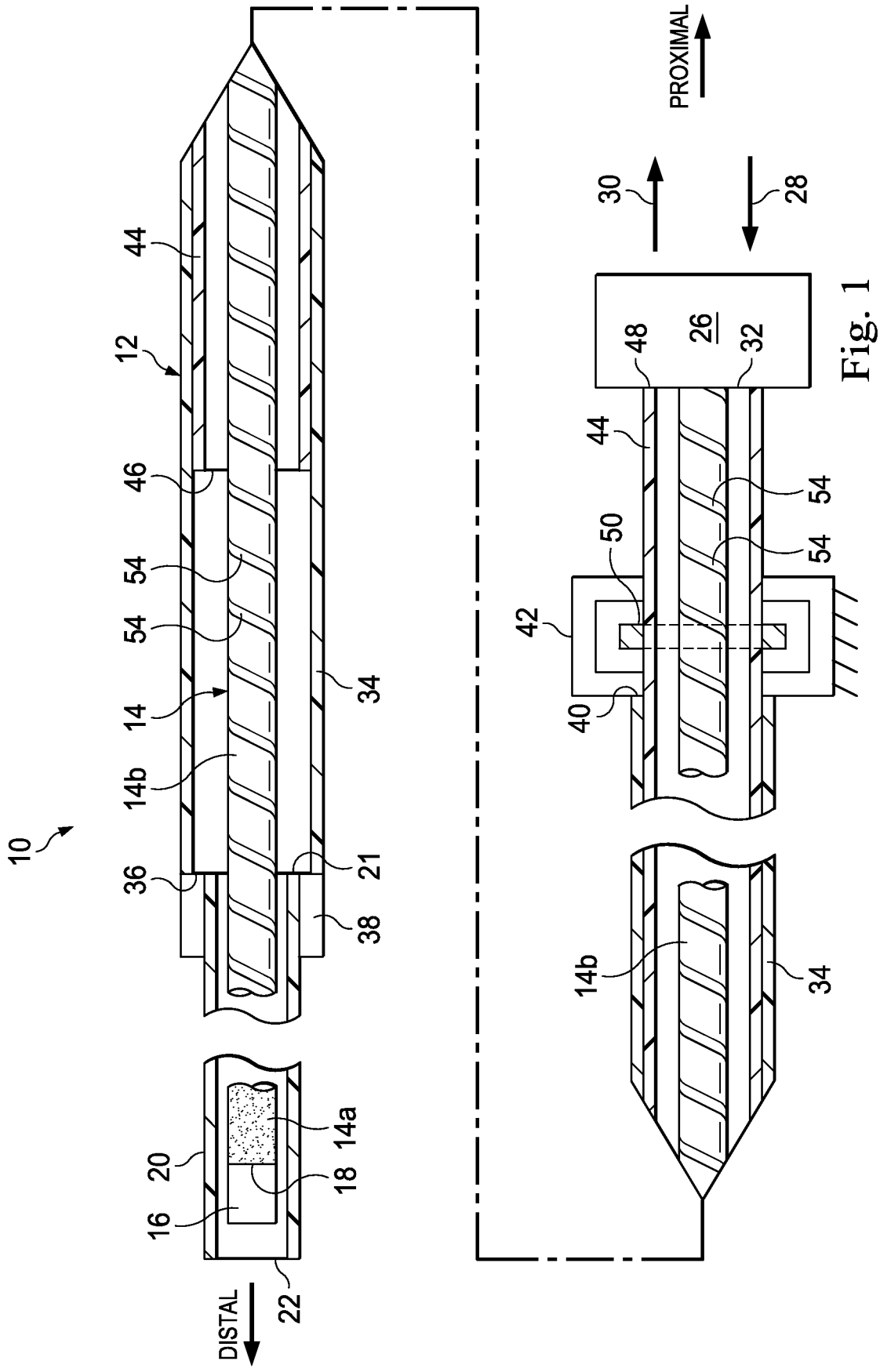
said distal and second portions of said elongated flexible drive member are end-welded to one another.

14. The catheter apparatus of Claim 8 wherein:

said sheath and said flexible drive member are constructed and configured in a manner permitting operational rotation of said flexible drive member relative to said sheath at speeds up to about 2000 rpm.

15. The catheter apparatus of Claim 8 wherein:

said catheter apparatus is an IVUS catheter apparatus.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14b
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54
DISTAL
PROXIMAL

Fig. 1

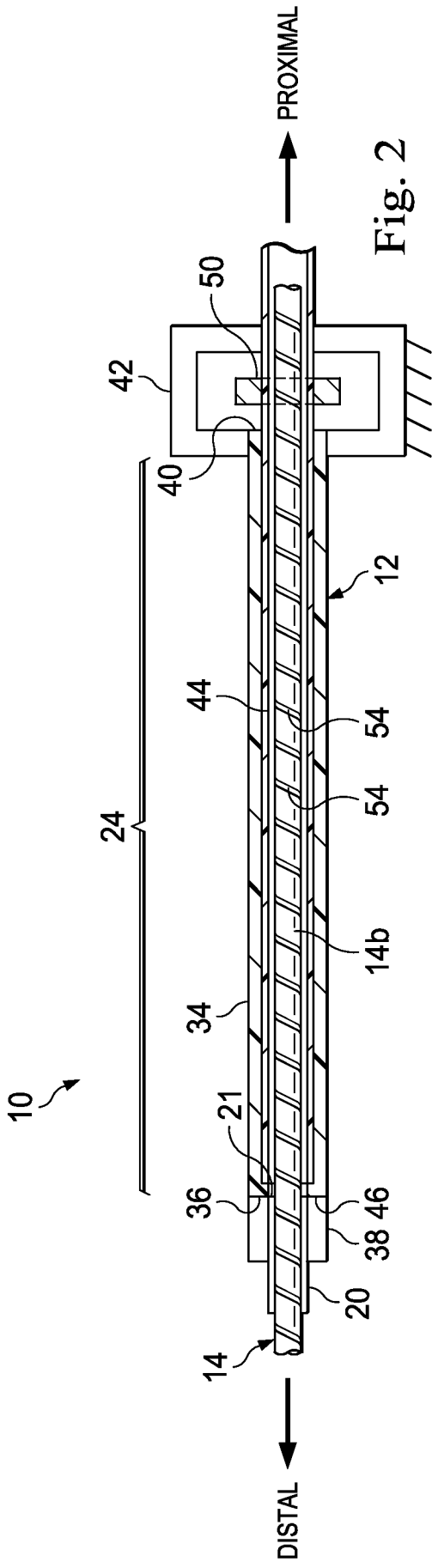
PROXIMAL
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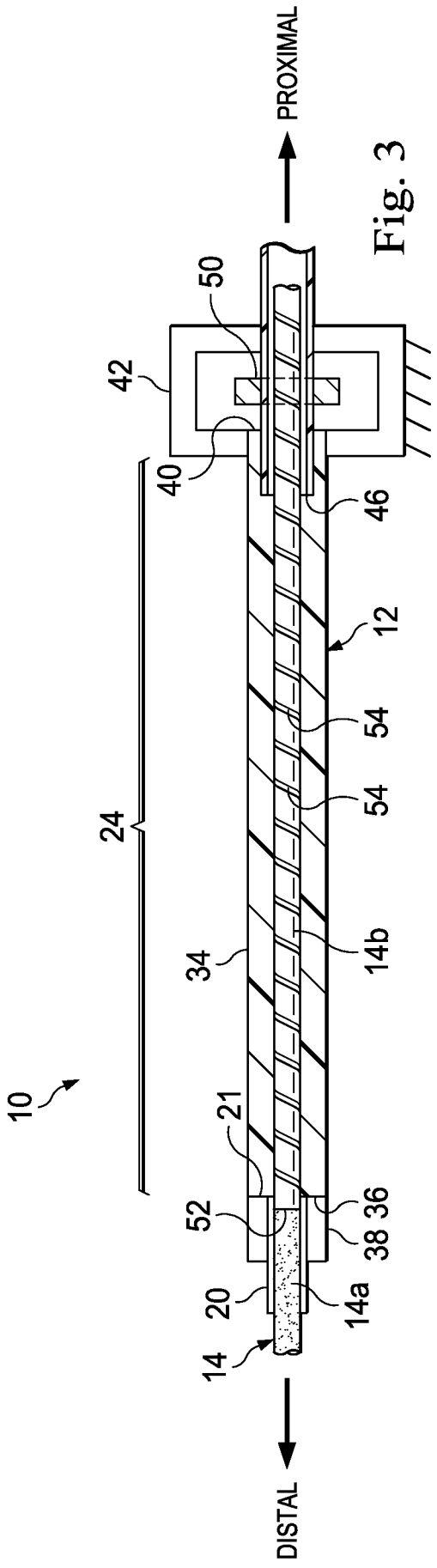
Fig. 2


PROXIMAL
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14b
14a

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/074344

A. CLASSIFICATION OF SUBJECT MATTER

A61B 8/12(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 8/12; A61M 25/00; B23P 11/00; A61B 8/14; A61N 7/02; A61B 18/02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: catheter, sheath, telescope, rotate, tubular, stiffness

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008-0167602 A1 (HENRY NITA et al.) 10 July 2008 See abstract, paragraphs [0045]-[0047], claim 1 and figures 3-5.	1-8,14,15
Y		9-13
Y	US 2004-0073203 A1 (XIAOYU YU et al.) 15 April 2004 See abstract, paragraph [0030], claim 1 and figures 1-8.	9-13
A	US 2010-0234736 A1 (PAUL DOUGLAS CORL) 16 September 2010 See abstract, paragraphs [0019]-[0025], claim 1 and figures 1,2	1-15
A	US 2010-0318064 A1 (HUGO GEORGE DERRICK et al.) 16 December 2010 See abstract, paragraphs [0045]-[0050] and figure 1.	1-15
A	US 2009-0156941 A1 (THOMAS C. MOORE) 18 June 2009 See abstract, paragraphs [0006],[0037] and figures 3-6.	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 March 2014 (27.03.2014)	**31 March 2014 (31.03.2014)**

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/074344

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Information on patent family members

International application No.
PCT/US2013/074344

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专利名称(译)	旋转传感导管，带自支撑传动轴部分		
公开(公告)号	EP2931130A4	公开(公告)日	2016-08-17
申请号	EP2013861861	申请日	2013-12-11
[标]申请(专利权)人(译)	火山公司		
申请(专利权)人(译)	火山CORPORATION		
当前申请(专利权)人(译)	火山CORPORATION		
[标]发明人	VAN HOVEN DYLAN		
发明人	VAN HOVEN, DYLAN		
IPC分类号	A61B8/12		
CPC分类号	A61B8/445 A61B5/0066 A61B5/0095 A61B8/12		
代理机构(译)	博尔特WADE TENNANT		
优先权	61/736588 2012-12-13 US		
其他公开文献	EP2931130A1		
外部链接	Espacenet		

摘要(译)

血管内导管具有包括伸缩的内管状导管构件和外管状导管构件的望远镜部分，具有固定到内导管构件和外导管构件之一的端部的近端的护套，以及同轴地设置在其内部并且在近端和远端的细长柔性驱动构件可以通过护套移动。驱动构件具有容纳在护套中的远端部分，以及延伸超过护套进入望远镜部分内部的第二未穿戴部分。驱动构件的未鞘部分的刚度大于驱动构件的设有护套的远端部分的刚度，并且具有足够的大小，使得驱动构件的未铠装部分在望远镜部分内自支撑。