

US Patent & Trademark Office

Patent Public Search | Text View

United States Patent	12390620
Kind Code	B2
Date of Patent	August 19, 2025
Inventor(s)	Beeckler; Christopher Thomas et al.

Contact force spring with mechanical stops

Abstract

A catheter apparatus, including an elongated deflectable element, a distal assembly, a force sensor disposed between the elongated deflectable element and the distal assembly, and comprising a spring including a tube with at least one helical cut extending around a circumference of the tube, the at least one helical cut including deviations extending in a longitudinal direction of the tube, the deviations being configured to prevent overstretching and overbending of the spring.

Inventors: Beeckler; Christopher Thomas (Brea, CA), Keyes; Joseph Thomas (Sierra Madre, CA)

Applicant: Biosense Webster (Israel) Ltd. (Yokneam, IL)

Family ID: 1000008764018

Assignee: Biosense Webster (Israel) Ltd. (Yokneam, IL)

Appl. No.: 16/726605

Filed: December 24, 2019

Prior Publication Data

Document Identifier	Publication Date
US 20210187254 A1	Jun. 24, 2021

Publication Classification

Int. Cl.: A61M25/10 (20130101); A61B5/00 (20060101); A61B18/14 (20060101); A61M39/10 (20060101); A61B18/00 (20060101); A61M25/00 (20060101)

U.S. Cl.:

CPC A61M25/10 (20130101); A61B5/6853 (20130101); A61B18/1482 (20130101); A61B18/1492 (20130101); A61M39/10 (20130101); A61B5/6885 (20130101);

A61B2018/00172 (20130101); A61B2018/0022 (20130101); A61B2018/00577 (20130101); A61M2025/0059 (20130101); A61M2039/1033 (20130101); A61M2205/332 (20130101)

Field of Classification Search

CPC: A61M (25/10); A61M (39/10); A61M (2025/0059); A61M (2205/332); A61M (2039/1033); A61B (5/6853); A61B (5/6885); A61B (18/1482); A61B (18/1492); A61B (2018/00172); A61B (2018/0022); A61B (2018/00577)

References Cited

U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
6623480	12/2002	Kuo	606/41	A61B 18/1492
9101734	12/2014	Selkee	N/A	A61M 25/0147
2008/0294158	12/2007	Pappone	606/41	A61B 18/1492
2011/0130648	12/2010	Beeckler et al.	N/A	N/A
2011/0263934	12/2010	Aeby et al.	N/A	N/A
2012/0253167	12/2011	Bonyak	600/409	A61B 5/062
2013/0253503	12/2012	Govari	606/41	A61B 18/1492
2014/0005661	12/2013	Shelton, IV	606/41	A61B 34/37
2016/0339207	12/2015	Beeckler et al.	N/A	N/A
2017/0319269	12/2016	Oliverius	N/A	A61M 39/12
2018/0256247	12/2017	Govari et al.	N/A	N/A
2018/0271590	12/2017	Basu	N/A	A61M 25/0043
2018/0338811	12/2017	Miklos et al.	N/A	N/A
2019/0247622	12/2018	Romano	N/A	A61M 25/09

FOREIGN PATENT DOCUMENTS

Patent No.	Application Date	Country	CPC
3189806	12/2016	EP	N/A
2013192947	12/2012	JP	N/A
2018143771	12/2017	JP	N/A

OTHER PUBLICATIONS

Active Spring Components http://www.dent-wiki.com/dental_technology/active-spring-components. cited by applicant

A (Near) Real-Time Simulation Method of Aneurysm Coil Embolization; ResearchGate; Book: Aug. 2012; <http://www.researchgate.net/publication/278763087>; pp. 232-233. cited by applicant

Extended European Search Report dated May 11, 2021, from corresponding European Application No. 20217038.7. cited by applicant

Examination Report dated May 28, 2024, from corresponding European Application No. 20217038.7. cited by applicant

Search Report dated Jun. 28, 2024, from corresponding Japanese Application No. 2020-213426. cited by applicant

English translation of Notice of Reasons for Refusal dated Jul. 9, 2024, from corresponding Japanese Application No. 2020-213426. cited by applicant

Background/Summary

FIELD OF THE INVENTION

(1) The present invention relates to medical equipment, and in particular, but not exclusively to, contact force springs.

BACKGROUND

(2) In some diagnostic and therapeutic techniques, a catheter is inserted into a chamber of the heart and brought into contact with the inner heart wall. In such procedures, it is generally important that the distal tip of the catheter engages the endocardium with sufficient pressure to ensure good contact. Excessive pressure, however, may cause undesired damage to the heart tissue and even perforation of the heart wall.

(3) For example, in intracardiac radio-frequency (RF) ablation, a catheter having an electrode at its distal tip is inserted through the patient's vascular system into a chamber of the heart. The electrode is brought into contact with a site (or sites) on the endocardium, and RF energy is applied through the catheter to the electrode in order to ablate the heart tissue at the site. Proper contact between the electrode and the endocardium during ablation is necessary in order to achieve the desired therapeutic effect without excessive damage to the tissue.

(4) US Patent Publication 2011/0263934 of Aeby, et al., describes a catheter for diagnosis or treatment of a vessel or organ is provided in which a flexible elongated body includes a tri-axial force sensor formed of a housing and a plurality of optical fibers associated with the housing that measure changes in the intensity of light reflected from the lateral surfaces of the housing resulting from deformation caused by forces applied to a distal extremity of the housing. A controller receives an output of the optical fibers and computes a multi-dimensional force vector corresponding to the contact force.

(5) US Patent Publication 2011/0130648 of Beeckler, et al., describes a medical probe, consisting of a flexible insertion tube, having a distal end for insertion into a body cavity of a patient, and a distal tip, which is disposed at the distal end of the flexible insertion tube is configured to be brought into contact with tissue in the body cavity. The probe also includes a coupling member, which couples the distal tip to the distal end of the insertion tube and which consists of a tubular piece of an elastic material having a plurality of intertwined helical cuts therethrough along a portion of a length of the piece.

(6) US Patent Publication 2016/0339207 of Beeckler, et al., describes a catheter having a catheter shaft that has a more uniform construction throughout its length and is able to provide more than one deflection curvature. The catheter shaft includes a flexible outer tubular member, and a less flexible inner tubular member extending through the outer tubular member in a proximal section of the catheter shaft, wherein the inner tubular member is afforded longitudinal movement relative to the outer tubular member. The catheter also includes at least one puller wire extending through the inner tubular member to deflect a distal deflection section of the catheter shaft, wherein longitudinal movement of the inner tubular member relative to the outer tubular member enables an operator to select and set a deflection curvature of the distal deflection section.

SUMMARY

(7) There is provided in accordance with an embodiment of the present disclosure, a catheter apparatus, including an elongated deflectable element, a distal assembly, a force sensor disposed between the elongated deflectable element and the distal assembly, and including a spring including

a tube with at least one helical cut extending around a circumference of the tube, the at least one helical cut including deviations extending in a longitudinal direction of the tube, the deviations being configured to prevent overstretching and overbending of the spring.

(8) Further in accordance with an embodiment of the present disclosure respective ones of the deviations include respective opposing sigmoid curves.

(9) Still further in accordance with an embodiment of the present disclosure respective ones of the deviations of the helical cuts define respective mechanical stops, each mechanical stop including opposing surfaces which are configured to come into contact with each other to prevent overstretching and overbending of the spring.

(10) Additionally, in accordance with an embodiment of the present disclosure respective ones of the mechanical stops are configured to engage simultaneously so that a force applied on the spring is shared among the respective mechanical stops to prevent sequential failure of the respective mechanical stops.

(11) Moreover, in accordance with an embodiment of the present disclosure the at least one helical cut includes multiple helical cuts, respective ones of the mechanical stops of each of the helical cuts being configured to engage simultaneously.

(12) Further in accordance with an embodiment of the present disclosure the at least one helical cut includes multiple helical cuts, the mechanical stops of each of the helical cuts being configured to engage simultaneously.

(13) Still further in accordance with an embodiment of the present disclosure respective ones of the mechanical stops include respective T-shape elements disposed in respective T-shape openings.

(14) Additionally, in accordance with an embodiment of the present disclosure respective ones of the mechanical stops include respective L-shape elements disposed in respective L-shape openings.

(15) Moreover, in accordance with an embodiment of the present disclosure respective ones of the mechanical stops include respective loops and sockets.

(16) Further in accordance with an embodiment of the present disclosure the at least one helical cut includes multiple helical cuts, the tube including three of the helical cuts.

(17) Still further in accordance with an embodiment of the present disclosure, the apparatus includes a proximal coupler having a proximal and distal end, wherein the elongated deflectable element has a distal end connected to the proximal end of the proximal coupler, the tube and the distal end of the proximal coupler including complementary bayonet connecting features connecting the distal end of the proximal coupler with the tube.

(18) Additionally, in accordance with an embodiment of the present disclosure, the apparatus includes a distal coupler, wherein the tube has a distal end including holes disposed around the circumference of the tube, the distal end of the tube being connected to the distal coupler via an adhesive which extends into respective ones of the holes.

(19) Moreover, in accordance with an embodiment of the present disclosure the tube includes a distal edge with openings therein, the distal coupler including protrusions configured for engaging the openings to prevent rotation of the distal coupler with respect to the tube.

(20) Further in accordance with an embodiment of the present disclosure the openings include U-shaped openings.

(21) Still further in accordance with an embodiment of the present disclosure, the apparatus includes a distal coupler, wherein the tube includes a distal edge with openings therein, the distal coupler including protrusions configured for engaging the openings to prevent rotation of the distal coupler with respect to the tube.

(22) Additionally, in accordance with an embodiment of the present disclosure the openings include U-shaped openings.

(23) Moreover, in accordance with an embodiment of the present disclosure the distal assembly includes an expandable distal assembly.

(24) Further in accordance with an embodiment of the present disclosure the expandable distal

assembly includes an inflatable balloon.

(25) Still further in accordance with an embodiment of the present disclosure the force sensor includes a transmitting coil and at least one receiving coil disposed on the tube.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) The present invention will be understood from the following detailed description, taken in conjunction with the drawings in which:

(2) FIG. 1 is a schematic view of a catheter constructed and operative in accordance with an embodiment of the present invention;

(3) FIGS. 2A-B are schematic views of the catheter of FIG. 1 with an outer sleeve removed;

(4) FIG. 3 is a schematic view of the catheter of FIG. 1 with several elements removed;

(5) FIG. 4 is a partially exploded view of the catheter as shown in FIG. 3;

(6) FIGS. 5A-C are schematic views of a proximal coupler of the catheter of FIG. 1;

(7) FIGS. 6A-B are schematic views of the distal coupler of the catheter of FIG. 1;

(8) FIGS. 7A-B are schematic views of a spring of the catheter of FIG. 1;

(9) FIGS. 8A-C are schematic views of a force sensor of the catheter of FIG. 1; and

(10) FIG. 9 is a schematic view of a spring constructed and operative in accordance with an alternative embodiment of the present invention.

DESCRIPTION OF EXAMPLE EMBODIMENTS

Overview

(11) An assembly, such as a balloon, at the tip of a contact force sensor of a catheter presents a unique challenge to a contact force spring of the force sensor. The spring experiences significantly higher tensile forces as the assembly is withdrawn into the catheter sheath, or other such maneuvers. In addition to the withdrawal forces, even during normal use side and other forces exerted on the spring are higher than those exerted with a focal catheter due to the length of the assembly, e.g., a balloon.

(12) For example, the contact force spring may be formed from one or more helices cut around a tube. The spring functions very well when attached to a focal catheter. However, in the case of other catheters such as a balloon catheter, the higher forces on the spring, typically when the balloon is withdrawn into its sheath, or pulling the balloon on a Haemostatic valve, can permanently damage the spring, for example, the ends of the helical cuts may open too much.

(13) Embodiments of the present invention solve the above problems by adding deviations in the helical cut(s) in a spring to provide mechanical stops which prevent overbending and overstretching of the spring. The mechanical stops are designed to engage once the spring has been extended by a preset amount, and the engagement prevents plastic deformation, which is irreversible, of the spring. The mechanical stops are generally designed to prevent overstretching while still allowing for compression of the spring so that the spring can still perform its main function in measuring force. Alternate shapes of mechanical stops are possible.

(14) In some embodiments, the mechanical stops are designed to engage simultaneously rather than sequentially in order to share the load evenly, otherwise one (or more) mechanical stop(s) will take the entire load until it (or they) fails, at which point the next mechanical stop(s) would take the load, etc.

(15) In some embodiments, a catheter includes an elongated deflectable element, a distal assembly (which may include an expandable distal assembly, e.g., including an inflatable balloon), a force sensor disposed between the elongated deflectable element and the distal assembly. The force sensor includes a tube with helical cuts extending around a circumference of the tube. Each helical cut includes deviations extending in a longitudinal direction of the tube. The deviations prevent

overstretching and overbending of the spring. The force sensor may include position coils disposed on the tube.

(16) The tube may include any suitable number of helical cuts, for example, two, three, or more than three. The term “helical cut”, as used in the specification and claims, is defined as a helical cut extending more than one turn around the tube, or extending at least half of a turn around the tube.

(17) Respective deviations of respective helical cuts define respective mechanical stops. Each mechanical stop includes opposing surfaces which come into contact with each other to prevent overstretching and overbending of the spring.

(18) In some embodiments, respective mechanical stops are designed to engage simultaneously so that a force applied on the spring is shared among the respective mechanical stops to prevent sequential failure of the respective mechanical stops. In some embodiments, at least two mechanical stops of each helical cut are designed to engage simultaneously. In some embodiments, all the mechanical stops of each helical cut are designed to engage simultaneously.

(19) In some embodiment the deviations include respective opposing sigmoid curves. In some embodiments, respective mechanical stops include respective loops and sockets. In some embodiments, respective mechanical stops include respective T-shape elements placed in respective T-shape openings. In some embodiment, respective mechanical stops include respective L-shape elements placed in respective L-shape openings.

(20) In some embodiments, the catheter includes a proximal coupler having a proximal end connected to the distal end of the elongated deflectable element. The tube and the distal end of the proximal coupler include complementary bayonet connecting features connecting the distal end of the proximal coupler with the tube.

(21) In some embodiments, the catheter includes a distal coupler and the distal end of the tube includes holes around its circumference. The distal end of the tube is connected to the distal coupler via an adhesive (such as epoxy) which extends into the holes to promote adhesion between the distal coupler and the tube.

(22) In some embodiments, the distal edge of the tube includes openings (e.g., U-shape openings) for engaging protrusions of the distal coupler to prevent rotation of the distal coupler with respect to the tube.

System Description

(23) Reference is now made to FIG. 1, which is a schematic view of a catheter **10** constructed and operative in accordance with an embodiment of the present invention. The catheter **10** includes an elongated deflectable element **12**, a distal assembly **14** and an outer sleeve **16** disposed about a longitudinal axis L-L (which will be used to reference various internal and external components of catheter **10**). The distal assembly **14** may include any suitable distal assembly, for example, a lasso catheter assembly or a focal catheter assembly. In some embodiments, the distal assembly **14** includes an expandable distal assembly **18**, which may include an inflatable balloon **20** or a basket, by way of example only. The elongated deflectable element **12** includes lumens (not shown) in which to carry electrical connections, irrigation channels, puller wires, and the like. The distal assembly **14** may also include multiple electrodes **22** (only two labeled for the sake of simplicity) disposed thereon for use in mapping and/or ablation or any other suitable function.

(24) Reference is now made to FIGS. 2A-B, which are schematic views of different sides of the catheter **10** of FIG. 1 with the outer sleeve **16** of FIG. 1 removed. The catheter **10** includes a proximal coupler **24**, a distal coupler **26**, and a force sensor **28**.

(25) The force sensor **28** is disposed between the elongated deflectable element **12** and the distal assembly **14**, and more specifically disposed between the proximal coupler **24** and the distal coupler **26**.

(26) The force sensor **28** includes a spring **38** including a tube **40** with one or more helical cuts **42** extending around a circumference of the tube **40**. As used herein, the circumference includes both the outer circumferential surface **41A** and the inner circumferential surface **41B** of the tubular

member **40**. Each helical cut **42** includes deviations **44** extending in a longitudinal direction of the tube **40**. The deviations **44** are configured to prevent overstretching and overbending of the spring **38**. The spring **38** is described in more detail with reference to FIGS. 7A-8C.

(27) The inflatable balloon **20** is mounted on the distal coupler **26** with the distal coupler **26** extending until a nose **30** in the center of the distal end of the inflatable balloon **20**. Therefore, the distal coupler **26** couples the inflatable balloon **20** with the force sensor **28**. The distal coupler **26** is described in more detail with reference to FIGS. 4, 6A-B.

(28) The proximal coupler **24** couples the force sensor **28** with a distal end **32** of the elongated deflectable element **12**. The catheter **10** includes a position sensor **34** (FIG. 2B), such as a single, dual, and/or triple-axis coil. The position sensor **34** is mounted on the proximal coupler **24** in the examples of FIG. 2B. The catheter **10** also includes a solder pad **36** (FIG. 2A) disposed on the proximal coupler **24** to which various electrical connections from components at the distal end of the catheter **10** and electrical connections from the proximal end of the catheter **10** may be connected. The proximal coupler **24** is described in more detail with reference to FIGS. 5A-C.

(29) Reference is now made to FIGS. 3 and 4. FIG. 3 is a schematic view of the catheter **10** of FIG. 1 with several elements removed. FIG. 3 shows the catheter **10** with the distal assembly **14** and the sleeve **16** of FIG. 1 removed, and with the solder pad **36** and the position sensor **34** of FIGS. 2A and 2B removed. FIG. 4 is a partially exploded view of the catheter **10** as shown in FIG. 3. FIG. 4 shows the distal coupler **26** pulled away from the spring **38** to show how the distal coupler **26** and the spring **38** are connected to each other.

(30) The distal end **32** of the elongated deflectable element **12** is connected to a proximal end **46** of the proximal coupler **24**. A proximal end **52** of the tube **40** and a distal end **48** of the proximal coupler **24** include complementary bayonet connecting features **50** connecting the distal end **48** of the proximal coupler with the proximal end **52** of the tube **40**. The bayonet connecting features **50** are described in more detail with reference to FIGS. 5A-C and FIGS. 7A-B.

(31) FIG. 4 shows that a distal end **54** of the tube **40** comprises holes **56** (only some labeled for the sake of simplicity) disposed around the circumference of the tube **40**. The distal end **54** of the tube **40** is connected to the distal coupler **26** distal coupler via an adhesive, e.g., epoxy, which extends into respective ones of the holes **56** thereby improving a bond between the distal end **54** of the tube **40** and an inner proximal surface **58** of the distal coupler **26**. The holes **56** are described in more detail with reference to FIGS. 7A-B.

(32) A distal edge **60** of the tube **40** includes openings **62** (only some labeled for the sake of simplicity) disposed around the circumference of the distal edge **60**. The inner proximal surface **58** of the distal coupler **26** includes protrusions **64** (only some labeled for the sake of simplicity), disposed circumferentially around the inner proximal surface **58**, and configured for engaging the openings **62** (or slots disposed around the perimeter of the generally tubular member **38**) to prevent rotation of the distal coupler **26** with respect to the tube **40**. The openings **62** and the protrusions **64** may be any suitable shape. In some embodiments, the openings **62** include U-shaped openings as shown in the example of FIG. 4 or rectangular shape openings. The openings **62** and the protrusions **64** are described in more detail with reference to FIG. 6B and FIGS. 7A-B.

(33) Reference is now made to FIGS. 5A-C, which are schematic views of various sides of the proximal coupler **24** of the catheter **10** of FIG. 1. The proximal coupler **24** has a generally cylindrical shape with a central lumen **70** for passing various elements therein such as wires and an irrigation tube (not shown). The distal end **48** includes the bayonet connecting features **50** which may have any suitable shape, for example, but not limited to an L-shape recess. In some embodiments the distal end **48** includes three bayonet connecting features **50**. However, the distal end **48** may include more or less than three bayonet connecting features **50**. The proximal coupler **24** includes a recess **66** (FIG. 5B) for accepting the solder pad **36** (FIG. 2A) therein in addition to allowing a passage for wires connected to solder pad **36** to pass into coupler **24**. Coupler **24** also includes two flat surfaces **68** (FIGS. 5A and 5C) for accepting the position sensor **34** (FIG. 2B)

thereon. The proximal coupler **24** may be formed from any suitable material or combination of materials, for example, but not limited to, polycarbonate with or without glass filler, polyether ether ketone (PEEK) with or without glass filler, or polyetherimide (PEI) with or without glass filler. The proximal coupler **24** may have any suitable outer diameter, for example, in a range of 1 mm to 10 mm.

(34) Reference is now made to FIGS. **6A-B**, which are schematic views of the distal coupler **26** of the catheter **10** of FIG. **1**. FIG. **6A** shows that the distal coupler **26** includes openings **72** for irrigation and/or feeding wires to the electrodes **22** (FIG. **1**) of the distal assembly **14** (FIG. **1**). In some embodiments, the openings **72** may be disposed around a circumference of the distal coupler **26** in a proximal portion of the distal coupler **26** and/or in a distal portion of the distal coupler **26**. The distal coupler **26** may include any suitable number of openings **72**, for example, in a range between 1 and 12 openings **72**, such as 8 openings.

(35) FIG. **6B** shows the inner proximal surface **58** and its protrusions **64** (only some labeled for the sake of simplicity). The distal coupler **26** may include any suitable number of protrusions **64** to engage with the openings **62** (FIG. **4**) of the tube **40** (FIG. **4**). In some embodiments, the distal coupler **26** includes eight protrusions **64**, but may be in the range of 1 to 30 protrusions **64**, by way of example. The protrusions **64** may have any suitable dimensions, in the order of 0.05 mm to 10 mm and may depend on the number of protrusions **64**. The distal coupler **26** may be formed from any suitable material or combination of materials, for example, but not limited to, polycarbonate with or without glass filler, polyether ether ketone (PEEK) with or without glass filler, or polyetherimide (PEI) with or without glass filler. The distal coupler **26** may have any suitable outer diameter, for example, in a range of 1 mm to 10 mm.

(36) Reference is now made to FIGS. **7A-B**, which are schematic views of the spring **38** of the catheter **10** of FIG. **1**. As previously mentioned, the spring **38** includes the tube **40** with helical cuts **42** extending around a circumference of the tube **40**. As seen in FIG. **7A**, two generally parallel helical cuts extend through the tubular member **38** while traversing along the longitudinal axis L-L to define a helical shaped spring member **45** (between the gaps **42**) which is separated from the tubular member **38** by the gaps or cuts **42**. As shown in FIG. **7A**, three helical spring members **45** are provided. The helical cuts **42** provide the coupler **38** with its ability to bend and compress while provide a resistance to bending and compression. Each helical cut **42** includes deviations **44** extending in a longitudinal direction (approximately parallel to the axis L-L) of the tube **40**. The deviations **44** are configured to prevent overstretching and overbending of the spring **45** by having a portion of the spring **45** configured to interlock with another portion of the tubular member **38** via a suitable interlock **44**.

(37) The helical cuts **42** extend from the outer surface of the tube **40** through to the inner surface of the tube **40**. The helical cuts **42** may be right-handed helices or left-handed helices. The pitch of each helical cut **42** may be any suitable value, for example in the range of 0.2 mm to 5 mm. The helical cuts **42** may have any suitable width, for example, in the range of 0.05 mm to 0.5 mm, such as 0.1 mm. The spring **38** may include any suitable number of helical cuts **42**, for example, two helical cuts **42** forming a double helix, or three helical cuts **42** forming a triple helix, and so on. The helical cuts **42** are generally circular helices disposed about a longitudinal axis L-L extending through the center of member **38**. Each of the helical cuts **42** may extend around the circumference for any suitable amount of turns, including extending for less than one turn but at least half a turn. For example, any of the helical cuts **42** may extend 1.5 turns, 1 turn, two-thirds of a turn (as shown in FIGS. **7A** and **7B**), or half a turn. In the example of FIGS. **7A-B**, respective ones of the helical cuts **42** extend from respective ones of the bayonet connecting features **50** up and around the circumference of the tube **40**.

(38) Respective ones of the deviations **44** of respective ones of the helical cuts **42** define respective mechanical stops **74** (only some labeled for the sake of simplicity). Each mechanical stop **74** includes opposing surfaces **76** (only some labeled for the sake of simplicity) which are configured

to come into contact with each other to prevent overstretching and overbending of the spring **38**. In some embodiments, the opposing surfaces **76** of respective ones of the mechanical stops **74** are configured to engage simultaneously so that a force applied on the spring **38** is shared among the respective mechanical stops **74** to prevent sequential failure of the respective mechanical stops **74**. In some embodiments, at least two, and generally all, of the mechanical stops **74** of each helical cut **42** are configured to engage simultaneously. In some embodiments, respective ones of the mechanical stops **74** include respective loops **78** and sockets **80** (only one labeled for the sake of simplicity).

(39) In some embodiments, respective one of the deviations **44** include respective opposing sigmoid curves **82** (only two labeled for the sake of simplicity) with characteristic S-shapes so that the deviations **44**, and the mechanical stops **74**, are formed by an S-shape and a reversed S-shape as shown in FIGS. 7A-B. In some embodiments, respective ones of the mechanical stops **74** include respective T-shape elements **84** disposed in respective T-shape openings **86**.

(40) The bayonet connecting features **50** of the tube **40** are generally L-shaped and are configured to connect with the bayonet connecting features **50** of the proximal coupler **24** (FIGS. 5A-C). The tube **40** may include any suitable number of bayonet connecting features **50**, for example, one, two, three or more.

(41) The holes **56** (only some labeled for the sake of simplicity) in the distal end **54** of the tube **40** are disposed around the circumference of the tube **40**. The tube **40** may include any suitable number of holes **56**, for example, two or more. The maximum number of holes **56** is generally restricted by the available space on the tube **40** above the helical cuts **42**. Each hole **56** may have any suitable diameter, for example, in the range of 0.05 mm to 0.5 mm.

(42) In some embodiments, the tube **40** includes eight openings **62** (only some labeled for the sake of simplicity), but may have any suitable number of openings **62**, for example, in the range of 1 to 30 openings **62**. The openings **62** may have any suitable dimensions, in the order of 0.05 mm to 10 mm and may depend on the number of openings **62**.

(43) The lower surface of the tube **40** may include notches **90** (only some labeled for the sake of simplicity) to enhance adhesive connection between the lower surface of the tube **40** and other elements of the catheter **10**, such as proximal coupler **24**.

(44) The helical cuts **42**, holes **56**, and openings **62** may be formed by any suitable method, for example, by laser machining, electric discharge machining, or conventional machining. The tube **40** may have any suitable outer diameter, for example, in the range of 1 mm to 10 mm. The tube **40** may have any suitable wall thickness, for example, in the range of 0.1 mm to 3 mm. The tube may be formed from any suitable material, for example, Nitinol, beta titanium, beryllium copper, or phosphor bronze.

(45) Reference is now made to FIGS. 8A-C, which are schematic views of the force sensor **28** of the catheter **10** of FIG. 1. The force sensor **28** includes the spring **38** and a transmitting coil **92** disposed on the top and receiving coils **93** disposed on the bottom of the tube **40**. The receiving coils **93** receive a transmitted signal from the transmitting coil **92**. The received signal is representative of a distance between the transmitting coil **92** and the receiving coils **93** thereby providing an indication of a force applied to the force sensor **28**. Any suitable transmitting coil **92**, and receiving coils **93** may be used, for example, the coils described in US Patent Publication 2018/0256247 of Govari, et al. which is incorporated by reference with a copy provided in the Appendix. In some embodiments, the positioning of the transmitting coil **92** and the receiving coils **93** may be reversed or in any suitable position. In some embodiments, the force sensor **28** may include a single receiving coil and multiple transmitting coils, or any suitable combination thereof.

(46) Reference is now made to FIG. 9, which is a schematic view of a spring **94** constructed and operative in accordance with an alternative embodiment of the present invention. The spring **94** includes mechanical stops **96**. Respective mechanical stops **96** include respective L-shape elements **98** disposed in respective L-shape openings **100**.

(47) As used herein, the terms “about” or “approximately” for any numerical values or ranges indicate a suitable dimensional tolerance that allows the part or collection of components to function for its intended purpose as described herein. More specifically, “about” or “approximately” may refer to the range of values $\pm 20\%$ of the recited value, e.g. “about 90%” may refer to the range of values from 72% to 108%.

(48) Various features of the invention which are, for clarity, described in the contexts of separate embodiments may also be provided in combination in a single embodiment. Conversely, various features of the invention which are, for brevity, described in the context of a single embodiment may also be provided separately or in any suitable sub-combination.

(49) The embodiments described above are cited by way of example, and the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

Claims

1. A catheter apparatus, comprising: an elongated deflectable element; a distal assembly; a force sensor disposed between the elongated deflectable element and the distal assembly, and comprising a spring including a tube with at least one helical cut defining a helical path extending less than one full turn around a circumference of the tube and defining at least a portion of a helical-shaped spring member, the helical-shaped spring member comprising a proximal side positioned on a first side of the helical path and having a first mechanical stop and a distal side positioned on a second side of the helical path and having a second mechanical stop arranged immediately following the first mechanical stop in a direction along the helical path, the second mechanical stop being spaced a distance away from the first mechanical stop in the direction along the helical path such that a first line drawn through any of the first mechanical stop in a direction transverse to the helical path extends only through the first mechanical stop and a second line drawn through any of the second mechanical stop in the direction transverse to the helical path extends only through the second mechanical stop, the first and second mechanical stops positioned offset from the helical path and configured to come in contact with an opposing surface of the force sensor to prevent overstretching and overbending of the spring.
2. The apparatus according to claim 1, wherein the first and second mechanical stops include opposing sigmoid curves.
3. The apparatus according to claim 1, wherein the first and second mechanical stops are configured to engage simultaneously so that a force applied on the spring is shared among the first and second mechanical stops to prevent sequential failure of the first and second mechanical stops.
4. The apparatus according to claim 3, wherein the at least one helical cut comprises multiple helical cuts, respective ones of the first and second mechanical stops of each of the helical cuts being configured to engage simultaneously.
5. The apparatus according to claim 3, wherein the at least one helical cut comprises multiple helical cuts, the first and second mechanical stops of each of the helical cuts being configured to engage simultaneously.
6. The apparatus according to claim 1, wherein respective ones of the first and second mechanical stops including respective T-shape elements disposed in respective T-shape openings.
7. The apparatus according to claim 1, wherein of the first and second mechanical stops include respective loops and sockets.
8. The apparatus according to claim 1, wherein the at least one helical cut comprises multiple helical cuts, the tube comprising three of the helical cuts.
9. The apparatus according to claim 1, further comprising a proximal coupler having a proximal

and distal end, wherein the elongated deflectable element has a distal end connected to the proximal end of the proximal coupler, the tube and the distal end of the proximal coupler including complementary bayonet connecting features connecting the distal end of the proximal coupler with the tube.

10. The apparatus according to claim 1, further comprising a distal coupler, wherein the tube has a distal end comprising holes disposed around the circumference of the tube, the distal end of the tube being connected to the distal coupler via an adhesive which extends into respective ones of the holes.

11. The apparatus according to claim 10, wherein the tube includes a distal edge with openings therein, the distal coupler including protrusions configured for engaging the openings to prevent rotations of the distal coupler with respect to the tube.

12. The apparatus according to claim 11, wherein the openings include U-shaped openings.

13. The apparatus according to claim 1, further comprising a distal coupler, wherein the tube includes a distal edge with openings therein, the distal coupler including protrusions configured for engaging the openings to prevent rotation of the distal coupler with respect to the tube.

14. The apparatus according to claim 13, wherein the openings include U-shaped openings.

15. The apparatus according to claim 1, wherein the distal assembly includes an expandable distal assembly.

16. The apparatus according to claim 15, wherein the expandable distal assembly includes an inflatable balloon.

17. The apparatus according to claim 1, wherein the force sensor includes a transmitting coil and at least one receiving coil disposed on the tube.

18. The apparatus according to claim 1, wherein the first and second mechanical stops are positioned such that the first mechanical stop is oriented symmetrically from the second mechanical stop.

19. The apparatus according to claim 1, wherein the helical path extends at most two-thirds around the circumference of the tube.
