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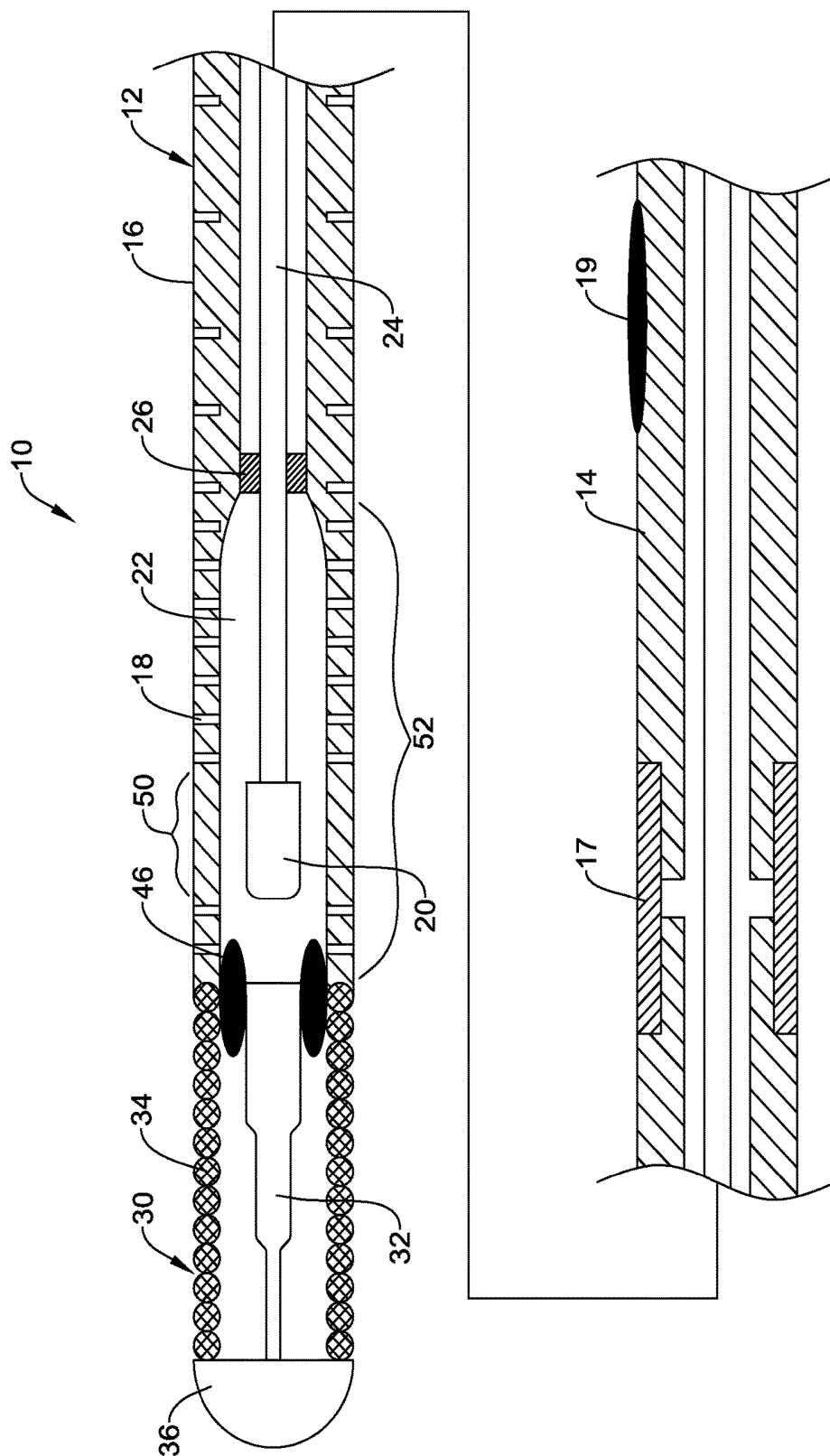


Figure 1

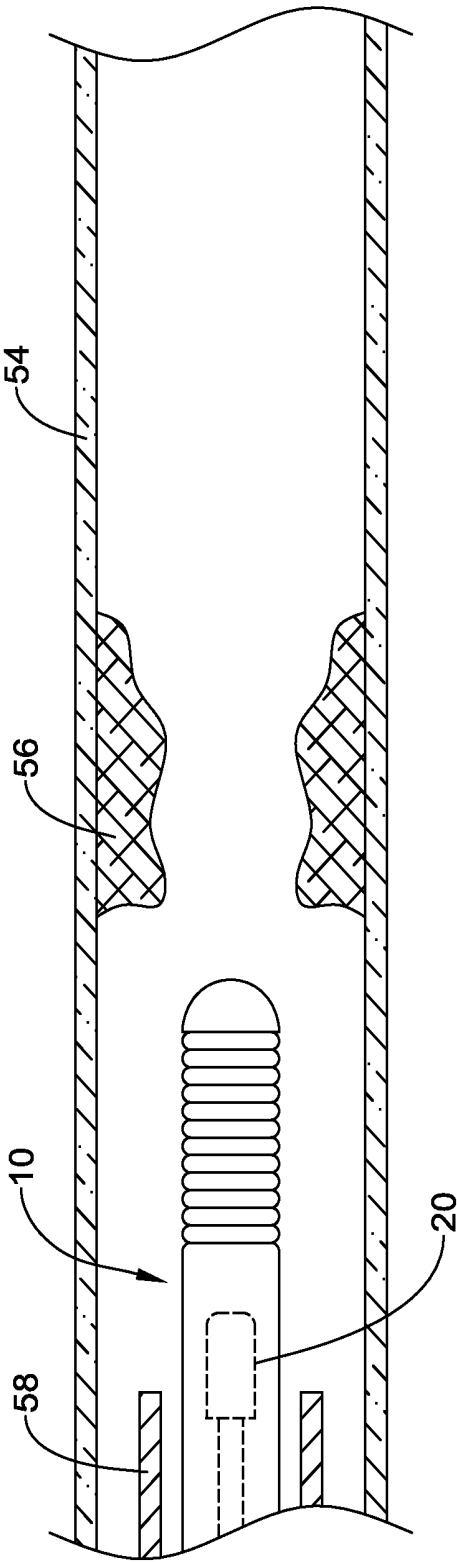


Figure 2

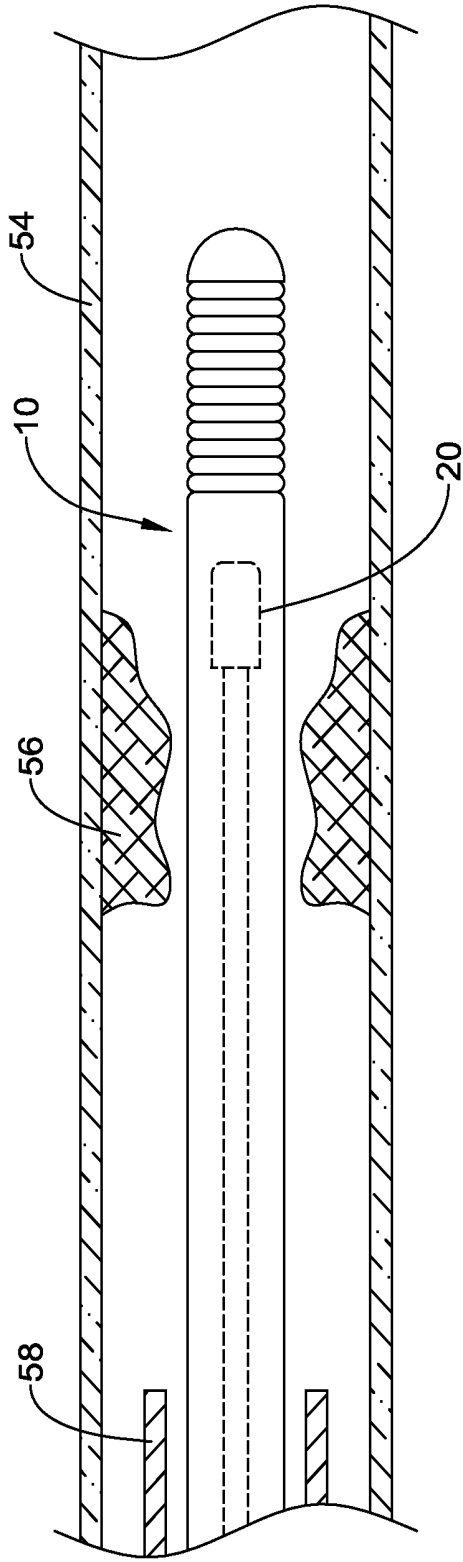


Figure 3

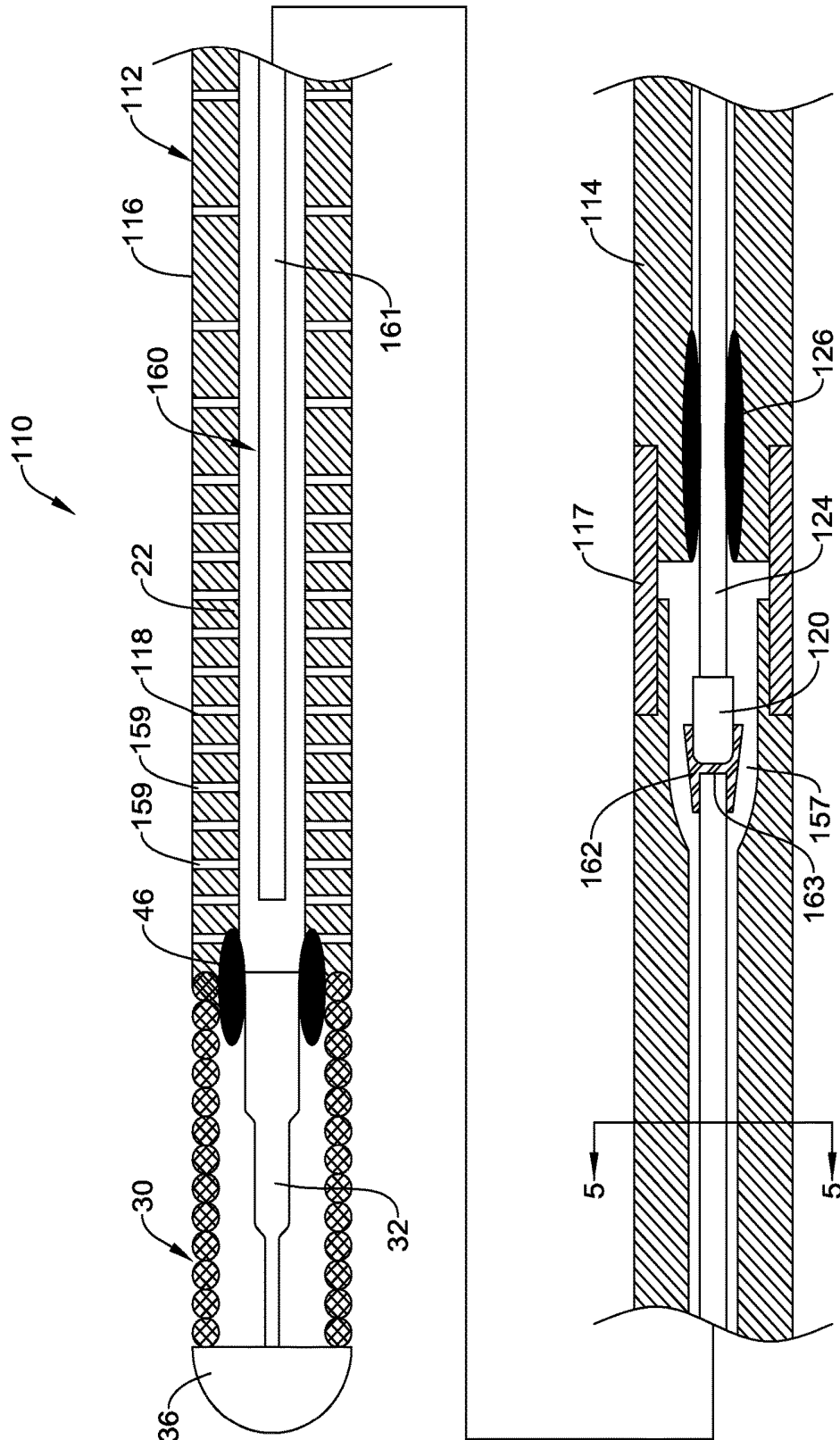


Figure 4

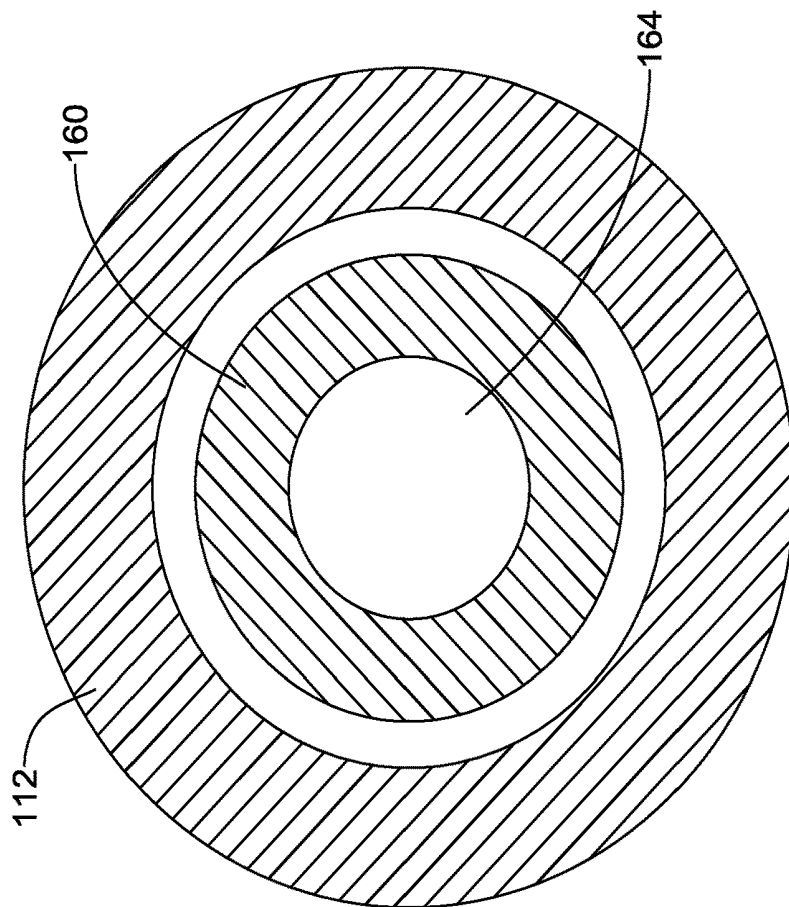


Figure 5

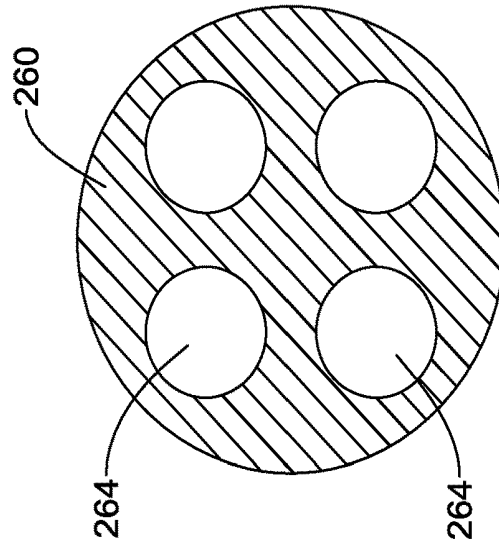


Figure 6

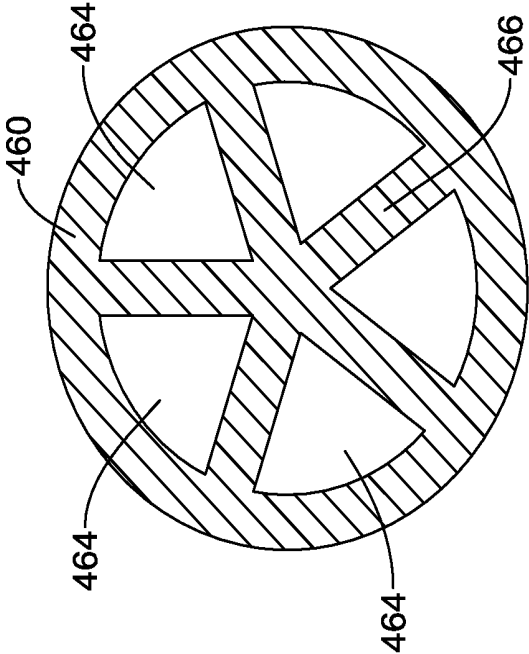


Figure 8

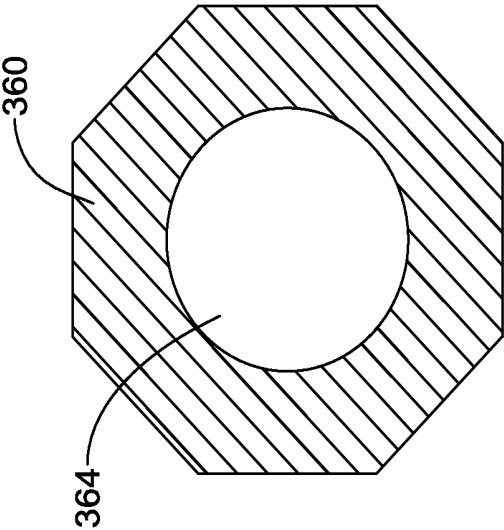


Figure 7

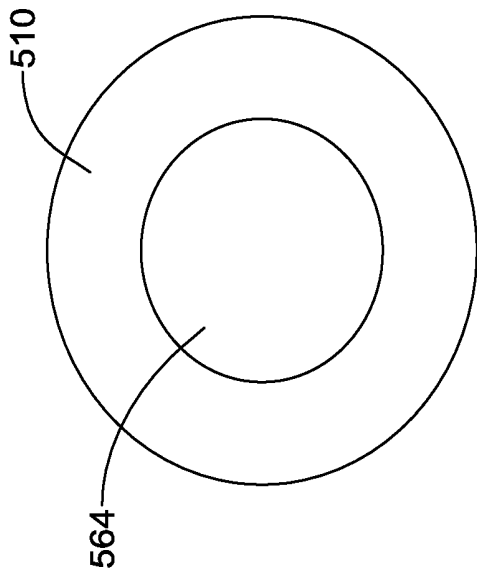


Figure 9B

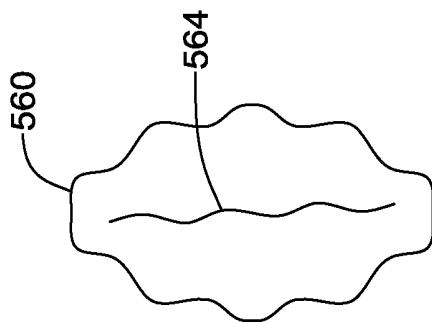


Figure 9A

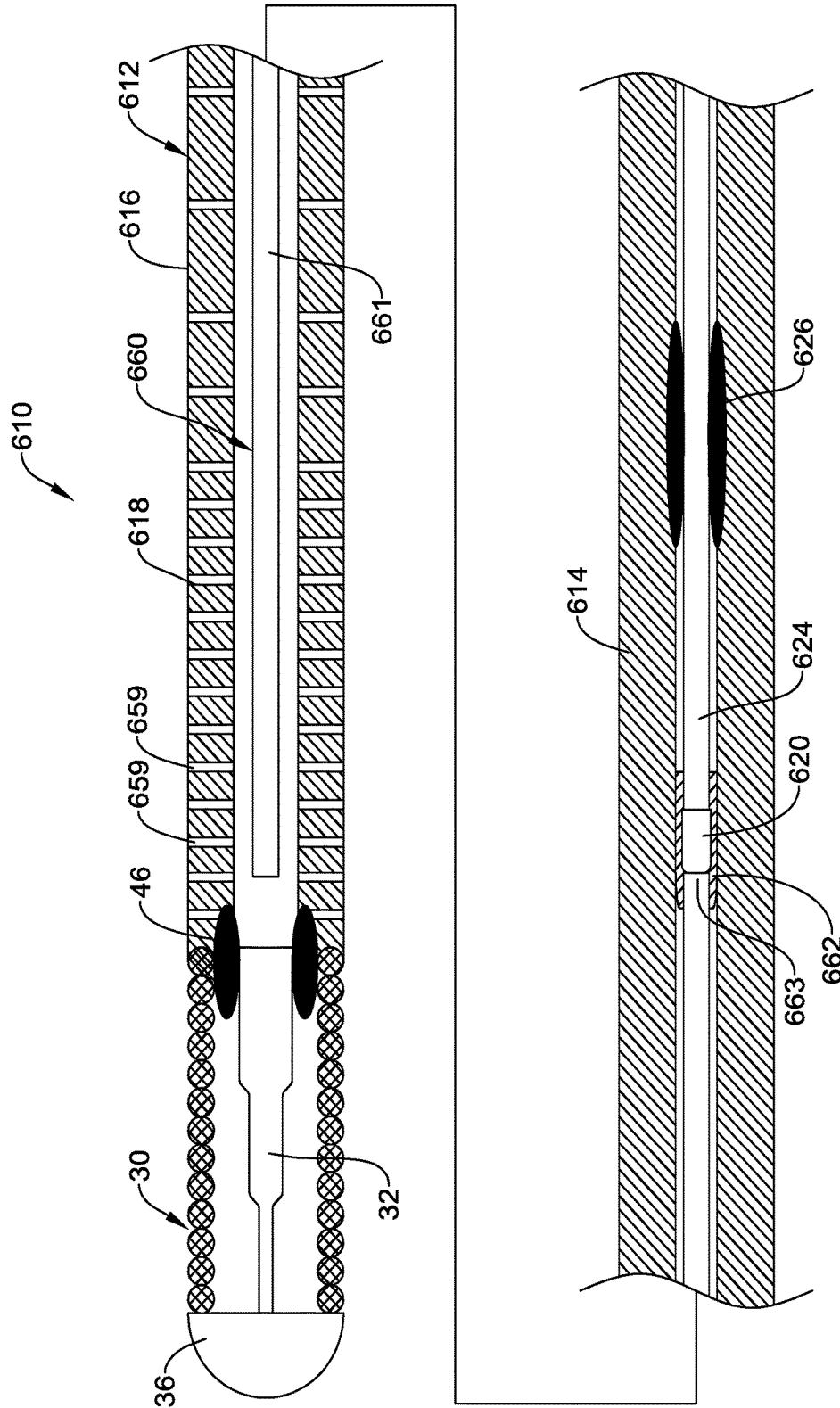


Figure 10

PRESSURE SENSING GUIDEWIRE SYSTEMS WITH REDUCED PRESSURE OFFSETS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority under 35 U.S.C. § 119 to U.S. Provisional Application Ser. No. 62/007,728, filed Jun. 4, 2014, the entirety of which is incorporated herein by reference.

TECHNICAL FIELD

The present disclosure pertains to medical devices, and methods for manufacturing medical devices. More particularly, the present disclosure pertains to blood pressure sensing guidewires and methods for using pressure sensing guidewires.

BACKGROUND

A wide variety of intracorporeal medical devices have been developed for medical use, for example, intravascular use. Some of these devices include guidewires, catheters, and the like. These devices are manufactured by any one of a variety of different manufacturing methods and may be used according to any one of a variety of methods. Of the known medical devices and methods, each has certain advantages and disadvantages. There is an ongoing need to provide alternative medical devices as well as alternative methods for manufacturing and using medical devices.

BRIEF SUMMARY

This disclosure provides design, material, manufacturing method, and use alternatives for medical devices. A medical device for measuring blood pressure is disclosed. The medical device comprises an elongated shaft having a proximal region and a distal region, an optical fiber extending along the proximal region, an optical pressure sensor coupled to the optical fiber, and a tubular member having a proximal end disposed adjacent to the optical pressure sensor and a distal portion extending along the distal region of the shaft.

Alternatively or additionally to any of the embodiments above, the optical pressure sensor is positioned 10 centimeters or more from a distal end of the shaft.

Alternatively or additionally to any of the embodiments above, the optical pressure sensor is positioned 20 centimeters or more from a distal end of the shaft.

Alternatively or additionally to any of the embodiments above, the optical pressure sensor is positioned 30 centimeters or more from a distal end of the shaft.

Alternatively or additionally to any of the embodiments above, the optical pressure sensor is positioned 35 centimeters or more from a distal end of the shaft.

Alternatively or additionally to any of the embodiments above, the distal region of the shaft has a plurality of slots formed therein.

Alternatively or additionally to any of the embodiments above, the tubular member has a plurality of lumens formed therein.

Alternatively or additionally to any of the embodiments above, the tubular member has a non-circular cross-sectional shape.

Alternatively or additionally to any of the embodiments above, the tubular member includes one or more reinforcing members.

Alternatively or additionally to any of the embodiments above, the tubular member is capable of shifting between a collapsed configuration and an open configuration.

Alternatively or additionally to any of the embodiments above, the proximal end of the tubular member is coupled to a face of the optical pressure sensor with a seal member.

Alternatively or additionally to any of the embodiments above, the shaft has a substantially constant inner diameter.

Alternatively or additionally to any of the embodiments above, at least a portion of the shaft has an enlarged inner diameter.

A pressure-sensing guidewire is disclosed. The pressure-sensing guidewire comprises an elongated shaft having a proximal region and a distal region. The distal region has one or more slits formed therein. A pressure sensor is positioned within the proximal region of the shaft. The pressure-sensing guidewire also includes a tubular member having a proximal end sealingly engaged with the pressure sensor and a distal portion extending along the distal region of the shaft. The distal region includes at least one opening formed therein that is designed to allow for fluid communication between an exterior of the shaft and a distal end of the tubular member.

Alternatively or additionally to any of the embodiments above, the pressure sensor includes an optical pressure sensor.

Alternatively or additionally to any of the embodiments above, the pressure sensor is disposed at least 30 centimeters from a distal end of the shaft.

Alternatively or additionally to any of the embodiments above, the tubular member has a plurality of lumens formed therein.

Alternatively or additionally to any of the embodiments above, the tubular member has a non-circular cross-sectional shape.

Alternatively or additionally to any of the embodiments above, the tubular member is capable of shifting between a closed configuration and an open configuration.

A guidewire for determining fractional flow reserve is disclosed. The guidewire comprises an elongated shaft having a proximal region and a distal region. The distal region has one or more slits formed therein. An optical pressure sensor is disposed within the proximal region of the shaft and positioned at least 30 centimeters from a distal end of the shaft. An optical fiber is attached to the optical pressure sensor. The guidewire also includes a tubular member having a proximal end sealed to the optical pressure sensor and a distal portion extending along the distal region of the shaft. The distal region includes at least one opening formed therein that is designed to allow for fluid communication between an exterior of the shaft and a distal end of the tubular member.

Other examples may include a pressure-sensing guidewire. The guidewire may include an elongated shaft having a proximal region and a distal region. The distal region may have one or more slits formed therein. A pressure sensor may be positioned within the proximal region of the shaft. The guidewire may also include a tubular member having a proximal end sealingly engaged with the pressure sensor and a distal portion extending along the distal region of the shaft. The distal region may include at least one opening formed therein that is designed to allow for fluid communication between an exterior of the shaft and a distal end of the tubular member.

Other examples may include a guidewire for determining fractional flow reserve. The guidewire may include an elongated shaft having a proximal region and a distal region.

The distal region may have one or more slits formed therein. An optical pressure sensor may be disposed within the proximal region of the shaft and positioned at least 30 centimeters from a distal end of the shaft. An optical fiber may be attached to the optical pressure sensor. The guide-

wire may also include a tubular member having a proximal end sealed to the optical pressure sensor and a distal portion extending along the distal region of the shaft. The distal region may include at least one opening formed therein that is designed to allow for fluid communication between an exterior of the shaft and a distal end of the tubular member.

The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The Figures, and Detailed Description, which follow, more particularly exemplify these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure may be more completely understood in consideration of the following detailed description in connection with the accompanying drawings, in which:

FIG. 1 is a partial cross-sectional side view of a portion of an example medical device;

FIG. 2 is a partial cross-sectional view of an example medical device disposed at a first position adjacent to an intravascular occlusion;

FIG. 3 is a partial cross-sectional view of an example medical device disposed at a second position adjacent to an intravascular occlusion;

FIG. 4 is a partial cross-sectional side view of a portion of an example medical device system;

FIG. 5 is a cross-sectional view taken through line 5-5 in FIG. 4;

FIG. 6 is a cross-sectional view of a portion of an example medical device system;

FIG. 7 is a cross-sectional view of a portion of an example medical device system;

FIG. 8 is a cross-sectional view of a portion of an example medical device system;

FIG. 9A is an end view of a portion of an example medical device system in a first configuration;

FIG. 9B is an end view of a portion of an example medical device system in a second configuration; and

FIG. 10 is a partial cross-sectional side view of a portion of an example medical device system.

While the disclosure is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term “about,” whether or not explicitly indicated. The term “about” generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms “about” may include numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g. 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

It is noted that references in the specification to “an embodiment”, “some embodiments”, “other embodiments”, etc., indicate that the embodiment described may include one or more particular features, structures, and/or characteristics. However, such recitations do not necessarily mean that all embodiments include the particular features, structures, and/or characteristics. Additionally, when particular features, structures, and/or characteristics are described in connection with one embodiment, it should be understood that such features, structures, and/or characteristics may also be used connection with other embodiments whether or not explicitly described unless clearly stated to the contrary.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

During some medical interventions, it may be desirable to measure and/or monitor the blood pressure within a blood vessel. For example, some medical devices may include pressure sensors that allow a clinician to monitor blood pressure. Such devices may be useful in determining fractional flow reserve (FFR), which may be understood as the pressure after a stenosis relative to the pressure before the stenosis (and/or the aortic pressure).

FIG. 1 illustrates a portion of an example medical device 10. In this example, medical device 10 is a blood pressure sensing guidewire 10. However, this is not intended to be limiting as other medical devices are contemplated including, for example, catheters, shafts, leads, wires, or the like. Guidewire 10 may include a tubular member or shaft 12. Shaft 12 may include a proximal portion 14 and a distal portion 16. The materials for proximal portion 14 and distal portion 16 may vary and may include those materials disclosed herein. For example, distal portion 16 may include a nickel-cobalt-chromium-molybdenum alloy (e.g., MP35-N). Proximal portion 14 may include stainless steel. These are just examples. Other materials may also be utilized.

In some embodiments, proximal portion 14 and distal portion 16 are formed from the same monolith of material. In other words, proximal portion 14 and distal portion 16 are portions of the same tube defining shaft 12. In other embodiments, proximal portion 14 and distal portion 16 are separate tubular members that are joined together. For example, a section of the outer surface of portions 14/16 may be removed and a sleeve 17 may be disposed over the removed sections to join portions 14/16. Alternatively, sleeve 17 may be simply disposed over portions 14/16. Other bonds may also be used including welds, thermal bonds, adhesive bonds, or the like. If utilized, sleeve 17 used to join proximal portion 14 with distal portion 16 may include a material that desirably bonds with both proximal portion 14 and distal portion 16. For example, sleeve 17 may include a nickel-chromium-molybdenum alloy (e.g., INCONEL).

A plurality of slots 18 may be formed in shaft 12. In at least some embodiments, slots 18 are formed in distal portion 16. In at least some embodiments, proximal portion

14 lacks slots 18. However, proximal portion 14 may include slots 18. Slots 18 may be desirable for a number of reasons. For example, slots 18 may provide a desirable level of flexibility to shaft 12 (e.g., along distal portion 16) while also allowing suitable transmission of torque. Slots 18 may be arranged/distributed along distal portion 16 in a suitable manner including any of those arrangements disclosed herein. For example, slots 18 may be arranged as opposing pairs of slots 18 that are distributed along the length of distal portion 16. In some embodiments, adjacent pairs of slots 18 may have a substantially constant spacing relative to one another. Alternatively, the spacing between adjacent pairs may vary. For example, more distal regions of distal portion 16 may have a decreased spacing (and/or increased slot density), which may provide increased flexibility. In other embodiments, more distal regions of distal portion 16 may have an increased spacing (and/or decreased slot density). These are just examples. Other arrangements are contemplated.

A pressure sensor 20 may be disposed within shaft 12 (e.g., within a lumen 22 of shaft 12). While pressure sensor 20 is shown schematically in FIG. 1, it can be appreciated that the structural form and/or type of pressure sensor 20 may vary. For example, pressure sensor 20 may include a semiconductor (e.g., silicon wafer) pressure sensor, piezoelectric pressure sensor, a fiber optic or optical pressure sensor, a Fabry-Perot type pressure sensor, an ultrasound transducer and/or ultrasound pressure sensor, a magnetic pressure sensor, a solid-state pressure sensor, or the like, or any other suitable pressure sensor.

As indicated above, pressure sensor 20 may include an optical pressure sensor. In at least some of these embodiments, a fiber optic cable 24 may be attached to pressure sensor 20 and may extend proximally therefrom. An attachment member 26 may attach fiber optic cable 24 to shaft 12. Attachment member 26 may be circumferentially disposed about and attached to optical fiber 24 and may be secured to the inner surface of shaft 12 (e.g., distal portion 16). In at least some embodiments, attachment member 26 is proximally spaced from pressure sensor 20. Other arrangements are contemplated.

In at least some embodiments, distal portion 16 may include a region with a thinned wall and/or an increased inner diameter that defines a housing region 52. In general, housing region 52 is the region of distal portion 16 that ultimately “houses” the pressure sensor (e.g., pressure sensor 20). By virtue of having a portion of the inner wall of shaft 12 being removed at housing region 52, additional space may be created or otherwise defined that can accommodate sensor 20.

In at least some embodiments, it may be desirable for pressure sensor 20 to have reduced exposure along its side surfaces to fluid pressure (e.g., from the blood). Accordingly, it may be desirable to position pressure sensor 20 along a landing region 50 defined along housing region 52. Landing region 50 may be substantially free of slots 18 so that the side surfaces of pressure sensor 20 have a reduced likelihood of being deformed due to fluid pressures at these locations. Distal of landing are 50, housing region 52 may include slots 18 that provide fluid access to pressure sensor 20.

Moreover, one or more of slots 18 may define a fluid pathway that allows blood (and/or a body fluid) to flow from a position along the exterior or outer surface of guidewire 10 (and/or shaft 12), through slots 18, and into the lumen 22 of shaft 12, where the blood can come into contact with pressure sensor 20. Because of this, no additional side openings/holes (e.g., other than one or more slots 18, a

single slot 18 extending through the wall of shaft 12, and/or a dedicated pressure port or opening) may be necessary in shaft 12 for pressure measurement. This may also allow the length of distal portion 16 to be shorter than typical sensor mounts or hypotubes that would need to have a length sufficient for a suitable opening/hole (e.g., a suitable “large” opening/hole) to be formed therein that provides fluid access to sensor 20.

A tip member 30 may be coupled to distal portion 16. Tip member 30 may include a shaping member 32 and a spring or coil member 34. A distal tip 36 may be attached to shaping member 32 and/or spring 34. In at least some embodiments, distal tip 36 may take the form of a solder ball tip. Tip member 30 may be joined to distal portion 16 of shaft 12 with a bonding member 46 such as a weld.

Shaft 12 may include a hydrophilic coating 19. In some embodiments, hydrophilic coating 19 may extend along substantially the full length of shaft 12. In other embodiments, one or more discrete sections of shaft 12 may include hydrophilic coating 19.

In use, a clinician may use guidewire 10 to measure and/or calculate FFR (e.g., the pressure after an intravascular occlusion relative to the pressure before the occlusion and/or the aortic pressure). Measuring and/or calculating FFR may include measuring the aortic pressure in a patient. This may include advancing guidewire 10 through a blood vessel or body lumen 54 to a position that is proximal or upstream of an occlusion 56 as shown in FIG. 2. For example, guidewire 10 may be advanced through a guide catheter 58 to a position where at least a portion of sensor 20 is disposed distal of the distal end of guide catheter 58 and measuring the pressure within body lumen 54. This pressure may be characterized as an initial pressure. In some embodiments, the aortic pressure may also be measured by another device (e.g., a pressure sensing guidewire, catheter, or the like). The initial pressure may be equalized with the aortic pressure. For example, the initial pressure measured by guidewire 10 may be set to be the same as the measured aortic pressure. Guidewire 10 may be further advanced to a position distal or downstream of occlusion 56 as shown in FIG. 3 and the pressure within body lumen 54 may be measured. This pressure may be characterized as the downstream or distal pressure. The distal pressure and the aortic pressure may be used to calculate FFR.

It can be appreciated that an FFR system that utilizes an optical pressure sensor in a pressure sensing guidewire may be navigated through the tortuous anatomy. This may include crossing relatively tight bends in the vasculature. Because of this, and for other reasons, it may be desirable of pressure sensing guidewire to be relatively flexible, for example adjacent to the distal end. A pressure sensor disposed along the distal region of the guidewire could increase the stiffness of the guidewire. This could reduce the ability of the guidewire to be navigated. Disclosed herein are pressure-sensing guidewires with increased flexibility, particularly along the distal portions thereof.

FIG. 4 illustrates another example guidewire 110 that may be similar in form and function to other guidewire disclosed herein. Guidewire 110 may include shaft 112 having proximal portion 114 and distal portion 116. Distal portion 116 may have slots or slits 118 formed therein. At least some of slits 118 may extend through only a portion of the wall of shaft 112. Proximal portion 114 and distal portion 116 of shaft 112 may be coupled by connector 117.

Pressure sensor 120 may be disposed within shaft 112. In at least some embodiments, pressure sensor 120 may be an optical pressure sensor having optical fiber 124 coupled

thereto. Optical fiber **124** may be coupled to shaft **112** at attachment member **126**. In other embodiments, pressure sensor **120** may be another type of pressure sensor such as those disclosed herein. In at least some embodiments, pressure sensor **120** may be disposed adjacent to a widened region **157** of shaft **112**. Widened region **157** may be positioned along a suitable portion of shaft **112** including along portions or all of proximal portion **114**, distal portion **116**, or both. Widened region **157** may allow for pressure sensors having a relatively larger outer diameter (e.g., greater than 125 micron to approximately 260 microns) to be used within guidewire **110**.

Pressure sensor **120** may be positioned a distance away from the distal end of shaft **112** (and/or the distal end of guidewire **110**). For example, pressure sensor **120** may be disposed 10 centimeters or more away from the distal end of shaft **112** (and/or the distal end of guidewire **110**), or pressure sensor **120** may be disposed 15 centimeters or more away from the distal end of shaft **112** (and/or the distal end of guidewire **110**), or pressure sensor **120** may be disposed 20 centimeters or more away from the distal end of shaft **112** (and/or the distal end of guidewire **110**), or pressure sensor **120** may be disposed 25 centimeters or more away from the distal end of shaft **112** (and/or the distal end of guidewire **110**), or pressure sensor **120** may be disposed 30 centimeters or more away from the distal end of shaft **112** (and/or the distal end of guidewire **110**), or pressure sensor **120** may be disposed 35 centimeters or more away from the distal end of shaft **112** (and/or the distal end of guidewire **110**), or pressure sensor **120** may be disposed 40 centimeters or more away from the distal end of shaft **112** (and/or the distal end of guidewire **110**). In one example, pressure sensor **120** may be disposed approximately 35 centimeters away from the distal end of shaft **112** (and/or the distal end of guidewire **110**). These are just examples.

By spacing pressure sensor **120** from the distal end of shaft **112** (and/or the distal end of guidewire **110**), the distal end region of guidewire **110** may have greater flexibility. This may allow guidewire **110** to more easily navigate through the anatomy/vasculature. Furthermore, more proximal portions of guidewire **110** may be exposed to fewer curves/bends such that pressure sensor **120** (e.g., by virtue of being positioned relatively further proximal) may be less likely to encounter an inner wall surface of shaft **112**, which could deform or otherwise impact pressure sensor **120** and alter the pressure reading.

A tubular member **160** may be disposed with shaft **112** may help to communicate the fluid pressure within a patient from distal regions of guidewire **110** to pressure sensor **120**. Tubular member **160** may have a distal section **161** disposed along distal portion **116** of shaft **112**. Distal section **161** may be disposed adjacent to one or more openings **159**. Openings **159** may allow fluid (e.g., blood) along the exterior of guidewire **110** to access the interior of guidewire **110**. The pressure of the fluid (e.g., blood pressure) may exert a force on fluid that may be contained within tubular member **160** such that the pressure may be fluidly communicated or otherwise transmitted along tubular member **160** to pressure sensor **120**.

A proximal end **163** of tubular member **160** may be coupled to pressure sensor **120**. For example proximal end **163** of tubular member **160** may be coupled to pressure sensor **120** with a seal member **162**. Seal member **162** may help to ensure that the pressure of the fluid can be accurately measured at pressure sensor **120**. In other embodiments, proximal end **163** may be merely disposed adjacent pressure sensor **120** in a manner that allows for suitable transmission

of pressure along tubular member **160** to sensor **120**. The distal end of tubular member **160** may be disposed along distal portion **116** of shaft. In some embodiments, the distal end of tubular member **160** may be disposed at or near the distal end of guidewire **110**. This may include disposing the distal end of tubular member within tip member **30** or otherwise at a location that is at or near the distal end of guidewire **110**. This may desirably impact guidewire **110**, for example, by allowing the structure where a pressure reading is "taken" to be positioned further distally than in previous pressure sensing devices (and/or may also make it less likely that pressure sensor **120** may encounter an inner wall surface of shaft **112**, which could deform or otherwise impact pressure sensor **120** and alter the pressure reading).

It can be appreciated that it may be desirable for the interior regions of guidewire **110** to be filled with a fluid so that a clinician can be reasonably assured that guidewire **110** is free of air, which could impact pressure readings and/or otherwise be undesirable. In some embodiments, guidewire **110** may be pre-filled during manufacturing and then sealed with membrane or coating to contain the fluid within guidewire **110** (e.g., by sealing openings **159** and/or other openings). In some instances, the membrane or coating may be dissolvable in body fluids such that navigation of guidewire **110** through the vasculature would expose the membrane or coating to sufficient body fluids in order to dissolve. Other configurations are contemplated. For example, a suitable fluid delivery device (e.g., a syringe) may be used to fill guidewire **110** prior to use and/or otherwise purge guidewire **110** of any air that may be present therein.

FIG. 5 is a cross-sectional view of guidewire **110**. Here it can be seen that tubular member **160** has a generally round cross-sectional shape and defines a lumen **164**. Other shapes, forms, and configuration are contemplated. For example, FIG. 6 illustrates tubular member **260** having a plurality of lumens **264** formed therein. Lumens **264** may be sufficient for fluid communication there through while allowing tubular member **260** to be constructed with a relatively larger, more robust form with greater resistance to collapse. It can be appreciated that collapse of tubular member **260** (as well as other tubular members disclosed herein) could distort the pressure of fluid within tubular member **260** and, thus, distort the blood pressure reading. Therefore, reducing the likelihood of collapse of tubular member **260** (and/or other tubular members disclosed herein) may improve the accuracy in the guidewires disclosed herein.

FIG. 7 illustrates another example tubular member **360** with a non-circular cross-sectional shape and defining lumen **364**. In this example, tubular member **360** has a hexagon shape. However, other suitable shapes may be utilized including polygonal, regular, irregular, oval, rounded or semi-rounded, or the like. These are just examples.

FIG. 8 illustrates another example tubular member **460** that may be similar in form and function to other tubular members disclosed herein. Tubular member **460** may have a plurality of ribs or splines **466** that define a plurality of lumens **464**. Splines **466** may provide structural support to tubular member **460** so as to, for example, resist radially collapse of tubular member **460**. The inclusion of a support or reinforcing structure such as splines **466** may allow for a wider variety of materials to be utilized when manufacturing tubular member **460**. For example, a reinforced tubular member **460** (e.g., including splines **466**) may be formed from polymeric materials such as those disclosed herein.

FIGS. 9A-9B illustrate another example tubular member **560** that may be similar in form and function to other tubular members disclosed herein. Tubular member **560** may be

designed to shift between a first or “closed” configuration where lumen 564 is substantially closed and a second or “open” configuration where lumen 564 is substantially open. Shifting between configurations may be accomplished in a number of ways such as, for example, through the use of shape memory materials like nickel-titanium alloys (e.g., nitinol). For example, a guidewire can be manufactured that includes tubular member 560 arranged in the first configuration. Because of this, lumen 564 may be substantially closed, “unfilled”, evacuated, or the like. Tubular member 560 may be configured to shift to the second configuration when exposed to a higher temperature such as body temperature (e.g., about 37 degrees Celsius). Accordingly, when inserting the guidewire into a patient, tubular member 560 may warm and shift to the second configuration. When doing so, the opening of the previously closed lumen 564 may essentially “automatically” cause lumen 564 to fill with blood.

FIG. 10 illustrates another example guidewire 610 that may be similar in form and function to other guidewire disclosed herein. Guidewire 610 may include shaft 612 having proximal portion 614 and distal portion 616. Distal portion 616 may have slots or slits 618 formed therein. At least some of slits 618 may extend through only a portion of the wall of shaft 612. Pressure sensor 620 may be disposed within shaft 612. In at least some embodiments, pressure sensor 620 may be an optical pressure sensor having optical fiber 624 coupled thereto. Optical fiber 624 may be coupled to shaft 612 at attachment member 626.

Tubular member 660 may be disposed with shaft 612. Tubular member 660 may have a distal section 661 disposed along distal portion 616 of shaft 612. Distal section 661 may be disposed adjacent to one or more openings 659. Proximal end 663 of tubular member 660 may be coupled to pressure sensor 620. For example proximal end 663 of tubular member 660 may be coupled to pressure sensor 620 with seal member 662.

In this embodiment, shaft 612 may have an essentially constant inner diameter. This may allow for shaft 612 to be of a unitary or monolithic construction. In addition, in some examples a relatively smaller sized pressure sensor 620 may be utilized within shaft 612. For example, pressure sensor 620 may have an outer diameter less than 260 microns, or about 125 microns. These are just examples.

The materials that can be used for the various components of guidewire 10 (and/or other guidewires disclosed herein) and the various tubular members disclosed herein may include those commonly associated with medical devices. For simplicity purposes, the following discussion makes reference to shaft 12 and other components of guidewire 10. However, this is not intended to limit the devices and methods described herein, as the discussion may be applied to other tubular members and/or components of tubular members or devices disclosed herein.

Shaft 12 may be made from a metal, metal alloy, polymer (some examples of which are disclosed below), a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable material. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400,

and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

As alluded to herein, within the family of commercially available nickel-titanium or nitinol alloys, is a category designated “linear elastic” or “non-super-elastic” which, although may be similar in chemistry to conventional shape memory and super elastic varieties, may exhibit distinct and useful mechanical properties. Linear elastic and/or non-super-elastic nitinol may be distinguished from super elastic nitinol in that the linear elastic and/or non-super-elastic nitinol does not display a substantial “superelastic plateau” or “flag region” in its stress/strain curve like super elastic nitinol does. Instead, in the linear elastic and/or non-super-elastic nitinol, as recoverable strain increases, the stress continues to increase in a substantially linear, or a somewhat, but not necessarily entirely linear relationship until plastic deformation begins or at least in a relationship that is more linear than the super elastic plateau and/or flag region that may be seen with super elastic nitinol. Thus, for the purposes of this disclosure linear elastic and/or non-super-elastic nitinol may also be termed “substantially” linear elastic and/or non-super-elastic nitinol.

In some cases, linear elastic and/or non-super-elastic nitinol may also be distinguishable from super elastic nitinol in that linear elastic and/or non-super-elastic nitinol may accept up to about 2-5% strain while remaining substantially elastic (e.g., before plastically deforming) whereas super elastic nitinol may accept up to about 8% strain before plastically deforming. Both of these materials can be distinguished from other linear elastic materials such as stainless steel (that can also can be distinguished based on its composition), which may accept only about 0.2 to 0.44 percent strain before plastically deforming.

In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy is an alloy that does not show any martensite/austenite phase changes that are detectable by differential scanning calorimetry (DSC) and dynamic metal thermal analysis (DMTA) analysis over a large temperature range. For example, in some embodiments, there may be no martensite/austenite phase changes detectable by DSC and DMTA analysis in the range of about -60 degrees Celsius (° C.) to about 120° C. in the linear elastic and/or non-super-elastic nickel-titanium alloy. The mechanical bending properties of such material may therefore be generally inert to the effect of temperature over this very broad range of temperature. In some embodiments, the mechanical bending properties of the linear elastic and/or non-super-elastic nickel-titanium alloy at ambient or room temperature are substantially the same as the mechanical properties at body temperature, for example, in that they do not display a super-elastic plateau and/or flag region. In other words, across a broad temperature range, the linear elastic and/or non-super-elastic nickel-titanium alloy maintains its linear elastic and/or non-super-elastic characteristics and/or properties.

In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy may be in the range of about 50 to about 60 weight percent nickel, with the remainder being

essentially titanium. In some embodiments, the composition is in the range of about 54 to about 57 weight percent nickel. One example of a suitable nickel-titanium alloy is FHP-NT alloy commercially available from Furukawa Techno Material Co. of Kanagawa, Japan. Some examples of nickel titanium alloys are disclosed in U.S. Pat. Nos. 5,238,004 and 6,508,803, which are incorporated herein by reference. Other suitable materials may include ULTANIUM™ (available from Neo-Metrics) and GUM METAL™ (available from Toyota). In some other embodiments, a superelastic alloy, for example a superelastic nitinol can be used to achieve desired properties.

In at least some embodiments, portions or all of shaft **12** may also be doped with, made of, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. This relatively bright image aids the user of guidewire **10** in determining its location. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like. Additionally, other radiopaque marker bands and/or coils may also be incorporated into the design of guidewire **10** to achieve the same result.

In some embodiments, a degree of Magnetic Resonance Imaging (MRI) compatibility is imparted into guidewire **10**. For example, shaft **12** or portions thereof may be made of a material that does not substantially distort the image and create substantial artifacts (i.e., gaps in the image). Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. Shaft **12**, or portions thereof, may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nitinol, and the like, and others.

A sheath or covering (not shown) may be disposed over portions or all of shaft **12** that may define a generally smooth outer surface for guidewire **10**. In other embodiments, however, such a sheath or covering may be absent from a portion of all of guidewire **10**, such that shaft **12** may form the outer surface. The sheath may be made from a polymer or other suitable material. Some examples of suitable polymers may include polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM, for example, DELRIN® available from DuPont), polyether block ester, polyurethane (for example, Polyurethane 85A), polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL® available from DSM Engineering Plastics), ether or ester based copolymers (for example, butylene/poly(alkylene ether) phthalate and/or other polyester elastomers such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), Marlex high-density polyethylene, Marlex low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide

(PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly paraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID® available from EMS American Grilon), perfluoro(propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), poly(styrene-*b*-isobutylene-*b*-styrene) (for example, SIBS and/or SIBS 50A), polycarbonates, ionomers, biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like. In some embodiments the sheath can be blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 6 percent LCP.

In some embodiments, the exterior surface of the guidewire **10** (including, for example, the exterior surface of shaft **12**) may be sandblasted, beadblasted, sodium bicarbonate-blasted, electropolished, etc. In these as well as in some other embodiments, a coating, for example a lubricious, a hydrophilic, a protective, or other type of coating may be applied over portions or all of the sheath, or in embodiments without a sheath over portion of shaft **12**, or other portions of guidewire **10**. Alternatively, the sheath may comprise a lubricious, hydrophilic, protective, or other type of coating. Hydrophobic coatings such as fluoropolymers provide a dry lubricity which improves guidewire handling and device exchanges. Lubricious coatings improve steerability and improve lesion crossing capability. Suitable lubricious polymers are well known in the art and may include silicone and the like, hydrophilic polymers such as high-density polyethylene (HDPE), polytetrafluoroethylene (PTFE), polyarylene oxides, polyvinylpyrrolidones, polyvinylalcohols, hydroxy alkyl celluloses, algin, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility. Some other examples of such coatings and materials and methods used to create such coatings can be found in U.S. Pat. Nos. 6,139,510 and 5,772,609, which are incorporated herein by reference.

The coating and/or sheath may be formed, for example, by coating, extrusion, co-extrusion, interrupted layer co-extrusion (ILC), or fusing several segments end-to-end. The layer may have a uniform stiffness or a gradual reduction in stiffness from the proximal end to the distal end thereof. The gradual reduction in stiffness may be continuous as by ILC or may be stepped as by fusing together separate extruded tubular segments. The outer layer may be impregnated with a radiopaque filler material to facilitate radiographic visualization. Those skilled in the art will recognize that these materials can vary widely without deviating from the scope of the present invention.

Various embodiments of arrangements and configurations of slots are also contemplated that may be used in addition to what is described above or may be used in alternate embodiments. For simplicity purposes, the following disclosure makes reference to guidewire **10**, slots **18**, and shaft **12**. However, it can be appreciated that these variations may also be utilized for other slots and/or tubular members. In some embodiments, at least some, if not all of slots **18** are disposed at the same or a similar angle with respect to the longitudinal axis of shaft **12**. As shown, slots **18** can be disposed at an angle that is perpendicular, or substantially perpendicular, and/or can be characterized as being disposed in a plane that is normal to the longitudinal axis of shaft **12**. However, in other embodiments, slots **18** can be disposed at

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an angle that is not perpendicular, and/or can be characterized as being disposed in a plane that is not normal to the longitudinal axis of shaft 12. Additionally, a group of one or more slots 18 may be disposed at different angles relative to another group of one or more slots 18. The distribution and/or configuration of slots 18 can also include, to the extent applicable, any of those disclosed in U.S. Pat. Publication No. US 2004/0181174, the entire disclosure of which is herein incorporated by reference.

Slots 18 may be provided to enhance the flexibility of shaft 12 while still allowing for suitable torque transmission characteristics. Slots 18 may be formed such that one or more rings and/or tube segments interconnected by one or more segments and/or beams that are formed in shaft 12, and such tube segments and beams may include portions of shaft 12 that remain after slots 18 are formed in the body of shaft 12. Such an interconnected structure may act to maintain a relatively high degree of torsional stiffness, while maintaining a desired level of lateral flexibility. In some embodiments, some adjacent slots 18 can be formed such that they include portions that overlap with each other about the circumference of shaft 12. In other embodiments, some adjacent slots 18 can be disposed such that they do not necessarily overlap with each other, but are disposed in a pattern that provides the desired degree of lateral flexibility.

Additionally, slots 18 can be arranged along the length of, or about the circumference of, shaft 12 to achieve desired properties. For example, adjacent slots 18, or groups of slots 18, can be arranged in a symmetrical pattern, such as being disposed essentially equally on opposite sides about the circumference of shaft 12, or can be rotated by an angle relative to each other about the axis of shaft 12. Additionally, adjacent slots 18, or groups of slots 18, may be equally spaced along the length of shaft 12, or can be arranged in an increasing or decreasing density pattern, or can be arranged in a non-symmetric or irregular pattern. Other characteristics, such as slot size, slot shape, and/or slot angle with respect to the longitudinal axis of shaft 12, can also be varied along the length of shaft 12 in order to vary the flexibility or other properties. In other embodiments, moreover, it is contemplated that the portions of the tubular member, such as a proximal section, or a distal section, or the entire shaft 12, may not include any such slots 18.

As suggested herein, slots 18 may be formed in groups of two, three, four, five, or more slots 18, which may be located at substantially the same location along the axis of shaft 12. Alternatively, a single slot 18 may be disposed at some or all of these locations. Within the groups of slots 18, there may be included slots 18 that are equal in size (i.e., span the same circumferential distance around shaft 12). In some of these as well as other embodiments, at least some slots 18 in a group are unequal in size (i.e., span a different circumferential distance around shaft 12). Longitudinally adjacent groups of slots 18 may have the same or different configurations. For example, some embodiments of shaft 12 include slots 18 that are equal in size in a first group and then unequally sized in an adjacent group. It can be appreciated that in groups that have two slots 18 that are equal in size and are symmetrically disposed around the tube circumference, the centroid of the pair of beams (i.e., the portion of shaft 12 remaining after slots 18 are formed therein) is coincident with the central axis of shaft 12. Conversely, in groups that have two slots 18 that are unequal in size and whose centroids are directly opposed on the tube circumference, the centroid of the pair of beams can be offset from the central axis of shaft 12. Some embodiments of shaft 12 include only slot groups with centroids that are coincident with the

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central axis of the shaft 12, only slot groups with centroids that are offset from the central axis of shaft 12, or slot groups with centroids that are coincident with the central axis of shaft 12 in a first group and offset from the central axis of shaft 12 in another group. The amount of offset may vary depending on the depth (or length) of slots 18 and can include other suitable distances.

Slots 18 can be formed by methods such as micro-machining, saw-cutting (e.g., using a diamond grit embedded semiconductor dicing blade), electron discharge machining, grinding, milling, casting, molding, chemically etching or treating, or other known methods, and the like. In some such embodiments, the structure of the shaft 12 is formed by cutting and/or removing portions of the tube to form slots 18. Some example embodiments of appropriate micromachining methods and other cutting methods, and structures for tubular members including slots and medical devices including tubular members are disclosed in U.S. Pat. Publication Nos. 2003/0069522 and 2004/0181174-A2; and U.S. Pat. Nos. 6,766,720; and 6,579,246, the entire disclosures of which are herein incorporated by reference. Some example embodiments of etching processes are described in U.S. Pat. No. 5,106,455, the entire disclosure of which is herein incorporated by reference. It should be noted that the methods for manufacturing guidewire 110 may include forming slots 18 shaft 12 using these or other manufacturing steps.

In at least some embodiments, slots 18 may be formed in tubular member using a laser cutting process. The laser cutting process may include a suitable laser and/or laser cutting apparatus. For example, the laser cutting process may utilize a fiber laser. Utilizing processes like laser cutting may be desirable for a number of reasons. For example, laser cutting processes may allow shaft 12 to be cut into a number of different cutting patterns in a precisely controlled manner. This may include variations in the slot width, ring width, beam height and/or width, etc. Furthermore, changes to the cutting pattern can be made without the need to replace the cutting instrument (e.g., blade). This may also allow smaller tubes (e.g., having a smaller outer diameter) to be used to form shaft 12 without being limited by a minimum cutting blade size. Consequently, shaft 12 may be fabricated for use in neurological devices or other devices where a relatively small size may be desired.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A guidewire for determining fractional flow reserve, the guidewire comprising:

an elongated shaft having a proximal region and a distal region;

wherein the shaft has a constant outer diameter;

wherein the shaft includes a housing region having an enlarged inner diameter relative to other regions of the shaft;

wherein the distal region has one or more slits formed therein;

an optical pressure sensor disposed within the housing region of the shaft and positioned at least 30 centimeters from a distal end of the shaft;

an optical fiber attached to the optical pressure sensor;

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a tubular member having a proximal end sealed to the optical pressure sensor and a distal portion extending along the distal region of the shaft, the tubular member being axially-aligned with the optical fiber;
wherein an outer surface of the tubular member is radially spaced from an inner surface of the distal region of the shaft; and
wherein the distal region includes at least one opening formed therein that is designed to allow for fluid communication between an exterior of the shaft and a distal end of the tubular member.

* * * * *

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专利名称(译)	具有减小的压力偏移的压力传感导丝系统		
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申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED , INC.		
当前申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED , INC.		
[标]发明人	LEE GREGORY MCGOWAN ROGER W KOLBREK JON ROBERTSON KIMBERLY A		
发明人	LEE, GREGORY MCGOWAN, ROGER W. KOLBREK, JON ROBERTSON, KIMBERLY A.		
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摘要(译)

公开了用于制造和使用医疗装置的医疗装置和方法。示例性医疗设备可包括用于测量血压的医疗设备。医疗装置可包括细长轴，细长轴具有近端区域和远端区域。光纤可以沿近端区域延伸。光学压力传感器可以耦合到光纤。医疗装置还可包括管状构件，该管状构件具有邻近光学压力传感器设置的近端和沿轴的远端区域延伸的远端部分。

