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(54) **PRESSURE SENSING GUIDEWIRE**

DRUCKMESSUNGSFÜHRUNGSDRAHT

FIL-GUIDE À DÉTECTION DE PRESSION

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Description

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. 61/788,604, filed March 15, 2013.

TECHNICAL FIELD

[0002] The present disclosure pertains to medical devices, and methods for manufacturing medical devices. More particularly, the present disclosure pertains to blood pressure sensing guidewires. The document EP0738495A1 discloses a prior art device.

BACKGROUND

[0003] 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

[0004] This disclosure provides design, material, manufacturing method, and use alternatives for medical devices. An example medical device includes a pressure sensing guidewire. The pressure sensing guidewire includes a shaft having a proximal portion, a distal portion, and a distal tip portion. The distal portion has a plurality of slots formed therein. A pressure sensor is disposed within the distal portion of the shaft.

[0005] Another example pressure sensing guidewire includes a tubular member having a proximal portion, a distal portion, and a lumen defined therein. The distal portion has a plurality of slots formed therein. The plurality of slots may be configured to allow fluid to flow from an outer surface of the tubular member, through the slots, and into the lumen. A pressure sensor is disposed within the lumen of the tubular member and is positioned within the distal portion of the tubular member. A tip member may be coupled to the distal portion of the tubular member.

[0006] A pressure sensing guidewire system is also disclosed. The pressure sensing guidewire system includes a tubular member having a proximal portion, a slotted portion, and a lumen defined therein. The slotted portion has a plurality of slots formed therein. The plurality of slots may be configured to allow fluid to flow from an outer surface of the tubular member, through the slots, and into the lumen. An optical pressure sensor may be disposed within the lumen of the tubular member and may be positioned within the distal portion of the tubular member. A fiber optic cable may be attached to the optical pressure sensor and may extend proximally therefrom. A handle member may be coupled to the proximal portion of the tubular member and the fiber optic cable. The system may also include an interferometer and a cable extending between the handle member and the interferometer.

[0007] Another example pressure sensing guidewire includes a tubular member having a proximal portion and a distal portion. The distal portion has a plurality of slots formed therein. The distal portion has a first wall thickness along a first region and a second wall thickness different from the first wall thickness along a second region. A pressure sensor is disposed within the distal portion of the tubular member.

[0008] Another example pressure sensing guidewire includes a tubular member having a proximal portion, a distal portion, and a lumen defined therein. The distal portion has a first region having a first wall thickness and a second region with a second wall thickness that is larger than the first wall thickness. The distal portion has a plurality of slots formed therein. At least some of the slots disposed along the first region have an increased slot width relative to slots disposed along the second region. The first region includes a landing area that is free of slots. A pressure sensor is disposed along the first region and may be positioned adjacent to the landing area.

[0009] An example method for manufacturing a pressure sensing guidewire may include providing a tubular member having a proximal portion, a distal portion, and a lumen defined therein. The method may also include drilling the distal portion of the tubular member so as to define a thinned wall region having a reduced wall thickness, forming a plurality of slots in the distal portion, and disposing an optical pressure sensor along the thinned wall region of the distal portion.

[0010] Another example pressure sensing guidewire includes a tubular member having a proximal portion, a distal portion, and a lumen defined therein. The distal portion includes a housing region having an increased inner diameter relative to proximal portion of the tubular member. The distal portion has a plurality of slots formed therein. At least some of the slots disposed along the housing region have an increased slot width relative to slots disposed along other sections of the distal portion of the tubular member. The housing region includes a landing area that is free of slots. A pressure sensor is disposed along the housing region and positioned adjacent to the landing area.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The disclosure may be more completely understood in consideration of the following detailed description in connection with the accompanying drawings, in which:

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

Figure 2 is a side view of a portion of an example tubular member;

Figure 3 is a side view of a portion of another example tubular member;

Figure 4 is a cross-sectional side view of a portion of another example medical device;

Figure 5 is a partial cross-sectional side view of a portion of another example medical device;

Figures 6-10 illustrate a portion of an example method for manufacturing an example medical device;

Figure 11 is a cross-sectional side view of an example tubular member; and

Figure 12 is a perspective view of an example tubular member.

DETAILED DESCRIPTION

[0012] 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. A number of pressure sensing devices, however, may pose technical challenges for steering, tracking, torqueing or otherwise navigating the device within the vasculature. For example, medical devices may include a relatively stiff pressure sensor located at or near the distal tip of the device and/or a sensor housing (in which the sensor is mounted) that may also be relatively stiff. Disclosed herein are a number of medical device that include pressure sensing capabilities and may be more easily steered, tracked, torqued, and/or otherwise navigated through the anatomy.

[0013] Figure 1 illustrates a portion of an example medical device 10. In this example, medical device 10 is a blood pressure sensing guidewire 10. Guidewire 10 includes a guidewire shaft or tubular member 12. Tubular member 12 includes a proximal portion 14 and a distal portion 16. In some embodiments, proximal portion 14 and distal portion 16 are simply portions of the same monolith of material. In other embodiments, proximal portion 14 and distal portion 16 are discrete members that are attached to one another using a suitable attachment process (e.g., solder, weld, adhesive, or the like).

[0014] A plurality of slots 18 are formed in tubular member 12. In the 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 tubular member 12 (e.g., along distal portion 16) while also allowing suitable transmission of torque.

[0015] A pressure sensor 20 is disposed within tubular member 12 (e.g., within a lumen 22 of tubular member 12). While pressure sensor 20 is shown schematically in Figure 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 senor, 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.

[0016] Typically, pressure sensors in guidewires are mounted within a mount or mounting structure at the distal end of the guidewire. The mount may take the form of a hypotube with a side hole or opening formed therein that provides access for the blood to reach the pressure sensor. Because the pressure sensor itself may be somewhat rigid and/or stiff and because the mount may also be somewhat rigid and/or stiff, such a configuration may define a region with increased stiffness at or near the distal end of the guidewire. This could pose technical challenges for navigating the guidewire within the vasculature.

[0017] The use of tubular member 12 (e.g., distal portion 16 having slots 18 formed therein) may improve the overall flexibility profile of guidewire 10 and/or improve the navigation, steerability, and trackability of guidewire 10. For example, the flexibility of distal portion 16 may be reduced when compared to a typical hypotube pressure sensor mount. Furthermore, the design of distal portion 16 can be tailored to provide a flexibility profile suitable for a given guidewire/intervention through a variety of different patterns and/or configurations for slots 18. Numerous slot configurations are contemplated including those disclosed herein.

[0018] Moreover, 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 tubular member 12), through slots 18, and into the lumen 22 of tubular member 12, where the blood can come into contact with pressure sensor 20. Because of this, no additional side openings/holes (e.g., other than slots 18) may be necessary in tubular member 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.

[0019] In use, a clinician may use guidewire 10 to measure or calculate FFR (e.g., the pressure after an intravascular lesion relative to the pressure before the lesion). This may include taking an initial pressure reading before or upstream of the lesion and then a comparative reading after or downstream of the lesion. This may also include monitoring the pressure while advancing guidewire 10 through a blood vessel until a pressure differential or drop in pressure is observed, indicating that

guidewire 10 has reached and/or partially past the lesion as well as monitoring increases in pressure during and/or following a treatment intervention. In some embodiments, a second pressure measuring device may be used to measure pressure at another intravascular location and this pressure may be utilized in the calculation of FFR or otherwise used as part of the intervention.

[0020] As indicated above, pressure sensor 20 may include an optical pressure sensor. In at least some of these embodiments, a fiber optic cable 24 is attached to pressure sensor 20 and extends proximally therefrom. An attachment member 26 may attach fiber optic cable 24 to tubular member 12. Attachment member 26 may be circumferentially disposed about and attached to fiber optic 24 and be secured to the inner surface of tubular member 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.

[0021] In at least some embodiments, a sealing member 28 may be disposed within tubular member 12. Sealing member 28 may be generally configured to seal or otherwise prevent body fluids that enter lumen 22 (e.g., through slots 18) from passing through tubular member 12 to more proximal regions of guidewire 10 (including the proximal end of guidewire 10 and/or outside the patient). Sealing member 28 may be positioned at a suitable location along tubular member. This may include being positioned proximal of slots 18. While a single sealing member 28 is illustrated, additional sealing members 28 may also be utilized and the additional sealing members 28 may be positioned at a suitable location along tubular member 12.

[0022] A tip member 30 may be coupled to tubular member 12. The precise form of tip member 30 can vary. For example, tip member may include a core member 32, a spring or coil 34, and a tip 36. Core member 32 may include one or more tapers. Core member 32 and/or coil 34 may be attached to tubular member 12 using a suitable attachment technique such as soldering, thermal bonding, welding, adhesive, or the like. Tip 36 may be a solder ball tip. Other tips are contemplated. In some embodiments, tip 36 may be secured directly to tubular member 12. According to these embodiments, core member 32 and/or coil 34 may be omitted from tip member 30 and/or guidewire 10.

[0023] The proximal end of guidewire 10 may be configured to attach to a connector or handle member 38. Handle 38 may include a suitable connector for a cable 40 to attached thereto and extend to another suitable device such as a signal conditioner or interferometer 42. Another cable 44 may extend from signal conditioner 42 to a suitable output device or display and/or monitoring unit 46. A clinician may utilize the readings from the display device 46 to tailor the intervention to the needs of the patient or otherwise advance the goals of the intervention. These are just examples. Other devices and/or arrangements may be utilized with guidewire 10.

[0024] Figure 2 illustrates distal portion 16 of tubular member 12. Here it can be seen that at least some of slots 18 may lie in a plane transverse to a longitudinal axis of tubular member 12. In this example, slots 18 are arranged in groups of opposed pairs of slots 18. Subsequent opposed pairs of slots 18 may be rotated (e.g., 90 degrees as shown or any other suitable angle). Numerous other arrangements are contemplated. For example, Figure 3 illustrates distal portion 116 of another example tubular member 112. Here it can be seen that at least some of the slots 118 are arranged into a pattern defining an interrupted helix. These are just examples. Numerous other patterns and/or slot configurations are contemplated including those disclosed herein.

[0025] Figure 4 illustrates a portion of another example tip member 230 that may be used with guidewire 10 (and/or other guidewires disclosed or otherwise contemplated herein). Tip member 230 may include a shaping ribbon 232 and a coil 234. Shaping ribbon 232 may be formed from a shapeable material such as, for example, stainless steel, linear elastic nitinol, other materials disclosed herein, or the like. Shaping ribbon 232 and/or coil 234 may be attached to tubular member 12 with a bonding member 246. Bonding member 246 may include an adhesive, solder, or the like, or other suitable bonding members.

[0026] Figure 5 illustrates another example medical device 300, taking the form of pressure sensing guidewire, that may be similar in form and function to other devices/guidewire disclosed herein. Guidewire 300 may include a tubular member 312 having a proximal portion 349 and a distal portion 348. In some embodiments, proximal portion 349 and distal portion 348 are formed from the same monolith of material. In other words, proximal portion 349 and distal portion 348 are portions of the same tube defining tubular member 312. In other embodiments, proximal portion 349 and distal portion 348 are separate tubular members that are joined together. For example, a section of the outer surface of portions 349/348 may be removed and a sleeve 353 may be disposed over the removed sections to join portions 349/348. Alternatively, sleeve 353 may be simply disposed over portions 349/348. Other bonds may also be used including welds, thermal bonds, adhesive bonds, or the like.

[0027] The materials for proximal portion 349 and distal portion 348 may vary and may include those materials disclosed herein. For example, distal portion 348 may include a nickel-cobalt-chromium-molybdenum alloy (e.g., MP35-N). Proximal portion 349 may include stainless steel. These are just examples. Other materials may also be utilized. If included, sleeve 351 used to join proximal portion 349 with distal portion 348 may include a material that desirably bonds with both proximal portion 349 and distal portion 348. For example, sleeve 351 may include a nickel-chromium-molybdenum alloy (e.g., INCONEL).

[0028] Tubular member 312 may include a hydrophilic

coating 353 (on a portion of which is shown in Figure 5). In some embodiments, hydrophilic coating 353 may extend along substantially the full length of tubular member 312. In other embodiments, one or more discrete sections of tubular member 312 may include hydrophilic coating 353.

[0029] Distal portion 348 may have a plurality of slots 318 formed therein. The slots 318 may be arranged/distributed along distal portion 348 in a suitable manner including any of those arrangements disclosed herein. For example, slots 318 may be arranged as opposing pairs of slots 318 that are distributed along the length of distal portion 348. In some embodiments, adjacent pairs of slots 318 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 318 may have a decreased spacing (and/or increased slot density), which may provide increased flexibility. In other embodiments, more distal regions of distal portion 318 may have an increased spacing (and/or decreased slot density). Other arrangements are contemplated.

[0030] In some embodiments, proximal portion 349 may also include slots 318. According to these embodiments, the slots 318 in proximal portion 349 may be arranged in a suitable manner include those disclosed herein. In other embodiments, proximal portion 349 may be substantially free of slots 318.

[0031] A tip member330 may be coupled to distal portion 348. Tip member 330 may be similar to other tips/tip members disclosed herein. For example, tip member 330 may include a spring or coil member 334. A distal tip 336 may be attached to spring 334. In at least some embodiments, tip 336 may take the form of a solder ball tip. Tip member 330 may also include a shaping member 335. Tip member 330 may be joined to distal portion 348 of tubular member 312 with a bonding member 346 such as a weld.

[0032] In at least some embodiments, distal portion 348 may include a region with a thinned wall and/or an increased inner diameter that defines a housing region 352. In general, housing region 352 is the region of distal portion 348 that ultimately "houses" the pressure sensor (e.g., a pressure sensor 320). By virtue of having a portion of the inner wall of tubular member 312 being removed at housing region 352, additional space may be created or otherwise defined that can accommodate sensor 320.

[0033] As indicated above, pressure sensor 320 may be disposed within housing region 352. In at least some embodiments, pressure sensor 320 may be an optical (and/or fabry-perot) pressure sensor similar to other pressure sensors disclosed herein. An optical fiber 324 may be attached to pressure sensor 320 and extend proximally therefrom. At its proximal end (not shown) optical fiber 324 may connect to a suitable processing device (e.g., signal processing unit, interferometer, or the like). In some of these and in other embodiments, an intermediate or adapter cable may be connected to the proximal end of guidewire 300 (and optical fiber 324), which, in turn, connects to a suitable processing unit.

[0034] In at least some embodiments, it may be desirable for pressure sensor 320 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 320 along a landing region 350 defined along housing region 352. Landing region 350 may be substantially free of slots 318 so that the side surfaces of pressure sensor 320 have a reduced likelihood of being deformed due to fluid pressures at these locations. Distal of landing are 350, housing region 352 may include slots 318 that provide fluid access to pressure sensor 320.

[0035] Figures 6-10 schematically illustrate a portion of an example method for manufacturing guidewire 300. For example, Figure 6 illustrates tubular member 312. As indicated above, tubular member 312 may be single monolith of material or may include two or more sections joined together. Distal portion 348 of tubular member 312 may be honed or drilled to define housing region 352 as shown in Figure 7. In general, this may include disposing a drill (e.g., a suitable drill bit) into the distal end of distal portion 348. In doing so, a portion of the wall of tubular member 312 is removed to define housing region 352. As can be seen, distal portion 348 of tubular member 312 at housing region 352 may have a reduced wall thickness and an increased inner diameter.

[0036] Slots 318 may be cut into distal portion 318 of tubular member 312 as shown in Figure 8. This may include a suitable cutting process such as a laser cutting process, mechanical or micromachining process, or the like. As indicated above, the cutting process may be utilized to arrange slots 318 along distal portion 348 of tubular member 312 in the desired pattern and/or configuration. This may include defining landing region 350 (e.g., which may be free of slots 318).

[0037] The cutting process may leave behind traces of removed material or dross 354 adjacent to slots 318, along the inner and/or outer surface of tubular member 312, or the like. Dross 354 can be removed via a cleaning and/or etching process (e.g., a chemical etching process) as schematically shown in Figure 9.

[0038] When suitable prepared/cleaned, pressure sensor 320 and optical fiber 324 may be inserted into tubular member 312 (e.g., via the distal end of tubular member 312) as shown in Figure 10. Optical fiber 324 may be secure to tubular member 312 at one or more locations. This may include securing optical fiber 324 with a suitable adhesive or joining member (and/or the like).

[0039] Figures 11-12 illustrate tubular member 312', showing additional details of some of the patterns contemplated for slots 318. These patterns/configurations may be utilized in guidewire 300 (e.g., with pressure sensor 320, optical fiber 324, etc.). For example, a first slot region 318a may be defined in distal portion 348 where the slots 318 are substantially evenly distributed. In other words, slots 318 may be arranged as opposed pairs of slots 318 that are longitudinally distributed along distal

portion 348. A second slot region 318b may also be defined where the stiffness of tubular member 312' may be altered by altering the distribution of slots 318. Second slot region 318b may be disposed adjacent to housing region 352. Along second slot region 318b, the spacing between adjacent pairs of slots 318 may vary. This may include increased spacing, decreased spacing, or both. For example, along housing region 352 (where a portion of tubular member 312 is removed, fewer slots 318 may be needed to provide the desired flexibility. Thus, along housing region 352, the spacing between slots 318 may be increased (e.g., with fewer slots per unit area) in the distal direction. These are just examples. Numerous additional slot arrangements and/or patterns are contemplated.

[0040] In addition, some of the slots 318' positioned along housing region 352 may be widened or enlarged. These "widened" slots 318' may be generally wider than slots 318. In at least some embodiments, widened slots 318' may provide a desired level of flexibility. In addition, widened slots 318' may be positioned adjacent to landing region 350 (e.g., just distal of landing region 350) so as to provide a slightly wider opening for fluid to flow into and access pressure sensor 320. Furthermore, widened slots 318' may also help to reduce stress concentrations in the thinner wall areas along housing region 352.

[0041] The materials that can be used for the various components of guidewire 10 (and/or other guidewires disclosed herein including guidewire 300) and the various tubular members disclosed herein may include those commonly associated with medical devices. For simplicity purposes, the following discussion makes reference to tubular member 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 similar tubular members and/or components of tubular members or devices disclosed herein.

[0042] Tubular member 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® C-22®, 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.

[0043] 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 that 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.

[0044] 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.

[0045] 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.

[0046] 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. Patent Nos. 5,238,004 and 6,508,803. 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.

[0047] In at least some embodiments, portions or all of tubular member 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.

[0048] In some embodiments, a degree of Magnetic Resonance Imaging (MRI) compatibility is imparted into guidewire 10. For example, tubular member 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. Tubular member 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.

[0049] A sheath or covering (not shown) may be disposed over portions or all of tubular member 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 tubular member 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.

[0050] In some embodiments, the exterior surface of the guidewire 10 (including, for example, the exterior surface of tubular member 12) may be sandblasted, bead-blasted, 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 tubular member 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, polyvinylpyrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, 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. Patent Nos. 6,139,510 and 5,772,609.

[0051] 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.

[0052] 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 tubular member 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 tubular member 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 tubular member 12. However, in other embodiments, slots 18 can be disposed at 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 tubular member 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.

[0053] Slots 18 may be provided to enhance the flexibility of tubular member 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 tubular member 12, and such tube segments and beams may include portions of tubular member 12 that remain after slots 18 are formed in the body of tubular member 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 tubular member 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.

[0054] Additionally, slots 18 can be arranged along the length of, or about the circumference of, tubular member 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 tubular member 12, or can be rotated by an angle relative to each other about the axis of tubular member 12. Additionally, adjacent slots 18, or groups of slots 18, may be equally spaced along the length of tubular member 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 tubular member 12, can also be varied along the length of tubular member 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 tubular member 12, may not include any such slots 18.

[0055] 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 tubular member 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 tubular member 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 tubular member 12). Longitudinally adjacent groups of slots 18 may have the same or different configurations. For example, some embodiments of tubular member 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 tubular member 12 remaining after slots 18 are formed therein) is coincident with the central axis of tubular member 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 tubular member 12. Some embodiments of tubular member 12 include only slot groups with centroids that are coincident with the central axis of the tubular member 12, only slot groups with centroids that are offset from the central axis of tubular member 12, or slot groups with centroids that are coincident with the central axis of tubular member 12 in a first group and offset from the central axis of tubular member 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.

[0056] 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 tubular member 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. Some example embodiments of etching processes are described in U.S. Pat. No. 5,106,455. It should be noted that the methods for manufacturing guidewire 110 may include forming slots 18 tubular member 12 using these or other manufacturing steps.

[0057] 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 tubular member 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 tubular member 12 without being limited by a minimum cutting blade size. Consequently, tubular member 12 may be fabricated for use in neurological devices or other devices where a relatively small size may be desired.

Claims

1. A pressure sensing guidewire (10), comprising:

a tubular member (12) having a proximal portion (14) and a distal portion (16);
wherein the distal portion (16) has a plurality of slots (18) formed therein;
wherein the distal portion (14) has a first wall thickness along a first region and a second wall thickness different from the first wall thickness along a second region;
a pressure sensor (20) disposed within the distal portion (14) of the tubular member; and
wherein the tubular member (12) has a substantially constant outer diameter (99).

2. The pressure sensing guidewire of claim 1, wherein the pressure sensor (20) is an optical pressure sensor.

3. The pressure sensing guidewire of any one of claims 1-2, wherein the pressure sensor (20) is a fabry-perot pressure sensor.

4. The pressure sensing guidewire of any one of claims 1-3, wherein a fiber optic cable is attached to the pressure sensor (20) and extends proximally therefrom.

5. The pressure sensing guidewire of any one of claims 1-4, wherein the plurality of slots (18) include at least a pair of slots lying in a plane transverse to a longitudinal axis of the tubular member (12).

6. The pressure sensing guidewire of any one of claims 1-5, wherein the slots (18) have a first slot density along the first region of the distal portion of the tubular member (12) and a second slot density different from the first slot density along the second region of the distal portion of the tubular member (12).

7. The pressure sensing guidewire of any one of claims 1-6, wherein the first wall thickness is greater than the second wall thickness.

8. The pressure sensing guidewire of claim 7, wherein the first region is disposed distally of the second region.

9. The pressure sensing guidewire of any one of claims 7-8, wherein the pressure sensor is disposed along the first region.

10. The pressure sensing guidewire of any one of claims 7-9, wherein at least some of the slots (18) disposed adjacent to the first region have an enlarged slot width relative to the slots (18) disposed along the second region.

11. The pressure sensing guidewire of any one of claims 7-10, wherein the first region includes a landing portion that is free of slots and wherein the pressure sensor (20) is disposed adjacent to the landing portion.

12. The pressure sensing guidewire of any one of claims 1-11, wherein the distal portion of the tubular member (12) is formed from a first tube and wherein the proximal portion of the tubular member (12) is formed from a second tube different from the first tube.

13. The pressure sensing guidewire of claim 12, wherein the first tube includes MP-35N.

14. A pressure sensing guidewire (10), comprising:

a tubular member (12) with a substantially constant outer diameter having a proximal portion, a distal portion (14), and a lumen defined therein;
wherein the distal portion (14) has a first region having a first wall thickness and a second region with a second wall thickness that is larger than the first wall thickness;
wherein the distal portion (14) has a plurality of slots formed therein;
wherein at least some of the slots disposed along the first region have an increased slot width relative to slots disposed along the second region;
wherein the first region includes a landing area that is free of slots; and
a pressure sensor (20) disposed along the first region and positioned adjacent to the landing area.

Patentansprüche

1. Druckerfassender Führungsdraht (10), der aufweist:

ein Röhrenteil (12) mit einem proximalen Abschnitt (14) und einem distalen Abschnitt (16);
wobei der distale Abschnitt (16) mehrere darin gebildete Schlitze (18) hat;
wobei der distale Abschnitt (14) eine erste Wanddicke entlang eines ersten Bereichs und eine sich von der ersten Wanddicke unterscheidende zweite Wanddicke entlang eines zweiten Bereichs hat;
einen Drucksensor (20), der im distalen Abschnitt (14) des Röhrenteils angeordnet ist; und
wobei das Röhrenteil (12) einen im Wesentlichen konstanten Außendurchmesser (99) hat.

2. Druckerfassender Führungsdraht nach Anspruch 1, wobei der Drucksensor (20) ein optischer Drucksensor ist.

3. Druckerfassender Führungsdraht nach Anspruch 1 oder 2, wobei der Drucksensor (20) ein Fabry-Perot-Drucksensor ist.

4. Druckerfassender Führungsdraht nach einem der Ansprüche 1 bis 3, wobei ein Faseroptikkabel am Drucksensor (20) angebracht ist und sich davon proximal erstreckt.

5. Druckerfassender Führungsdraht nach einem der Ansprüche 1 bis 4, wobei die mehreren Schlitze (18) mindestens ein Paar Schlitze aufweisen, die in einer Ebene quer zu einer Längsachse des Röhrenteils (12) liegen.

6. Druckerfassender Führungsdraht nach einem der Ansprüche 1 bis 5, wobei die Schlitze (18) eine erste Schlitzdichte entlang des ersten Bereichs des distalen Abschnitts des Röhrenteils (12) und eine sich von der ersten Schlitzdichte unterscheidende zweite Schlitzdichte entlang des zweiten Bereichs des distalen Abschnitts des Röhrenteils (12) haben.

7. Druckerfassender Führungsdraht nach einem der Ansprüche 1 bis 6, wobei die erste Wanddicke größer als die zweite Wanddicke ist.

8. Druckerfassender Führungsdraht nach Anspruch 7, wobei der erste Bereich distal vom zweiten Bereich angeordnet ist.

9. Druckerfassender Führungsdraht nach Anspruch 7 oder 8, wobei der Drucksensor entlang des ersten Bereichs angeordnet ist.

10. Druckerfassender Führungsdraht nach einem der Ansprüche 7 bis 9, wobei mindestens einige der benachbart zum ersten Bereich angeordneten Schlitze (18) eine vergrößerte Schlitzbreite relativ zu den entlang des zweiten Bereichs angeordneten Schlitzen (18) haben.

11. Druckerfassender Führungsdraht nach einem der Ansprüche 7 bis 10, wobei der erste Bereich einen Absatzabschnitt aufweist, der frei von Schlitzen ist, und wobei der Drucksensor (20) benachbart zum Absatzabschnitt angeordnet ist.

12. Druckerfassender Führungsdraht nach einem der Ansprüche 1 bis 11, wobei der distale Abschnitt des Röhrenteils (12) aus einer ersten Röhre gebildet ist und wobei der proximale Abschnitt des Röhrenteils (12) aus einer zweiten Röhre gebildet ist, die sich von der ersten Röhre unterscheidet.

13. Druckerfassender Führungsdraht nach Anspruch 12, wobei die erste Röhre MP-35N aufweist.

14. Druckerfassender Führungsdraht (10), der aufweist:

ein Röhrenteil (12) mit einem im Wesentlichen konstanten Außendurchmesser, das einen proximalen Abschnitt, einen distalen Abschnitt (14) und ein darin gebildetes Lumen hat;
wobei der distale Abschnitt (14) einen ersten Bereich mit einer ersten Wanddicke und einen zweiten Bereich mit einer zweiten Wanddicke hat, die größer als die erste Wanddicke ist;
wobei der distale Abschnitt (14) mehrere darin gebildete Schlitze hat;
wobei mindestens einige der entlang des ersten

Bereichs angeordneten Schlitze eine vergrößerte Schlitzbreite relativ zu Schlitzen haben, die entlang des zweiten Bereichs angeordnet sind;
wobei der erste Bereich eine Absatzfläche aufweist, die frei von Schlitzen ist; und
einen Drucksensor (20), der entlang des ersten Bereichs angeordnet und benachbart zur Absatzfläche positioniert ist.

Revendications

1. Fil-guide à détection de pression (10) comprenant :

un élément tubulaire (12) présentant une partie proximale (14) et une partie distale (16) ;
dans lequel la partie distale (16) présente une pluralité de fentes (18) qui y sont formées ;
dans lequel la partie distale (14) a une première épaisseur de paroi le long d'une première région et une seconde épaisseur de paroi, différente de la première épaisseur de paroi, le long d'une seconde région ;
un capteur de pression (20) disposé au sein de la partie distale (14) de l'élément tubulaire ; et
dans lequel l'élément tubulaire (12) présente un diamètre extérieur sensiblement constant (99).

2. Fil-guide à détection de pression selon la revendication 1, dans lequel le capteur de pression (20) est un capteur de pression optique.

3. Fil-guide à détection de pression selon l'une quelconque des revendications 1 à 2, dans lequel le capteur de pression (20) est un capteur de pression de type Fabry-Pérot.

4. Fil-guide à détection de pression selon l'une quelconque des revendications 1 à 3, dans lequel un câble à fibre optique est attaché au capteur de pression (20) et s'étend proximalement par rapport à celui-ci.

5. Fil-guide à détection de pression selon l'une quelconque des revendications 1 à 4, dans lequel la pluralité de fentes (18) inclut au moins une paire de fentes se trouvant dans un plan transversal à un axe longitudinal de l'élément tubulaire (12).

6. Fil-guide à détection de pression selon l'une quelconque des revendications 1 à 5, dans lequel les fentes (18) ont une première densité de fentes le long de la première région de la partie distale de l'élément tubulaire (12) et une seconde densité de fentes, différente de la première densité de fentes, le long de la seconde région de la partie distale de l'élément tubulaire (12).

7. Fil-guide à détection de pression selon l'une quelconque des revendications 1 à 6, dans lequel la première épaisseur de paroi est supérieure à la seconde épaisseur de paroi.

8. Fil-guide à détection de pression selon la revendication 7, dans lequel la première région est disposée distalement par rapport à la seconde région.

9. Fil-guide à détection de pression selon l'une quelconque des revendications 7 à 8, dans lequel le capteur de pression est disposé le long de la première région.

10. Fil-guide à détection de pression selon l'une quelconque des revendications 7 à 9, dans lequel au moins certaines des fentes (18) disposées au voisinage de la première région ont une largeur accrue de fentes par rapport aux fentes (18) disposées le long de la seconde région.

11. Fil-guide à détection de pression selon l'une quelconque des revendications 7 à 10, dans lequel la première région inclut une partie formant plateau qui est dépourvue de fentes, et dans lequel le capteur de pression (20) est disposé au voisinage de la partie formant plateau.

12. Fil-guide à détection de pression selon l'une quelconque des revendications 1 à 11, dans lequel la partie distale de l'élément tubulaire (12) est formée à partir d'un premier tube et dans lequel la partie proximale de l'élément tubulaire (12) est formée à partir d'un second tube différent du premier tube.

13. Fil-guide à détection de pression selon la revendication 12, dans lequel le premier tube contient du MP-35N.

14. Fil-guide à détection de pression (10) comprenant :

un élément tubulaire (12) de diamètre extérieur sensiblement constant, présentant une partie proximale, une partie distale (14), et une lumière qui y est définie ;
dans lequel la partie distale (14) présente une première région ayant une première épaisseur de paroi et une seconde région ayant une seconde épaisseur de paroi qui est supérieure à la première épaisseur de paroi ;
dans lequel la partie distale (14) présente une pluralité de fentes qui y sont formées ;
dans lequel au moins certaines des fentes disposées le long de la première région ont une largeur accrue de fentes par rapport à des fentes disposées le long de la seconde région ;
dans lequel la première région comporte une zone formant plateau qui est dépourvue de

fentes ; et
un capteur de pression (20) disposé le long de la première région et positionné au voisinage de la zone formant plateau.

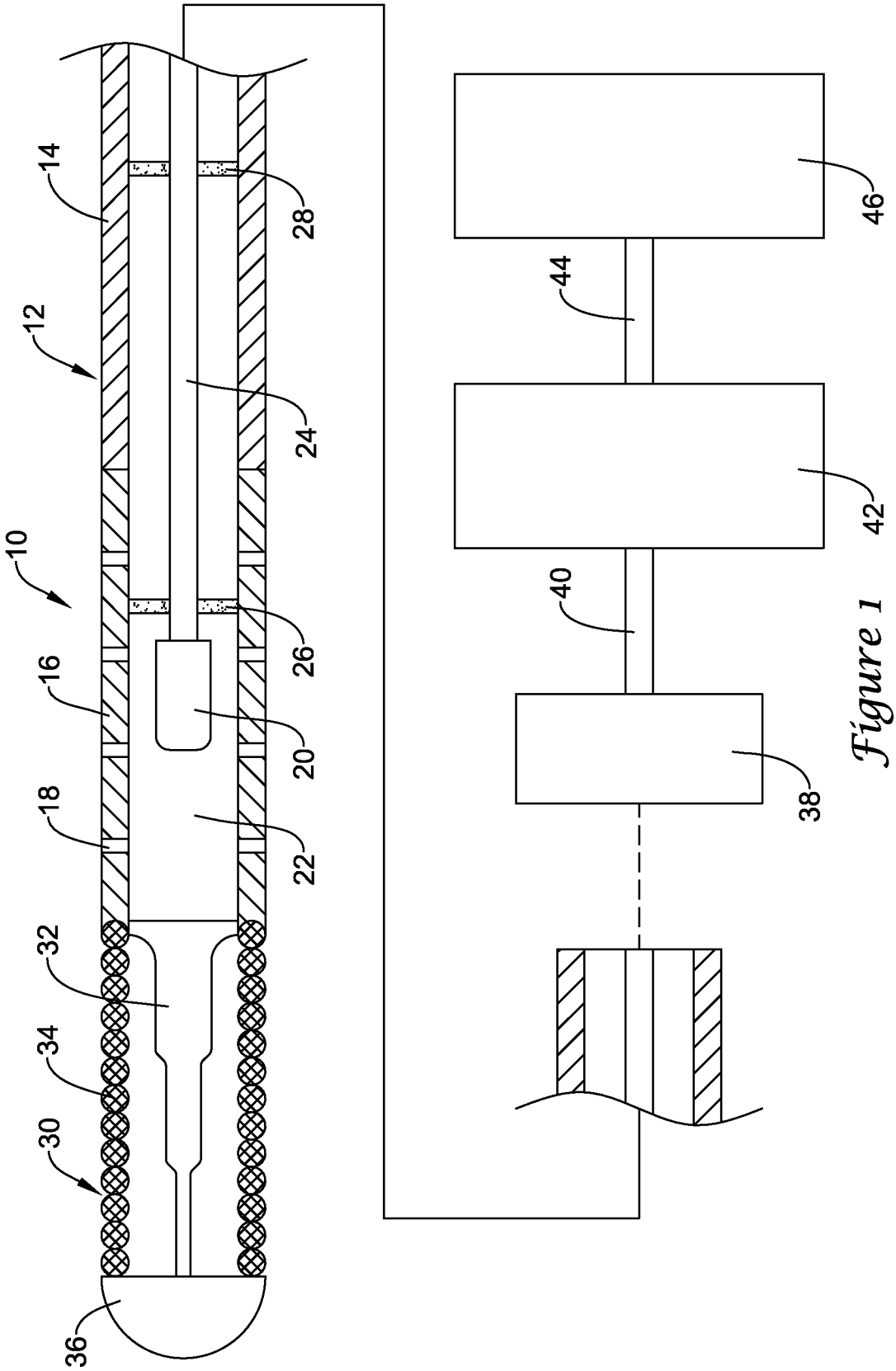

Figure 1

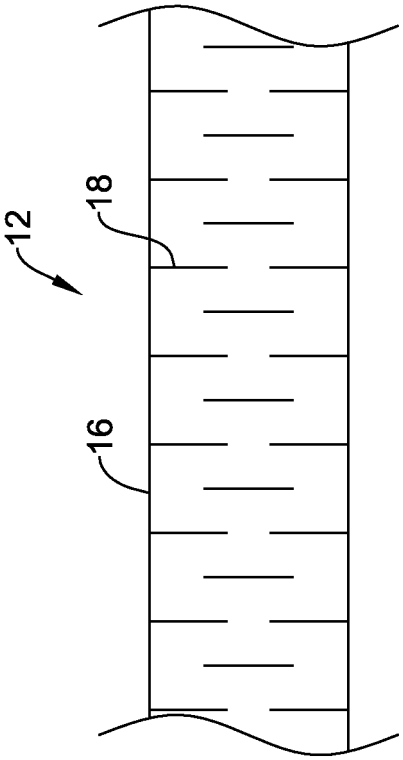

Figure 2

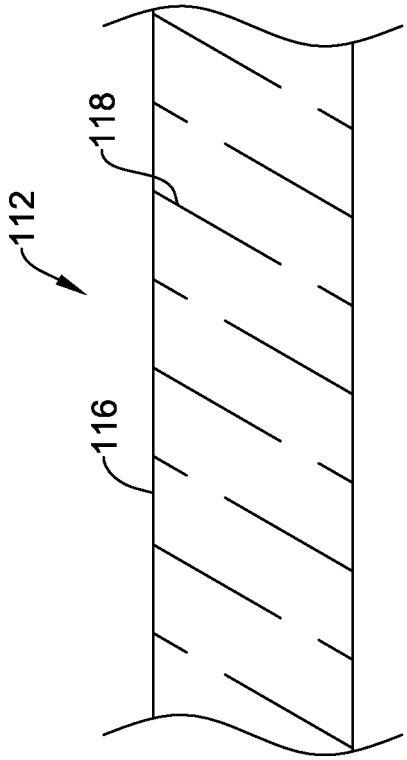

Figure 3

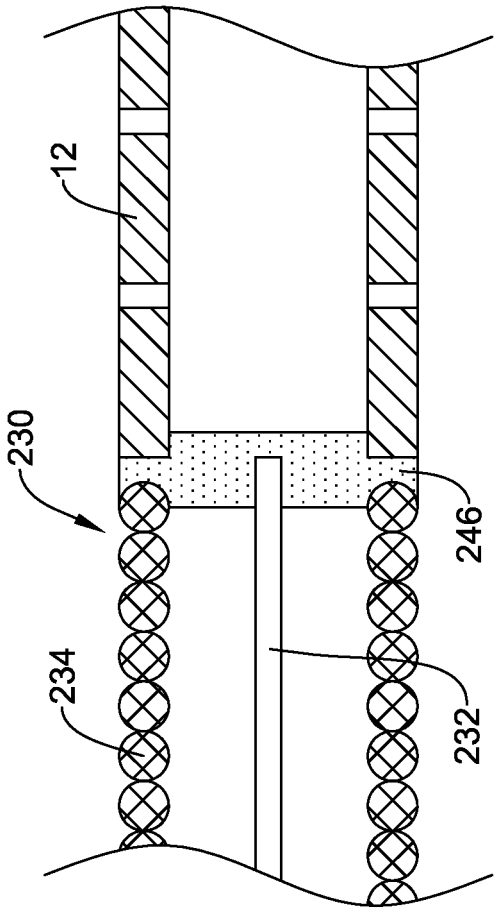

Figure 4

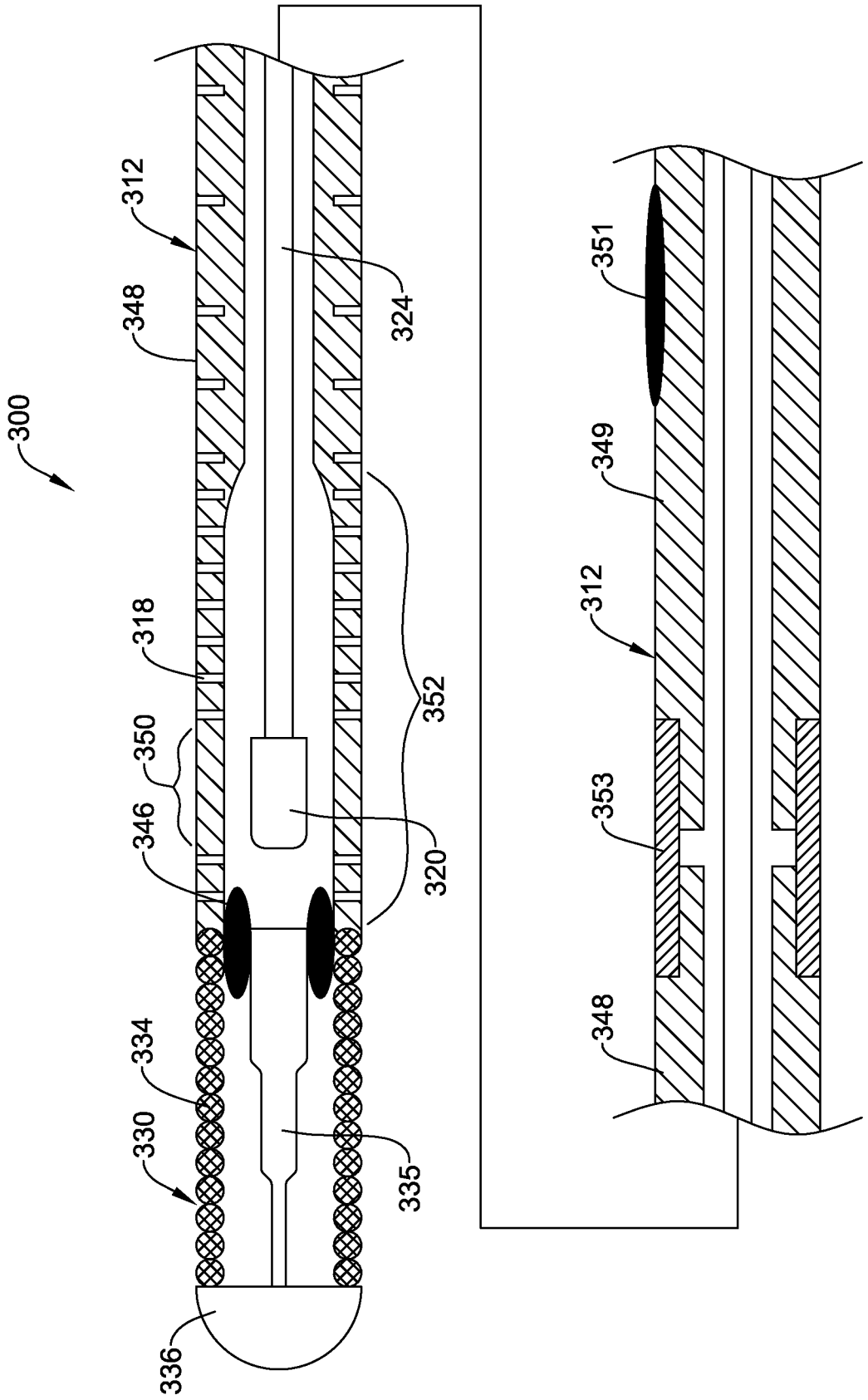
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Figure 5

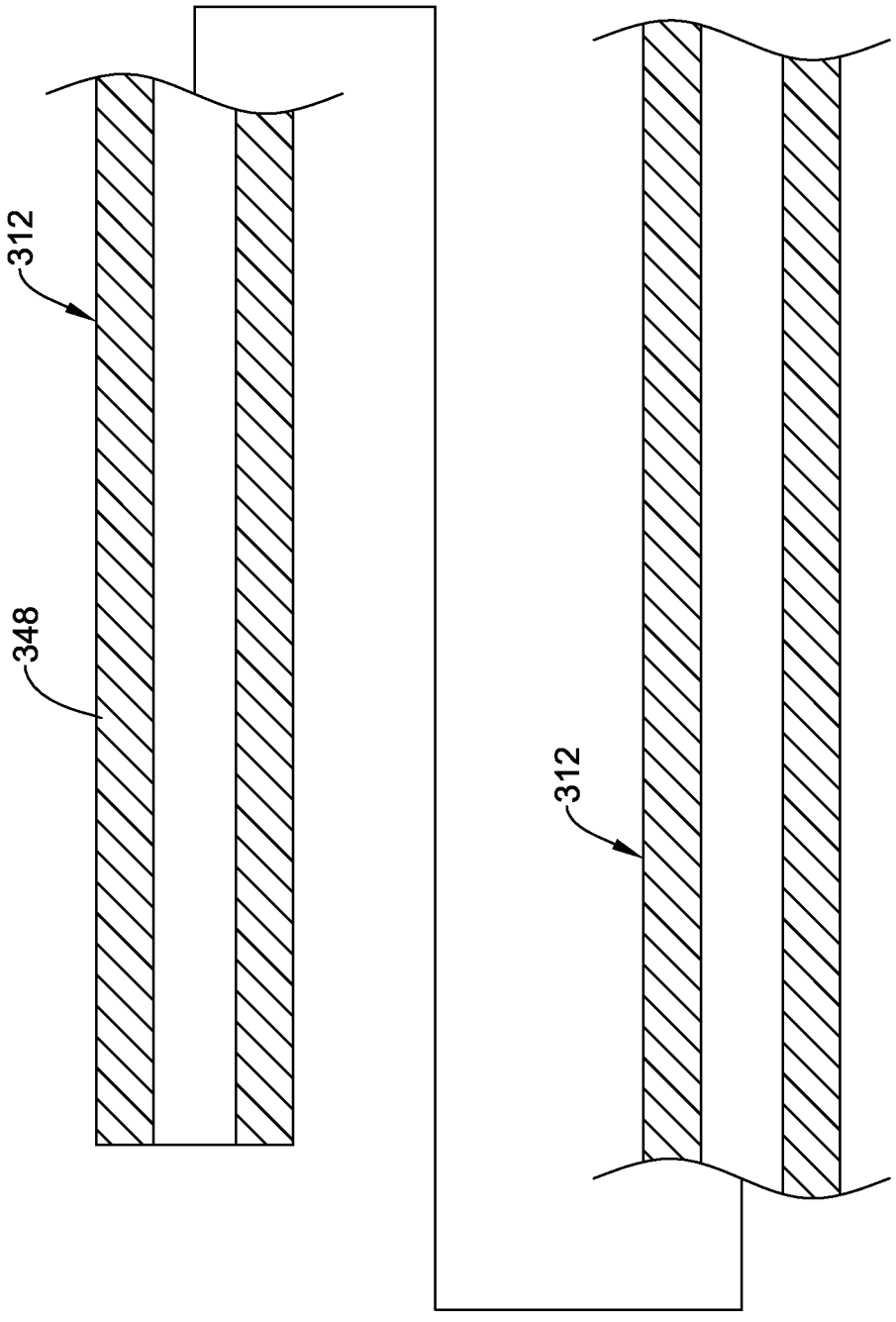

Figure 6

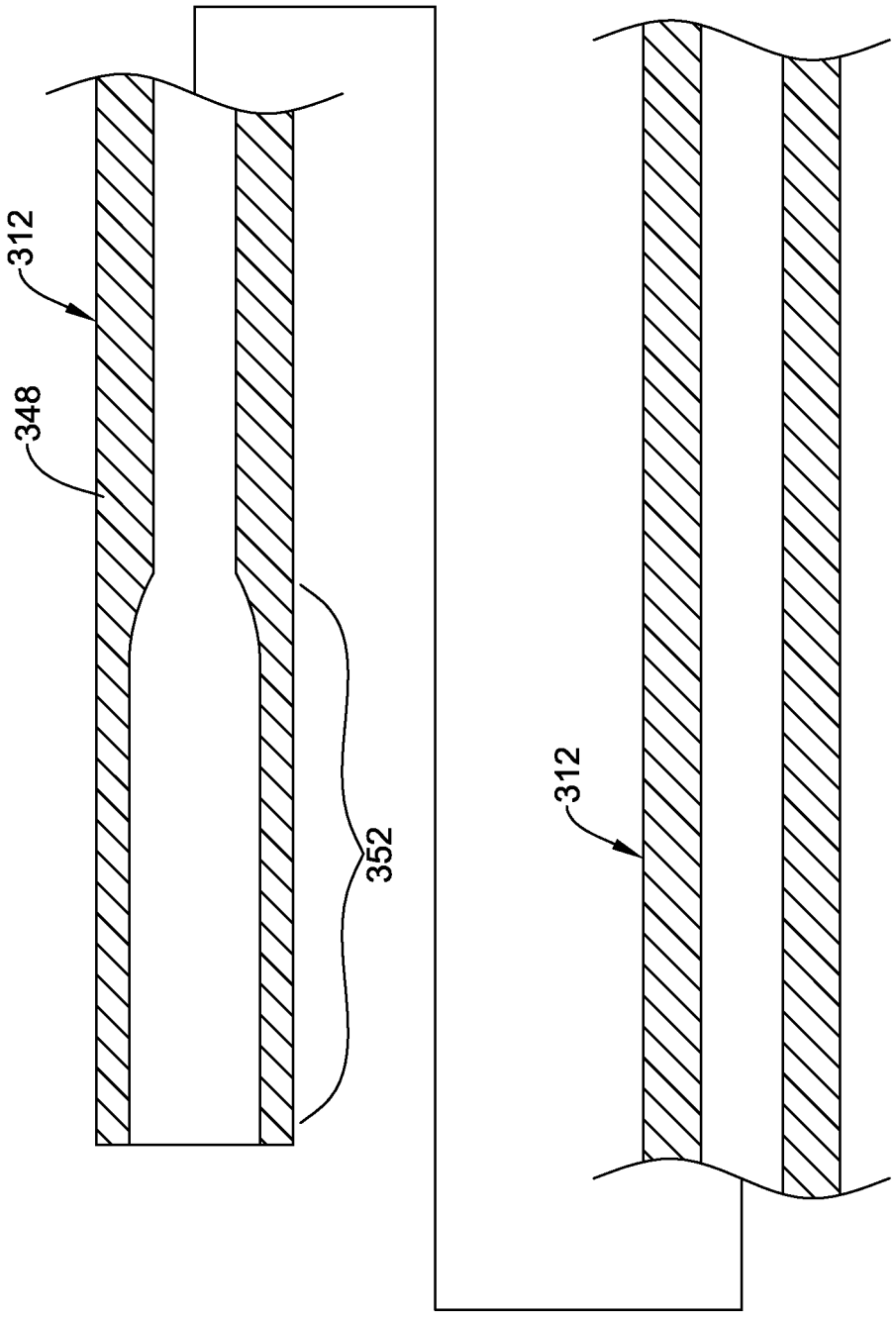

Figure 7

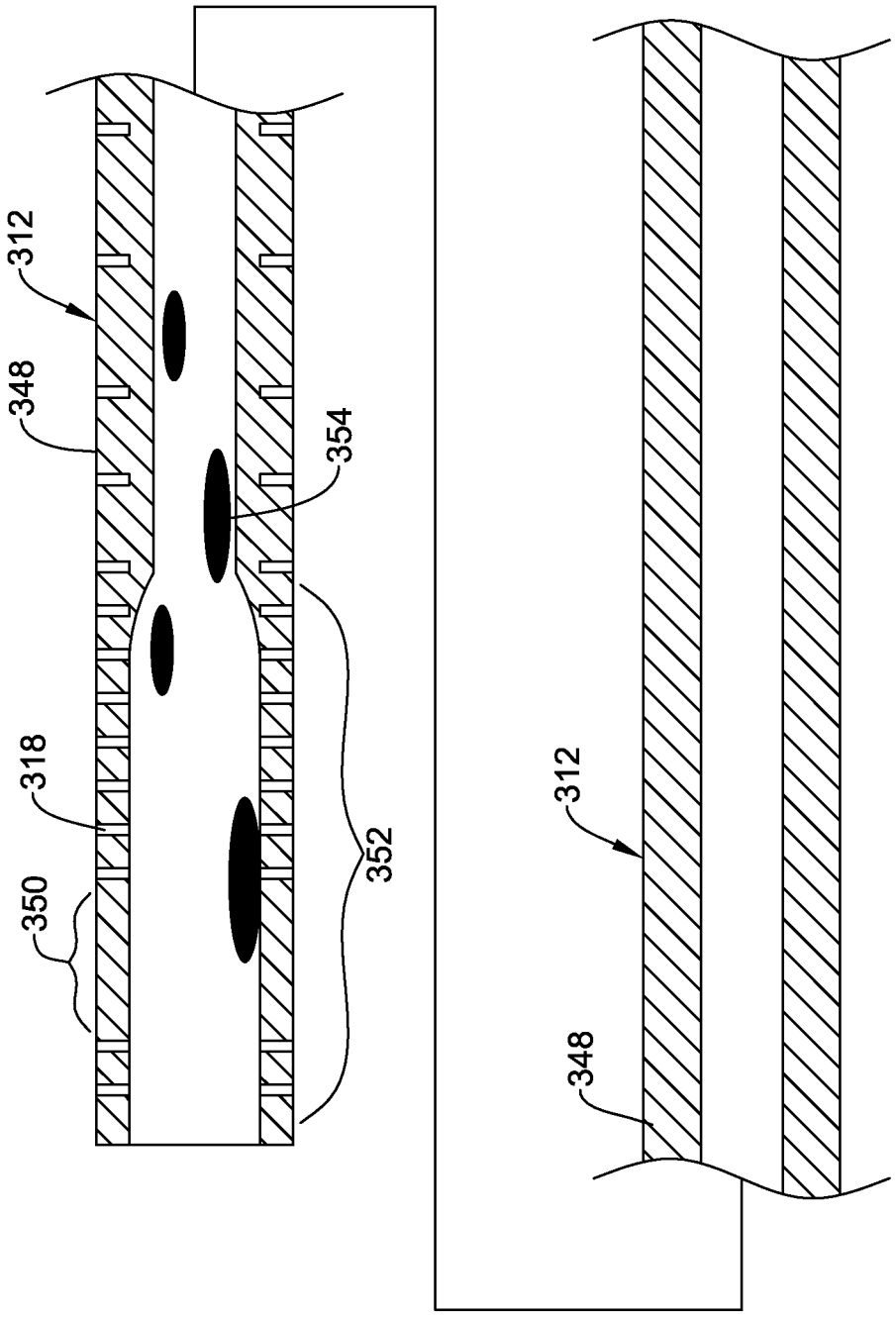

Figure 8

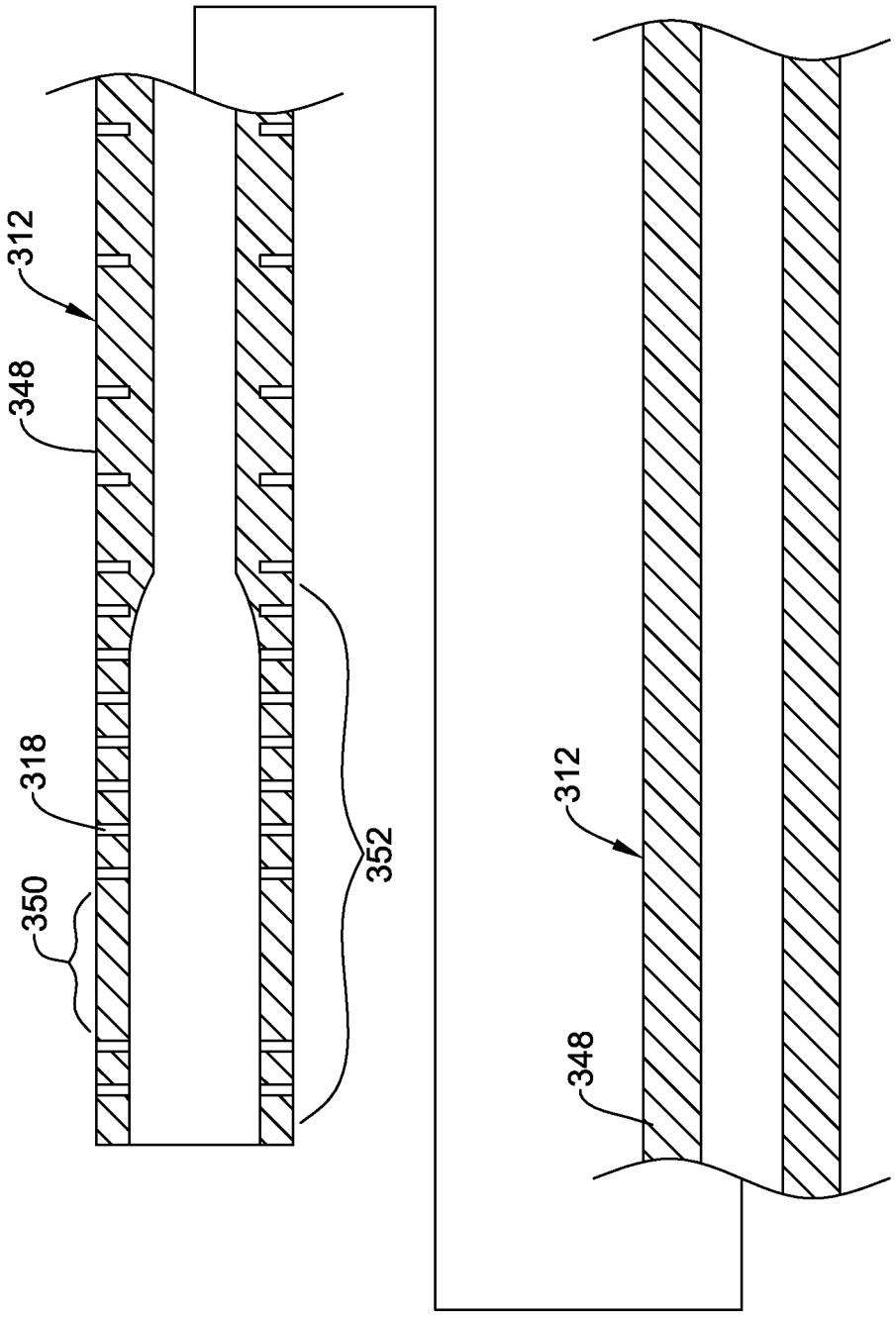

Figure 9

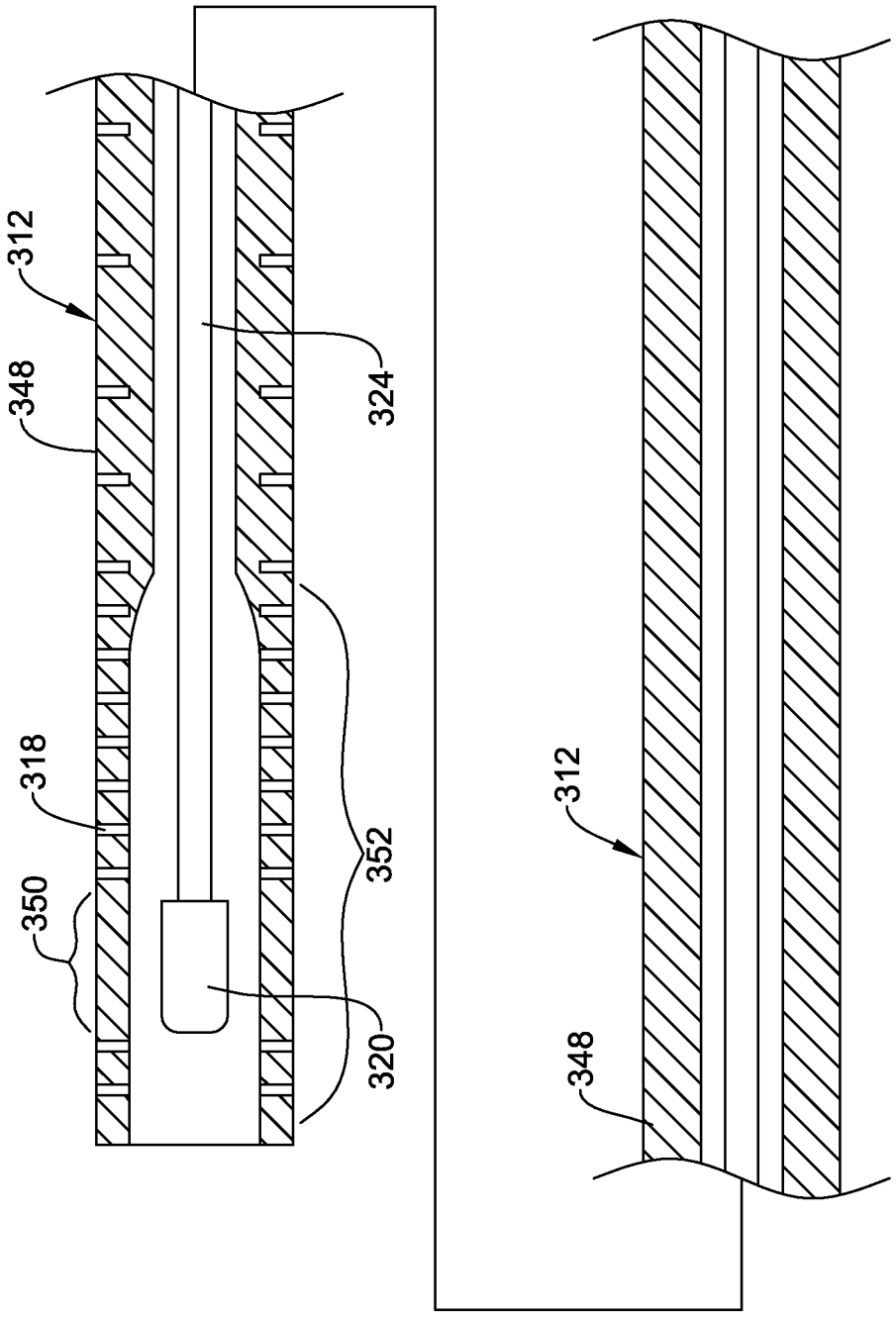

Figure 10

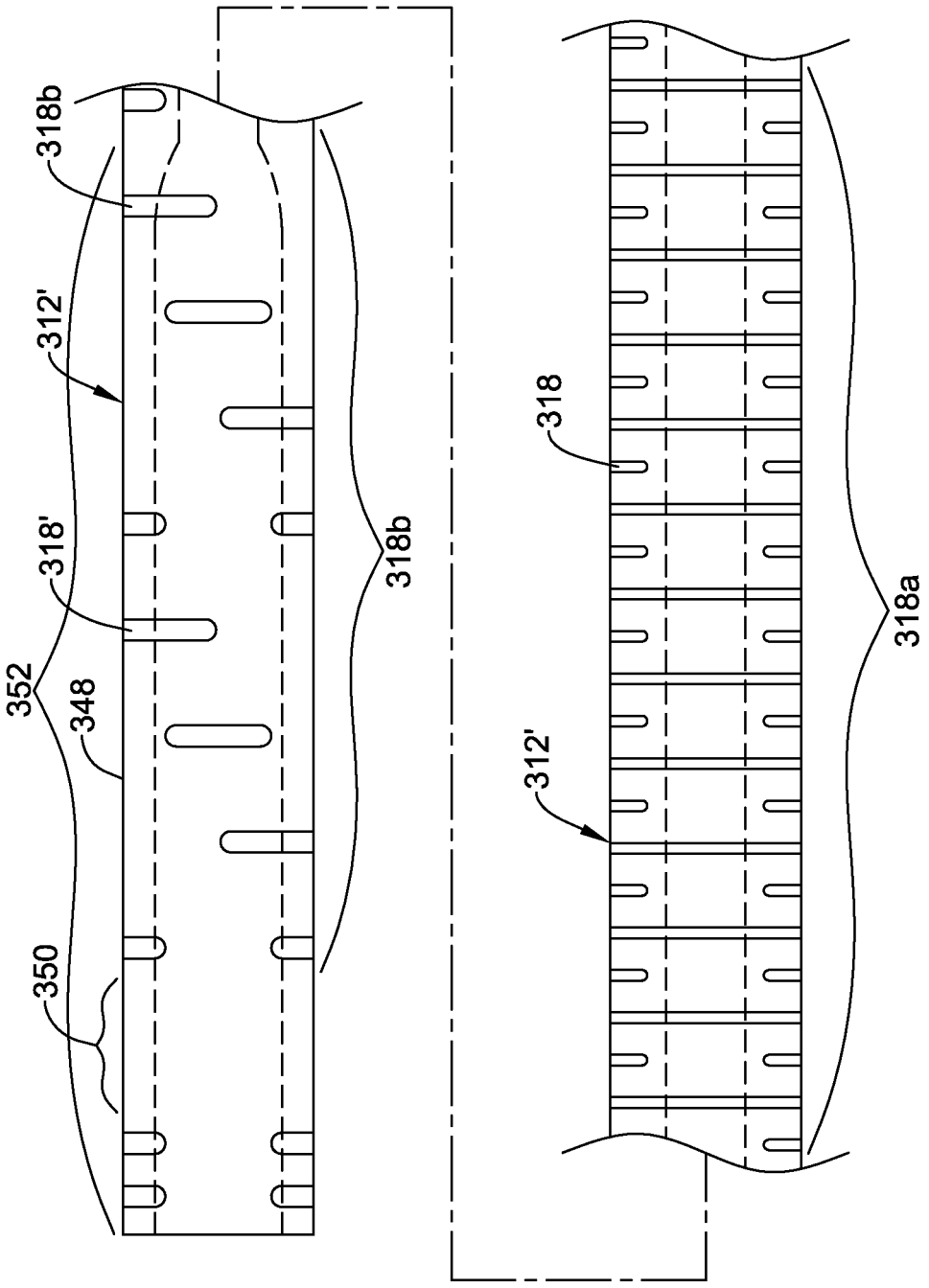

Figure 11

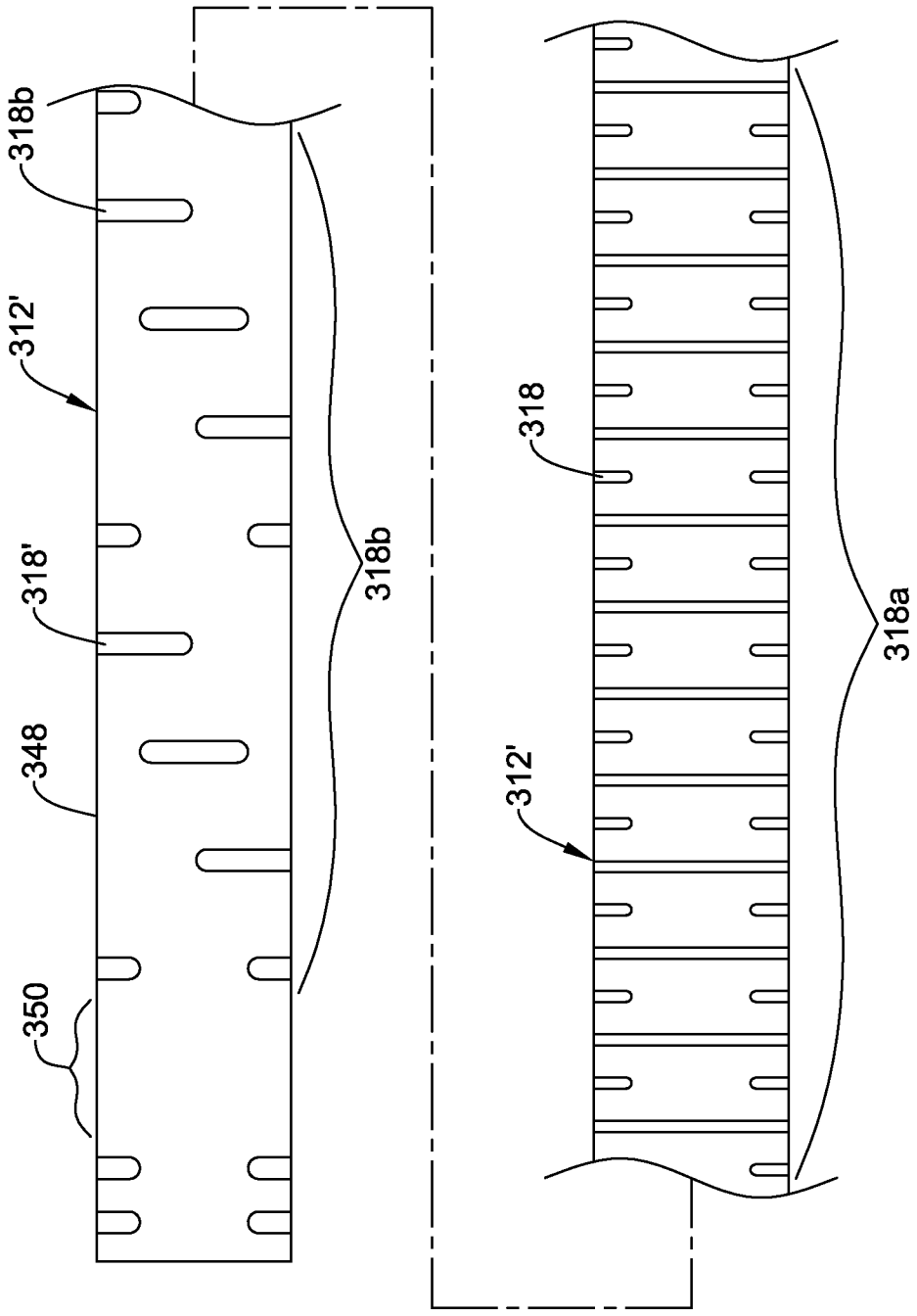

Figure 12

REFERENCES CITED IN THE DESCRIPTION

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- US 5106455 A **[0056]**

专利名称(译)	压力传感导丝		
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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。示例性医疗装置包括压力传感导丝。压力传感导丝可包括具有近端部分和远端部分的管状构件。远端部分可以具有形成在其中的多个槽。远端部分可具有沿第一区域的第一壁厚度和沿第二区域不同于第一壁厚度的第二壁厚度。压力传感器可以设置在管状构件的远端部分内。