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(54) **MEDICAL DEVICES WITH A SLOTTED TUBULAR MEMBER HAVING IMPROVED STRESS DISTRIBUTION**

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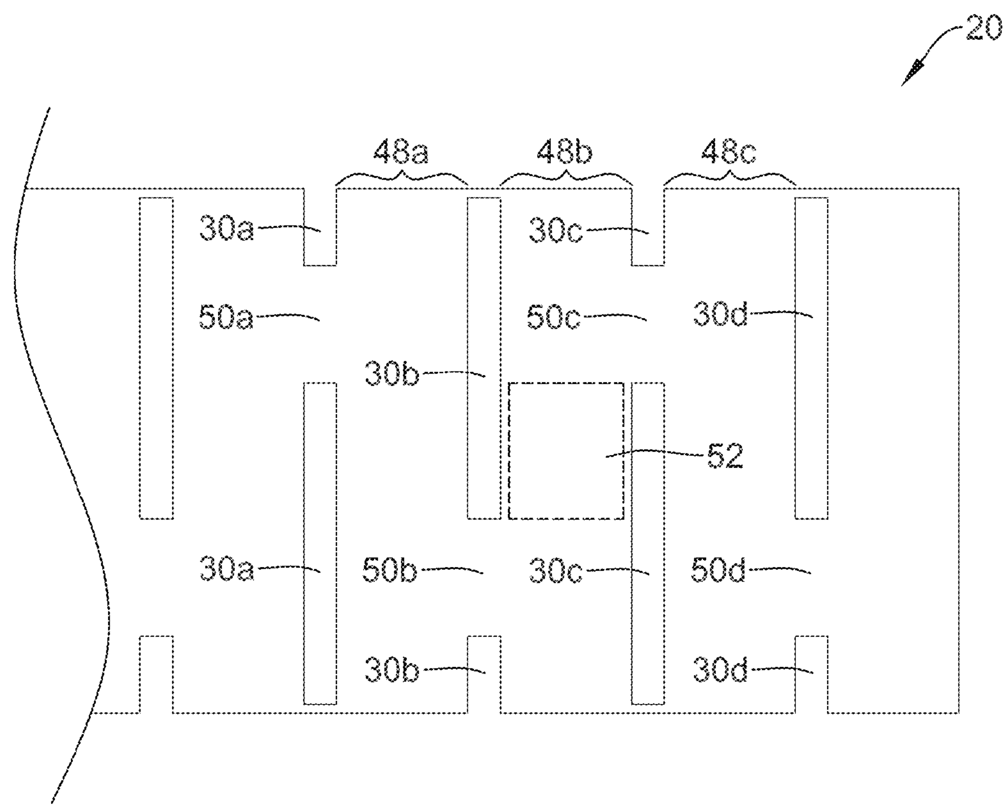
USPC **604/523**; 604/528; 219/121.72

(57) **ABSTRACT**

Medical devices and methods for making and using the same. A medical device may include an elongate tubular member. The tubular member may include a first circumferential tube segment, a second circumferential tube segment disposed next to the first circumferential tube segment, and a third circumferential tube segment disposed next to the second circumferential tube segment. The first tube segment and the second tube segment may be separated by a first set of slots formed in the tubular member. The second tube segment and the third tube segment may be separated by a second set of slots formed in the tubular member. The second tube segment may be connected to the first tube segment with a proximally-extending beam formed in the tubular member. The second tube segment may also be connected to the third tube segment with a distally-extending beam formed in the tubular member. A ring may be defined in the second tube segment between the proximally-extending beam and the distally-extending beam. The ring may have a first portion with a first width and a second portion with a second width different from the first width.



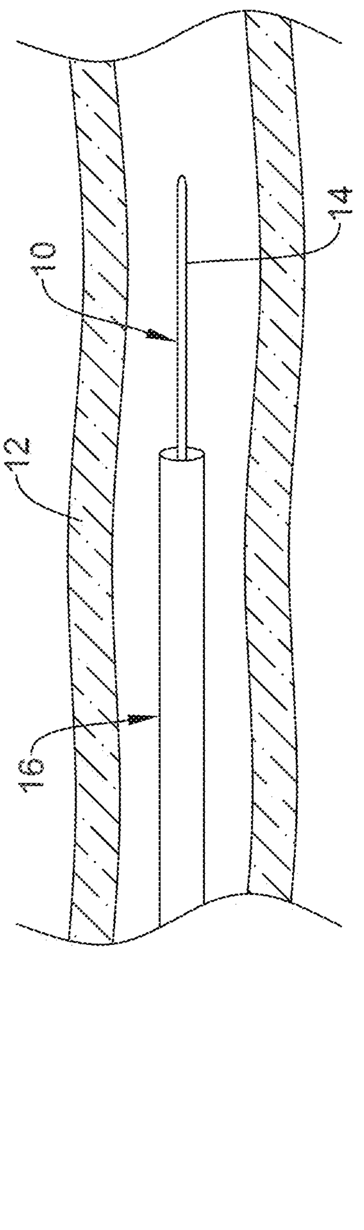


Figure 1

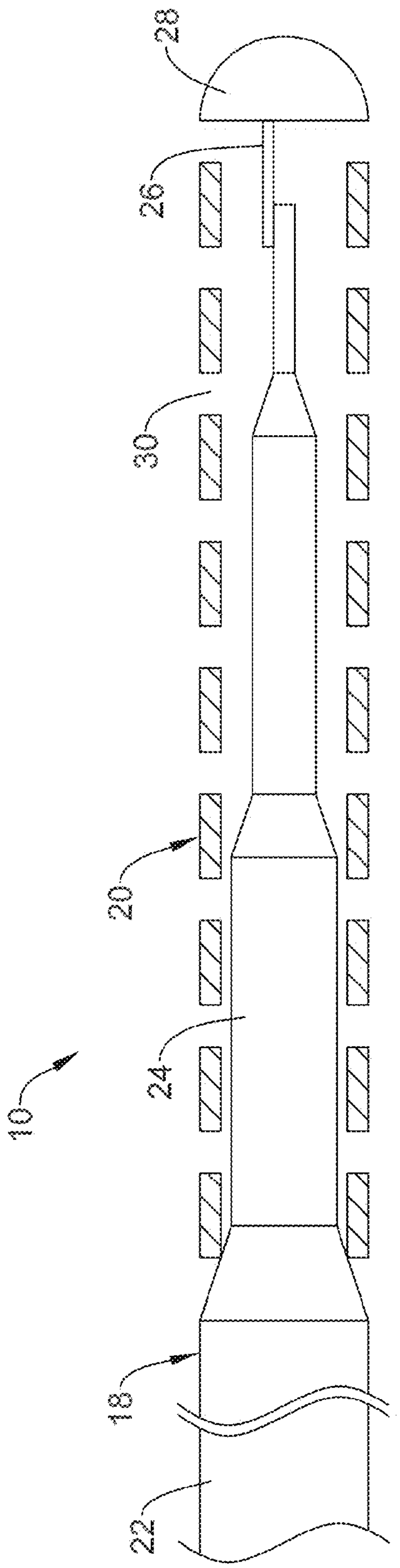


Figure 2

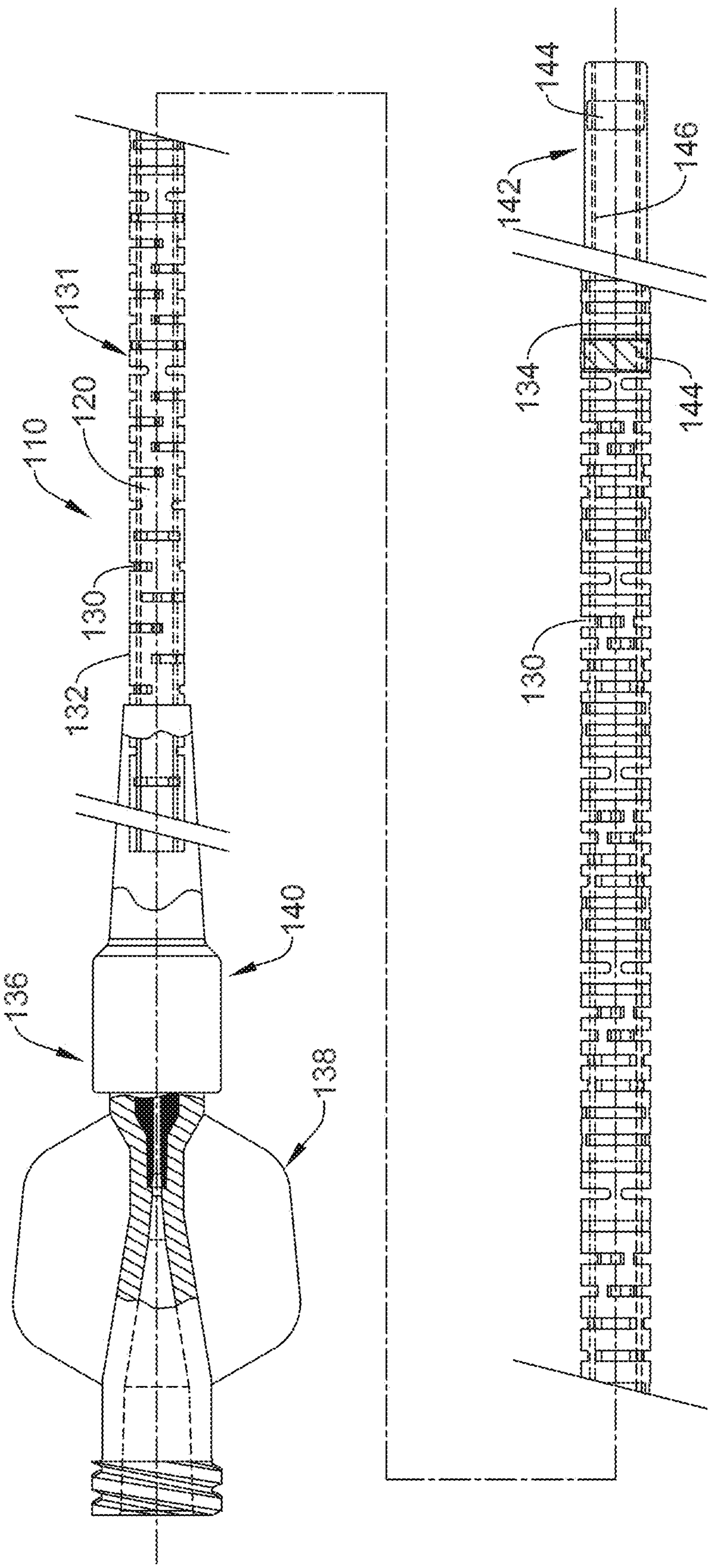


Figure 3

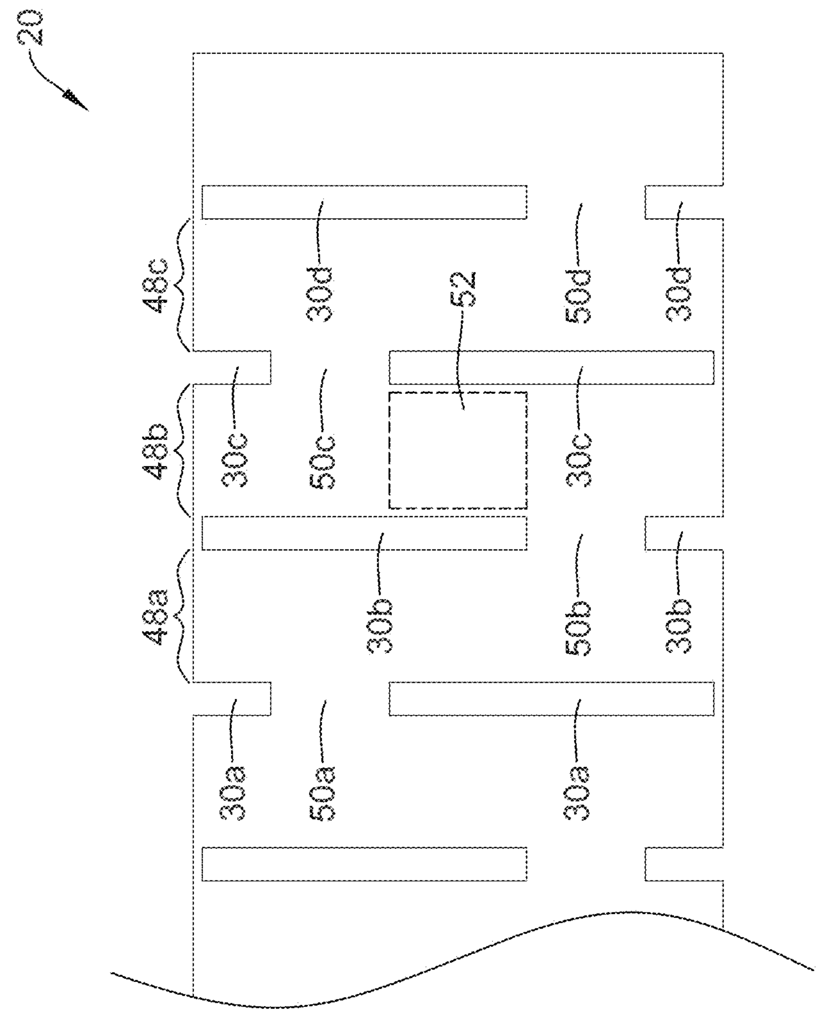


Figure 4

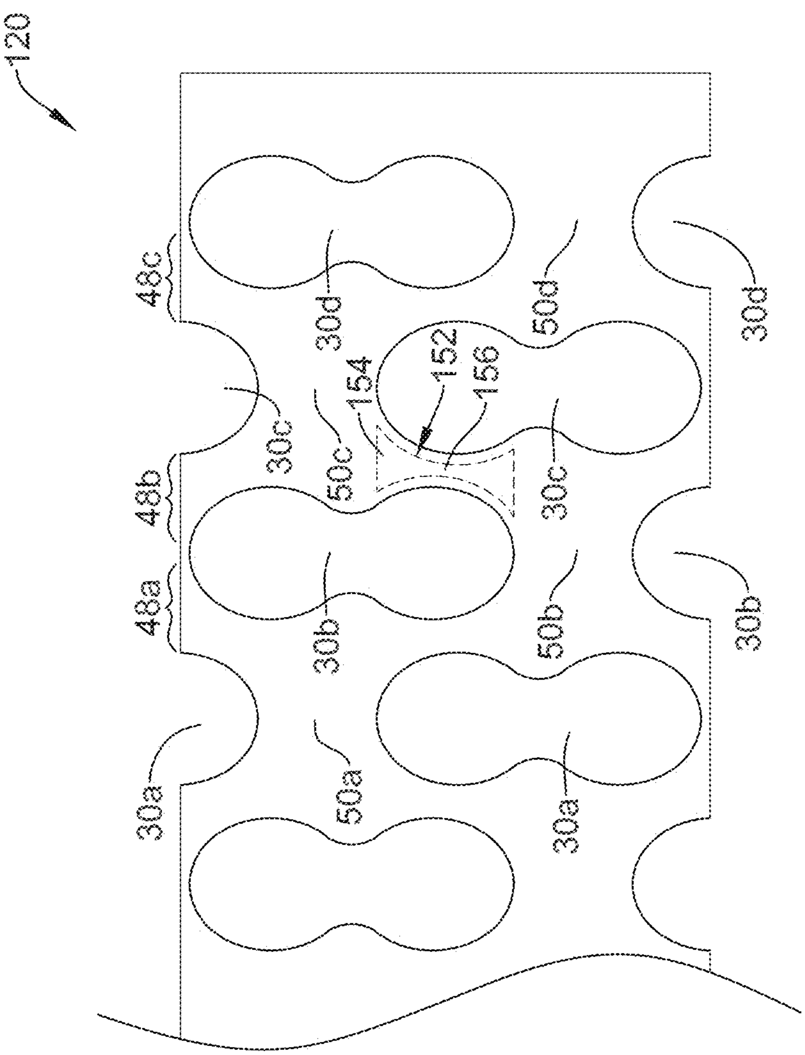


Figure 5

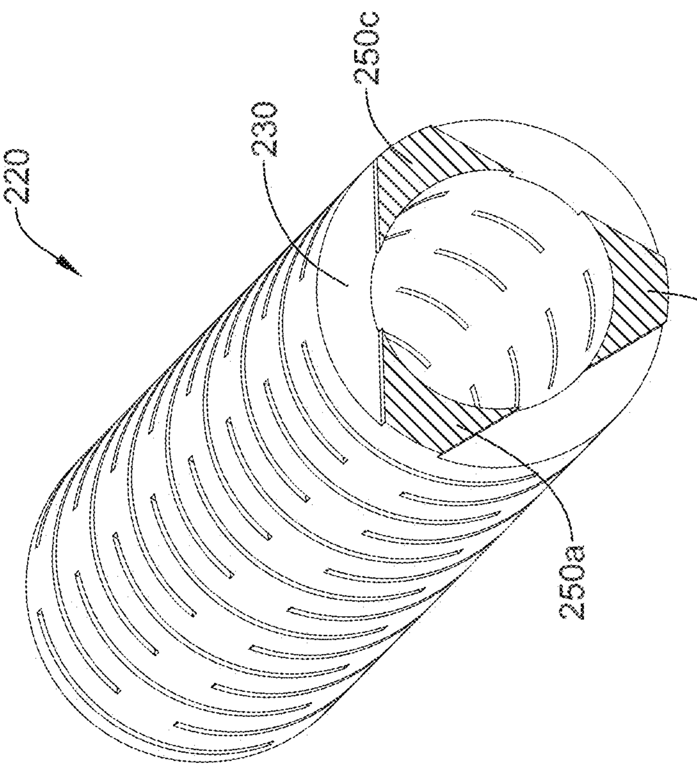


Figure 6

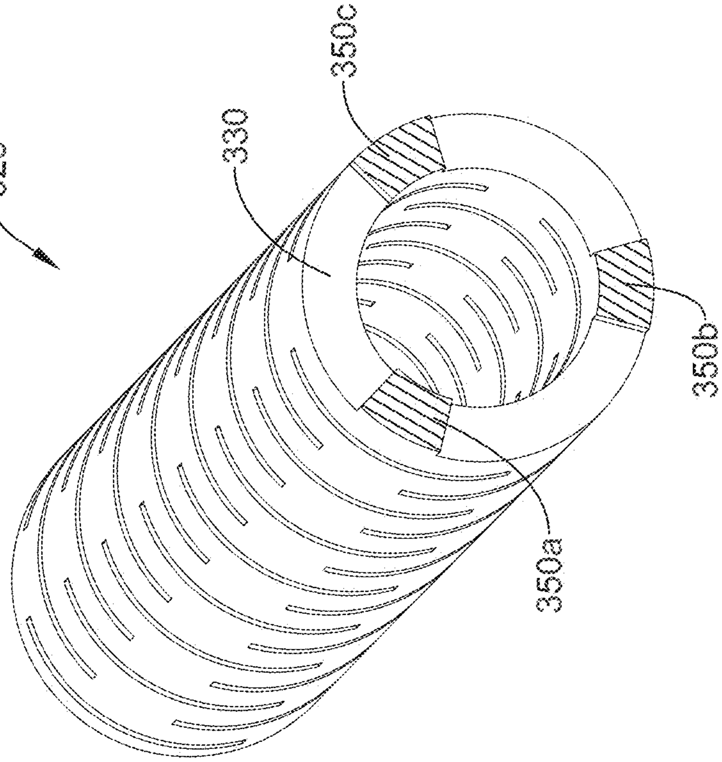


Figure 7

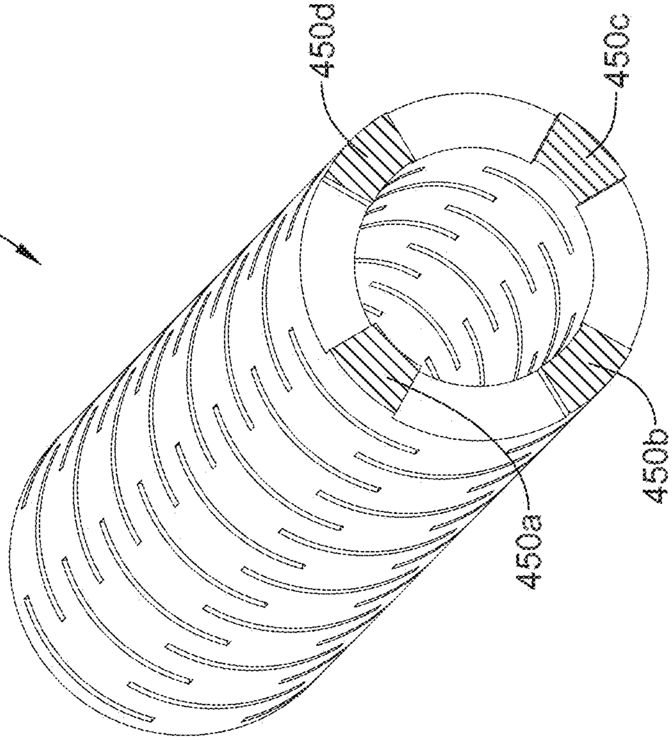


Figure 8

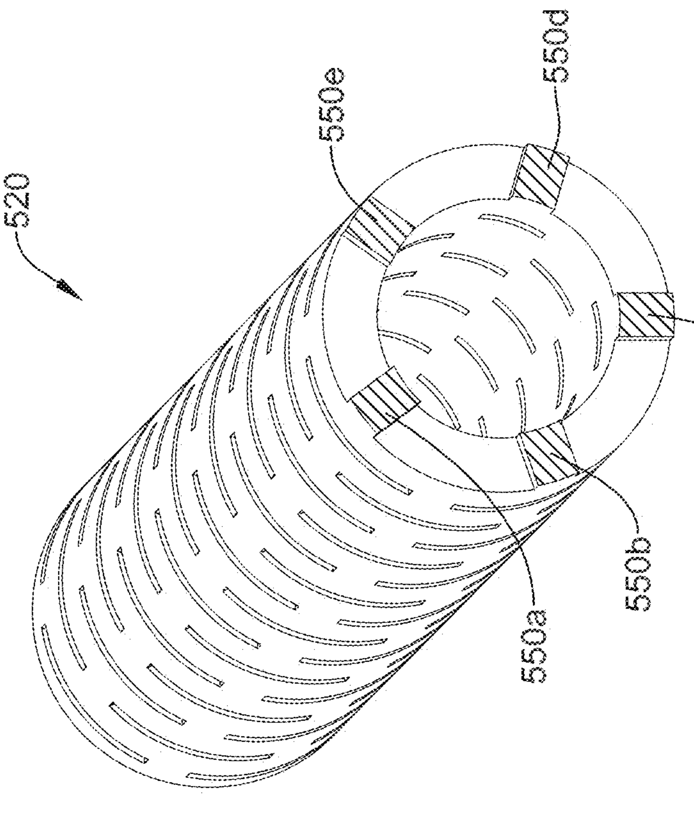


Figure 9

MEDICAL DEVICES WITH A SLOTTED TUBULAR MEMBER HAVING IMPROVED STRESS DISTRIBUTION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 12/635,577, filed Dec. 10, 2009, which claims the benefit of U.S. Provisional Application No. 61/121,510, filed Dec. 10, 2008, the entire disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention pertains to medical devices, and methods for manufacturing medical devices. More particularly, the present invention pertains to elongated intracorporeal medical devices including a slotted tubular member and methods for manufacturing and using such devices.

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] The invention provides design, material, manufacturing method, and use alternatives for medical devices and tubular members for use in medical devices. An example medical device may include an elongate tubular member. The tubular member may include a first circumferential tube segment, a second circumferential tube segment disposed next to the first circumferential tube segment, and a third circumferential tube segment disposed next to the second circumferential tube segment. The first tube segment and the second tube segment may be separated by a first set of slots formed in the tubular member. The second tube segment and the third tube segment may be separated by a second set of slots formed in the tubular member. The second tube segment may be connected to the first tube segment with a proximally-extending beam formed in the tubular member. The second tube segment may also be connected to the third tube segment with a distally-extending beam formed in the tubular member. A ring may be defined in the second tube segment between the proximally-extending beam and the distally-extending beam. The ring may have a first portion with a first width and a second portion with a second width different from the first width.

[0005] Another example medical device may include an elongate tubular member. The tubular member may include a plurality of circumferential tube segments that are each defined between two longitudinally-adjacent sets of slots formed in the tubular member. Longitudinally-adjacent tube segments may be connected together by flanking sets of beams that are disposed on opposite sides of each tube segment. Each tube segment may include one or more rings that are defined between a pair of beams on opposing sides of the tube segment. At least one of the one or more rings may have a varying width.

[0006] An example slotted tubular member for use in a medical device may include a first circumferential tube segment, a second circumferential tube segment disposed next to the first circumferential tube segment, and a third circumferential tube segment disposed next to the second circumferential tube segment. A proximally-extending beam may be formed in the tubular member and may extend between the first tube segment and the second tube segment. A distally-extending beam may be formed in the tubular member and may extend between the second tube segment and the third tube segment. A ring may be defined in the second tube segment between the proximally-extending beam and the distally-extending beam. The ring may have a varying width.

[0007] An example method for manufacturing a medical device may include providing an elongate tubular member and forming a plurality of slots in the tubular member. The tubular member may include a first circumferential tube segment, a second circumferential tube segment disposed next to the first circumferential tube segment, and a third circumferential tube segment disposed next to the second circumferential tube segment. The first tube segment and the second tube segment may be separated by a first set of slots formed in the tubular member. The second tube segment and the third tube segment may be separated by a second set of slots formed in the tubular member. The second tube segment may be connected to the first tube segment with a proximally-extending beam formed in the tubular member. The second tube segment may also be connected to the third tube segment with a distally-extending beam formed in the tubular member. A ring may be defined in the second tube segment between the proximally-extending beam and the distally-extending beam. The ring may have a first portion with a first width and a second portion with a second width different from the first width.

[0008] Another example medical device may include a slotted tubular member including a plurality of tube segments interconnected by beams disposed on opposite sides of the tube segments. A ring may be defined in the tubular member between the beams disposed on opposite sides of one of tube segments. The ring may have a varying width.

[0009] Another example medical device may include a slotted tubular member including a plurality of tube segments interconnected by beams disposed on opposite sides of the tube segments. A ring may be defined in the tubular member between the beams disposed on opposite sides of one of tube segments. The ring may be configured to distribute stress in a substantially uniform manner throughout the tubular member.

[0010] The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present invention. The Figures, and Detailed Description, which follow, more particularly exemplify these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

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

[0012] FIG. **1** is a plan view of an example medical device disposed in a blood vessel;

[0013] FIG. **2** is a partial cross-sectional side view of an example medical device;

[0014] FIG. **3** is a partial cross-sectional side view of another example medical device;

[0015] FIG. **4** is a side view of an example tubular member;

[0016] FIG. **5** is a side view of another example tubular member;

[0017] FIG. **6** is a partial cross-sectional view of another example tubular member;

[0018] FIG. **7** is a partial cross-sectional view of another example tubular member;

[0019] FIG. **8** is a partial cross-sectional view of another example tubular member; and

[0020] FIG. **9** is a partial cross-sectional view of another example tubular member.

[0021] While the invention 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 invention.

DETAILED DESCRIPTION

[0022] For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

[0023] 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.

[0024] 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).

[0025] 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.

[0026] 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.

[0027] FIG. **1** is a plan view of an example medical device **10**, for example a guidewire, disposed in a blood vessel **12**. Guidewire **10** may include a distal section **14** that may be generally configured for probing within the anatomy of a patient. Guidewire **10** may be used for intravascular procedures. For example, guidewire **10** may be used in conjunction with another medical device **16**, which may take the form of a catheter, to treat and/or diagnose a medical condition. Of course, numerous other uses are known amongst clinicians for guidewires, catheters, and other similarly configured medical devices.

[0028] FIG. **2** is a partial cross-sectional view of guidewire **10**. Here it can be seen that guidewire **10** may include a core member or core wire **18** and a tubular member **20** disposed over at least a portion of core wire **18**. Tubular member **20** may have a plurality of slots **30** formed therein. Core wire **18** may include a proximal section **22** and a distal section **24**. A connector (not shown) may be disposed between and attach proximal section **22** to distal section **24**. Alternatively, core wire **18** may be a unitary member without a connector. A shaping member **26** may be coupled to core wire **18** (for example distal section **24** of core wire **18**), tubular member **20**, or both. Shaping member **26** may be made from a relatively inelastic material so that a clinician can bend or shape the distal end of guidewire **10** into a shape that may facilitate navigation of guidewire **10** through the anatomy. Some examples of suitable materials for core wire **18**, tubular member **20**, shaping member **26**, etc. can be found below. A tip member **28** may also be coupled to core wire **18**, tubular member **20**, or both that may define an atraumatic distal tip of guidewire **10**. In general, tip member **28** may include solder. However, other versions of tip member **28** are contemplated including tip members **28** that comprise or form a polymeric tip.

[0029] Although medical device **10** is depicted in FIG. **1** as a guidewire, it is not intended to be limited to just being a guidewire. Indeed, medical device **10** may take the form of any suitable guiding, diagnosing, or treating device (including catheters, endoscopic instruments, laparoscopic instruments, etc., and the like) and it may be suitable for use at essentially any location and/or body lumen within a patient. For example, FIG. **3** illustrates another example device **110** in the form of a catheter. Catheter **110** may include a generally elongate shaft **131** having a proximal portion **132** and a distal portion **134**. A proximal manifold **136** may be disposed at proximal portion **132**. Manifold **136** may include a hub **138** and strain relief **140**. A tip member **142** may be disposed at distal portion **134**. Tip member **142** may include a radiopaque marker member **144**. One or more additional marker members **144** may be disposed along other portions of catheter **110**, for example along distal portion **134** of shaft **131**. Shaft **131** may include a tubular member **120** that may be similar in form and function to other tubular members disclosed herein including tubular member **20**. Tubular member **120** may have a plurality of slots **130** formed therein. A liner **146** may be disposed within tubular member **120**. Liner **146** may be similar to the analogous structure disclosed in U.S. Pat. No. 7,001,369 and U.S. Patent Application Publication No. U.S. 2006/0264904, the entire disclosures of which are herein incorporated by reference.

[0030] As indicated above, tubular member **20** (and/or other tubular members disclosed herein) may include a plurality of cuts, apertures, and/or slots **30** formed therein. Various embodiments of arrangements and configurations of slots **30** are contemplated. In some embodiments, at least some, if not all of slots **30** are disposed at the same or a similar angle with respect to the longitudinal axis of tubular member **20**. As shown, slots **30** 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 **20**. However, in other embodiments, slots **30** 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 **20**. Additionally, a group of one or more slots **30** may be disposed at different angles relative to another group of one or more slots **30**. The distribution and/or configuration of slots **30** can also include, to the extent applicable, any of those disclosed in U.S. Pat. Publication No. U.S. 2004/0181174, the entire disclosure of which is herein incorporated by reference.

[0031] Slots **30** may be provided to enhance the flexibility of tubular member **20** while still allowing for suitable torque transmission characteristics. Slots **30** 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 **20**, and such tube segments and beams may include portions of tubular member **20** that remain after slots **30** are formed in the body of tubular member **20**. 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 **30** can be formed such that they include portions that overlap with each other about the circumference of tubular member **20**. In other embodiments, some adjacent slots **30** 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.

[0032] Additionally, slots **30** can be arranged along the length of, or about the circumference of, tubular member **20** to achieve desired properties. For example, adjacent slots **30**, or groups of slots **30**, can be arranged in a symmetrical pattern, such as being disposed essentially equally on opposite sides about the circumference of tubular member **20**, or can be rotated by an angle relative to each other about the axis of tubular member **20**. Additionally, adjacent slots **30**, or groups of slots **30**, may be equally spaced along the length of tubular member **20**, 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 **20**, can also be varied along the length of tubular member **20** 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 **26**, or a distal section **28**, or the entire tubular member **20**, may not include any such slots **30**.

[0033] As suggested above, slots **30** may be formed in groups of two, three, four, five, or more slots **30**, which may be located at substantially the same location along the axis of tubular member **20**. Alternatively, a single slot **30** may be disposed at some or all of these locations. Within the groups of slots **30**, there may be included slots **30** that are equal in size (i.e., span the same circumferential distance around tubular member **20**). In some of these as well as other embodiments, at least some slots **30** in a group are unequal in size (i.e., span a different circumferential distance around tubular member **20**). Longitudinally adjacent groups of slots **30** may have the same or different configurations. For example, some embodiments of tubular member **20** include slots **30** 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 **30** 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 **20** remaining after slots **30** are formed therein) is coincident with the central axis of tubular member **20**. Conversely, in groups that have two slots **30** that are unequal in size and whose centroids are directly opposed on the tube circumference, the centroid of the pair of beams is offset from the central axis of tubular member **20**. Some embodiments of tubular member **20** include only slot groups with centroids that are coincident with the central axis of the tubular member **20**, only slot groups with centroids that are offset from the central axis of tubular member **20**, or slot groups with centroids that are coincident with the central axis of tubular member **20** in a first group and offset from the central axis of tubular member **20** in another group. The amount of offset may vary depending on the depth (or length) of slots **30** and can include essentially any suitable distance.

[0034] Slots **30** can be formed by methods such as micromachining, 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 **20** is formed by cutting and/or removing portions of the tube to form slots **30**. 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 **10** may include forming slots **30** in tubular member **20** using any of these or other manufacturing steps.

[0035] In at least some embodiments, slots **30** may be formed in tubular member using a laser cutting process. The laser cutting process may include essentially any 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 **20** to be cut into a number of different cutting patterns in a precisely controlled manner. This may include variations in the slot width (which also may be termed "kerf"), 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., a blade). This may also allow smaller tubes (e.g., having a smaller outer diameter) to be used to form tubular member **20** without being limited by a minimum cutting blade size. Consequently, tubular members **20** may be fabricated for use in neurological devices or other devices where a small size may be desired.

[0036] Because of the precision and control that may be achieved by cutting slots **30** with a laser, numerous additional variation can be achieved in slot **30** configurations, arrangements, etc. Turning now to FIG. **4**, a side view of tubular member **20** is illustrated. In this figure and the accompanying description, some of the structural aspects of tubular member **20** are defined and described for the purposes of this disclosure. Here it can be seen that tubular member **20** may include a plurality of circumferential tube segments including tube segment **48*a***, tube segment **48*b***, and tube segment **48*c***. In this example, segment **48*a*** is disposed longitudinally-adjacent (i.e., right next to) segment **48*b*** and segment **48*c*** is disposed longitudinally-adjacent segment **48*b*** (oppositely segment **48*a***). The number of tube segments in a given tubular member **20** may vary depending on the structure of tubular member **20**. For example, as the number of slots **30** increases, the number of tube segments may similarly increase. The invention is not intended to be limited to any particular number or arrangement of tube segments for any given tubular member **20** or device including a tubular member.

[0037] Segments **48***a*/**48***b*/**48***c* can be understood to be generally circumferential or "round" portions of tubular member **20** that are defined between groups or sets of slots **30**. For example, segment **48***a* is defined between a first group of slots **30***a* and a second group of slots **30***b*. Likewise, segment **48***b* is defined between group **30***b* and a third group of slots **30***c*. Moreover, segment **48***c* is defined between group **30***c* and a fourth group of slots **30***d*. In this example, each group **30***a*/**30***b*/**30***c*/**30***d* includes two slots. However, any suitable number of slots **30** may be utilized for any group **30***a*/**30***b*/**30***c*/**30***d*. Just like the tube segments, the invention is not intended to be limited to any number of slots, groups of slots, or number of slots per group for any given tubular member **20** or device including a tubular member with slots.

[0038] When slots **30** are formed in tubular member, a portion of tubular member **20** remains at the longitudinal location where slots **30** are formed and extends between longitudinally-adjacent tube segments. This portion may be termed a "beam". Several beams are illustrated in FIG. **4** including beam **50***a*, beam **50***b*, beam **50***c*, and beam **50***d*. Beams **50***a*/**50***b*/**50***c*/**50***d* can be understood to be a portion of tubular member **20** that connects or attaches longitudinally-adjacent tube segments. For example, segment **48***b* is attached to segment **48***a* by beam **50***b*. Similarly, segment **48***b* is attached to segment **48***c* by beam **50***c*. In this example, each group **30***a*/**30***b*/**30***c*/**30***d* of slots defines or leaves behind two, corresponding beams at a given longitudinal location. In FIG. **4**, which illustrates tubular member **20** from the side, often only one full beam can be seen. It can be appreciated that another beam may be defined in tubular member **20** on a portion of tubular member **20** that is not illustrated in FIG. **4** (e.g., the "back" or opposite side of tubular member **20**). In addition, just like group **30***a*/**30***b*/**30***c*, the invention is not intended to be limited to any number of beams, groups of beams, or number of beams per group for any given tubular member **20** or device including a tubular member with beams.

[0039] Finally, along any given tube segment, one or more rings **52** may be defined. A ring **52** may be understood to be a portion of a tube segment that extends between two beams, for example a pair of beams on opposite sides of the tube segment. For example, a first or proximally-extending beam **50***b* and a second or distally-extending beam **50***c* may extend in opposite directions from tube segment **48***b*. Between beams **50***b*/**50***c*, ring **52** may be defined. Using this same definition, several other "rings" may be seen and may be defined in tubular member **20**.

[0040] In typical slotted tubular members, bending stresses that might be applied to the tube tend to be greater adjacent the beams. Similarly, torsional loading or stresses also tends to be greater adjacent the beams, although the tube segments and rings tend to have compressive and tensile loading along their centerline axes (e.g., radially aligned relative to the tube center). It may be desirable to change the stress distribution in a tubular member so that, for example, stresses are not localized to just one locale such as adjacent the beams. Accordingly, tubular member **20** may include one or more structural variations that may help to distribute stresses throughout tubular member **20**. For example, tubular member **20** may include one or more structural variations that may help distribute stresses in a substantially uniform manner throughout tubular member **20**.

[0041] In some embodiments, the shape of the rings may be varied to help distribute stresses throughout the tubular member. For example, FIG. **5** illustrates tubular member **120**, that may be similar in form and function to other tubular members disclosed herein, where at least one of the rings **152** has a first portion **154** having a first width and a second portion **156** having a second width different from the first width. In at least some embodiments, the first width **154** is larger (wider) than the second width **156**, as illustrated. This may result in ring **152** having an hourglass shape or likeness. This may also be described as a varying or changing width for ring **152**. Other arrangements, of course are contemplated including the reverse arrangement or other configurations. The changes in width may occur in any suitable manner including linearly, in a curved or curvilinear manner, in a parabolic manner, in a stepwise manner, combinations thereof, or the like.

[0042] By virtue of tubular member **120** having ring **152** with a varying width, stress in bending and/or torsional loading that might otherwise tend to be localized to positions adjacent beams **150** may be distributed more evenly throughout tubular member **120**. In addition, such a configuration may have a minimal or relatively small impact on torsional stiffness because the rings and/or tube segments may be loaded substantially in compression/tension during torsional structural loading. Consequently, tubular member **120** may having an improved fatigue life, improved and/or increased strength, and/or other desirable properties.

[0043] Complex ring structures like ring **152** may be challenging, if not impossible to form using conventional saw-cutting or micromachining techniques. Consequently, forming ring **152** may include the use of a laser and/or laser cutting techniques, as suggested above. Such techniques may desirably allow for a plethora of differently shaped slot, beam, tube segment, and ring configurations. In addition, such laser cutting techniques may allow for additional changes to tubular members as will be elaborated on further below.

[0044] FIG. **6** illustrates a tubular member **220** that includes slots **230** (arranged in groups of three slots **230** at each longitudinal location along tubular member **220**) formed by saw cutting or micromachining Here it can be seen that the resultant beams **250***a*/**250***b*/**250***c* have a more irregular or triangular shape. The shape of beams **250***a*/**250***b*/**250***c* may result because of the nature of using a blade and/or the blade geometry and its approach tangent to the surface of tubular member **220**. Because of the shape of beams **250***a*/**250***b*/**250***c*, stresses may not be evenly distributed across tubular member **220**. Moreover, the blade geometry may limit the number of cuts and/or beams that can be formed at any given longitudinal position along tubular member **220**. For example, it may be only possible to get three slots and/or beams at any given longitudinal location along tubular member **220** using saw cutting or micromachining

[0045] FIG. **7** illustrates tubular member **320** that also includes slots **330** (arranged in groups of three slots **330** at each longitudinal location along tubular member **320**) formed by laser cutting. Here it can be seen that the shape of the resultant beams **350***a*/**350***b***350***c* is more even or square-like in shape. This may result in improved stress distribution throughout tubular member **320**. Furthermore, utilizing laser cutting techniques may allow for additional numbers of beams to formed in tubular members. For example, FIG. **8** illustrates tubular member **420** with a four beam **450***a*/**450***b*/**450***c*/**450***d* structure and FIG. **9** illustrates tubular member **520** with a five beam **550***a*/**550***b*/**550***c*/**550***d*/**550***e* structure.

Other tubular members are contemplated that include more beams and/or different arrangements or configurations of beams.

[0046] 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 tubular member **20** and other components of guidewire **10**. However, this is not intended to limit the invention as the discussion may be applied to other similar tubular members and/or components of tubular members or devices disclosed herein.

[0047] Tubular member **20** and/or other components of guidewire **10** 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 any 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.

[0048] As alluded to above, 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.

[0049] 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 0.2-0.44% strain before plastically deforming.

[0050] 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 DSC and 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° 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.

[0051] 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 super-elastic alloy, for example a superelastic nitinol can be used to achieve desired properties.

[0052] In at least some embodiments, portions or all of core wire **18** and/or tubular member **20** 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.

[0053] In some embodiments, a degree of MRI compatibility is imparted into guidewire **10**. For example, to enhance compatibility with Magnetic Resonance Imaging (MRI) machines, it may be desirable to make core wire **18** and/or tubular member **20**, or other portions of the guidewire **10**, in a manner that would impart a degree of MRI compatibility. For example, core wire **18** and/or tubular member **20**, or portions thereof, may be made of a material that does not substantially distort the image and create substantial artifacts (artifacts are gaps in the image). Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. Core wire **18** and/or tubular member **20**, 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.

[0054] Referring now to core wire **18**, the entire core wire **18** can be made of the same material along its length, or in some embodiments, can include portions or sections made of different materials. In some embodiments, the material used to construct core wire **18** is chosen to impart varying flexibility and stiffness characteristics to different portions of core wire **18**. For example, proximal section **22** and distal section **24** of core wire **18** may be formed of different materials, for example materials having different moduli of elasticity, resulting in a difference in flexibility. In some embodiments, the material used to construct proximal section **22** can be relatively stiff for pushability and torqueability, and the material used to construct distal section **24** can be relatively flexible by comparison for better lateral trackability and steerability. For example, proximal section **22** can be formed of straightened 304v stainless steel wire or ribbon and distal section **24** can be formed of a straightened super elastic or linear elastic alloy, for example a nickel-titanium alloy wire or ribbon.

[0055] In embodiments where different portions of core wire **18** are made of different materials, the different portions can be connected using any suitable connecting techniques and/or with a connector. For example, the different portions of core wire **18** can be connected using welding (including laser welding), soldering, brazing, adhesive, or the like, or combinations thereof. These techniques can be utilized regardless of whether or not a connector is utilized. The connector may include any structure generally suitable for connecting portions of a guidewire. One example of a suitable structure includes a structure such as a hypotube or a coiled wire which has an inside diameter sized appropriately to receive and connect to the ends of the proximal portion and the distal portion. Essentially any suitable configuration and/or structure can be utilized for connector **26** including those connectors described in U.S. Pat. Nos. 6,918,882 and 7,071,197 and/or in U.S. Patent Pub. No. 2006-0122537, the entire disclosures of which are herein incorporated by reference.

[0056] A sheath or covering (not shown) may be disposed over portions or all of core wire **18** and/or tubular member **20** 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 **20** and/or core wire **18** may form the outer surface. The sheath may be made from a polymer or any 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% LCP.

[0057] In some embodiments, the exterior surface of the guidewire **10** (including, for example, the exterior surface of core wire **18** and/or the exterior surface of tubular member **20**) 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 core wire **18** and/or tubular member, or other portions of device **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. Pat. Nos. 6,139,510 and 5,772,609, which are incorporated herein by reference.

[0058] 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 same may be true of tip member **28**. 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.

[0059] 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. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A medical device comprising:

an elongated tubular member extending from a proximal end to a distal end; and

a first group of two or more opposed slots formed in the tubular member at a first longitudinal position separated from a second group of two or more opposed slots formed in the tubular member at a second longitudinal position, wherein the first group of two or more opposed slots is radially offset from the second group of two or more slots,

wherein each of the slots includes a first rounded region having a first width, a second rounded region having a second width the same as the first width, and a middle region between the first rounded region and the second rounded region having a third width smaller than the first width.

2. The medical device of claim **1**, the tubular member further comprising a ring defined between the first and second group of two or more opposed slots.

3. The medical device of claim **2**, the ring having a varying width.

4. The medical device of claim **1**, wherein the first rounded region of at least one slot of the first group of slots is longitudinally aligned with the second rounded region of at least one slot of the second slots defining a ring disposed between the at least one slot of the first group of slots and the at least one slot of the second group of slots, the ring having a varying width.

5. The medical device of claim **1**, further comprising a first longitudinally extending beam defined between at least a first slot and a second slot of the first group of slots and a second longitudinally extending beam defined between at least a first slot and a second slot of the second group of slots.

6. The medical device of claim **5**, each beam has a longitudinal axis extending parallel to a longitudinal axis of the elongate tubular member, each beam axis extending through at least one slot, and wherein each beam has a varying height along its longitudinal axis from a first end to a second of the beam.

7. The medical device of claim **5**, wherein the first and second longitudinally extending beams are radially offset from one another.

8. The medical device of claim **1**, wherein the medical device is a guidewire.

9. The medical device of claim **1**, wherein the medical device is a catheter.

10. The medical device of claim **1**, wherein the elongate tubular member comprises a nickel-titanium alloy.

11. The medical device of claim **1**, further comprising a third group of two or more opposed slots formed in the tubular member at a third longitudinal position separated from the second group of two or more opposed slots formed in the tubular member at the second longitudinal position, wherein the third group of two or more opposed slots is radially aligned with the first group of two or more slots and radially offset from the second group of two or more slots, wherein each of the slots includes a first rounded region having a first width, a second rounded region having a second width the same as the first width, and a middle region between the first rounded region and the second rounded region having a third width smaller than the first width.

12. A medical device comprising:

an elongate tubular member extending from a proximal end to a distal end; and

a first group of alternating slots and beams formed in the tubular member radially spaced apart about an outer circumference of the tubular member and longitudinally offset from a second group of alternating slots and beams formed in the tubular member,

wherein each of the slots includes a first rounded region having a first width, a second rounded region having a second width the same as the first width, and a middle region between the first rounded region and the second rounded region having a third width smaller than the first width.

13. The medical device of claim **12**, wherein the first rounded region of at least one slot of the first group of alternating slots and beams is longitudinally aligned with the second rounded region of at least one slot of the second group of alternating slots and beams defining a ring disposed between the at least one slot of the first group of slots and the at least one slot of the second group of slots, the ring having a varying width.

14. The medical device of claim **13**, wherein the ring comprises an hourglass shape.

15. The medical device of claim **12**, further at least one ring disposed between a first slot of the first group of alternating slots and beams from a second slot of the second group if alternating slots and beams.

16. The medical device of claim **12**, wherein the medical device is a guidewire.

17. The medical device of claim **12**, wherein the medical device is a catheter.

18. The medical device of claim **12**, wherein the elongate tubular member comprises a nickel-titanium alloy.

19. The medical device of claim **12**, each beam has a longitudinal axis extending parallel to a longitudinal axis of the elongate tubular member, each beam axis extending through at least one slot, and wherein each beam has a varying height along its longitudinal axis from a first end to a second of the beam.

20. A method of manufacturing a medical device comprising:

providing an elongate tubular member; and

laser cutting the elongate tubular member to form a first group of two or more opposed slots formed in the tubular member at a first longitudinal position and a second group of two or more opposed slots formed in the tubular member at a second longitudinal position such the first group of two or more opposed slots is radially offset from the second group of two or more slots, and wherein each of the slots includes a first rounded region having a first width, a second rounded region having a second width the same as the first width, and a middle region between the first rounded region and the second rounded region having a third width smaller than the first width.

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