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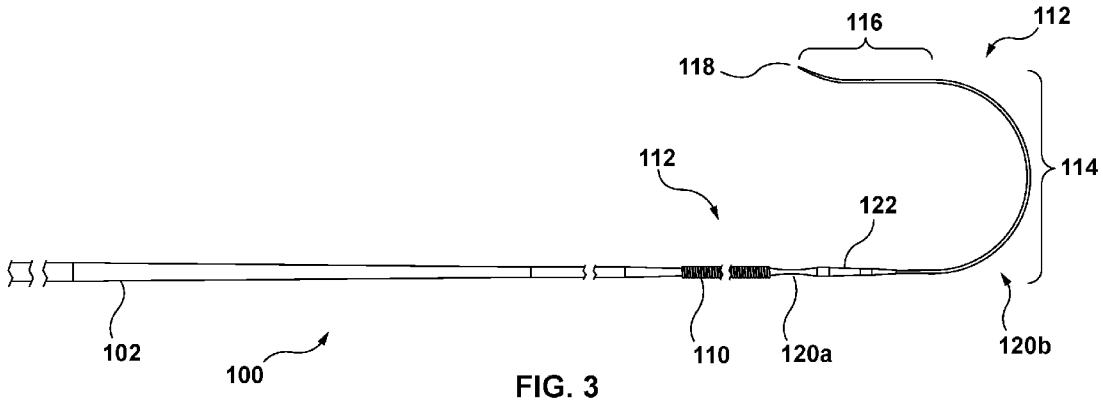

FIG. 3

(57) Abstract: A guidewire (100) that comprises an elongate member (102) with a proximal and distal (112) portion. The distal portion (112) includes a distal curved portion (114), ending in a distal tip (118), and a tapered region that reduces the cross-section from a larger cross-section to a smaller cross-section. The elongate member (102) further includes a plurality of flattened regions (120a, 120b) positioned at discrete locations along the elongate member. Each of the plurality of flattened regions (120a, 120b) are separated from one another by an unflattened region (122) whereby when a force is exerted onto the guidewire (100), the guidewire undergoes bending at the plurality of flattened regions (120a, 120b).

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A Guidewire with Portions of Reduced Stiffness

BACKGROUND

[0001] The disclosure relates to devices and methods for puncturing a septum of a heart. More specifically, the disclosure relates to a guidewire configured to perforate the intra-atrial septum.

[0002] Medical guidewires are typically constructed using a metal core mandrel with a round (circular) cross-section. In order to make the guidewire more compliant, and less traumatic, a distal portion of the core wire is ground down, tapering from a larger outer diameter to a smaller outer diameter. Additionally, the core mandrel may be shaped or curved to assume an atraumatic configuration, such as a J-shape, in order to mitigate tissue trauma. In this configuration, the contact force experienced by the guidewire upon tissue contact is spread over a larger surface area.

[0003] To retain the curve of the guidewire, the mandrel may be crushed or flattened. This results in the metal mandrel being work-hardened, thereby providing curve retention properties, and enhancing the atraumatic nature of the guidewire. However, when the mandrel is crushed or flattened, a bending point is created at the point where the cross-section changes from a round or circular cross-section to the crushed or flattened cross-section. In other words, at the intersection of the circular cross-section and the start of the flattened portion a bending point is formed or created when the guidewire is pressed against a tissue. Thus, if the guidewire is manipulated roughly or undergoes significant force against the tissue, the guidewire may become kinked or pinched (excessive bending resulting in plastic deformation) at the bending point. In some instances, if the guidewire is subjected to repeated kinking or pinching, the guidewire may break.

SUMMARY

[0004] In one broad aspect of the disclosure, a guidewire comprises an elongate member with a proximal and distal portion. The distal portion includes a distal curved portion, ending in a distal tip, and a tapered region that reduces the cross-section from a larger cross-section to a smaller cross-section. The elongate member further includes a plurality of flattened regions positioned at discrete locations along the elongate member. Each of the plurality of flattened regions are separated from one another by an unflattened region whereby when a force is exerted onto the guidewire, the guidewire undergoes bending at the plurality of flattened regions.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] In order that the invention may be readily understood, embodiments of the invention are illustrated by way of examples in the accompanying drawings, in which:

[0006] Fig. 1 depicts a side view of an embodiment of the prior art of a guidewire; and

[0007] Fig. 2 depicts a side view of the prior art of a guidewire comprising a curved distal portion; and

[0008] Fig. 3 depicts a side view of a guidewire comprising a plurality of reduced stiffness portions and a curved distal portion; and

[0009] Fig. 4 depicts a side perspective view of a guidewire depicted in Fig. 3; and

[0010] Fig. 5 depicts a front view of a guidewire comprising a radiopaque coil; and

[0011] Fig. 6 depicts a side view of a guidewire comprising a plurality of tapered portions; and

[0012] Fig. 7A – 7B depicts a cross-section view of a guidewire of an alternative embodiment; and

[0013] Fig. 8A – 8B depicts a side view of a guidewire with a plurality of coiled portions of an alternative embodiment; and

[0014] Fig. 9A – 9B depicts a side view of a guidewire with a plurality of less stiff portions of an alternative embodiment.

DETAILED DESCRIPTION

[0015] With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of certain embodiments of the present invention only. Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

[0016] As further described hereinbelow, the present invention provides a guidewire comprising a plurality of crushed or flattened portions to provide enhanced curve retention and reduce the likelihood of kinking or breakage.

[0017] With reference now to **Fig. 1** of the prior art depicts a core mandrel **102** of a guidewire that is configured for puncturing a target tissue (e.g., a septum of a heart). The mandrel **102** may comprise multiple tapered portions, separated by non-tapered regions. This configuration provides greater compliance over a shorter length of the mandrel. The tapered portions and intermediate regions may be formed by grinding down the mandrel **102**. The core mandrel **102** may comprise a first, proximal, tapered region **104** and a second, intermediate, tapered region **106**. The guidewire **100** may further comprise a radiopaque coil **110** (not shown) and coil stopper **111**. Transition regions **105a** and **105b** may be positioned between the tapered regions **104, 106**. The transition regions **105a** and **105b** are regions of constant diameter.

[0018] With reference to **Fig. 2** of the prior art, the guidewire **100** comprises a curved distal region **114** configured to assume an atraumatic shape. The curved distal region **114** may comprise a straightened portion **116** positioned distal to the curve **114**, thereby forming a J-shape, and terminating at the distal tip **118.** The curved distal region **114** extends the length of the distal portion **112**, with the distal portion **112** terminating at the distal tip **118**. The distal tip **118** is configured to puncture the target tissue. The curved distal region **114** redirects the distal tip **118** such that it does not contact tissue during advancement, thereby preventing inadvertent damage to surrounding tissues.

[0019] To promote curve retention, the distal portion **112** may be crushed or flattened. In some embodiments, the flattened region extends along the length of the distal portion **112**. In an alternative embodiment, the flattened region may be positioned at a different location along the guidewire **100** and does not necessarily need to extend the entire length of the distal portion **112**. The point where the mandrel **102** changes from a circular cross-section to the flattened cross-section is the most compliant. This results in a bending point at that location when there is force exerted against the curved distal portion **112**. Due to this, the guidewire **100** may kink or become pinched at this location which, in some instances, may result in breakage.

[0020] **Fig. 3** depicts a side view of a guidewire according to one aspect of the present invention. Typically, guidewires **100** can vary in length between 80.0cm (31.5") to 450.0cm (177.2") and tapers down from a larger cross-section to a smaller cross-section. This results in the distal portion **112** having the smallest cross-section, and thus, being compliant and less traumatic when contacting tissues. The mandrel **102** may have a round or circular cross-section with an outer diameter between 0.355mm (0.014") to 0.965mm (0.038"); alternatively, the cross-section of the mandrel may assume any other shape. The mandrel **102** may comprise multiple tapered portions, separated by non-tapered regions. This configuration provides greater compliance over a shorter length of the mandrel. The tapered portions and intermediate regions may be formed by grinding down the mandrel **102**. The core mandrel **102** may comprise a first, proximal, tapered region **104** and a

second, intermediate, tapered region **106**. The guidewire **100** may further comprise a radiopaque coil **110** (not shown) and coil stopper **111**. Transition regions **105a** and **105b** may be positioned between the tapered regions **104, 106** and the coil stopper **111**. The transition regions **105a** and **105b** are regions of constant diameter. In one embodiment, the radiopaque coil **110** would be positioned overtop the transition region **105b** proximal to the coil stopper **111**. Alternatively, the mandrel **102** may have a smooth taper from a larger outer diameter to a smaller outer diameter.

[0021] The guidewire further comprises a curved distal region **114.** The curved distal region **114** may comprise a straightened portion **116** positioned distal to the curve **114**, thereby forming a J-shape, and terminating at the distal tip **118.** In an alternative embodiment, the distal curve **114** may be in the form of a pigtail curve. The guidewire **100** may be configured such that when the guidewire **100** is constrained or positioned within an ancillary device, the distal portion **112** may assume a straightened configuration. When the guidewire **100** is unconstrained, it may assume the curved configuration. The curved distal region **114** extends the length of the distal portion **112**, with the distal portion **112** terminating at the distal tip **118**. The distal tip **118** may be a sharp tip which requires mechanical force to puncture the target tissue. The curved distal region **114** redirects the sharp distal tip **118** such that it does not contact tissue during advancement, thereby preventing inadvertent damage to surrounding tissues. The distal tip **118** may be configured to deliver energy to the tissue. In one example, the distal tip **118** may be an electrode that electrically communicates with an energy generator.

[0022] The mandrel **102** may comprise multiple tapered portions, separated by non-tapered regions. This configuration provides greater compliance over a shorter length of the mandrel. The tapered portions and intermediate regions may be formed by grinding down the mandrel **102**. The core mandrel **102** may comprise a first, proximal, tapered region **104** and a second, intermediate, tapered region **106**. The guidewire **100** may further comprise a radiopaque coil **110** (not shown) and coil stopper **111**. In one embodiment, the guidewire **100** may comprise a plurality of flattened portions **120a** and **120b**. The flattened

portions **120a** and **120b** have, comparatively, lower stiffness than the unflattened mandrel **102**. The flattened portions **120a** and **120b** may be positioned along the guidewire **100** where the majority of stresses during use are expected to occur. Typically, these are near the distal portion **112** that may contact tissues directly. The flattened portions **120a** and **120b** may be positioned such that there is an unflattened portion **122** (e.g., a portion of mandrel **102** with a circular cross-section) within relative proximity to each other. In a particular embodiment, the flattened portions **120a** and **120b** may be positioned such that there is an unflattened portion **122** separating them. In other words, the flattened portions **120a** and **120b** may alternate with unflattened portions **122** along the length of the guidewire **100**. With this configuration, the guidewire **100** distributes bending across multiple points. In other words, as the guidewire **100** contacts tissue, the guidewire **100** undergoes bending at the plurality of flattened portions **120a** and **120b** (as depicted in **Fig. 4**). Although a guidewire **100** with two flattened portions is described, it would be appreciated that any number of flattened portions may be positioned at various positions along the guidewire **100**. These flattened portions may be positioned such that they alternate in between unflattened portions **122**.

[0023] In an alternative embodiment, the unflattened portions **122** may undergo some flattening but to a lesser extent than the flattened portions **120a** and **120b**. This would still result in the flattened portions **120a** and **120b** to undergo bending while the less flattened portions would be stiffer than the flattened portions **120a** and **120b**.

[0024] The distribution of bending along the guidewire **100** reduces the potential of the metal breaking through the Bauschinger effect. When metal is work-hardened in the direction it is bent, it strengthens the metal in that direction while reducing the strength (weakening it) in the reverse direction. Continuous strain reversals via bending at the same location on the guidewire **100** will eventually lead to failure of the material. In some instances, the device may withstand multiple strain reversals (repeated back-and-forth bending at a single point) prior to breaking; in other instances, the device may only withstand a single strain reversal. The distribution of bending across multiple points

reduces the likelihood of kinking and plastic deformation. Without plastic deformation, the Bauschinger effect won't occur. Additionally, configuring the guidewire **100** with alternating flattened **120a** and **120b** and unflattened **122** portions enables the guidewire **100** to twist more easily by facilitating flexural-torsional buckling of the unflattened portion as it seeks a lower-stress state, therefore reducing the likelihood of reoccurring kinking at the same location on the guidewire **100**.

[0025] The flattened portions, in some embodiment, are at least 0.3mm in length, or in other embodiment, at least 1.0mm in length to allow for a smooth transition from the unflattened height to the flattened height. Ideally, the flattened height of the mandrel **102** may be flattened to a height such that the guidewire **100** selectively bends at the flattened portions. In some embodiments, the first (proximal) flattened portion **120a** may have a length between 1.5mm (0.059") to 2.0mm (0.079"). The second (distal) flattened portion **120b** may have a length between 20.0mm (0.797") to 22.0mm (0.866") and a height of 0.089mm (0.0035") to 0.114mm (0.0045"). In yet another embodiment, a round or unflattened portion **122** may be positioned between the flattened portions **120a** and **120b**. The unflattened portion **122,** in embodiments, can be at least 0.3mm in length, or at least 1.0mm in length, in other embodiments, to ensure that each flattened portion **120a** and **120b** can be able to bend independent from each other, thereby preventing pinching at one single region. The unflattened portion **122**, in some embodiments, has a greater stiffness than each flattened portion **120a** and **120b**, in a least one plane of reference, to help ensure bending selectively occurs at the flattened portions. Furthermore, to prevent the need for additional reinforcing components (e.g., a coil), the outer diameter of the mandrel **102** undergoing flattening can be no less than 0.152mm (0.006").

[0026] In another embodiment, the mandrel **102** may be composed of nitinol. Nitinol possesses super elastic properties, allowing the guidewire **100** to be kink-resistant, removing the need for additional reinforcing components (e.g., inner and/or outer coils over the flattened region(s)). In an alternative embodiment, the core mandrel **102** may be composed of stainless steel. However, stainless steel may be more prone to kinking and,

thus, reinforcing components such as an inner or outer coil over the flattened portions may be necessary.

[0027] In some embodiments, the guidewire **100** may comprise visualization elements to enable the device to be visible under various visualization systems (e.g., fluoroscopy and/or ultrasound). In one embodiment, the guidewire **100** may include a radiopaque coil **110** (as depicted in **Fig. 2** and **Fig. 3**). The radiopaque coil **110** may comprise a round wire that is coiled and close wound around the diameter of the mandrel **102**. The radiopaque coil **110** may be positioned proximal the plurality of flattened portions **120a** and **120b**. In some embodiments, the portion of the mandrel **102** comprising the radiopaque coil **110** may be ground down such that when the radiopaque coil **110** is positioned over the mandrel **102**, it does not significantly increase the outer diameter of the device. The radiopaque coil **110** may be composed of any material that may be visible under fluoroscopy, such as platinum-iridium, tungsten, gold, or any other material which attenuates x-rays. The radiopaque coil **110** may be held in place distally by a coil stopper **111**. In some embodiments, a flattened region **120a** may act as the stopper **111,** where the radiopaque coil **110** may be positioned proximal to the flattened region **120a**. In this embodiment, the flattened region **120a** may be flattened to a specific width to hold the coil **110** in place (as seen in **Fig. 5**), for example, to a width of 0.432mm (0.017") to 0.609mm (0.024"). In an alternative embodiment, the coil **110** may be placed between two of the plurality of flattened portions **120a** and **120b**, where each of the flattened portions **120a** and **120b** act as a stopper **111**. Alternatively, a radiopaque marker such as a band or ring of dense metal contained on the guidewire **100** via a stopper **111** may be used. Further, a radiopaque coating that is sprayed or deposited directly on the guidewire **100** and adheres to the guidewire **100** surface without use of any stoppers **111** may be used instead of a radiopaque coil **110**.

[0028] In a specific example, with reference to **Fig. 6**, a guidewire **100** is disclosed, with a distal tip **118,** configured for puncturing a target tissue. The guidewire **100** comprises a mandrel **102** composed of super elastic nitinol with a circular or round cross-

section. The length of the guidewire **100** may be between 180cm (70.8") to 230cm (90.5") with an outer maximum diameter ranging between 0.787mm (0.031") to 0.80mm (0.0315"). The start of the proximal tapered region **104** may be positioned 76.61mm (3.01") to 79.15mm (3.11") from the distal tip **118**. The proximal tapered region **104** length may range from 15.75mm (0.620") to 22.35mm (0.880") and tapers from the maximum outer diameter (0.787mm (0.031") to 0.80mm (0.0315")) to an outer diameter of between 0.399mm (0.0157") to 0.414mm (0.0163"). The start of the middle tapered region **106** may be positioned 43.84mm (1.72") to 44.6mm (1.75") from the distal tip **118**. The middle tapered portion **106** length may range from 2.29mm (0.09") to 2.79mm (0.11") in length and reduce the outer diameter such that it ranges between 0.297mm (0.0117") to 0.312mm (0.0123"). The start of the distal tapered region **108** may be positioned 20.65mm (0.81") to 21.42mm (0.84") from the distal tip **118**. The length of the distal tapered region **108** may range between 1.02mm (0.04") to 1.52mm (2.04"). The outer diameter tapers down until it reaches between the range of 0.1955mm (0.0077") to 0.2108mm (0.0083"). In between each tapered region **104, 106,** and **108** is a transition region **105a** and **105c**.

[0029] In this example, the guidewire **100** further comprises two flattened portions **120a** and **120b**. The first, proximal, flattened portion **120a** may extend for a length between 1.5mm (0.059") to 2.0mm (0.079") and a width of 0.432mm (0.017") to 0.609mm (0.024). The location of the first, proximal, flattened portion **120a** is at the location of the second transition region **105b,** between the middle tapered region **106** and the distal tapered region **108**. The second, distal, flattened portion extends to the distal tip **118** and may range between 20.0mm (0.797") to 22.0mm (0.866") and a height of 0.089mm (0.0035") to 0.114mm (0.0045"). An unflattened, round, section **122** of guidewire **100** is situated between the proximal **120a** and distal **120b** flattened portions. The length of the unflattened, round, section **122,** may be between 1 mm and 3.0 mm. The distal tip **118** of the guidewire **100** comprises a sharp tip with a radius less than or equal to .001" for mechanically puncturing the target tissue.

[0030] The guidewire **100** further comprises a J-shaped curved distal region **114**. The curved distal region **114** extends the entire length of the distal tapered region **108.** The curve may have a diameter that ranges between 7.0mm (0.27") to 9.0mm (0.35"). Distal to the curve, the straightened region **116** has a length between 4.5mm (0.177") to 6.5mm (0.255"), terminating at the distal tip **118**.

[0031] A radiopaque coil **110** is positioned on the guidewire **100** to allow users to visualize the device under fluoroscopy and/or ultrasound. The radiopaque coil **110** is composed of platinum-iridium and positioned proximal to the first, proximal, flattened portion **120a** and may comprise a length between 20.0mm (0.797") to 22.0mm (0.866"). In this example, the radiopaque coil **110** may have an inner diameter between 0.317mm (0.0125") and 0.342mm (0.0135") and an outer diameter between 0.419mm (0.0165") and 0.445mm (0.0175").

[0032] Although a plurality of flattened portions **120a** and **120b** has been described above, the flattened portions **120a** and **120b** can be portions of reduced stiffness, thereby being more compliant, and may comprise various modifications to achieve a portion of reduced stiffness.

[0033] In one alternative embodiment, the plurality of portions with reduced stiffness may comprise a plurality of portions with a reduction in outer diameter. These portions would have a diameter that is reduced compared to the areas directly adjacent to it, resulting in bending at these areas.

[0034] In a further alternative embodiment, the portions with reduced stiffness may be achieved by introducing surface irregularities to the mandrel **102**. As an example, the mandrel **102** may comprise portions with cut-outs or slits which will reduce the stiffness of those portions, compared to the adjacent portions that do not comprise any surface irregularities, which will result in those portions undergoing bending.

[0035] An alternative embodiment is depicted in **Fig. 7a – 7b**. In this embodiment, the mandrel **102** may be discontinuous or broken along its length **130a** and **130b**. To hold the discontinuous mandrel **102** together, an outer coil **132** may be wound around the mandrel **106**, resulting in a single device. In some embodiments, the outer coil **132** may be composed of radiopaque material (such as platinum-iridium) to enable visualization under fluoroscopy. As shown in **Fig. 7b**, the breaks or discontinuous portions **130a** and **130b** would bend when force is applied to the guidewire **100**.

[0036] Another alternative embodiment may comprise a mandrel **102** with a plurality of coiled portions **140a** and **140b**, as illustrated in **Figs. 8a – 8b**. The coiled portions **140a** and **140b** of the mandrel **102** act as flexible spring section. The coiled portions **140a** and **140b** may be separated by a straight segment **142**. As depicted in **Fig. 7b**, the coiled portions **140a** and **140b** would deflect and bend when force is applied to the guidewire **100**.

[0037] In another alternative embodiment, the guidewire **100** may comprise a mandrel **102** composed of various materials. For example, as illustrated in **Figs. 9a – 9b**, the mandrel **102** may be formed with portions of material that have lower stiffness **150a** and **150b**. separated by material with higher stiffness **152.** In some embodiments the material of higher stiffness **152** may be a different material than the mandrel **102**. In alternative embodiments, the material of higher stiffness **152** may be the same material as the mandrel **102**. The stiffer and less stiff materials may be secured (e.g., welded) together, forming a single device. Similar to previous embodiments, the portions of the guidewire **100** comprising the material of lower stiffness **150a** and **150b** would selectively bend (as seen in **Fig. 9b**).

[0038] It is appreciated that these means of introducing reduced stiffness to the mandrel **102** of the guidewire **100** may be used independently or in combination with one another. Additionally, a person skilled in the art would recognize that each of the plurality of reduced stiffness portions may vary between one another. For example, the first portion of

reduced stiffness may be less than the second portion of reduced stiffness with both the first and second portions of reduced stiffness being less than the stiffness of the sections adjacent to them.

[0039] Various exemplary embodiments are listed below:

1) A guidewire comprising:

an elongate member comprising:

a proximal portion;

a distal portion, the distal portion comprising:

a distal curved portion ending in a distal tip;

a tapered region, wherein the tapered region reduces a cross-section of the elongate member from a large cross-section to a small cross-section;

a plurality of flattened regions positioned at discrete locations along the elongate member; and,

wherein each of the plurality of flattened regions are separated from one another by an unflattened region;

whereby, when a force is exerted onto the guidewire, the guidewire undergoes bending at the plurality of flattened regions.

2) The guidewire of example 1, wherein the elongate member is composed of nitinol.

3) The guidewire of any one of examples 1 or 2, wherein the elongate member comprises a circular cross section.

4) The guidewire of any one of examples 1 to 3, further comprising a radiopaque coil positioned along the distal portion.

5) The guidewire of example 4, wherein the radiopaque coil is composed of platinum-iridium.

6) The guidewire of any one of examples 4 or 5, wherein the radiopaque coil is held in place by a coil stopper.

7) The guidewire of any one of examples 1 to 6, wherein the tapered region comprises a plurality of tapers, wherein the plurality of tapers are separated by an intermediate portion of constant diameter.

8) The guidewire of any one of examples 1 to 7, wherein the plurality of flattened regions comprises a proximal flattened region and a distal flattened region.

9) The guidewire of example 8, wherein the distal flattened region extends from the sharp distal tip and ends proximal to the curved distal portion.

10) The guidewire of any one of examples 1 to 9, wherein the curved distal portion is J-shaped.

11) The guidewire of any one of examples 1 to 9, wherein the curved distal portion is in a pigtail configuration.

12) The guidewire of any one of examples 1 to 11, wherein the distal tip comprises a sharp tip configured to puncture a target tissue.

13) The guidewire of any one of examples 1 to 11, wherein the distal tip comprises an electrode configured to deliver energy to a target tissue.

14) A guidewire comprising:

an elongate member having a first stiffness, the elongate member comprising:

a proximal portion;

a distal portion, the distal portion ending in a distal tip; and,

a plurality of regions of a second stiffness positioned at discrete locations along the elongate member and separated by a portion of the first stiffness;

wherein the second stiffness is less than that of the first stiffness;

whereby, when a force is exerted onto the guidewire, the guidewire undergoes bending at the plurality of regions of the second stiffness preventing kinking of the guidewire.

15) The guidewire of example 14, wherein the distal portion comprises a distal curved portion, ending at the distal tip.

16) The guidewire of any one of examples 14 or 15, wherein the distal curved portion is J-shaped.

17) The guidewire of any one of examples 14 or 15, wherein the distal curved portion is in a pigtail configuration.

18) The guidewire of any one of examples 14 to 17, wherein the distal tip is a sharp tip configured to puncture a target tissue.

19) The guidewire of any one of examples 14 to 18, wherein the distal tip is an electrode configured to deliver energy to a target tissue.

20) The guidewire of any one of examples 14 to 19, further comprising a radiopaque coil.

21) The guidewire of example 20, wherein the radiopaque coil is positioned along the distal portion.

22) The guidewire of any one of examples 19 or 21, wherein the radiopaque coil is composed of platinum-iridium.

23) The guidewire of any one of examples 19 to 22, wherein the radiopaque coil is held in place by a stopper.

24) The guidewire of any one of examples 14 to 23, wherein the elongate member is composed of nitinol.

25) The guidewire of any one of examples 14 to 24, wherein the distal portion comprises a tapered region, the tapered region tapering from a large cross-section to a small cross-section.

26) The guidewire of example 24, wherein the tapered region comprises a plurality of tapered portions and wherein each of the plurality of tapered portions are separated from one another by an intermediate portion having a constant cross-section.

27) The guidewire of example 26, wherein the plurality of tapered portions comprises a proximal tapered portion, a middle tapered portion, and a distal tapered portion.

28) The guidewire of any one of examples 1 to 27, wherein each of the plurality of regions of the second stiffness vary in stiffness from one another.

29) The guidewire of any one of examples 1 to 28, wherein the plurality of regions of the second stiffness comprises a plurality of flattened portions and wherein the portion of the first stiffness comprises an unflattened portion.

30) The guidewire of example 29, wherein the plurality of flattened portions comprises a proximal flattened portion and a distal flattened portion.

31) The guidewire of example 30, wherein the distal flattened portion extends from the distal tip and ends proximal to the curved distal region.

32) The guidewire of any one of examples 1 to 28, wherein the portion of the first stiffness comprises a first material and wherein the plurality of regions of the second stiffness comprises a plurality of regions composed of a second material.

33) The guidewire of example 32, wherein the first material is the same material as the elongate member.

34) The guidewire of any one of examples 1 to 28, wherein the plurality of regions of the second stiffness comprises a plurality of coiled regions and where the portion of the first stiffness comprises a straight portion.

35) The guidewire of any one of examples 1 to 28, wherein the plurality of regions of the second stiffness comprises a plurality of regions with surface irregularities.

36) The guidewire of example 35, wherein the surface irregularities comprises a series of cut-outs.

37) The guidewire of any one of examples 1 to 28, wherein the plurality of regions of the second stiffness comprises a plurality of regions selected from a group consisting of flattened portions, or less stiff material, or coiled portions, or a combination thereof.

38) The guidewire of any one of examples 1 to 37, wherein the elongate member comprises a circular cross-section.

39) A guidewire comprising:

an elongate member comprising:

a proximal portion;

a distal portion, the distal portion comprising:

a distal curved portion ending in a distal tip;

a plurality of broken portions; and,

an outer coil, wherein the outer coil wraps around the elongate member such that the elongate member forms a single piece;

whereby, when a force is exerted onto the guidewire, the guidewire undergoes bending at the plurality of broken portions, preventing kinking of the guidewire.

[0040] The embodiment(s) of the invention described above is(are) intended to be exemplary only. The scope of the invention is therefore intended to be limited solely by the scope of the appended claims.

[0041] It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

[0042] Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

We claim:

1) A guidewire comprising:

an elongate member having a first stiffness, the elongate member comprising:

a proximal portion;

a distal portion, the distal portion ending in a distal tip; and,

a plurality of regions of a second stiffness positioned at discrete locations along the elongate member and separated by a portion of the first stiffness;

wherein the second stiffness is less than that of the first stiffness;

whereby, when a force is exerted onto the guidewire, the guidewire undergoes bending at the plurality of regions of the second stiffness preventing kinking of the guidewire.

2) The guidewire of claim 1, wherein the distal portion comprises a distal curved portion, ending at the distal tip.

3) The guidewire of any one of claims 1 or 2, wherein the distal curved portion is J-shaped.

4) The guidewire of any one of claims 1 or 2, wherein the distal curved portion is in a pigtail configuration.

5) The guidewire of any one of claims 1 to 4, wherein the distal tip is a sharp tip configured to puncture a target tissue.

6) The guidewire of any one of claims 1 to 5, wherein the distal tip is an electrode configured to deliver energy to a target tissue.

7) The guidewire of any one of claims 1 to 6, further comprising a radiopaque coil.

8) The guidewire of claim 7, wherein the radiopaque coil is positioned along the distal portion.

9) The guidewire of any one of claims 6 or 8, wherein the radiopaque coil is composed of platinum-iridium.

10) The guidewire of any one of claims 6 to 9, wherein the radiopaque coil is held in place by a stopper.

11) The guidewire of any one of claims 1 to 10, wherein the elongate member is composed of nitinol.

12) The guidewire of any one of claims 1 to 11, wherein the distal portion comprises a tapered region, the tapered region tapering from a large cross-section to a small cross-section.

13) The guidewire of claim 12, wherein the tapered region comprises a plurality of tapered portions and wherein each of the plurality of tapered portions are separated from one another by an intermediate portion having a constant cross-section.

14) The guidewire of claim 13, wherein the plurality of tapered portions comprises a proximal tapered portion, a middle tapered portion, and a distal tapered portion.

15) The guidewire of any one of claims 1 to 14, wherein each of the plurality of regions of the second stiffness vary in stiffness from one another.

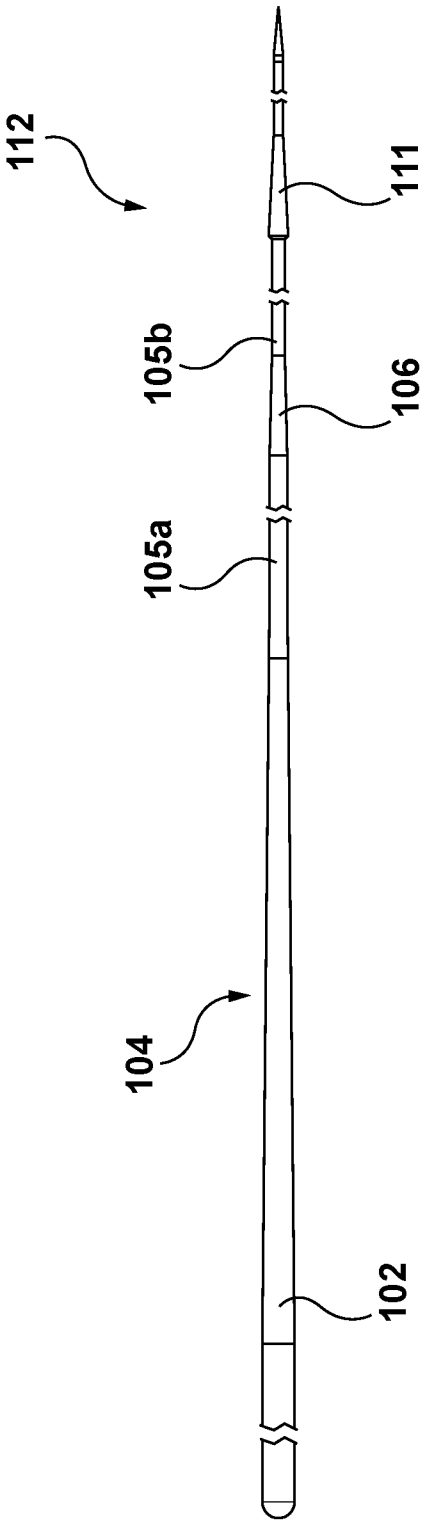

FIG. 1

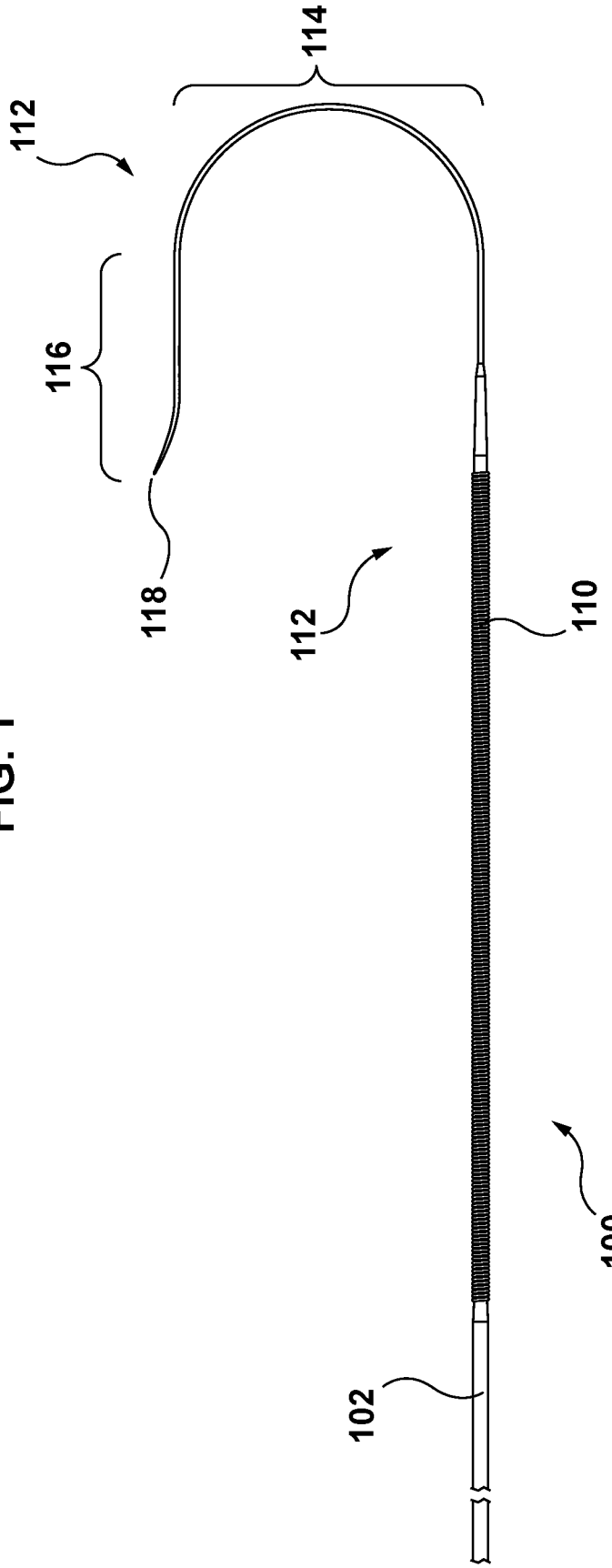

FIG. 2

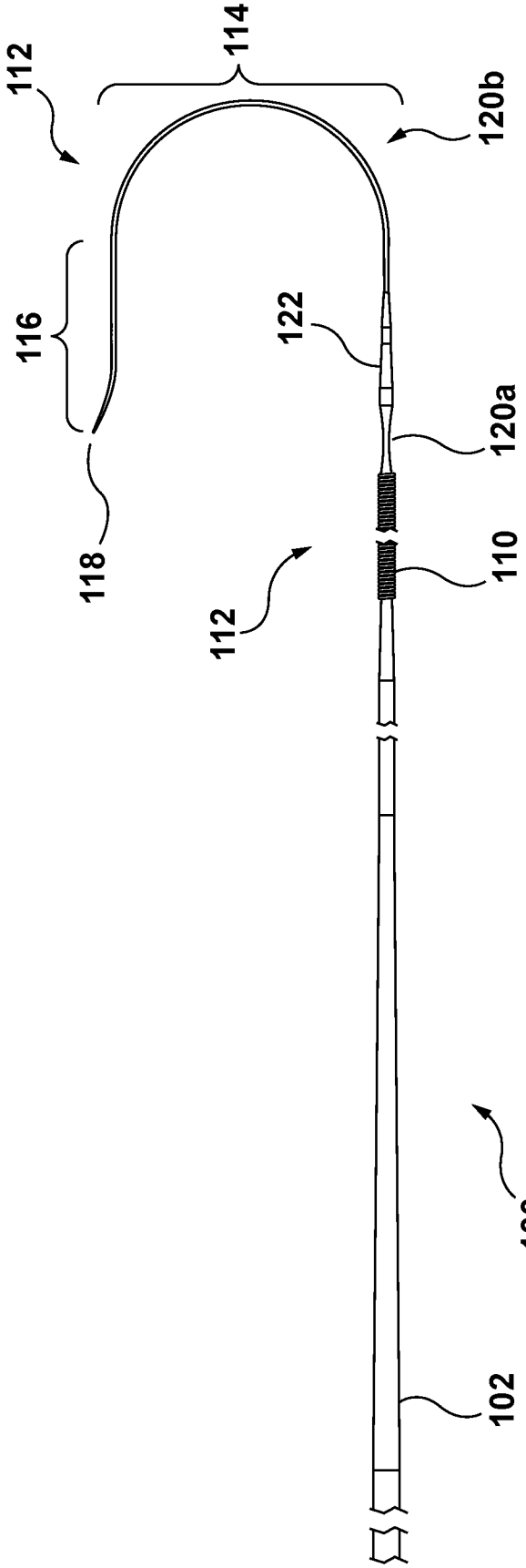
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FIG. 3

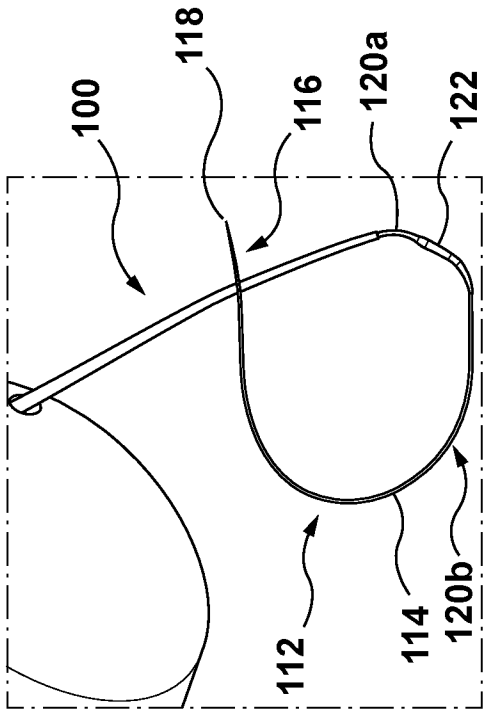
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FIG. 4

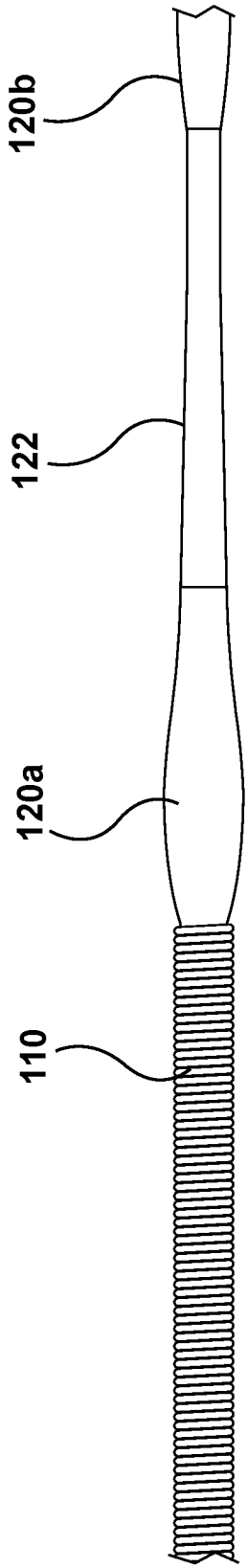

FIG. 5

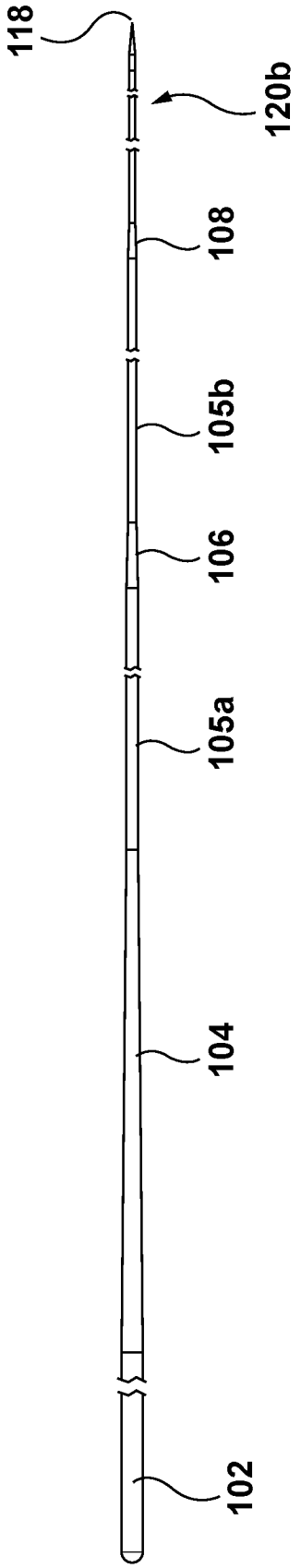

FIG. 6

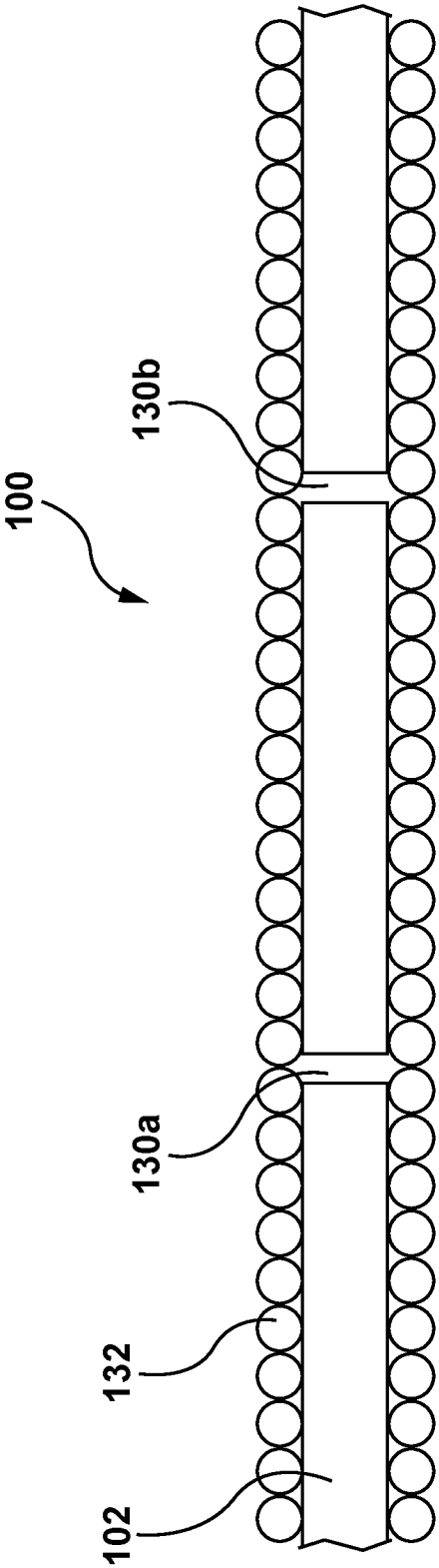

FIG. 7A

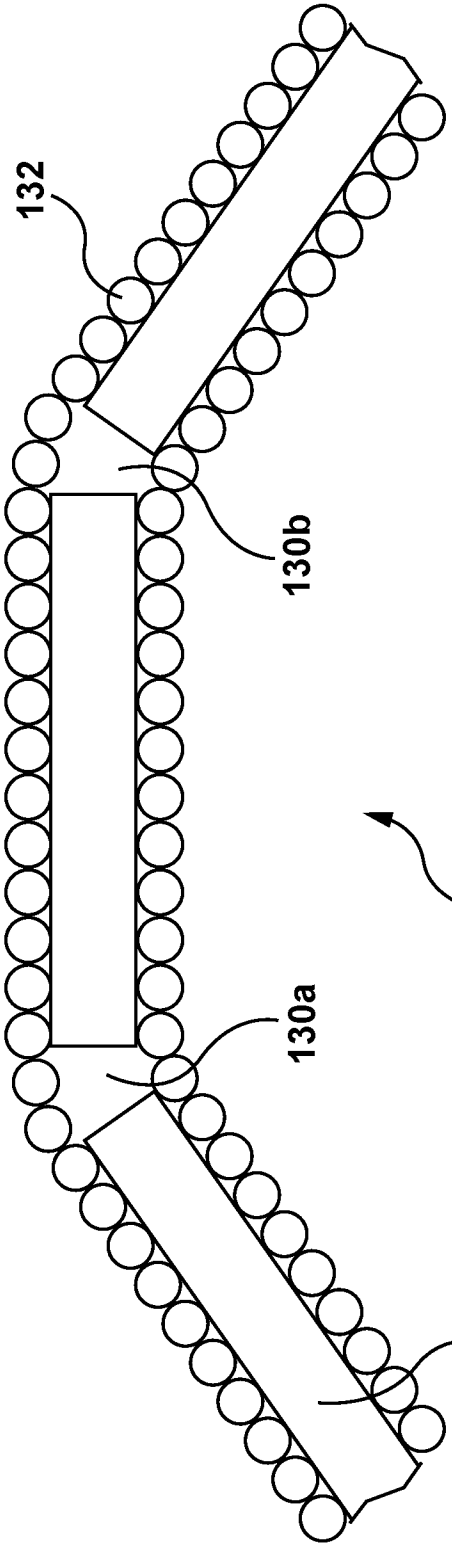

FIG. 7B

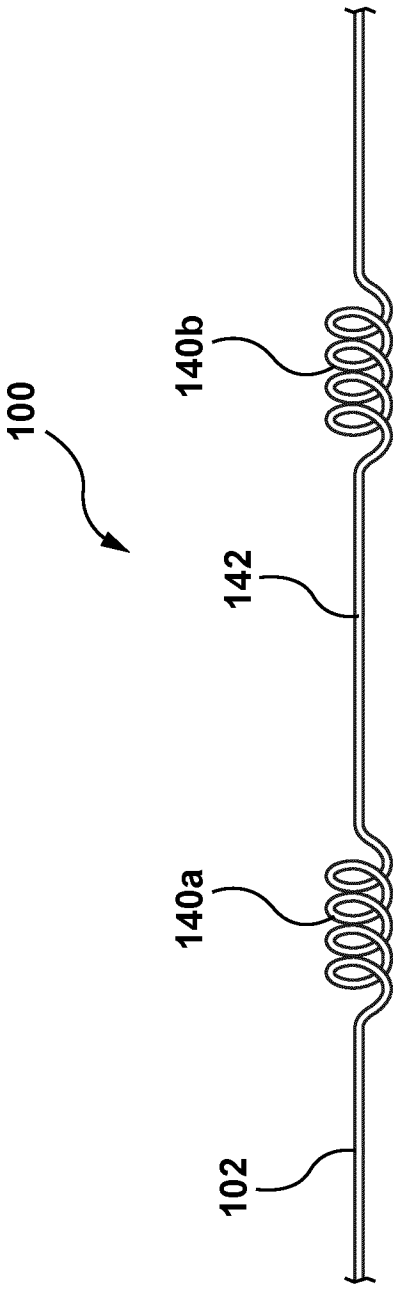

FIG. 8A

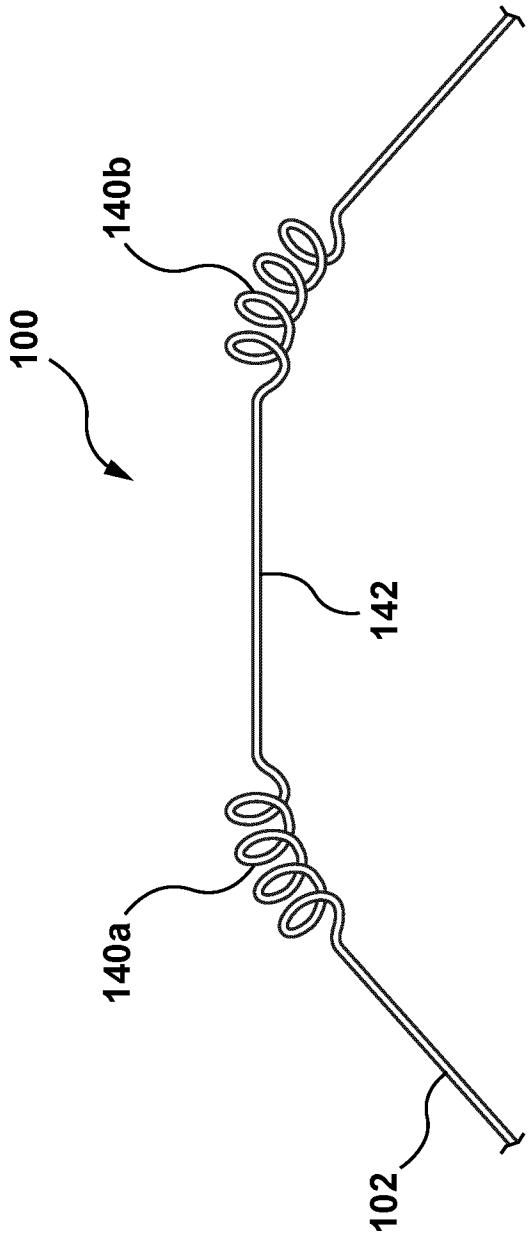

FIG. 8B

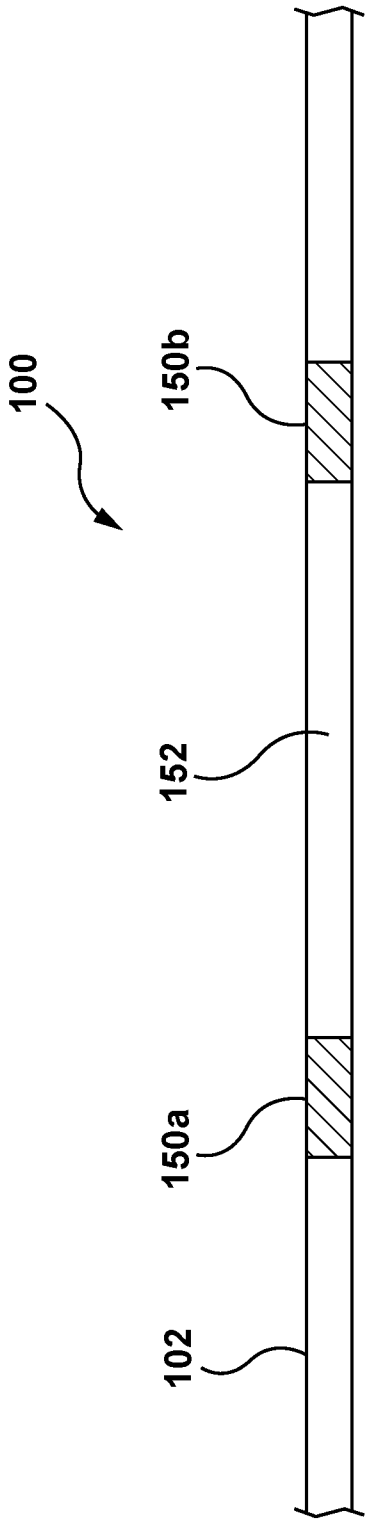

FIG. 9A

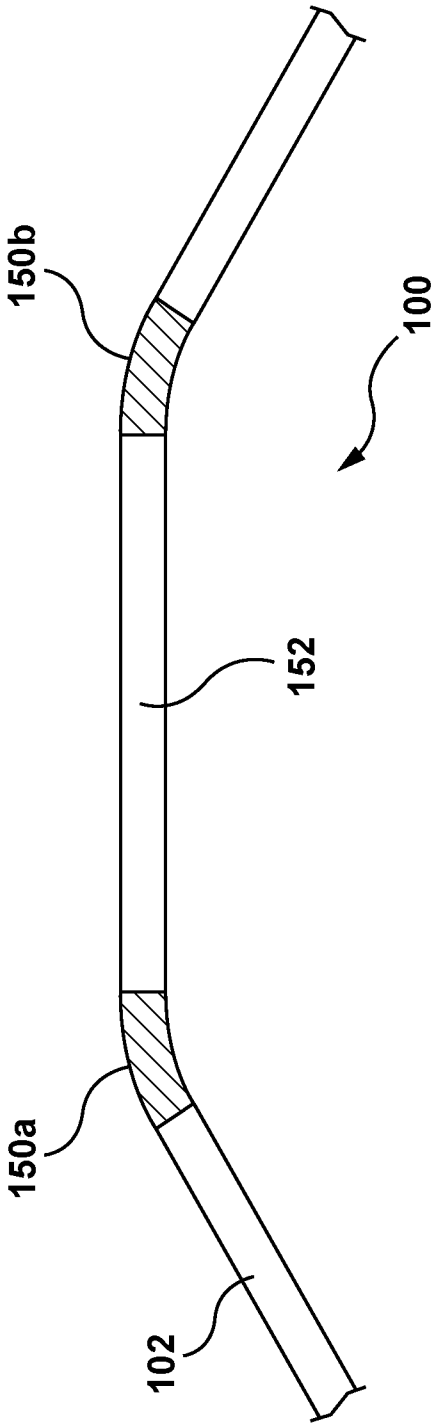

FIG. 9B

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2023/056773

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/09 A61B17/00 A61B17/22
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2013/114985 A1 (PIOLAX MEDICAL DEVICES INC [JP]) 8 August 2013 (2013-08-08) page 4, paragraph 3-4 page 5, paragraph 5 page 6, last paragraph - page 7, paragraph 1 page 8, paragraph 8 page 10, paragraph 6 - page 11, paragraph 1 figures 1-5	1-4,7-12
X	US 2008/269641 A1 (O'SHAUGHNESSY DONAGH [IE] ET AL) 30 October 2008 (2008-10-30) paragraphs [0005], [0007] paragraph [0019] - paragraph [0024] paragraph [0026] - paragraph [0028] figures 1-2	1,7-9,15

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[x] Further documents are listed in the continuation of Box C.

[x] See patent family annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 July 2023	18/07/2023

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Jankowska, M

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2023/056773

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	paragraphs [0013] - [0014] paragraph [0022] - paragraph [0024] figures 1-3	2-6
Y	US 2009/105654 A1 (KURTH PAUL [US] ET AL) 23 April 2009 (2009-04-23) paragraph [0066] paragraph [0068] - paragraph [0069] paragraph [0072] paragraph [0074] paragraph [0080] paragraph [0082] paragraph [0084] paragraph [0100] - paragraph [0103] figures	2-5
Y	EP 0 773 037 A2 (PACESETTER AB [SE]) 14 May 1997 (1997-05-14) column 6, line 47 - column 10, line 24 figures 1-14	6

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Information on patent family members

International application No
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