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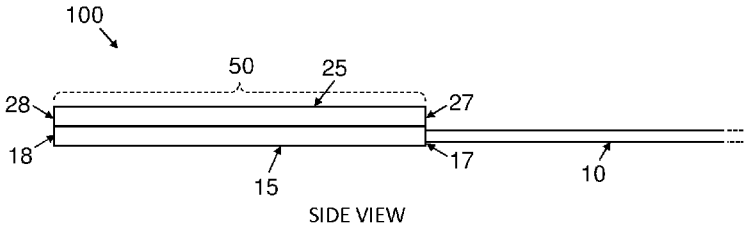
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(54) **Title:** ASSEMBLIES AND METHODS FOR INTRODUCING AN ADDITIONAL GUIDEWIRE



SIDE VIEW

FIG. 2A

(57) **Abstract:** Embodiments of the present invention relate generally to medical devices and more particularly to methods and apparatus for introducing a second guidewire to a previously-introduced guidewire in a lumen of a subject. Assemblies, systems, apparatus, methods and kits (for example, for introducing an additional guidewire), provided in accordance with embodiments of the invention, are disclosed herein.

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ASSEMBLIES AND METHODS FOR INTRODUCING AN ADDITIONAL GUIDEWIRE

FIELD OF THE INVENTION

Embodiments of the present invention relate generally to medical devices and more particularly to methods and apparatus for introducing a second guidewire to a previously-introduced guidewire in a lumen of a subject.

BACKGROUND

Guidewires are used for navigating to reach a location within a patient such as a surgical or other treatment site. Once the tip of the guidewire arrives at its destination, it acts as a guide that larger elements, e.g., catheters, can rapidly follow for easier delivery to the treatment site. Introduction of a second guidewire in parallel to a previously-introduced guidewire can be useful in many different procedures. In order to ensure that the second guidewire follows the same path as the first, the introduction can be done using a coupling device.

'Coupling tips' designed to be affixed to the distal end of the second guidewire have been suggested, but to date all such coupling tips have suffered from a number of design flaws. The most serious flaws include: the pathway provided for the previously-introduced guidewire through the coupling tip is not uniformly parallel to the second guidewire, or close enough to parallel; the pathway provided for the previously-introduced guidewire through the coupling tip is not at a fixed orientation to the second guidewire, i.e., the orientation can change when an external force is applied on the coupling device; the pathway provided for the previously-introduced guidewire through the coupling tip is not uniformly straight, i.e., the previously-introduced guidewire is forced to bend, often in more than one place, as the coupling device traverses the length of the guidewire; the pathway provided for the previously-introduced guidewire through

the coupling tip is too short; and the passage provided in the coupling tip for the distal end of the second guidewire is not adaptable to the diameter of the guidewire. Any or all of these design flaws can mean that when introducing the second guidewire using such coupling tips, the surgeon can meet resistance and inadvertently cause shear forces on the previously-introduced guidewire, or even force uncouple the coupling device from the second guidewire. Therefore, there is a need for assemblies and methods employing a coupling tip design that reduces or eliminates the foregoing disadvantageous effects.

SUMMARY OF THE INVENTION

According to embodiments disclosed herein, an apparatus comprises: (a) a first guidewire for use in a medical procedure; and (b) a coupling device comprising: (i) a first tubular portion formed to accommodate, through at least a proximal majority of a length thereof, passage of a distal portion of the first guidewire, and (ii) a second tubular portion formed to accommodate slidable passage therethrough of a second guidewire in a straight-line path between respective proximal and distal openings of the second tubular section, the straight-line path having a length-to-diameter ratio of at least 10:1, the first and second tubular sections being joined laterally in a fixed orientation to each other along the lengths of respective overlapping longitudinal sections, the lateral joining being such that respective longitudinal centerlines of the first and second tubular portions are parallel to each other or within ±10° of parallel in said fixed orientation.

In some embodiments, the lateral joining can be such that the respective longitudinal centerlines are parallel to each other or within ±5° of parallel, in said fixed orientation.

In some embodiments, the lateral joining can be such that a distance between respective distal ends of the first and second tubular sections is less than 2 cm. In some embodiments, the lateral joining can be such that a distance between respective distal ends of the first and second tubular sections is less than 1 cm. In some embodiments, the lateral joining can be such that a distance between respective distal ends of the first and second tubular sections is less than 0.5 cm.

In some embodiments, the respective overlapping longitudinal sections can have a length of at least 1 cm. In some embodiments, the respective overlapping longitudinal sections can have a length of at least 2 cm. In some embodiments, the respective overlapping longitudinal sections can have a length of at least 3 cm. In some embodiments, the respective overlapping longitudinal sections can have a length of at least 4 cm.

In some embodiments, the length of the second tubular portion can be at least 1 cm. In some embodiments, the length of the second tubular portion can be at least 2 cm. In some embodiments, the length of the second tubular portion can be at least 3 cm. In some embodiments, the length of the second tubular portion can be at least 4 cm.

In some embodiments, the apparatus can be in an assembled state in which the coupling device is affixed to the distal portion of the first guidewire such that a longitudinal section of the first tubular portion surrounds the distal portion of the first guidewire. In some such embodiments, at least part of the longitudinal section of the first tubular portion that surrounds the distal portion of the first guidewire can be mechanically and/or thermally deformed as a result of an affixing process.

In some embodiments, the apparatus can additionally comprise an assembly material used in an affixing process.

According to embodiments disclosed herein, an apparatus provided as a kit comprises: (a) a coupling device for use in a medical procedure, the coupling device comprising: (i) a first tubular portion formed to accommodate, through at least a proximal majority of a length thereof, passage of a distal portion of a first guidewire, and (ii) a second tubular portion formed to accommodate slidable passage therethrough of a second guidewire in a straight-line path between respective proximal and distal openings of the second tubular section, the straight-line path having a length-to-diameter ratio of at least 10:1, the first and second tubular sections being joined laterally in a fixed orientation to each other along the lengths of respective overlapping longitudinal sections such that respective longitudinal centerlines of the first and second tubular portions are parallel to

each other or within ±10° of parallel, or parallel to each other or within ±5° of parallel. The apparatus additionally comprises (b) an assembly aid for affixing the coupling device to a distal portion of the first guidewire, the assembly aid selected from the group of assembly aids consisting of assembly materials and assembly tools.

In some embodiments, the respective overlapping longitudinal sections can be parallel to each other or within ±5° of parallel.

In some embodiments, the apparatus can additionally comprise the first guidewire.

In some embodiments, the apparatus can be in an assembled state in which the coupling device is affixed to the distal portion of the first guidewire such that a longitudinal section of the first tubular portion surrounds the distal portion of the first guidewire. In some such embodiments, the assembly aid can comprise an assembly material, and the apparatus in the assembled state can comprise at least a portion of the assembly material.

In some embodiments, the assembly aid can comprise an assembly tool, and at least part of the longitudinal section of the first tubular portion that surrounds the distal portion of the first guidewire can be mechanically and/or thermally deformed by use of the assembly tool in an affixing process.

A method is disclosed, according to embodiments, for coupling a first guidewire to a previously introduced second guidewire during a medical procedure. The method comprises: (a) affixing a coupling device to a distal portion of the first guidewire, the coupling device comprising two first tubular portions joined laterally in a fixed orientation to each other along the lengths of respective overlapping longitudinal sections, the lateral joining being such that respective longitudinal centerlines of the first and second tubular portions are parallel to each other or within ±10° of parallel in said fixed orientation, the affixing being such that that a longitudinal section of a first tubular portion of the coupling device surrounds a distal portion of the first guidewire; and (b) slidably passing an end of the second guidewire through a second tubular portion of the coupling device in a straight-line path between respective proximal and distal openings of

the second tubular section, the straight-line path having a length-to-diameter ratio of at least 10:1.

In some embodiments, the respective longitudinal centerlines can be parallel to each other or within ±5° of parallel in said fixed orientation.

In some embodiments, the lateral joining can be such that a distance between respective distal ends of the first and second tubular sections is less than 2 cm. In some embodiments, the lateral joining can be such that a distance between respective distal ends of the first and second tubular sections is less than 1 cm. In some embodiments, the lateral joining can be such that a distance between respective distal ends of the first and second tubular sections is less than 0.5 cm.

In some embodiments, the respective overlapping longitudinal sections of each of the first and second tubular portions can have a length of at least 1 cm. In some embodiments, the respective overlapping longitudinal sections of each of the first and second tubular portions can have a length of at least 2 cm. In some embodiments, the respective overlapping longitudinal sections of each of the first and second tubular portions can have a length of at least 3 cm. In some embodiments, the respective overlapping longitudinal sections of each of the first and second tubular portions can have a length of at least 4 cm.

In some embodiments, the length of the second tubular portion can be at least 1 cm. In some embodiments, the length of the second tubular portion can be at least 2 cm. In some embodiments, the length of the second tubular portion can be at least 3 cm. In some embodiments, the length of the second tubular portion can be at least 4 cm.

In some embodiments, a maximum internal diameter of the second tubular portion can be not greater than 2 mm. In some embodiments, a maximum internal diameter of the second tubular portion can be not greater than 1 mm.

In some embodiments, the affixing can include mechanically and/or thermally deforming at least part of the longitudinal section of the first tubular portion that surrounds the distal portion of the first guidewire using an assembly tool.

In some embodiments, the affixing can include using an assembly material.

A method is disclosed, according to embodiments, for coupling a first guidewire to a previously introduced second guidewire during a medical procedure. The method comprises: (a) providing an assembly comprising a first guidewire for use in a medical procedure, and a coupling device comprising first and second tubular portions joined laterally in a fixed orientation to each other along the lengths of respective overlapping longitudinal sections, the lateral joining being such that respective longitudinal centerlines of the first and second tubular portions are parallel to each other or within ±10° of parallel in said fixed orientation, the coupling device being affixed to the distal portion of the first guidewire such that a longitudinal section of the first tubular portion surrounds the distal portion of the first guidewire, and (b) slidably passing an end of the second guidewire through a second tubular portion of the coupling device in a straight-line path between respective proximal and distal openings of the second tubular section, the straight-line path having a length-to-diameter ratio of at least 10:1.

In some embodiments, the respective longitudinal centerlines can be parallel to each other or within ±5° of parallel in said fixed orientation.

In some embodiments, the lateral joining can be such that a distance between respective distal ends of the first and second tubular sections is less than 1 cm. In some embodiments, the lateral joining can be such that a distance between respective distal ends of the first and second tubular sections is less than 2 cm. In some embodiments, the lateral joining can be such that a distance between respective distal ends of the first and second tubular sections is less than 0.5 cm.

In some embodiments, the respective overlapping longitudinal sections of each of the first and second tubular portions can have a length of at least 1 cm. In some embodiments, the respective overlapping longitudinal sections of each of the first and second tubular portions can have a length of at least 2 cm. In some embodiments, the respective overlapping longitudinal sections of each of the first and second tubular portions can have a length of at least 3 cm. In some embodiments, the respective overlapping longitudinal sections of each of the first and second tubular portions can have a length of at least 4 cm.

In some embodiments, the length of the second tubular portion can be at least 1 cm. In some embodiments, the length of the second tubular portion can be at least 2 cm. In some embodiments, the length of the second tubular portion can be at least 3 cm. In some embodiments, the length of the second tubular portion can be at least 4 cm.

In some embodiments, a maximum internal diameter of the second tubular portion can be not greater than 2 mm. In some embodiments, a maximum internal diameter of the second tubular portion can be not greater than 1 mm.

In some embodiments, at least part of the longitudinal section of the first tubular portion that surrounds the distal portion of the first guidewire can be mechanically and/or thermally deformed as a result of an affixing process.

In some embodiments, the apparatus can additionally comprise an assembly material used in an affixing process.

A method is disclosed, according to embodiments, for assembling an apparatus. The method comprises: (a) providing a guidewire; (b) providing a coupling device comprising a first tubular portion, and a second tubular portion joined laterally in a fixed orientation to the first tubular portion along the lengths of respective overlapping longitudinal sections; and (c) affixing the coupling device to the distal portion of the guidewire, such that that a longitudinal section of a first tubular portion of the coupling device surrounds a distal portion of the guidewire, wherein the second tubular portion is formed to accommodate slidable passage therethrough of a different guidewire in a straight-line path between respective proximal and distal openings of the second tubular section, the straight-line path having a length-to-diameter ratio of at least 10:1.

In some embodiments, the affixing can include mechanically and/or thermally deforming at least part of the longitudinal section of the first tubular portion that surrounds the distal portion of the first guidewire using an assembly tool.

In some embodiments, the affixing can include using an assembly material.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described further, by way of example, with reference to the accompanying drawings, in which the dimensions of components and features shown in the figures are chosen for convenience and clarity of presentation and not necessarily to scale. In the drawings:

Fig. 1A shows a schematic side view of a coupling device according to embodiments of the present invention.

Fig. 1B shows, schematically, various non-limiting examples of cross-sections of coupling devices, including the coupling device of Fig. 1A, according to embodiments of the present invention.

Fig. 2A shows a schematic side view of an apparatus comprising a guidewire and a coupling device according to embodiments of the present invention.

Fig. 2B shows the apparatus of Fig. 2A in perspective view.

Figs. 3 and 4 show schematic side views of an apparatus comprising a guidewire and a coupling device, in an assembled state, coupled to the proximal end of another guidewire, according to embodiments of the present invention.

Figs. 5A and 5B show schematic side views of an apparatus comprising a guidewire and a coupling device, in an assembled state, coupled to the proximal end of another guidewire, and an angle between respective longitudinal centerlines of the two tubular portions of the coupling device, according to embodiments of the present invention.

Fig. 6 shows a schematic side view of an apparatus comprising a guidewire and a coupling device, in an assembled state, coupled to the proximal end of another guidewire, and an angle between respective longitudinal centerlines of the two guidewires, according to embodiments of the present invention.

Figs. 7A and 7B show schematic side views of an apparatus comprising a guidewire and a coupling device, in an assembled state, coupled to the proximal end of

another guidewire, and a distance between respective openings of the two tubular portions of the coupling device, according to embodiments of the present invention.

Fig. 7C shows a schematic side view of an apparatus comprising a guidewire and a coupling device, in an assembled state, coupled to the proximal end of another guidewire, wherein at least one of the two tubular portions is not continuous, according to embodiments of the present invention.

Fig. 8 shows a schematic side view of an apparatus comprising a guidewire and a coupling device, in an assembled state, coupled to the proximal end of another guidewire, the tubular portions having beveled distal and proximal openings, according to embodiments of the present invention.

Fig. 9 schematically illustrates a step of a method for assembling an apparatus, according to embodiments of the present invention.

Figs. 10A and 10B schematically illustrate steps of respective methods for assembling an apparatus using an assembly aid, according to embodiments of the present invention.

Figs. 11A, 11B and 11C are schematic end-view drawings of respective non-limiting examples of an apparatus comprising a guidewire and a coupling device, in an assembled state, according to embodiments of the present invention.

Figs. 12A, 12B, 12C, 13A, 13B, 14A and 14B are schematic illustrations of apparatuses provided as kits, according to embodiments of the present invention.

Figs. 15A, 15B, 15C and 15D illustrate steps of a method for coupling a first guidewire to a previously introduced second guidewire during a medical procedure, according to embodiments of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

The invention is herein described, by way of example only, with reference to the accompanying drawings. 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 the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice. Throughout the drawings, like-referenced characters are generally used to designate like elements.

The terms 'distal' and 'proximal' are used throughout this disclosure and the appended claims as follows: 'distal' means further into the body (along an insertion path) from a point of entry into the body, while 'proximal' means closer to the point of entry into the body. Where the terms are used in reference to apparatus outside of a patient's body, a distal portion or distal end is that portion or end of the apparatus configured to be inserted into the body first, while a proximal end or proximal portion is either inserted last or may never be inserted (as in the case of a guidewire, for example). Additionally, when used relatively, e.g. 'distally displaced from' or 'proximal of', the meaning is, respectively, closer to the distal end than' or 'closer to the proximal end than'. The respective distal and proximal directions are shown in many of the figures, and in all relevant figures the convention of 'distal to the left' and 'proximal to the right' is maintained.

The terms "first" and "second" with respect to guidewires and respective portions of coupling devices are used throughout this disclosure and in the appended claims in accordance with the following convention: The "first guidewire" means the guidewire that a surgeon affixes to a coupling device according to embodiments, and then couples to a guidewire previously introduced in a lumen of a patient. Thus, the previously-introduced guidewire is referred to as the "second guidewire". Similarly, a 'first' tubular portion of the coupling device is for accommodating therein a portion of the first guidewire, and the 'second' tubular portion of the coupling device is for accommodating the passage therethrough of the second guidewire.

According to embodiments, a coupling device is provided for coupling a first guidewire to a second guidewire that has already been introduced to a lumen. A non-limiting example of a coupling device **50** is illustrated schematically in Fig. 1A. The coupling device of Fig. 1A includes first tubular section **15** for accommodating, through at least a proximal majority of a length of the first tubular section **15**, passage of a distal portion of the first guidewire **10** (e.g., any of the first guidewires **10** of Figs. 2A-15D), and a second tubular section **10** for accommodating therethrough slidable passage of a second guidewire **20** (e.g., any of the second guidewires **20** of Figs. 3-8 or 15A-15D). In embodiments, a coupling device is formed from a flexible or elastic material, such as a polymer or a metal (or metal alloy), or from a super-elastic material, such as a nitinol.

As discussed hereinabove, when the portion of the coupling device **50** meant to be slidable along the second guidewire **20** (the previously-introduced guidewire) is too short, it can be more difficult to slide the coupling device **50** without damaging the guidewire **20** or getting stuck. Accordingly, the second tubular section **25** is provided, according to embodiments, with both a minimum length and a minimum length-to-diameter ratio that in combination equip the coupling device **50** with an enhanced ability to traverse the second guidewire **20** safely and effectively. The second tubular section **25** has a length indicated in Fig. 1 by the arrow marked L_{25}, and an inner diameter marked ID_{25}. In embodiments, the length L_{25} is suitably at least 1 cm. In some embodiments, the length L_{25} is suitably at least 2 cm. In other embodiments, the length L_{25} is suitably at least 3 cm. In yet other embodiments, the length L_{25} is suitably at least 4 cm. In embodiments, the inner diameter ID_{25} is suitably at least 0.95 mm and no more than 2 mm. In some embodiments, the inner diameter ID_{25} is suitably at least 0.95 mm and no more than 3 mm. In some other embodiments, the inner diameter ID_{25} is suitably at least 0.5 mm and no more than 2 mm. In some other embodiments, the inner diameter ID_{25} is suitably at least 0.5 mm and no more than 1.5 mm. In yet other embodiments, the inner diameter ID_{25} is suitably at least 0.5 mm and no more than 3 mm. In still other embodiments, the inner diameter ID_{25} is suitably at least 0.2 mm and no more than 2 mm. In yet other embodiments, the inner diameter ID_{25} is suitably at least 0.2 mm and no more than 1 mm. In still other embodiments, the inner diameter ID_{25} is suitably at least 0.2 mm and no more than 3 mm. The ratio of the length L_{25} to the inner diameter ID_{25} is suitably between

100:1 and 5:1, or between 50:1 and 5:1, or between 30:1 and 5:1, or between 100:1 and 10:1, or between 50:1 and 10:1, or between 30:1 and 10:1, or between 100:1 and 30:1, or between 50:1 and 30:1, all ranges inclusive. In any of the embodiments, an inner diameter ID_{15} of the first tubular portion **15** (not shown) can be the same as the inner diameter ID_{25} of the first tubular portion **25**, or within ±0.1 mm, or within ±0.2 mm, or within ±0.3 mm, or within ±0.4 mm, or within ±0.5 mm, or within ±0.6 mm, or within ±0.7 mm, or within ±0.8 mm, or within ±0.9 mm, or within ±1.0 mm, or within ±1.1 mm, or within ±1.25 mm, or within ±1.5 mm of the inner diameter ID_{25} of the first tubular portion **25**.

As illustrated in Figs. 1A and 1B, the first and second tubular portions **15**, **25** are joined laterally to each other along respective longitudinal sections. In some examples of coupling devices **50**, the respective longitudinal may be less than fully overlapping, e.g., as illustrated in Figs. 7A-7B, or may not be continuous sections (and/or at least one of the first and second tubular portions **15**, **25** may not be continuous, as illustrated in Fig. 7C).

Fig. 1B shows exemplary cross-sectional views of a coupling device **50** according to various embodiments. In all of the examples, the lower-illustrated portion, as is shown in Fig 1B for coupling device $\mathbf{50_A}$, is the first tubular portion **15** and the upper portion is the second tubular portion **25**. Coupling device $\mathbf{50_A}$ is the *A-A* cross-sectional view of the coupling device **50** of Fig. 1A, and indicates that the respective first and second tubular portions **15**, **25** are cylinders (or, alternatively, conic sections) of equal diameters and laterally joined along respective tangential longitudinal sections in a fixed orientation to each other. In contrast, in coupling device $\mathbf{50_B}$, the second tubular portion **25** has a larger diameter than the first tubular portion **15**. In other examples (not shown), the second tubular portion **25** can have a smaller diameter than the first tubular portion **15**. Exemplary coupling device $\mathbf{50_C}$ illustrates a lateral joining of the first and second tubular portions **15**, **25** without the tubular portions **15**, **25** actually touching each other. Exemplary coupling device $\mathbf{50_D}$ illustrates a lateral joining of the first and second tubular portions **15**, **25** in which the contact between the tubular portions **15**, **25** is more than just tangential, in contrast to, e.g., coupling device $\mathbf{50_A}$. Exemplary coupling devices $\mathbf{50_E}$ and

50$_F$ are additional non-limiting examples of the broad range of possible cross-sections of coupling devices **50**, any of which are within the scope of this invention.

Reference is made to Figs. 2A and 2B. A distal portion of a first guidewire **10** resides within the lumen **11** of the first tubular portion **15** of a coupling device **50** according to embodiments. A distal portion of the first guidewire **10** enters the lumen **11** of the first tubular portion **15** through its proximal opening **17** but in the illustrated example does not exit the distal opening **18**. In some examples the distal tip of the first guidewire **15** can extend slightly past the distal opening **18**, e.g., by <1 mm, by <2mm, by <3mm, by <4mm or by <5mm. In some examples, the distal portion of the first guidewire **10** does not traverse the entire first tubular portion **15**, but only a proximal majority of the length of the first tubular portion **15**.

Fig. 3 illustrates a first use-case example of an apparatus **100**, in an assembled state such that the distal portion of the first guidewire **10** passes through at least a proximal majority of the first tubular section **15**. A second guidewire **20** passes through the lumen **21** of the second tubular section **25** in a straight path from the distal opening **28** to the proximal opening **27**. In actual use, the second guidewire **20** is substantially stationary as it has already been introduced to the lumen of a patient, and it is the second tubular portion **25** of the coupling device **50** that actively slides along the length of the second guidewire **25**. As the motion of the coupling device **50** is relative to the guidewire **20**, one can say, equivalently, that the second guidewire **20** passes slidably through the second tubular portion **25**. Respective longitudinal centerlines CL_{15}, CL_{25} of the first and second tubular portions **15**, **25** of the coupling device 50 are shown in Fig. 3. The two centerlines CL_{15}, CL_{25} are parallel to each other, indicating that the first and second guidewires **10**, **20** can be accommodated within the first and second tubular portions **15**, **25** in parallel paths.

In a second use-case example illustrated in Fig. 4, the first and second tubular portions have a conic-frustum shape, reversed relative to each other, such that the distal opening **28** of the second tubular section **25** is larger than the distal opening **18** of the first tubular section **15**, and the proximal opening **22** of the second tubular section **25** is smaller than the proximal opening **17** of the first tubular section **15**. Nonetheless, the

coupling device **50** of Fig. 4 has been arranged such that the two centerlines CL_{15}, CL_{25} are parallel to each other, as was the case in the example illustrated in Fig. 3.

In a third use-case example illustrated in Fig. 5A, the first and second tubular portions **15**, **25** have the same conic-frustum shape as the coupling device **50** of Fig. 4, but are not reversed as was the case in Fig. 4. The lateral joining of the two tubular portions **15**, **25** causes them to be arranged such that the two centerlines CL_{15}, CL_{25} are not parallel to each other. Instead, the two centerlines CL_{15}, CL_{25} are rotated relative to each other to be oriented with an angle θ between them. In some embodiments, $\theta \leq 5°$ in either direction, i.e., $\theta \leq \pm 5°$ such that the two centerlines CL_{15}, CL_{25}, if not parallel, are within ±5° of being parallel.

In a fourth use-case example illustrated in Fig. 5B, the first and second tubular portions **15**, **25** have a right-frustum shape, and are longer than the first and second tubular portions **15**, **25** of Fig. 5A . The lateral joining of the two tubular portions **15**, **25** along respective longitudinal sections causes them to be arranged such that the two centerlines CL_{15}, CL_{25} are not parallel to each other. Instead, the two centerlines CL_{15}, CL_{25} are rotated relative to each other to be oriented with an angle θ between them. In some embodiments, $\theta \leq 5°$ in either direction, i.e., $\theta \leq \pm 5°$ such that the two centerlines CL_{15}, CL_{25}, if not parallel, are within ±5° of being parallel. In some other embodiments, $\theta \leq 10°$ in either direction, i.e., $\theta \leq \pm 10°$ such that the two centerlines CL_{15}, CL_{25}, if not parallel, are within ±10° of being parallel.

In a fifth use-case example illustrated in Fig. 6, the freedom of the guidewires **10**, **20** to pass through the first and second tubular portions **15**, **25** is illustrated by showing a maximum rotation of the guidewires **10**, **20** relative to each other to be oriented with an angle φ between the respective centerlines CL_{10}, CL_{20} of the guidewires **10**, **20**. In some embodiments, $\varphi \leq 5°$ in either direction, i.e., $\varphi \leq \pm 5°$ such that the two centerlines CL_{10}, CL_{20}, if not parallel, are within ±5° of being parallel. In some other embodiments, $\varphi \leq 10°$ in either direction, i.e., $\varphi \leq \pm 10°$ such that the two centerlines CL_{10}, CL_{20}, if not parallel, are within ±10° of being parallel.

In each of the use-case examples illustrated in Figs. 3-6, the first and second tubular portions **15**, **25** of each example completely overlap with each other. In sixth and

seventh use-case examples, illustrated, respectively, in Figs. 7A and 7B, the first and second tubular portions **15**, **25** do not completely overlap along their entire respective lengths. In Fig. 7A, the lateral joining of the first and second tubular portions **15**, **25** is such that the distal end of the first tubular section **15** is displaced distally from the distal end of the second tubular section **25** by a distance D_1. In Fig. 7B, the lateral joining is such that the distal end of the second tubular section **25** is displaced distally from the distal end of the first tubular section **15** by a distance D_2. Non-zero values of D1 or D2 can be desirable, in some cases, to improve usability of the coupling device **50**, although they are not required in order to practice the embodiments. In embodiments, both D_1 and D_2 are limited to being less than or equal to 2 cm. In some embodiments, both D_1 and D_2 are limited to being less than or equal to 1 cm. In other embodiments, both D_1 and D_2 are limited to being less than or equal to 0.5 cm. The longitudinal overlap of the first and second tubular portions **15**, **25**, for example the longitudinal overlap $L_{OVERLAP}$ shown in Fig. 7B, can contribute to the usability and/or efficacy of the coupling device **50**. In embodiments, longitudinal overlap $L_{OVERLAP}$ is at least 1 cm in length. In some embodiments, longitudinal overlap $L_{OVERLAP}$ is at least 2 cm in length. In other embodiments, longitudinal overlap $L_{OVERLAP}$ is at least 3 cm in length. In still other embodiments, longitudinal overlap $L_{OVERLAP}$ is at least 4 cm in length.

The longitudinal overlap between the laterally joined first and second tubular portions **15**, **25** can be a sum of multiple overlapping longitudinal sections, as illustrated in an eighth use-case example illustrated in Fig. 7C. The first tubular portion **15** includes multiple sections which may or may not be connected to each other. Each section can form a corresponding longitudinal overlap $L_{OVERLAP}$ with the second tubular portion **25**, e.g., longitudinal overlap sections $L_{OVERLAP_1}$ and $L_{OVERLAP_2}$ of Fig. 7C. In embodiments, the sum of $L_{OVERLAP_1}$ and $L_{OVERLAP_2}$ is at least 1 cm. In some embodiments, the sum of $L_{OVERLAP_1}$ and $L_{OVERLAP_2}$ is at least 2 cm. In some embodiments, the sum of $L_{OVERLAP_1}$ and $L_{OVERLAP_2}$ is at least 3 cm. In other embodiments, the sum of $L_{OVERLAP_1}$ and $L_{OVERLAP_2}$ is at least 4 cm.

In a ninth use-case example illustrated in Fig. 8, the distal and/or proximal ends of the first and/or second tubular portions **15**, **25** can have a curved or beveled profile to

improve usability and efficacy. In other examples, the beveling can be only at the distal ends and/or can create smaller bevels and/or rounded edges of the distal ends.

Figs. 9, 10A and 10B illustrate some steps of a method for assembling an apparatus including a guidewire and a coupling device. Fig. 9 illustrates the method steps of (a) providing a first guidewire **10** and (b) providing a coupling device **50** comprising a first tubular portion **15**, and a second tubular portion **25** joined laterally in a fixed orientation to the first tubular portion **15** along the lengths of respective overlapping longitudinal sections marked $L_{OVERLAP}$ in Fig. 9. The coupling device **50** can be any of the coupling devices **50** disclosed herein, including coupling devices **50** discussed with respect to any one or more of Figs. 1A-8. As indicated by arrow *1000* in Figs. 9 and 10A, the method also includes the step of affixing the coupling device **50** to the distal portion of the guidewire **10** by inserting the distal end of the guidewire **10** into the first tubular portion **15** of the coupling device **50**, such that such that a longitudinal section of the first tubular portion **15** – at least a proximal majority of the first tubular section **15** – surrounds a distal portion of the guidewire **10**. Fig. 11A is a schematic end view showing the distal portion of the guidewire **10** surrounded by the first tubular portion **15**.

In some embodiments, as illustrated schematically in Fig. 10A, the affixing step includes the use of an assembly aid, and specifically an assembly material **63**. The assembly material **63** can include, for example, but not exhaustively: an adhesive; a mechanical element interposed between the distal portion of the guidewire **10** and the first tubular portion **15** such as, in a non-limiting example, a shim; and/or any other material effective to secure the guidewire **10** within the first tubular section **15**, including, in non-limiting examples, by adding heat or pressure when using the assembly material **63** in the affixing. Fig. 11B is a schematic end view showing the distal portion of the guidewire **10** surrounded by the first tubular portion **15** with the assembly material **63** intervening therebetween. In other examples, the assembly material **63** intervenes therebetween in a portion of the circumference of the guidewire **10** and/or first tubular section **15** but not around the entire circumference.

In some embodiments, as illustrated schematically in Fig. 10B, the affixing step includes the use of an assembly tool **67**. The assembly tool **67** can include, for example,

but not exhaustively: a crimping tool or jig, a heat-shrinking tool, a welding or brazing tool, or a heat-welding tool. In embodiments, the assembly took **67** applies at least one of heat and pressure to secure the distal portion of the guidewire **10** within the first tubular section **15**. Fig. 11C is a schematic end view showing the distal portion of the guidewire **10** surrounded by the first tubular portion **15**, where at least a portion of the first tubular portion **15** has been mechanically and/or thermally deformed, e.g., by heat and/or pressure, so as to secure the distal portion of the guidewire **10** within.

Reference is now made to Figs. 12A-12C, 13A-13B, and 14A-14B. According to embodiments, the apparatus and devices disclosed herein can be provided in kits that can optionally include one or more containers such as sterile bags or pouches.

Fig. 12A shows a first kit in an unpackaged state, the first kit including (a) a coupling device **50** in accordance with any of the embodiments disclosed herein, (b) a guidewire **10**, and, optionally, (c) an internally-sterile storage bag **90**.

Fig. 12B shows the first kit arranged with the coupling device **50** packaged in a first storage bag **90**, and the guidewire **10** packaged in a second storage bag **90**.

Fig. 12C shows the first kit arranged with the coupling device **50** and the guidewire **10** packaged together in a single storage bag **90**.

Fig. 13A shows a second kit in an unpackaged state, the second kit including (a) a coupling device **50** in accordance with any of the embodiments disclosed herein, (b) an assembly material **63**, and, optionally, (c) an internally-sterile storage bag **90**.

Fig. 13B shows a third kit, packaged together in a single storage bag **90**, the third kit including (a) a coupling device **50** in accordance with any of the embodiments disclosed herein, (b) an assembly material **63**, and a guidewire **10**.

Fig. 14A shows a fourth kit in an unpackaged state, the fourth kit including (a) a coupling device **50** in accordance with any of the embodiments disclosed herein, (b) an assembly tool **67**, and, optionally, (c) an internally-sterile storage bag **90**.

Fig. 14B shows a fourth kit, packaged together in a single storage bag **90**, the fourth kit including (a) a coupling device **50** in accordance with any of the embodiments disclosed herein, (b) an assembly tool **67**, and a guidewire **10**.

We now refer to Figs. 15A-15D, which illustrate a method for coupling a first guidewire to a previously introduced second guidewire during a medical procedure.

In a first method step, an apparatus **100** comprising a coupling device **50** in accordance with any of the embodiments disclosed herein and a first guidewire **10** are provided. Assembly of the apparatus **100** can suitably be accomplished by using the method disclosed hereinabove in connection with the discussion of Figs. 9-11C. The coupling device **50** comprises first and second tubular portions **15**, **25** joined laterally in a fixed orientation to each other along the lengths of respective overlapping longitudinal sections. The lateral joining is such that respective longitudinal centerlines of the first and second tubular portions **15**, **25** are parallel to each other or within ±10° of parallel in said fixed orientation. The coupling device **50** is affixed to the distal portion of the first guidewire **10** such that a longitudinal section of the first tubular portion **15** surrounds the distal portion of the first guidewire **15**. Fig. 15A shows a surgeon **5** holding a proximal portion of a 'second' guidewire **20** previously introduced in a lumen of patient **2**. The surgeon **5** also holds the provided apparatus **100** comprising, and a 'first' guidewire **10**.

A second method step is illustrated in Fig. 15B, wherein the surgeon **5** slidably passes an end of the second guidewire **20** through the second tubular portion **25** of the coupling device **50** in a straight-line path between respective proximal and distal openings **27**, **28** of the second tubular section **25**. The straight-line path has a length-to-diameter ratio of at least 10:1.

Figs. 15C and 15D illustrate additional, optional method steps. In Fig. 15C, the surgeon **5** is shown sliding the coupling device **50** distally along the second guidewire **20** in preparation for inserting the first guidewire **10** into the lumen or vessel of the patient **2**. Fig. 15D shows the surgeon **5** holding both respective proximal ends of the guidewires **10**, **20**, both of which have been introduced into the lumen or vessel of the patient **2**, the 'first' guidewire **10** introduced using the coupling device **50** and the associated methods disclosed in the embodiments.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and sub-combinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

CLAIMS

1. Apparatus comprising:

    a. a first guidewire for use in a medical procedure; and

    b. a coupling device comprising:

        i. a first tubular portion formed to accommodate, through at least a proximal majority of a length thereof, passage of a distal portion of the first guidewire, and

        ii. a second tubular portion formed to accommodate slidable passage therethrough of a second guidewire in a straight-line path between respective proximal and distal openings of the second tubular section, the straight-line path having a length-to-diameter ratio of at least 10:1,

        the first and second tubular sections being joined laterally in a fixed orientation to each other along the lengths of respective overlapping longitudinal sections, the lateral joining being such that respective longitudinal centerlines of the first and second tubular portions are parallel to each other or within ±10° of parallel in said fixed orientation.

2. The apparatus of claim 1, wherein the lateral joining is such that the respective longitudinal centerlines are parallel to each other or within ±5° of parallel, in said fixed orientation.

3. The apparatus of either one of claims 1 or 2, wherein the lateral joining is such that a distance between respective distal ends of the first and second tubular sections is less than 2 cm.

4. The apparatus of either one of claims 1 or 2, wherein the lateral joining is such that a distance between respective distal ends of the first and second tubular sections is less than 1 cm.

5. The apparatus of either one of claims 1 or 2, wherein the lateral joining is such that a distance between respective distal ends of the first and second tubular sections is less than 0.5 cm.

6. The apparatus of any one of claims 1 to 5, wherein the respective overlapping longitudinal sections have a length of at least 1 cm.

7. The apparatus of any one of claims 1 to 5, wherein the respective overlapping longitudinal sections have a length of at least 2 cm.

8. The apparatus of any one of claims 1 to 5, wherein the respective overlapping longitudinal sections have a length of at least 3 cm.

9. The apparatus of any one of claims 1 to 5, wherein the respective overlapping longitudinal sections have a length of at least 4 cm.

10. The apparatus of any one of claims 1 to 9, wherein the length of the second tubular portion is at least 1 cm.

11. The apparatus of any one of claims 1 to 9, wherein the length of the second tubular portion is at least 2 cm.

12. The apparatus of any one of claims 1 to 9, wherein the length of the second tubular portion is at least 3 cm.

13. The apparatus of any one of claims 1 to 9, wherein the length of the second tubular portion is at least 4 cm.

14. The apparatus of any one of claims 1 to 13, in an assembled state in which the coupling device is affixed to the distal portion of the first guidewire such that a longitudinal section of the first tubular portion surrounds the distal portion of the first guidewire.

15. The apparatus of claim 14, wherein at least part of the longitudinal section of the first tubular portion that surrounds the distal portion of the first guidewire is mechanically and/or thermally deformed as a result of an affixing process.

16. The apparatus of either one of claims 14 or 15, additionally comprising an assembly material used in an affixing process.

17. Apparatus provided as a kit, comprising:

a. a coupling device for use in a medical procedure, the coupling device comprising:

i. a first tubular portion formed to accommodate, through at least a proximal majority of a length thereof, passage of a distal portion of a first guidewire, and

ii. a second tubular portion formed to accommodate slidable passage therethrough of a second guidewire in a straight-line path between respective proximal and distal openings of the second tubular section, the straight-line path having a length-to-diameter ratio of at least 10:1,

the first and second tubular sections being joined laterally in a fixed orientation to each other along the lengths of respective overlapping longitudinal sections such that respective longitudinal centerlines of the first and second tubular portions are parallel to each other or within ±10° of parallel; and

b. an assembly aid for affixing the coupling device to a distal portion of the first guidewire, the assembly aid selected from the group of assembly aids consisting of assembly materials and assembly tools.

18. The apparatus of claim 17, wherein the respective longitudinal centerlines are parallel to each other or within ±5° of parallel

19. The apparatus of either one of claims 17 or 18, additionally comprising the first guidewire.

20. The apparatus of claim 19, in an assembled state in which the coupling device is affixed to the distal portion of the first guidewire such that a longitudinal section of the first tubular portion surrounds the distal portion of the first guidewire.

21. The apparatus of claim 20, wherein the assembly aid comprises an assembly material, and the apparatus in the assembled state comprises at least a portion of the assembly material.

22. The apparatus of either one of claims 20 or 21, wherein the assembly aid comprises an assembly tool, and at least part of the longitudinal section of the first tubular portion that surrounds the distal portion of the first guidewire is mechanically and/or thermally deformed by use of the assembly tool in an affixing process.

23. A method of coupling a first guidewire to a previously introduced second guidewire during a medical procedure, the method comprising:

a. affixing a coupling device to a distal portion of the first guidewire, the coupling device comprising two first tubular portions joined laterally in a fixed orientation to each other along the lengths of respective overlapping longitudinal sections, the lateral joining being such that respective longitudinal centerlines of the first and second tubular portions are parallel to each other or within ±10° of parallel in said fixed orientation, the affixing being such that that a longitudinal section of a first tubular portion of the coupling device surrounds a distal portion of the first guidewire; and

b. slidably passing an end of the second guidewire through a second tubular portion of the coupling device in a straight-line path between respective proximal and distal openings of the second tubular section, the straight-line path having a length-to-diameter ratio of at least 10:1.

24. The method of claim 23, wherein the respective longitudinal centerlines are parallel to each other or within ±5° of parallel in said fixed orientation.

25. The method of either one of claims 23 or 24, wherein the lateral joining is such that a distance between respective distal ends of the first and second tubular sections is less than 2 cm.

26. The method of either one of claims 23 or 24, wherein the lateral joining is such that a distance between respective distal ends of the first and second tubular sections is less than 1 cm.

27. The method of either one of claims 23 or 24, wherein the lateral joining is such that a distance between respective distal ends of the first and second tubular sections is less than 0.5 cm.

28. The method of any one of claims 23 to 27, wherein the respective overlapping longitudinal sections of each of the first and second tubular portions have a length of at least 1 cm.

29. The method of any one of claims 23 to 27, wherein the respective overlapping longitudinal sections of each of the first and second tubular portions have a length of at least 2 cm.

30. The method of any one of claims 23 to 27, wherein the respective overlapping longitudinal sections of each of the first and second tubular portions have a length of at least 3 cm.

31. The method of any one of claims 23 to 27, wherein the respective overlapping longitudinal sections of each of the first and second tubular portions have a length of at least 4 cm.

32. The method of any one of claims 23 to 31, wherein the length of the second tubular portion is at least 1 cm.

33. The method of any one of claims 23 to 31, wherein the length of the second tubular portion is at least 2 cm.

34. The method of any one of claims 23 to 31, wherein the length of the second tubular portion is at least 3 cm.

35. The method of any one of claims 23 to 31, wherein the length of the second tubular portion is at least 4 cm.

36. The method of any one of claims 23 to 35, wherein a maximum internal diameter of the second tubular portion is not greater than 2 mm, or not greater than 1 mm.

37. The method of any one of claims 23 to 36, wherein the affixing includes mechanically and/or thermally deforming at least part of the longitudinal section of the first tubular portion that surrounds the distal portion of the first guidewire using an assembly tool.

38. The method of any one of claims 23 to 37, wherein the affixing includes using an assembly material.

39. A method of coupling a first guidewire to a previously introduced second guidewire during a medical procedure, the method comprising:

a. providing an assembly comprising a first guidewire for use in a medical procedure, and a coupling device comprising first and second tubular portions joined laterally in a fixed orientation to each other along the lengths of respective overlapping longitudinal sections, the lateral joining being such that respective longitudinal centerlines of the first and second tubular portions are parallel to each other or within ±10° of parallel in said fixed orientation, the coupling device being affixed to the distal portion of the first guidewire such that a longitudinal section of the first tubular portion surrounds the distal portion of the first guidewire, and

b. slidably passing an end of the second guidewire through a second tubular portion of the coupling device in a straight-line path between respective proximal and distal openings of the second tubular section, the straight-line path having a length-to-diameter ratio of at least 10:1.

40. The method of claim 39, wherein the respective longitudinal centerlines are parallel to each other or within ±5° of parallel in said fixed orientation.

41. The method of either one of claims 39 or 40, wherein the lateral joining is such that a distance between respective distal ends of the first and second tubular sections is less than 2 cm.

42. The method of either one of claims 39 or 40, wherein the lateral joining is such that a distance between respective distal ends of the first and second tubular sections is less than 1 cm.

43. The method of either one of claims 39 or 40, wherein the lateral joining is such that a distance between respective distal ends of the first and second tubular sections is less than 0.5 cm.

44. The method of any one of claims 39 to 43, wherein the respective overlapping longitudinal sections of each of the first and second tubular portions have a length of at least 1 cm.

45. The method of any one of claims 39 to 43, wherein the respective overlapping longitudinal sections of each of the first and second tubular portions have a length of at least 2 cm.

46. The method of any one of claims 39 to 43, wherein the respective overlapping longitudinal sections of each of the first and second tubular portions have a length of at least 3 cm.

47. The method of any one of claims 39 to 43, wherein the respective overlapping longitudinal sections of each of the first and second tubular portions have a length of at least 4 cm.

48. The method of any one of claims 39 to 47, wherein the length of the second tubular portion is at least 1 cm.

49. The method of any one of claims 39 to 47, wherein the length of the second tubular portion is at least 2 cm.

50. The method of any one of claims 39 to 47, wherein the length of the second tubular portion is at least 3 cm.

51. The method of any one of claims 39 to 47, wherein the length of the second tubular portion is at least 4 cm.

52. The method of any one of claims 39 to 51, wherein a maximum internal diameter of the second tubular portion is not greater than 2 mm, or not greater than 1 mm.

53. The method of any one of claims 39 to 52, wherein at least part of the longitudinal section of the first tubular portion that surrounds the distal portion of the first guidewire is mechanically and/or thermally deformed as a result of an affixing process.

54. The apparatus of either one of claims 52 or 53, additionally comprising an assembly material used in an affixing process.

55. A method of assembling an apparatus, comprising:

a. providing a guidewire;

b. providing a coupling device comprising a first tubular portion, and a second tubular portion joined laterally in a fixed orientation to the first tubular portion along the lengths of respective overlapping longitudinal sections; and

c. affixing the coupling device to the distal portion of the guidewire, such that that a longitudinal section of a first tubular portion of the coupling device surrounds a distal portion of the guidewire,

wherein the second tubular portion is formed to accommodate slidable passage therethrough of a different guidewire in a straight-line path between respective proximal and distal openings of the second tubular section, the straight-line path having a length-to-diameter ratio of at least 10:1.

56. The method of claim 55, wherein the affixing includes mechanically and/or thermally deforming at least part of the longitudinal section of the first tubular portion that surrounds the distal portion of the first guidewire using an assembly tool.

57. The method of either one of claims 55 or 56, wherein the affixing includes using an assembly material.

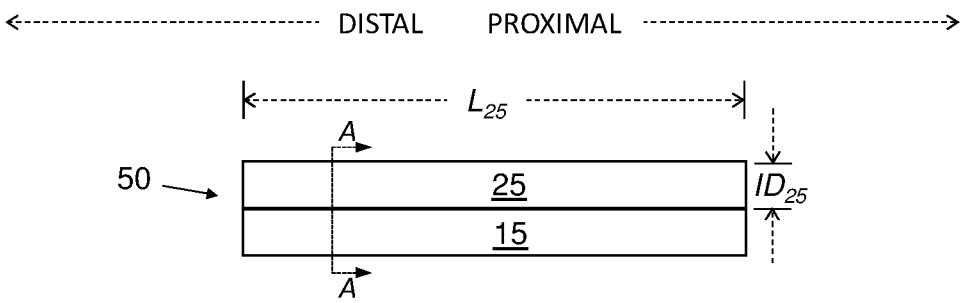
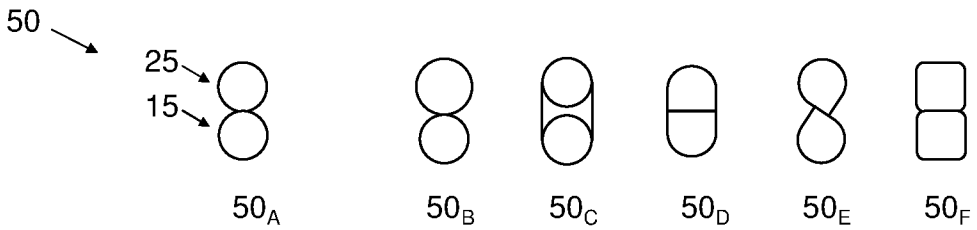


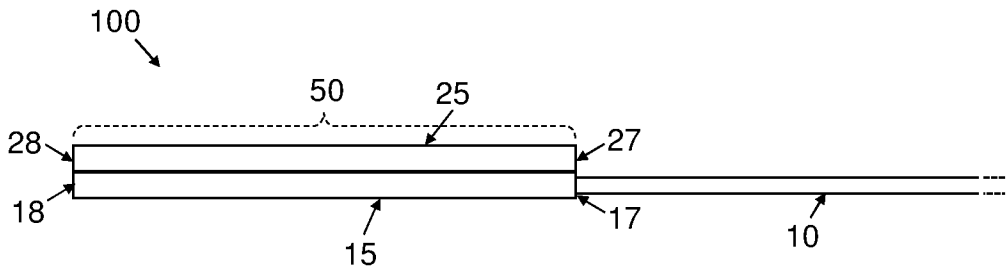
FIG. 1A



CROSS-SECTION A-A FROM FIG. 1A

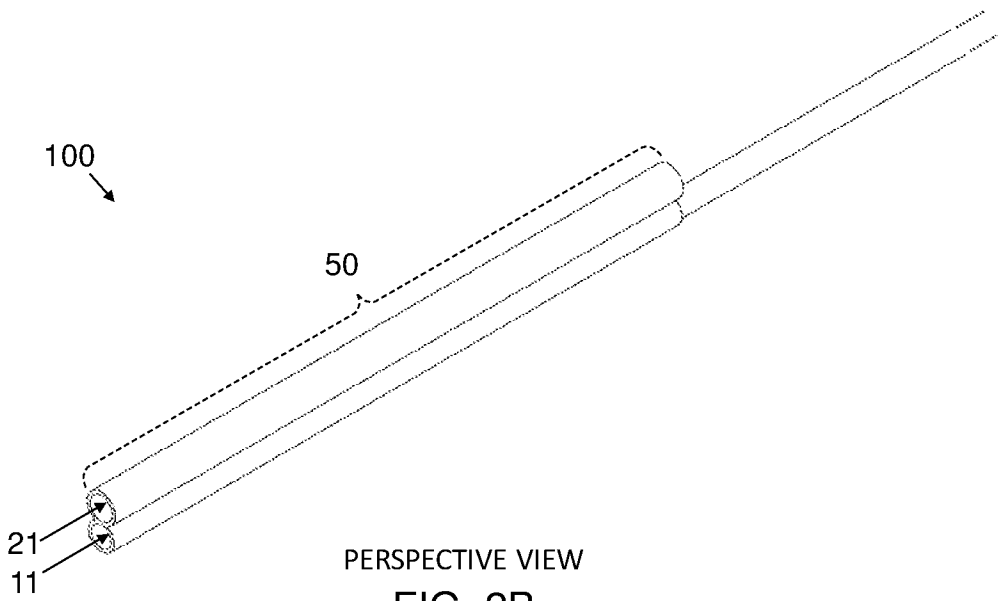
OTHER EXAMPLES OF CROSS-SECTIONS

FIG. 1B



SIDE VIEW

FIG. 2A



PERSPECTIVE VIEW

FIG. 2B

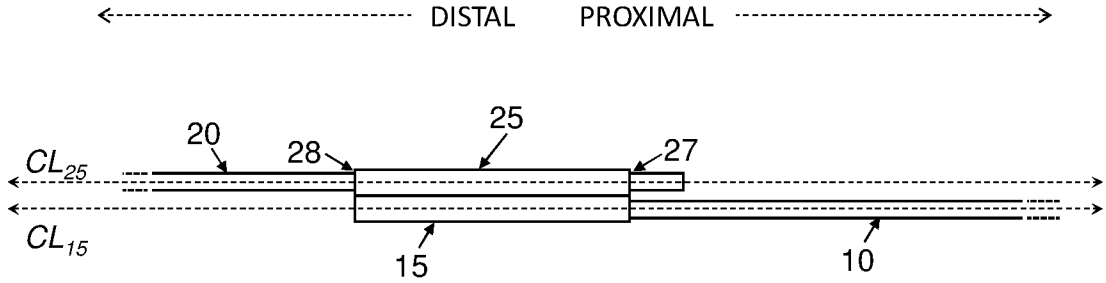


FIG. 3

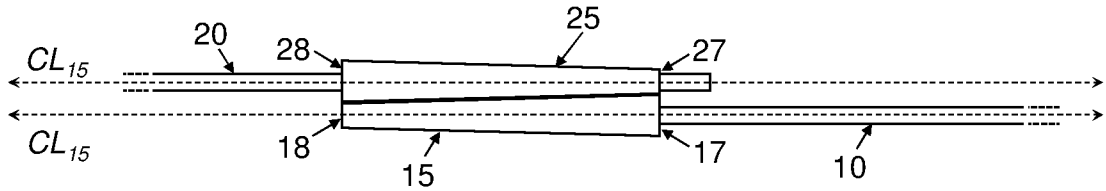


FIG. 4

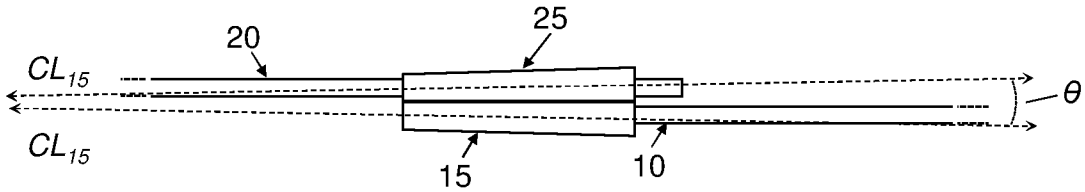


FIG. 5A

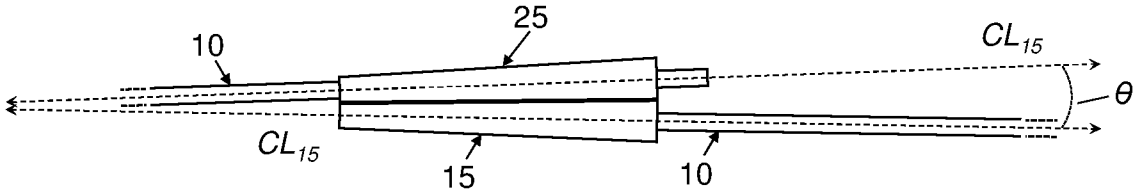


FIG. 5B

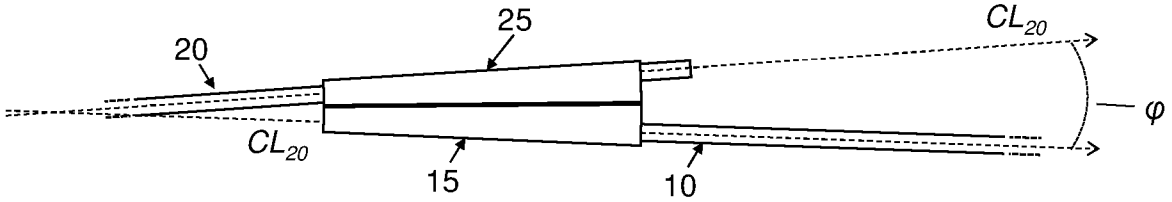


FIG. 6

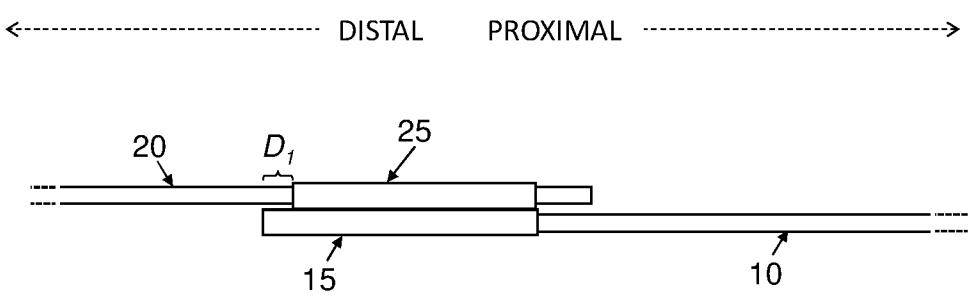


FIG. 7A

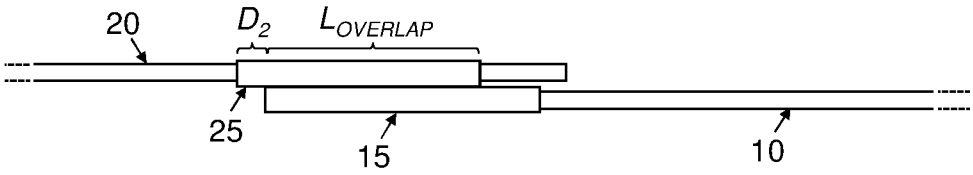


FIG. 7B

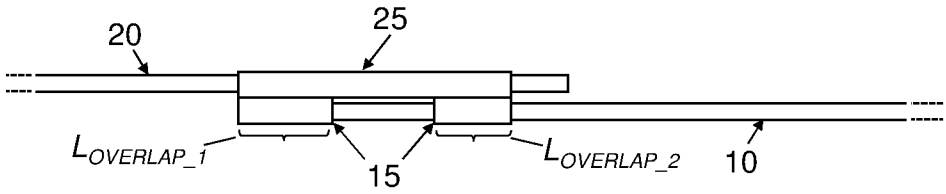


FIG. 7C

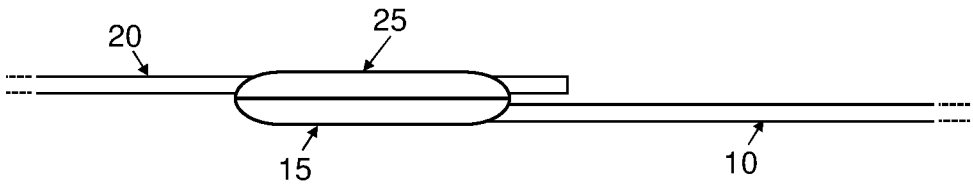


FIG. 8

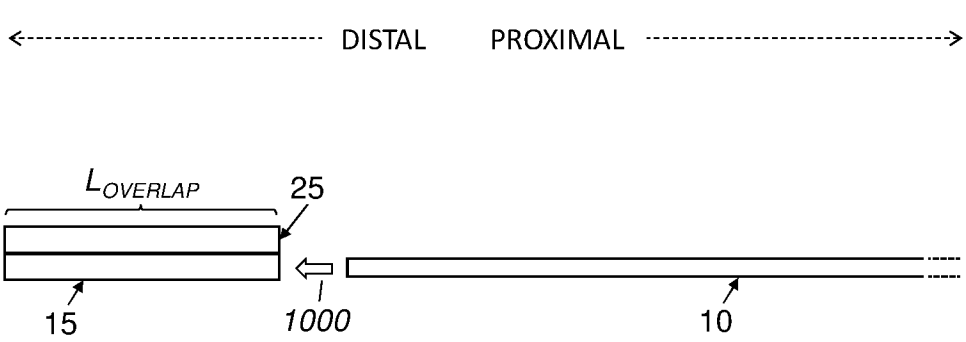


FIG. 9

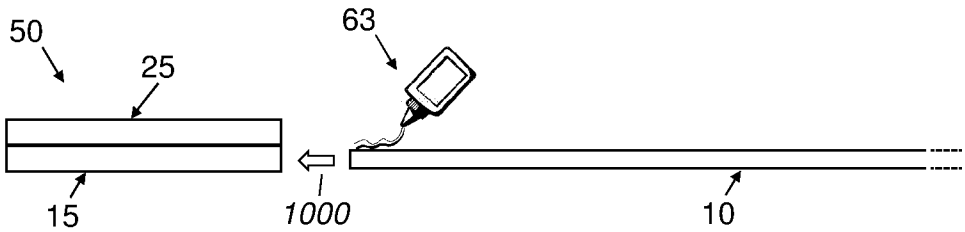


FIG. 10A

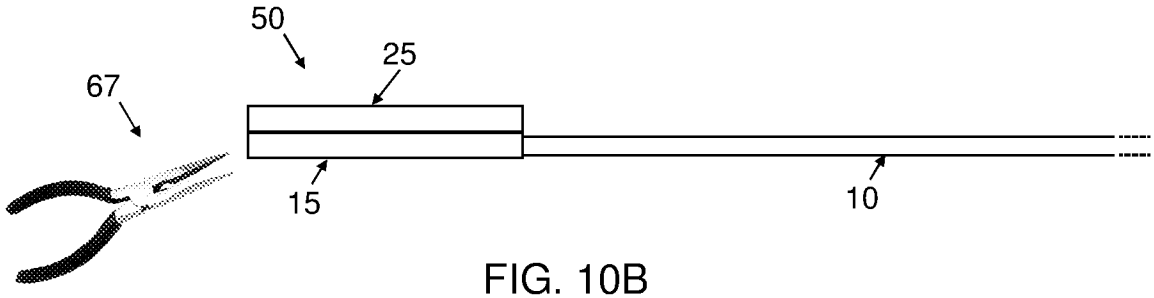


FIG. 10B

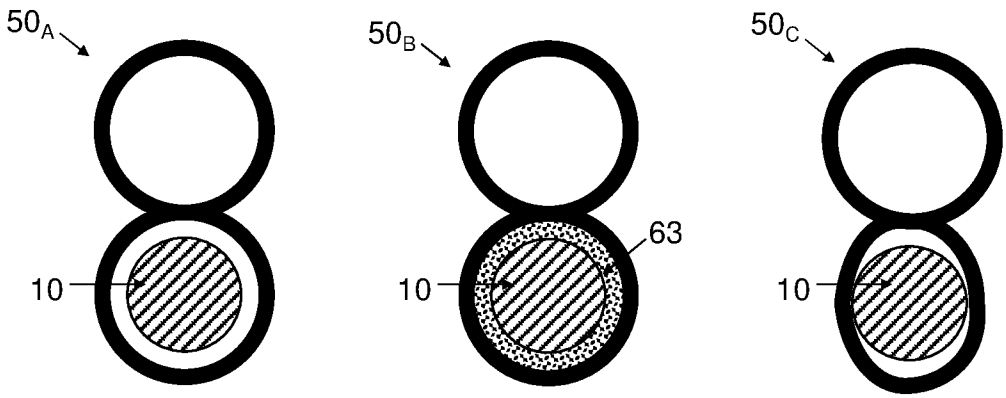


FIG. 11A FIG. 11B FIG. 11C

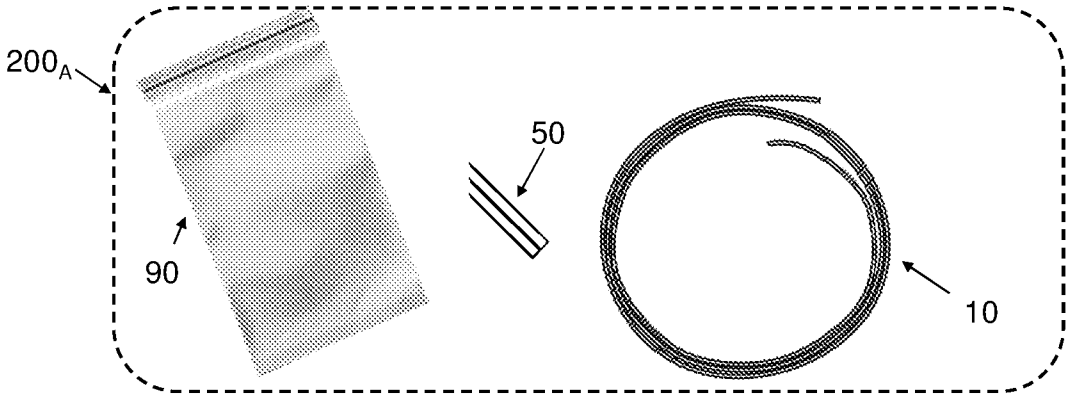


FIG. 12A

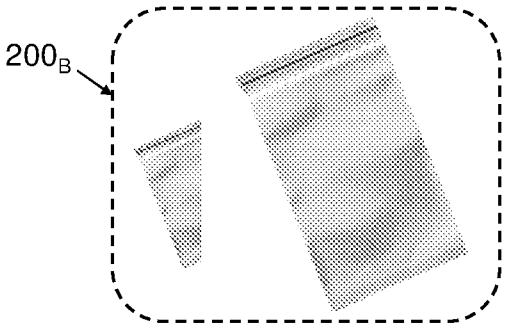


FIG. 12B

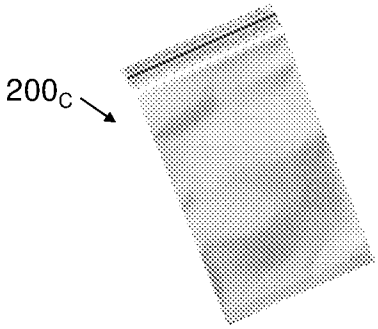


FIG. 12C

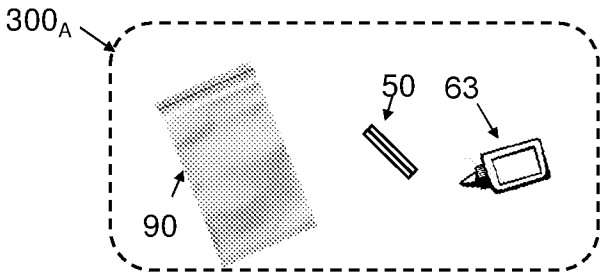


FIG. 13A

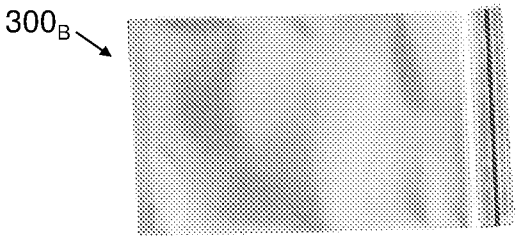


FIG. 13B

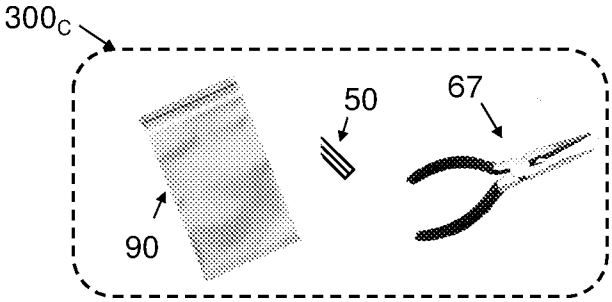


FIG. 14A

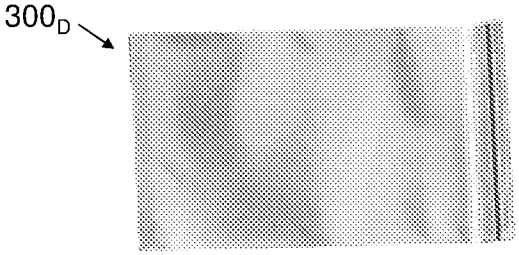


FIG. 14B

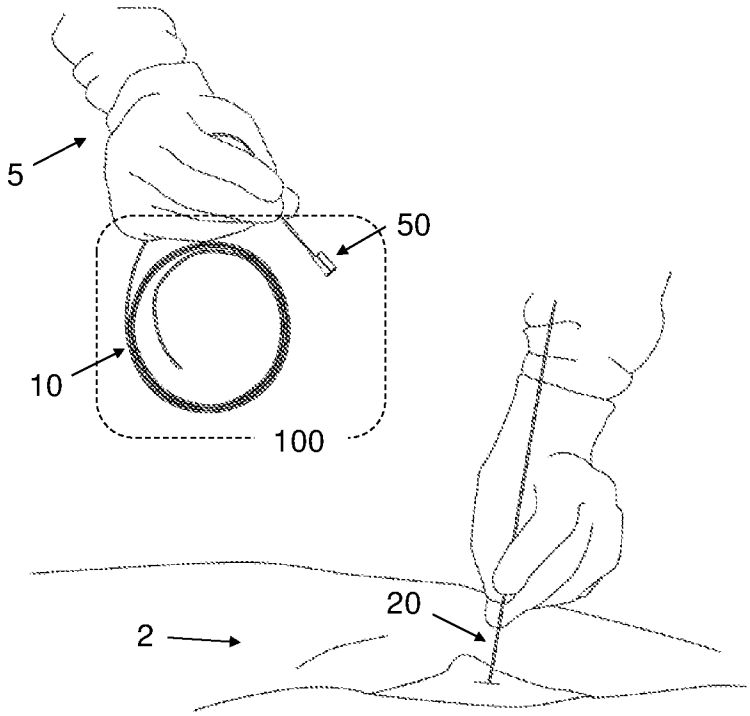


FIG. 15A

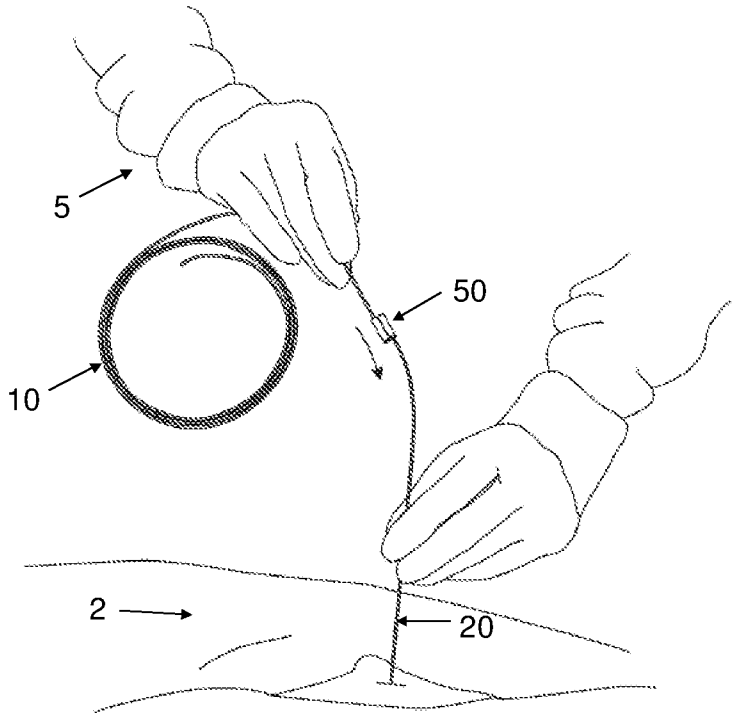


FIG. 15B

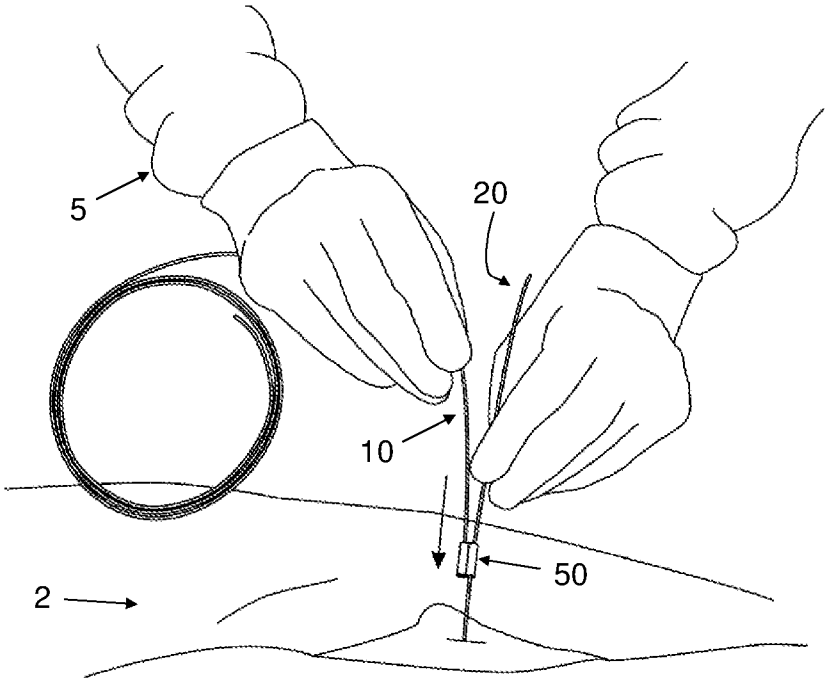


FIG. 15C

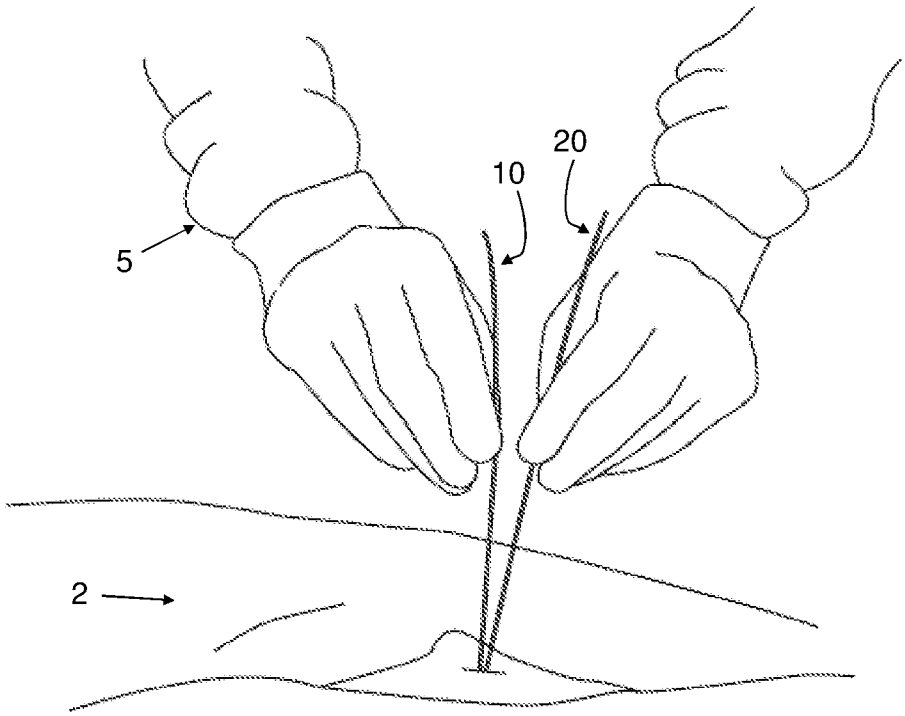


FIG. 15D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2022/051535

A. CLASSIFICATION OF SUBJECT MATTER

A61M 25/01(2022.01)i; ***A61M 25/09***(2022.01)i; ***A61M 25/00***(2022.01)i
CPC:A61M 25/01; A61M 25/09; A61M 25/09041; A61M 2025/0034; A61M 25/0043

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 25/01; A61M 25/09; A61M 25/00
CPC:A61M 25/01; A61M 25/09; A61M 25/09041; A61M 2025/0034; A61M 25/0043

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)

Databases consulted: Esp@cenet, Google Patents, Orbit, Similari (AI-based)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 2006259009 A1 (MEDTRONIC VASCULAR INC) 16 November 2006 (2006-11-16)	
X	The entire document	1,2,14-57
Y		3-13
	US 2007250001 A1 (HILAIRE PIERRE et al.) 25 October 2007 (2007-10-25)	
X	The entire document	1
Y		3-13
	JP 2007236633 A (KANEKA CORP et al.) 20 September 2007 (2007-09-20)	
A	The entire document	1-57

☐ Further documents are listed in the continuation of Box C. ☑ 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
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"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
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"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
14 June 2022	**16 June 2022**

Name and mailing address of the ISA/IL

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Authorized officer

BERGIG Keren

Telephone No.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IB2022/051535

Patent document cited in search report	Publication date (day/month/year)	Patent family member(s)	Publication date (day/month/year)
US 2006259009 A1	16 November 2006	US 2006259009 A1	16 November 2006
		EP 1885428 A2	13 February 2008
		JP 2008539954 A	20 November 2008
		WO 2006124353 A2	23 November 2006
		WO 2006124353 A3	29 March 2007
US 2007250001 A1	25 October 2007	US 2007250001 A1	25 October 2007
		EP 1789126 A2	30 May 2007
		EP 1789126 A4	12 March 2008
		WO 2005112798 A2	01 December 2005
		WO 2005112798 A3	14 December 2006
JP 2007236633 A	20 September 2007	JP 2007236633 A	20 September 2007
		JP 4785567 B2	05 October 2011