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(54) **JOINING DISSIMILAR METALS FOR GUIDEWIRE APPLICATIONS**

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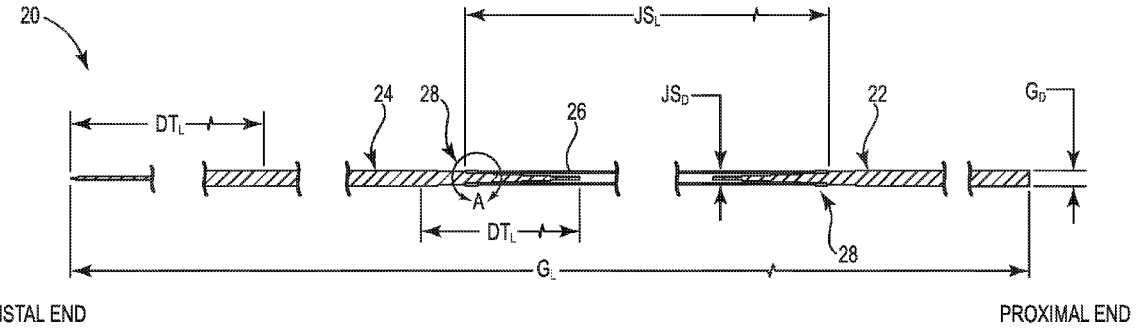
(57) **ABSTRACT**

One aspect is a medical guidewire having a first wire section of a first material and a second wire section having a second material different from the first material. A joining section is adjacent both the first and second wire sections, and the joining section has a feature configured hold the first wire section to the second wire section.



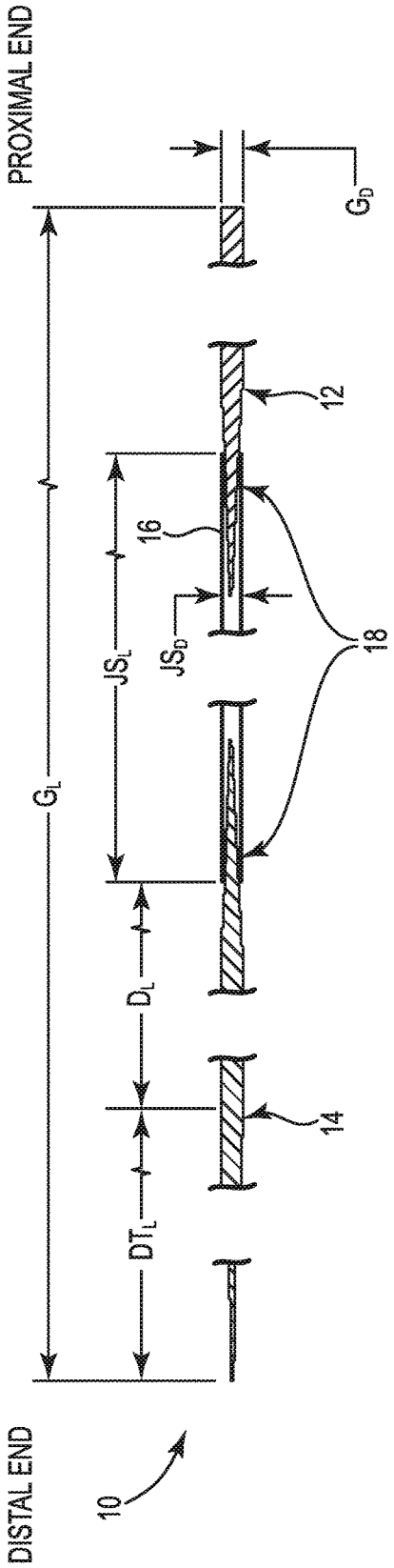


Fig. 1

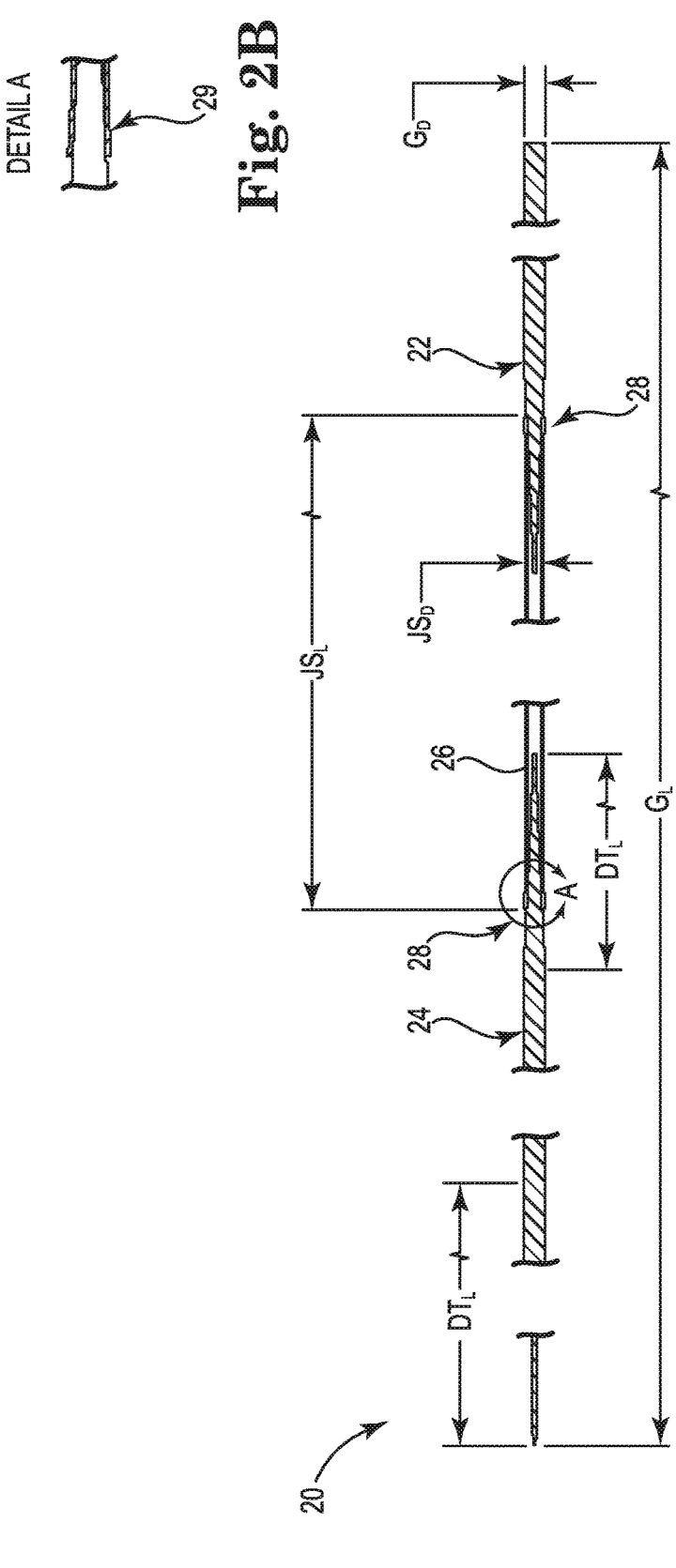

DETAIL A
29
G_D
PROXIMAL END
22
28
JS_D
JS_L
26
DT_L
G_L
A
28
24
DT_L
20
DISTAL END

Fig. 2B

Fig. 2A

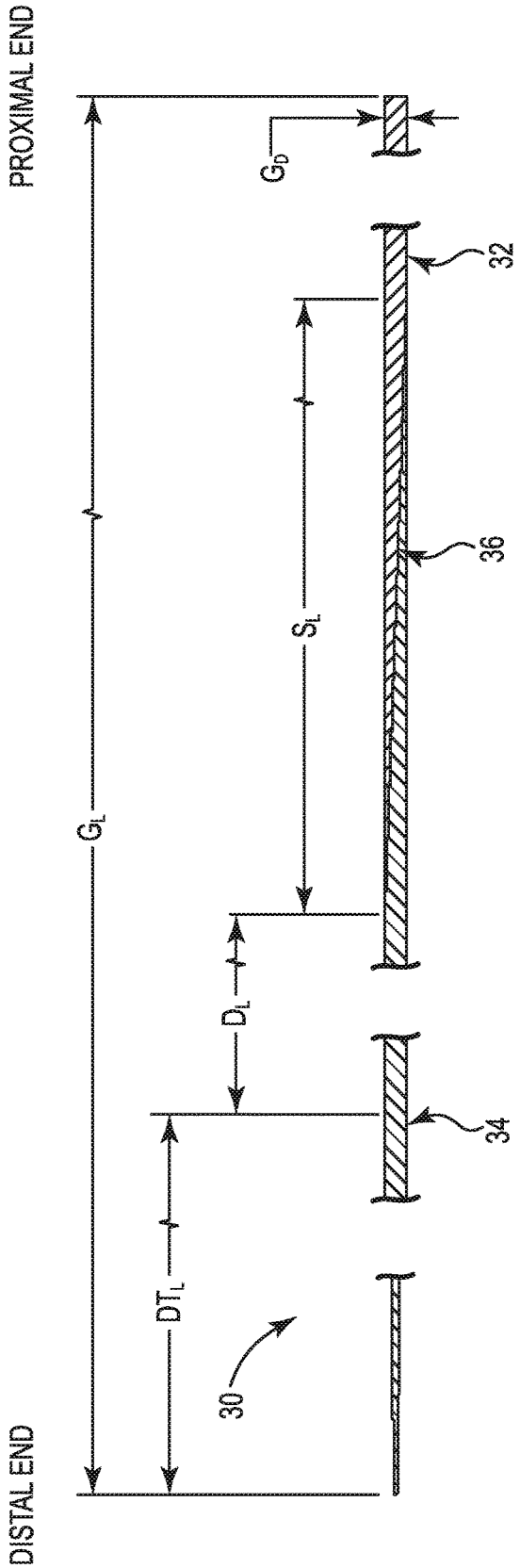


Fig. 3

JOINING DISSIMILAR METALS FOR GUIDEWIRE APPLICATIONS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This Non-Provisional Patent Application claims the benefit of the filing date of U.S. Provisional Patent Application Ser. No. 62/644,085, filed Mar. 16, 2018, ENTITLED "JOINING DISSIMILAR METALS FOR GUIDEWIRE APPLICATIONS," which is incorporated herein by reference.

TECHNICAL FIELD

[0002] One aspect relates to joined dissimilar materials. In one embodiment, the joined materials form a guide wire configured for intravascular use.

BACKGROUND

[0003] Intravascular guidewires are used in conjunction with intravascular devices such as catheters to facilitate navigation through the vasculature of a patient. Such guidewires are typically very small in diameter. In some applications, a guidewire can have multiple sections that are joined together in order to form a single wire. Joining sections of such a wire having a small diameter can be challenging, particularly where the sections being joined are configured of different materials. Because there are limitations to many present approaches, there is a need for the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] FIG. **1** illustrates a sectional view of joined dissimilar materials in accordance with one embodiment.

[0005] FIG. **2**A illustrates a sectional view of joined dissimilar materials in accordance with one embodiment.

[0006] FIG. **2**B illustrates an enlarged view of the section from FIG. **2**A in accordance with one embodiment.

[0007] FIG. **3** illustrates a sectional view of joined dissimilar materials in accordance with one embodiment.

DETAILED DESCRIPTION

[0008] In the following Detailed Description, reference is made to the accompanying drawings, which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. In this regard, directional terminology, such as "top," "bottom," "front," "back," "leading," "trailing," etc., is used with reference to the orientation of the Figure(s) being described. Because components of embodiments of the present invention can be positioned in a number of different orientations, the directional terminology is used for purposes of illustration and is in no way limiting. It is to be understood that other embodiments may be utilized and structural or logical changes may be made without departing from the scope of the present invention. The following detailed description, therefore, is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

[0009] FIG. **1** illustrates a guidewire **10** in accordance with one embodiment. In one embodiment, guidewire **10** has a proximal section **12**, a distal section **14** and a joining section **16**. In one case, proximal, distal and joining sections **12** and **14** are each configured of separate wire segments that are joined together at joining section **16**. In some embodiments, proximal and distal sections **12** and **14** are adapted with differing diameter regions, are adapted and configured to obtain a transition in stiffness, and provide a desired flexibility characteristic. In FIG. **1**, guidewire **10** is illustrated with a truncation in its ends, as its length may vary in accordance with particular applications.

[0010] As used herein, the proximal section **12** and the distal section **14** can generically refer to any two adjacent wire sections along any portion of guidewire **10**. Furthermore, although discussed with specific reference to guidewires, the wire segments can be applicable to almost any intravascular device. For example, they are applicable to hypotube shafts for drive shafts for intravascular rotational devices (atherectomy catheters, IVUS catheters, etc.). Such devices may be useful in clinical applications including, but not limited to, interventional oncology, electrophysiology, peripheral, cardiac, urology, neurology, and gastroenterology.

[0011] In one embodiment, proximal section **12** is configured of a relatively stiff material, such as stainless steel wire, CoCr alloy or other stiff alloy. In one embodiment, proximal section **12** has a material selected to be relatively stiff for pushability and torqueability.

[0012] In some embodiments, distal section **14** is configured of a relatively flexible material, such as a super elastic or linear elastic alloy, wire, such as linear elastic nickel-titanium (NiTi), nickel-titanium alloy, nickel-chromium alloy, nickel-chromium-iron alloy, nickel-titanium-cobalt alloy, or other suitable material, or alternatively, a polymer material, such as a high performance polymer. In one embodiment, the material used to configure distal section **14** can be selected to be relatively flexible for trackability and kink resistance.

[0013] In one embodiment, proximal section **12** and the distal section **14** are separate pieces that are joined together with joining section **16**. In one embodiment, joining section **16** is a hypotube configured to receive proximal section **12** and the distal section **14** at each of its ends to forms joints **18**. In one embodiment, proximal section **12** has a taper at its distal end that is configured to fit into joining section **16** at joint **18**. Similarly, distal section **14** has a taper at its proximal end that is configured to fit into joining section **16** at joint **18**.

[0014] In one embodiment, an adhesive, such as UV Cure, heat cure, Cyanoacrylate, etc., is placed in or adjacent joining section **16** before proximal section **12** and distal section **14** are inserted in order to secure them at joints **18**. In one embodiment, proximal section **12** and distal section **14** are secured in joining section **16** with solder, weld or other similar securing method(s). In one embodiment, joining section **16** is a Nitinol alloy hypotube. In other embodiments, similar alloy materials, or materials that are relatively compatible with the materials used for proximal section **12** and distal section **14** can be used for joining section **16**.

[0015] In various embodiments, the adjoining tapered sections of proximal section **12** and distal section **14** may or may not meet or overlap each other within joining section **16**. In one embodiment, average results for tensile-to-fail testing for 0.014 guidewires ranges from 6.9 to 9.1 lbf, depending upon configuration.

[0016] In one embodiment, guidewire **10** is configured for intravascular use and can be used in conjunction with intravascular devices such as catheters to facilitate naviga-

tion through the vasculature of a patient. Guidewire **10** can embody a range of dimensions that are considered as appropriate for various embodiments. In one embodiment, its outer diameter G_D ranges from about 0.005 to about 0.04 inches. Guidewire **10** is configured in a variety of lengths, and in one embodiment, its overall length G_L ranges from about 6.0 to about 140.0 inches. In one embodiment, the length of the distal taper DT_L on distal section **14** ranges from 0.5 to 12.0 inches. In one embodiment, outside the distal taper, the distal length D_L of the distal section **14** is from 0.25 to 20.0 inches. In one embodiment, the length JS_L of joining section **16** is from 0.5 to 4.0 inches, while the diameter JS_D of joining section **16** is from 0.005 to 0.04 inches.

[0017] FIG. **2**A illustrates a guidewire **20** in accordance with one embodiment. In one embodiment, guidewire **20** has a proximal section **22**, a distal section **24** and a joining section **26**. In one case, proximal, distal and joining sections **22** and **24** are each configured of separate wire segments that are joined together at joining section **26**. In some embodiments, proximal and distal sections **22** and **24** are adapted with differing diameter regions, are adapted and configured to obtain a transition in stiffness, and provide a desired flexibility characteristic. In FIG. **2**A, guidewire **20** is illustrated with a truncation in its ends, as its length may vary in accordance with particular applications.

[0018] As used herein, the proximal section **22** and the distal section **24** can generically refer to any two adjacent wire sections along any portion of guidewire **20**. Furthermore, although discussed with specific reference to guidewires, the wire segments can be applicable to almost any intravascular device. For example, they are applicable to hypotube shafts for drive shafts for intravascular rotational devices (atherectomy catheters, IVUS catheters, etc.). Such devices may be useful in clinical applications including, but not limited to, interventional oncology, electrophysiology, peripheral, cardiac, urology, neurology, and gastroenterology.

[0019] In one embodiment, proximal section **22** is configured of a relatively stiff material, such as stainless steel wire, CoCr alloy or other stiff alloy. In one embodiment, proximal section **22** has a material selected to be relatively stiff for pushability and torqueability.

[0020] In some embodiments, distal section **24** is configured of a relatively flexible material, such as a super elastic or linear elastic alloy, wire, such as linear elastic nickel-titanium (NiTi), nickel-titanium alloy, nickel-chromium alloy, nickel-chromium-iron alloy, nickel-titanium-cobalt alloy, or other suitable material, or alternatively, a polymer material, such as a high performance polymer. In one embodiment, the material used to configure distal section **24** can be selected to be relatively flexible for trackability.

[0021] In one embodiment, proximal section **22** and the distal section **24** are separate pieces that are joined together with joining section **26**. In one embodiment, joining section **26** is a hypotube configured to receive proximal section **22** and the distal section **24** at each of its ends to forms joints **28**. In one embodiment, proximal section **22** has a taper at its distal end that is configured to fit into joining section **26** at joint **28**. Similarly, distal section **24** has a taper at its proximal end that is configured to fit into joining section **26** at joint **28**.

[0022] In one embodiment, proximal section **22** and distal section **24** are coupled with joining section **26** via a cold press process, whereby joining section **26** is forcibly assembled to the two other sections. In one embodiment, before proximal section **22** and distal section **24** are inserted, joining section **26** is thermally cooled below 32° F., followed by the immediate, forceful insertion of proximal and distal sections **22**, **24** into the joining section **26**, such that a flaring deformation occurs on both ends of joining section **26**. Next, all the joined sections are warmed to room temperature, or about 70° F., at which point the joining section **26** attempts to return to its pre-formed configuration, thereby creating a compressive force on the proximal and distal sections **22**, **24**.

[0023] FIG. **2**B, illustrates further detail of detail area A in FIG. **2**A, illustrating a flare **29** in joining section **26** at joint **28** that results from the cold press process. This compressive force holds the components such that the assembly resists disassociation when acted upon by opposing tensile forces along the longitudinal axis.

[0024] In various embodiments, the adjoining tapered sections of proximal section **22** and distal section **24** may or may not meet or overlap each other within joining section **26**. In one embodiment, average results for tensile-to-fail testing for 0.018 inch guidewires incorporating this type of connection is 3.1 lbf. In one embodiment, joining section **26** is a Nitinol alloy hypotube. In other embodiments, similar alloy materials can be used for joining section **26**.

[0025] In one embodiment, guidewire **20** is configured for intravascular use and can be used in conjunction with intravascular devices such as catheters to facilitate navigation through the vasculature of a patient. Guidewire **20** can embody a range of dimensions that are considered as appropriate for various embodiments. In one embodiment, its outer diameter G_D ranges from about 0.005 to about 0.04 inches. Guidewire **20** is configured in a variety of lengths, and in one embodiment, its overall length G_L ranges from about 6.0 to about 140.0 inches. In one embodiment, the length of the distal taper DT_L on distal section **24** ranges from 0.5 to 12.0 inches. In one embodiment, outside the distal taper, the distal length D_L of the distal section **24** is from 0.25 to 20.0 inches. In one embodiment, the length JS_L of joining section **26** is from 0.5 to 4.0 inches, while the diameter JS_D of joining section **26** is from 0.005 to 0.04 inches. In one embodiment, the length DT_L of the distal taper of the distal section **24** extending into joining section **26**, is from 0.25 to 1.5 inches.

[0026] FIG. **3** illustrates a guidewire **30** in accordance with one embodiment. In one embodiment, guidewire **30** has a proximal section **32**, a distal section **34** and a joining section **36**. In one case, proximal, distal and joining sections **32** and **34** are each configured of separate wire segments that are joined together at joining section **36**. In some embodiments, proximal and distal sections **32** and **34** are adapted with differing diameter regions, are adapted and configured to obtain a transition in stiffness, and provide a desired flexibility characteristic. In FIG. **3**, guidewire **30** is illustrated with a truncation in its ends, as its length may vary in accordance with particular applications.

[0027] As used herein, the proximal section **32** and the distal section **34** can generically refer to any two adjacent wire sections along any portion of guidewire **30**. Furthermore, although discussed with specific reference to guidewires, the wire segments can be applicable to almost any intravascular device. For example, they are applicable to hypotube shafts for drive shafts for intravascular rotational

devices (atherectomy catheters, IVUS catheters, etc.). Such devices may be useful in clinical applications including, but not limited to, interventional oncology, electrophysiology, peripheral, cardiac, urology, neurology, and gastroenterology.

[0028] In one embodiment, proximal section **32** is configured of a relatively stiff material, such as stainless steel wire, CoCr alloy or other stiff alloy. In one embodiment, proximal section **32** has a material selected to be relatively stiff for pushability and torqueability.

[0029] In some embodiments, distal section **34** is configured of a relatively flexible material, such as a super elastic or linear elastic alloy, wire, such as linear elastic nickel-titanium (NiTi), nickel-titanium alloy, nickel-chromium alloy, nickel-chromium-iron alloy, nickel-titanium-cobalt alloy, or other suitable material, or alternatively, a polymer material, such as a high performance polymer. In one embodiment, the material used to configure distal section **34** can be selected to be relatively flexible for trackability.

[0030] In one embodiment, proximal section **32** and the distal section **34** are separate pieces that are joined together at joining section **36**. In one embodiment, proximal section **32** has a flat grind taper at its distal end, while distal section **34** has a flat grind taper at its proximal end that is complementary or a mirror image of the flat grind on proximal section **32**. As such, joining section **36** "scarf joint" with the two tapered portions joined together. In one embodiment, the two surfaces of the taper joint have a diagonally cut or ground mating surface. In one embodiment, the tapers are configured such that, when joined at joining section **36**, the outer diameter of guidewire **30** is constant from both sides of joining section **36**, as well as throughout joining section **36**. In one embodiment, the taper joint at joining section **36** is a flat diagonal line, while in other embodiments, it has a curved or parabolic shape. In various embodiments, the tapers can be achieved by grinding, machining, stamping, etc., and result in a configuration that, when joined to the mating component, results in an approximate restoration of the original component diameter.

[0031] In one embodiment, the tapered portions of proximal section **32** and distal section **34** are coupled at joining section **36** using a variety of methods. The mating surfaces can be secured together using solder, adhesive (UV Cure, heat cure, Cyanoacrylate, etc.), welding, etc., such that a secure, flexible bond is created between the two mating components. Following the assembly, the resulting assembly may be further ground, machined, etc. to create a smooth outer diameter, covered (with a polymer, heat shrink, coil, braid or other component) to further secure the joint and/or modify the assembly handling characteristics. Average results for tensile-to-fail testing for 0.014 guidewires with this type of connection is 7.3 lbf. FIG. **3** also includes a range of dimensions that could be considered as appropriate for the given features in some embodiments.

[0032] In one embodiment, guidewire **30** is configured for intravascular use and can be used in conjunction with intravascular devices such as catheters to facilitate navigation through the vasculature of a patient. Guidewire **30** can embody a range of dimensions that are considered as appropriate for various embodiments. In one embodiment, its outer diameter G_D ranges from about 0.005 to about 0.04 inches. Guidewire **30** is configured in a variety of lengths, and in one embodiment, its overall length G_L ranges from about 6.0 to about 140.0 inches. In one embodiment, the length of the distal taper DT_L on distal section **34** ranges from 0.5 to 12.0 inches. In one embodiment, outside the distal taper, the distal length D_L of the distal section **34** is from 0.25 to 20.0 inches. In one embodiment, the length JS_L of joining section **36** is from 0.25 to 1.5 inches.

[0033] With any of the above-described embodiments, dissimilar metals are joined together for use in guidewire applications. In many embodiments, the joining of a proximal component of relatively high stiffness (stainless steel, cobalt chromium, etc.) with a distal section that is relatively more flexible and resists kinking, manufactured from a material with superelastic properties (Nitinol, NiTiCo, etc.), provides useful characteristics for many guidewire applications.

[0034] With any of the above-described embodiments, one or more coils may be added to the distal end of the distal sections, which can be tapered at the distal end to receive such coil(s). Furthermore, any of the above-described embodiments can partially or fully be covered by a polymer jacket. Also, portions of any of the guidewires that have superelastic properties, e.g., Nitinol, NiTiCo, etc., can be annealed or semi-annealed, so that those portions can have a bend or kink introduced, which may be favorable feature in some applications.

[0035] The described joining structures and methods can be employed mid-shaft on a guidewire, more proximally or more distally as dictated by the specific requirements of the applications. Additionally, the connections may occur on a portion of the guidewire that has a shaft diameter that is reduced from the primary shaft diameter (e.g., a step-down portion of the distal tip) or on a tapered section of the guidewire.

[0036] Although specific examples have been illustrated and described herein, a variety of alternate and/or equivalent implementations may be substituted for the specific examples shown and described without departing from the scope of the present disclosure. This application is intended to cover any adaptations or variations of the specific examples discussed herein. Therefore, it is intended that this disclosure be limited only by the claims and the equivalents thereof.

1. A medical guidewire comprising:
- a first wire section comprising a first material;
- a second wire section comprising a second material different from the first material; and
- a joining section adjacent both the first and second wire sections, the joining section comprising a feature configured hold the first wire section to the second wire section.

2. The medical guidewire of claim **1**, wherein the feature comprises a joint between the first and second wire sections that extends diagonally relative to the first and second sections.

3. The medical guidewire of claim **1**, wherein the feature comprises a hypotube with a first and a second end, the hypotube receiving the first wire section at the first end and the second wire section at the second end, thereby securing them together.

4. The medical guidewire of claim **3**, wherein the portion of the first and second wire sections received in the hypotube have a taper or a radial taper.

5. The medical guidewire of claim **4**, wherein the tapered portions of the first and second wire sections overlap with the hypotube.

6. The medical guidewire of claim **1**, wherein the first material comprises one of stainless steel, nickel-chromium alloy, nickel-chromium-iron alloy, and cobalt alloy and wherein the second material comprises nickel-titanium alloy.

7. The medical guidewire of claim **3**, wherein the hypotube comprises nickel-titanium alloy.

8. The medical guidewire of claim **1**, wherein the first and second wire sections are further secured together with solder, adhesive, welding, or with adhesive, such as UV cure, heat cure, or cyanoacrylate.

9. The medical guidewire of claim **1**, wherein the joining section is a hypotube that has been cold pressed on to the first and second wire sections.

10. The medical guidewire of claim **2**, wherein the joint between the first and second wire sections is diagonal or parabolic in shape.

11. The medical guidewire of claim **1**, wherein the outer diameter of the guidewire is between 0.005 and about 0.04 inches.

12. A method of forming a wire comprising:
providing a first wire section comprising a first material;
providing a second wire section comprising a second material different from the first material;
cooling a joining section that comprises a superelastic material;
inserting the first and second wire sections into the joining section;
allowing the joining section to warm such that it compresses on to both the first and second wire section thereby joining them together.

13. The method of claim **12**, wherein the first material comprising one of stainless steel, nickel-chromium alloy, nickel-chromium-iron alloy, and cobalt alloy and wherein the second material comprising nickel-titanium.

14. The method of claim **12**, wherein cooling the joining section comprises cooling to a temperature below 32° F., and wherein allowing the joining section to warm comprises warming to room temperature.

15. The method of claim **12**, wherein the joining section comprises a Nitinol alloy.

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