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(54) **COMPOSITE GUIDEWIRE WITH A LINEAR ELASTIC DISTAL PORTION**

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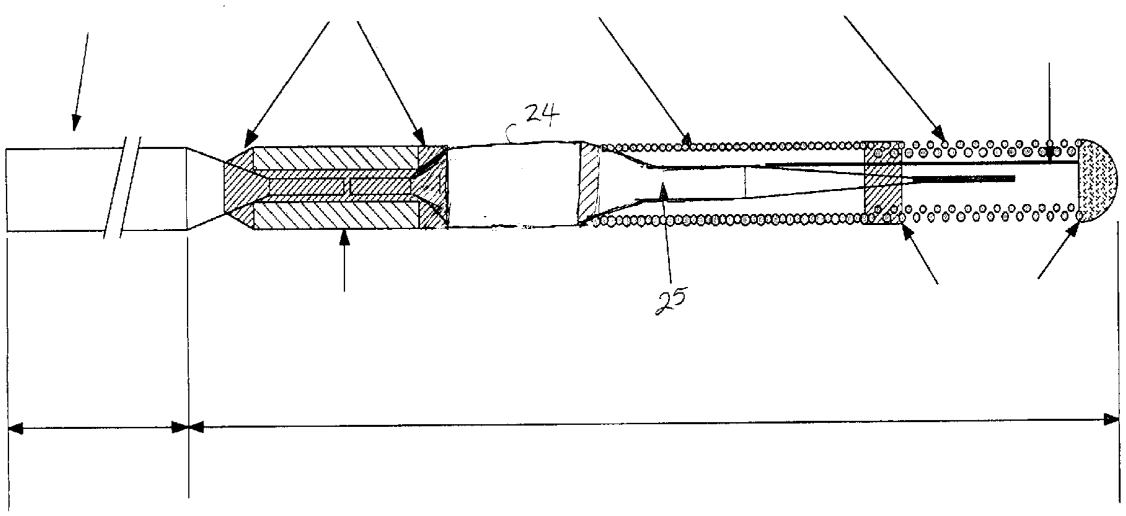
(57) **ABSTRACT**

A composite guidewire includes a central core that is made out of a "linear elastic" material, which at body temperature does not exhibit a yield point and/or change phase when subjected to the range of stresses that are common to guidewires. A core extension, which is made out of stiffer material, such as stainless steel, attaches to the central core through a coupling tube, which may be made of super elastic material, linear elastic material, or stainless steel. The coupling tube fits over a tapered distal end of the core extension and a proximal end of the central core that may but need not be tapered. The proximal end of the coupling tube abuts the tapered section of the core extension where the section has an outer diameter that is approximately the same size as the inner diameter of the coupling tube, and the tube is thus held against axial movement. The space between the inner diameter of the coupling tube and the ends that fit within the tube are filled with an adhesive, to create a strong yet flexible joint that transmits considerable torque without failure. An elongated coil, which may be radiopaque, fits over the distal portion of the central core. The coil may attach at a proximal end to the distal end of the coupling tube by, for example, adhesive, brazing or welding, such that the coil and the coupling tube provide support for the linear elastic core along the entire length of the core. The coil may instead extend over the coupling tube, such that the coil attaches to the distal end of the core extension. A shaping ribbon which is made of bendable material, such as, for example, stainless steel, is attached to a distal portion of the central core and extends beyond the end of the core, to provide a shapeable distal end to the guidewire. An atraumatic tip fits over the end of the guidewire and attaches to the coil and the shaping ribbon by brazing, welding or adhesive, to provide a cushioned end to the guidewire. As appropriate, a relatively short radiopaque outer coil may be positioned over the elongated coil, to provide visibility to the distal end of the guidewire.



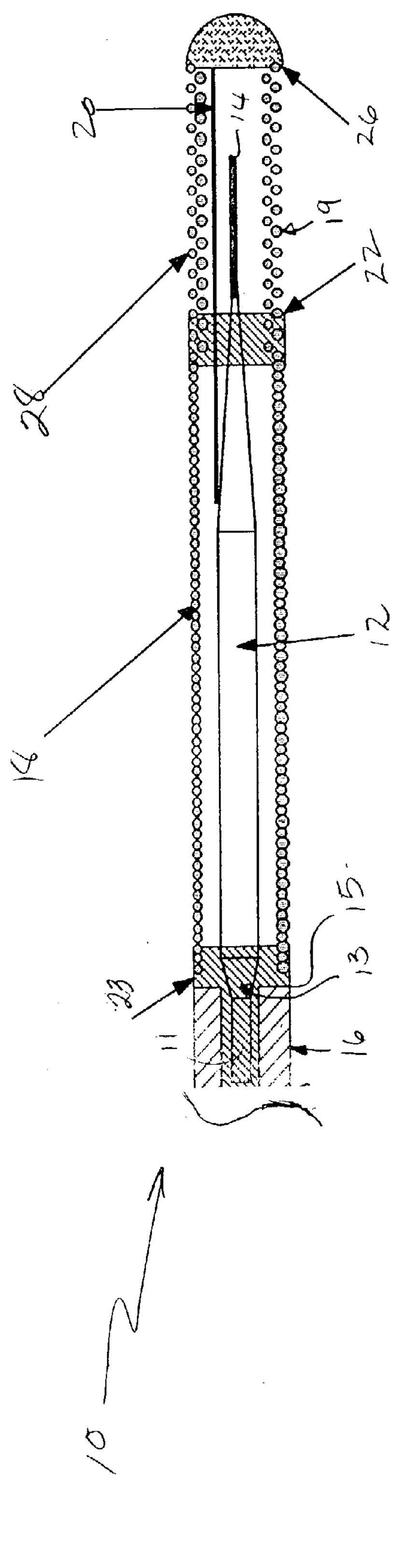


FIG. 1

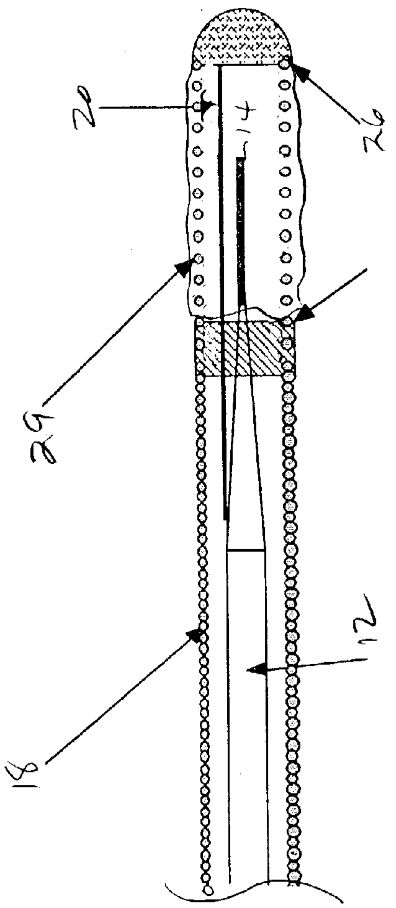


FIG. 2

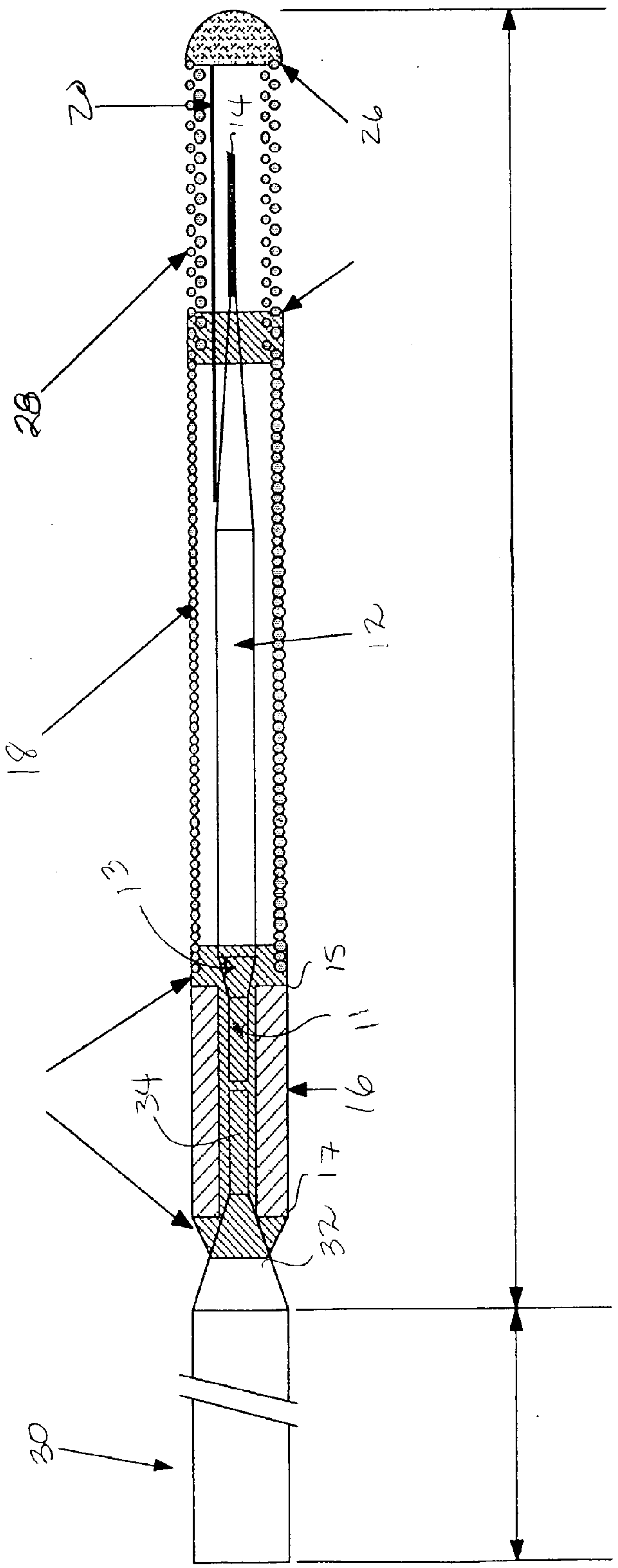


FIG. 3

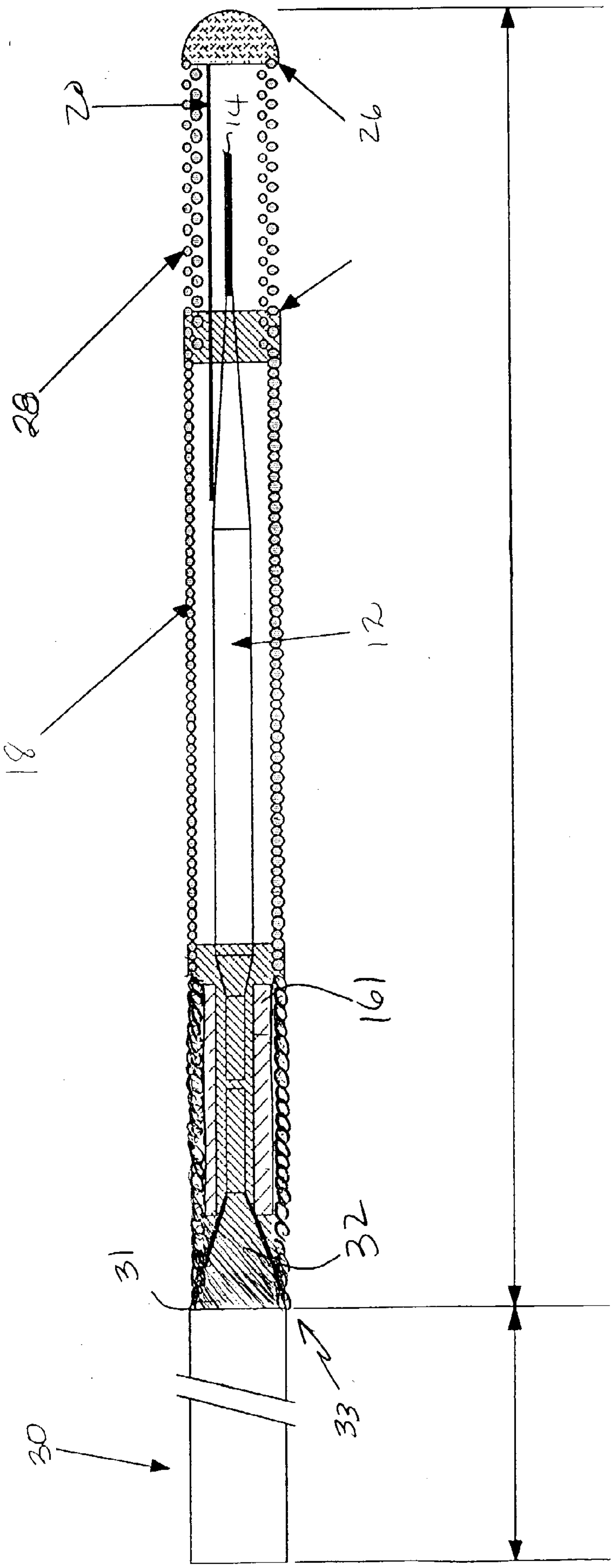


FIG. 4

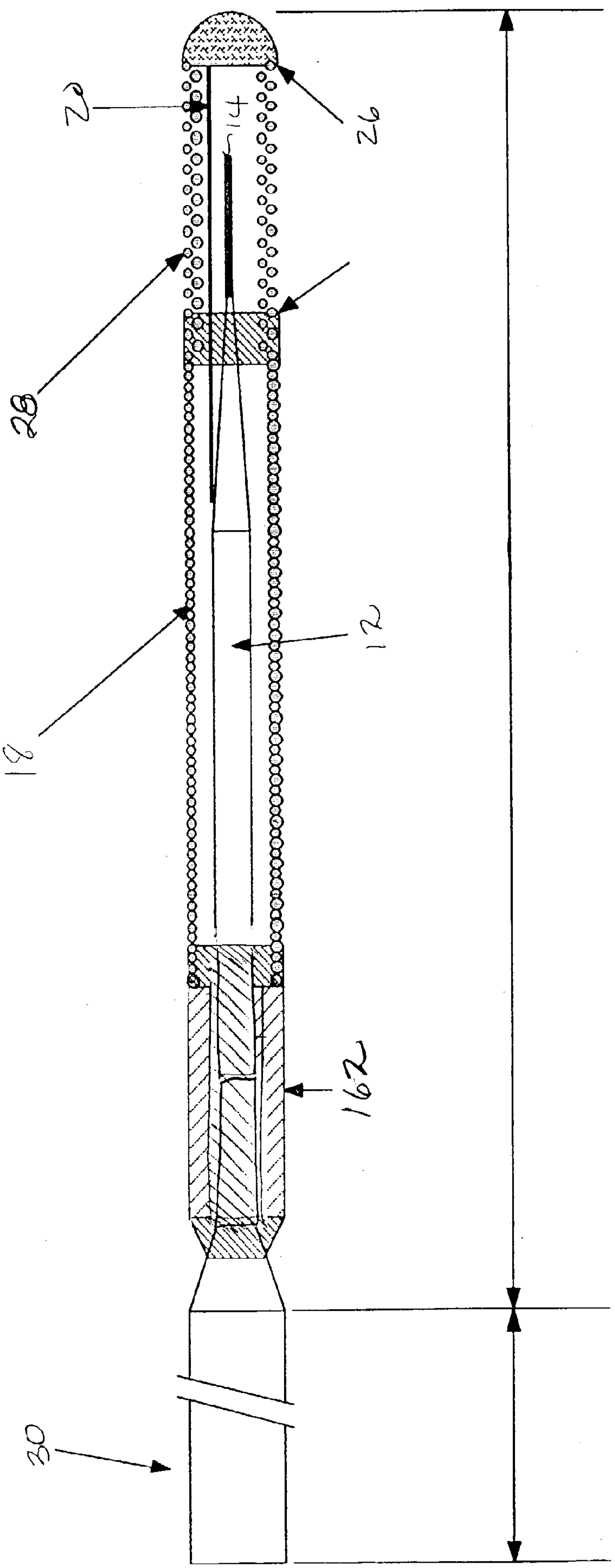


FIG. 5

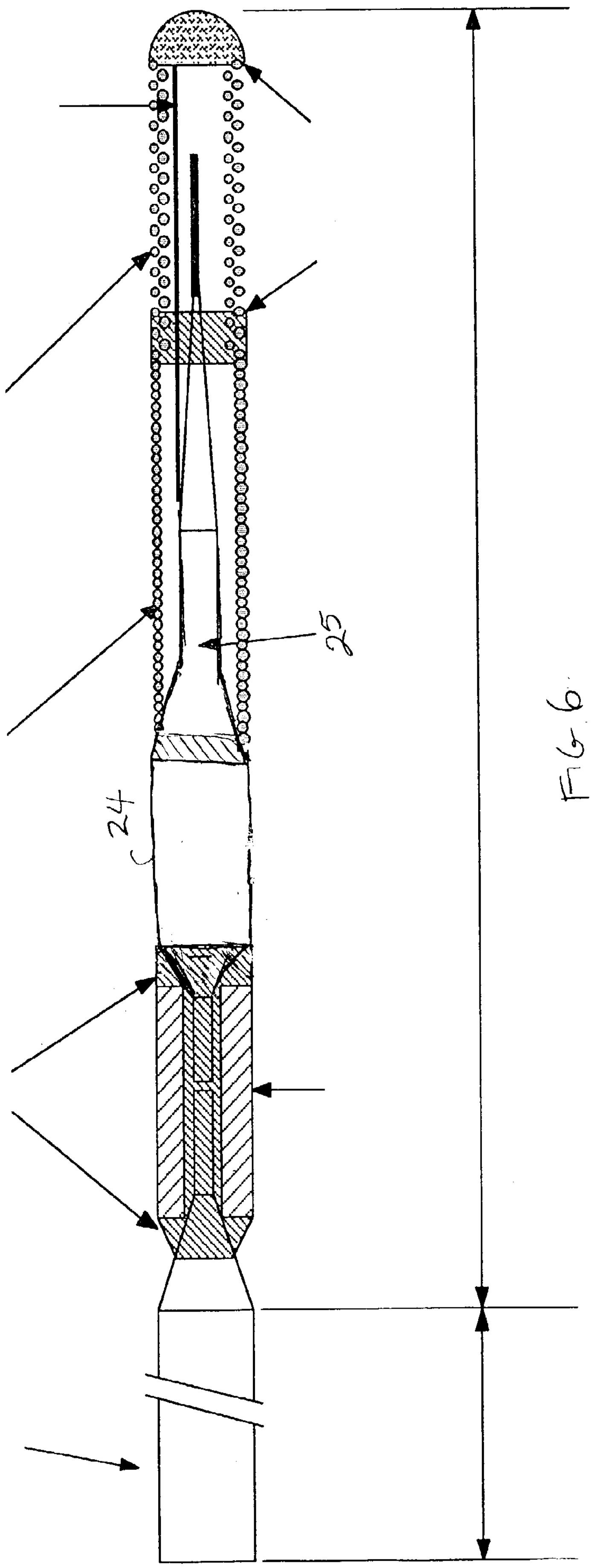


FIG. 6

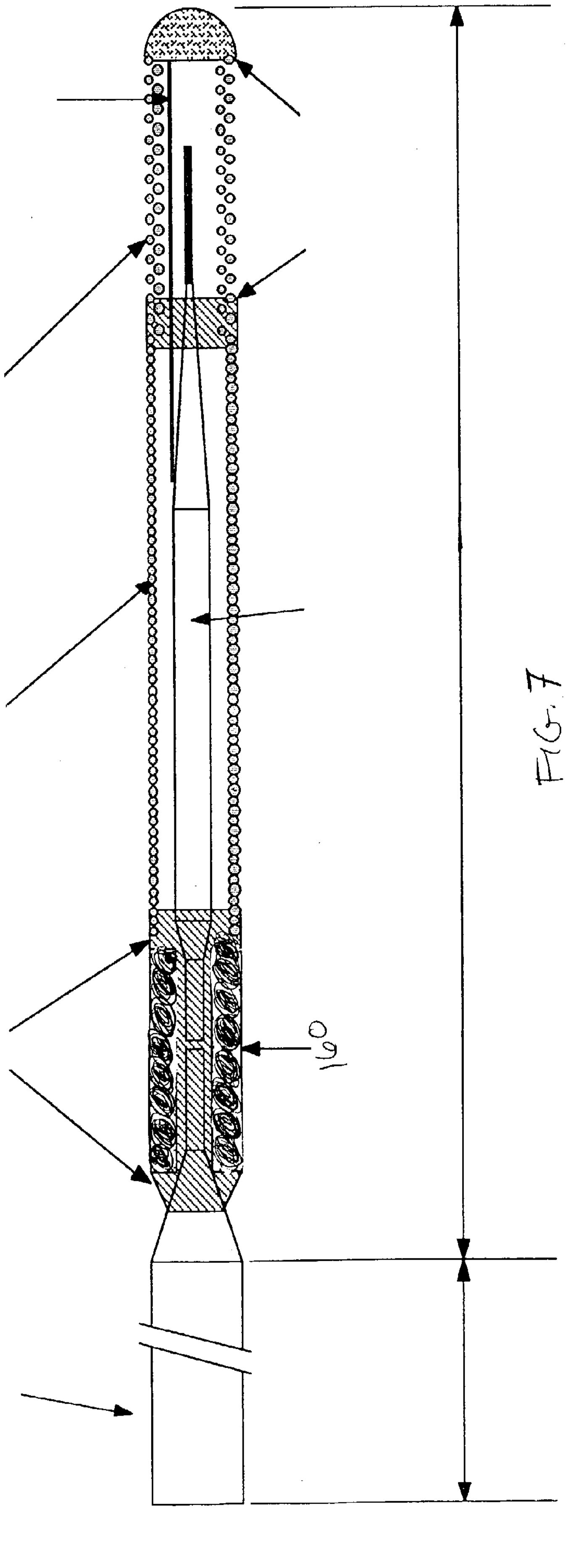


FIG. 7

COMPOSITE GUIDEWIRE WITH A LINEAR ELASTIC DISTAL PORTION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application incorporates by reference commonly assigned co-pending U.S. patent application Ser. No. 09/778,566 which was filed on Feb. 7, 2001 by Richard M. DeMello for a COMPOSITE GUIDEWIRE.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The invention relates generally to guidewires for directing catheters or other medical instruments through the cardiovascular system.

[0004] 2. Background Information

[0005] Guidewires for use in, for example, percutaneous transluminal coronary artery angioplasty (PTCA), must be thin and flexible enough to advance through small arteries within the coronary vasculature. These wires must also be sturdy enough to be manipulated from the outside of the body, such that a distal end of the wire can be brought into contact with a selected region of the coronary artery. Further, they must be strong enough to survive a "pull test" without breaking, to ensure that they do not come apart in the body.

[0006] Numerous guidewire designs exist. These designs have typically been made from stainless steel materials and may have platinum coils added to increase radiopacity. Coatings such as PTFE, silicon, and hydrophilic materials may be added to reduce friction and improve movement of devices that are passed over the guidewire.

[0007] Stainless steel guidewires are inherently stiff and offer excellent support along the proximal shaft portion of the guidewire. The distal ends of these wires may also be deliberately bent or shaped to aid in steering the guidewire into a particular vessel or lumen. The material, however, is susceptible to further plastic deformation during use and has been known to permanently deform and kink. The deformation is particularly noticeable when the guidewire is manipulated through a tortuous anatomy.

[0008] More recently, guidewires have been made from "super elastic" materials such as Nitinol, with coils added for radiopacity and coatings for lubricity, as mentioned above. The super elastic guidewires offer excellent kink resistance, and provide exceptional torque control when placed within tortuous anatomies. The super elastic material, however, is significantly less stiff than stainless steel and therefore does not provide a high level of support along the proximal portion of the guidewire.

[0009] Known prior composite construction guidewires combine a proximal portion of stainless steel with a distal portion of super elastic material, to take advantage of the best performance characteristics of both materials. Unfortunately, it is very difficult to attach non-super elastic materials to super elastic materials. The joint cannot, for example, be held together by conventional braising or welding. Accordingly, a special coupling must be used to lock the materials together.

[0010] In a known prior system the ends of the two guidewire portions, that is, the ends of the two materials, are butted against one another and a sleeve, which made of non-super elastic material, is fit over the joint. The guidewire portions are then held together by crimping, spot welding or gluing the sleeve in place. The coupling relies mainly on the mechanical interface between the two portions of the guidewire. If a mismatch in the cross-sectional dimensions exists, the distal and proximal portions may separate. Further, the repeated torqueing and bending that occurs when the guidewire is manipulated through the cardiovascular system may fatigue the coupling and result in the separation of the distal and proximal portions of the guidewire within the patient's body.

[0011] Another disadvantage of the super elastic material is that at body temperature the material undergoes a phase change to a low tensile strength martensite phase when the material is subjected to stress above a certain level. Accordingly, unless the system alters the temperature of the super elastic distal portion of the guidewire, the distal portion may not offer a sufficient level of support for the devices passed over the guidewire.

SUMMARY OF THE INVENTION

[0012] A composite guidewire constructed in accordance with the invention includes a central core that is made out of a "linear elastic" material, which at body temperature does not exhibit a yield point and/or change phase when subjected to the range of stresses that are common to guidewires. The linear elastic material thus maintains an overall stiffness that is greater than the stiffness of the super elastic material used in known prior composite guidewires. In particular, the linear elastic material maintains a greater stiffness at and above the stress level at which the super elastic material yields and/or undergoes a change to a lower tensile strength phase. Accordingly, the linear elastic core provides greater support for the devices that are passed over the guidewire, while also providing kink resistance that is similar to that of the super elastic material.

[0013] A core extension, which is made out of stiffer material, such as stainless steel, attaches to the central core through an appropriately sized coupling tube, which may be made of super elastic material, linear elastic material, or stainless steel. The coupling tube extends over a tapered distal end of the core extension and a tapered proximal end of the central core. The ends of the coupling tube abut the portions of the respective tapering sections that have diameters that are approximately the same size as the inner diameter of the coupling tube. The coupling tube is thus held against axial movement. The space between the inner diameter of the coupling tube and the core and core extension ends that fit within the coupling tube is filled with an adhesive, to create a strong yet flexible joint that is able to transmit considerable torque without failure. Further, the coupling tube provides support for the proximal end of the core.

[0014] An elongated coil, which may be radiopaque, fits over the distal portion of the central core. The coil may attach at a proximal end to the distal end of the coupling tube by, for example, adhesive, brazing or welding, such that the coil and the coupling tube provide support for the linear elastic core along the entire length of the core. A shaping ribbon which is made of bendable material, such as, for example, stainless steel, is attached to a distal portion of the central core and extends beyond the end of the core, to provide a shapeable distal end to the guidewire. An atraumatic tip fits over the end of the guidewire and attaches to the coil and the shaping ribbon by brazing, welding or adhesive, to provide a cushioned end to the guidewire. As appropriate, a relatively short radiopaque outer coil may be positioned over the elongated coil, to provide visibility to the distal end of the guidewire.

[0015] The joint between the core and the core extension may instead by formed using a stainless steel coupling coil. The coupling coil is filled with adhesive to hold the tapered ends of the core and the core extension in the same manner as the coupling tube.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The invention description below refers to the accompanying drawings, of which:

[0017] **FIG. 1** is a cross-sectional view of a guidewire constructed in accordance with the invention;

[0018] **FIG. 2** depicts the guidewire of **FIG. 1** with a radiopaque cover;

[0019] **FIG. 3** depicts the guidewire of **FIG. 1** with a core extension;

[0020] **FIG. 4** depicts the guidewire of **FIG. 3** with an alternative coil and coupling tube arrangement.

[0021] **FIG. 5** depicts the guidewire of **FIG. 3** with an alternative coupling arrangement.

[0022] **FIG. 6** depicts an alternative to the guidewire of **FIG. 3**; and

[0023] **FIG. 7** depicts the guidewire of FIGS. **3** or **4** with a coupling coil.

DETAILED DESCRIPTION OF AN ILLUSTRATIVE EMBODIMENT

[0024] Referring now to **FIG. 1, a** composite guidewire **10** includes a central core **12** which is made of a "linear elastic" Nitinol material. The linear elastic material exhibits an essentially linear stress-strain function at body temperature. The linear elastic material thus does not change to a lower tensile strength phase when the material is subjected to the stresses associated with guidewire advancement through the body. Accordingly, the linear elastic material is stiffer than the super elastic Nitinol material at stress levels that exceed the level associated with the phase change in the super elastic material. The linear elastic material thus provides a relatively high level of support for the distal end of the guidewire when the guidewire is in place in the body, without requiring a change in the temperature of the material.

[0025] A coupling tube **16** fits over a tapered proximal end **11** of the central core **12**, with the distal end **15** of the tube abutting a tapered core section **13**. The end of the tube abuts the tapered section where the section has an outer diameter that meets or exceeds the inner diameter of the tube. The coupling tube **16** is filled with an adhesive, such as an epoxy resin, and the tube is then held in place on the proximal end of the core. The coupling tube may be made of super elastic material, linear elastic material, stainless steel, or other flexible material.

[0026] A shaping ribbon **20** attaches to a distal portion of the central core **12** and extends beyond the distal end **14** of the central core **12**, to provide a shapeable end. The distal end of the central core may be tapered (as shown), to provide additional flexibility to the distal end of the wire. Further, the windings **19** of the coil **18** may be slightly spread apart to provide even greater flexibility.

[0027] An elongated coil **18** extends from a distal end of the guidewire along the central core **12** and attaches to the distal end **15** of the coupling tube **16**. The coil **18** and the coupling tube attach to one another at their respective ends by, for example, soldering, brazing or adhesive as indicated by reference numeral **23**. The coil also attaches at its distal end to the distal end of the shaping ribbon **20**. The coil and the ribbon may also attach to one another by, for example, soldering, at one or more locations **22** along their lengths.

[0028] An atraumatic tip **26** attaches to the distal ends of the coil **18** and the ribbon **20**, to provide a cushioned distal end to the guidewire **100**.

[0029] The elongated coil **18** is preferably non-radiopaque, and a shorter radiopaque coil **28** fits over the coil **18** to provide visibility under x-ray. As shown, the coil **18** may be tapered at its distal end and the radiopaque coil **28** positioned over the tapered section of the coil **18**, such that the guidewire has a uniform outer diameter along the length of the central core.

[0030] Alternatively, the coil **18**, or a portion thereof, may be radiopaque and the coil **28** may be omitted.

[0031] Referring now to **FIG. 2**, the radiopacity may instead be provided by a radiopaque plastic cover **29** that fits over the distal end of the wire and is attached to the coil **18** by, for example, heat shrinking. The cover **29** may fit over the tip **26** or may incorporate a cushion (not shown) and thus replace the tip.

[0032] Referring now to **FIG. 3**, the guidewire **10** further includes a core extension **30** that is made of a stiffer material, such as, stainless steel. The core extension operatively joins to the central core **12** through the coupling tube **16**. A distal end **32** of the core extension tapers to a tapered end section **34** that fits within the coupling tube, such that the outer diameter of the guidewire remains constant from a proximal end **17** of the coupling tube to the distal end of the coils **18** and **28**.

[0033] The proximal end **17** of the coupling tube **16** abuts the tapered section **32** of the core extension, where the outer diameter of the section is approximately same as the inner diameter of the coupling tube. The tapered sections **32** and **13** of the core extension and the central core hold the coupling tube **16** against axial movement. As discussed above, the coupling tube **16** is filled with an adhesive, in order to provide a strong and relatively flexible joint between the core and the core extension.

[0034] The distal portion of the guidewire, up to and including the coupling tube **16** and the tapered section **32** of the core extension **30** are preferably coated with a hydrophilic coating. The remainder of the guidewire is coated with a PTFE coating.

[0035] The coupling tube **16** is approximately ten centimeters in length. The respective ends **11** and **34** the core and the core extension extend approximately five centimeters within the tube, and thus provide relatively large bonding areas for the joint. In addition to providing a strong yet flexible joint, the relatively long coupling tube also provides support for the proximal end of the central core.

[0036] Referring now to **FIG. 4, a** coupling tube **161** is provided that has a smaller outer diameter than the coupling tube **16**, and the coil **18** extends over the coupling tube **161** to provide additional support for the proximal end of the core **12**. The lengthened coil **18** attaches at its proximal end to the proximal end **31** of the tapered section **32** of the core extension **30**, such that the guidewire has a uniform outer diameter essentially from the distal end of the guidewire to the proximal end of the guidewire. As indicated by reference numeral **33**, the coil **18** attaches to the core extension by adhesive, soldering, brazing, welding or other conventional attachment techniques. Further, an adhesive may be applied over the tapered section **32**, to attach the coil also to the proximal end of the coupling tube **161**.

[0037] Referring to **FIG. 5**, the core may not taper at its proximal end, and instead fit directly into the coupling tube **162**, which has a larger inner diameter than the coupling tube **16** discussed above. The coupling tube **162** then extends along the core and attaches to the portion of the non-tapering core to which the coil **18** extends. As discussed with reference to **FIG. 3** above, the coil **18** attaches to the distal end of the coupling tube **16**. The coupling arrangement depicted in **FIG. 5** is preferably used with larger diameter guidewires, such as guidewires with 0.018 inch outer diameters, that require less support at their proximal ends than the guidewires with smaller 0.014 inch outer diameters.

[0038] As shown, the proximal end of the coil **18** may extend to and connect with the distal end of the coupling tube and/or extend over the coupling tube, such that the linear elastic core is provided with support over its entire length. Alternatively, as depicted in **FIG. 6**, the linear elastic core may include a mid-section **24** that has the same outer diameter as the guidewire. The linear elastic material is sufficiently stiff that the thicker mid-section does not require the support of the coil **18**, and the coil **18** then extends from the distal end of the guidewire to a tapered distal end **25** of the mid-section **24**. The distal end **25** of the mid-section **24** tapers to a diameter that fits within the coil **18**, such that the guidewire has a constant outer diameter from the coupling tube to the distal end of the shaping ribbon.

[0039] As depicted in **FIG. 7** the coupling tube **16** may be replaced by a stainless steel coupling coil **160**. The tapered end sections **11** and **34** of the core and the core extension extend into the coupling coil, and the coil is then filled with an adhesive, to provide a strong yet flexible joint. The joint between the core and the core extension may instead be formed using any type of flexible member that accepts the ends of the core and the core extension and retains them by adhesive or other known retention techniques. The member must, however, be strong enough to transmit the torque generated during guidewire use.

[0040] In summary, the composite guidewire includes a linear elastic central core and a stainless steel core extension that are connected via a coupling tube or other flexible coupling member that provides a strong yet flexible joint and also supports the proximal end of the linear elastic core. The linear elastic core provides flexibility and has sufficient stiffness at body temperature and under stress to also provide support for devices that pass over the distal section of the guidewire. The shaping ribbon and one or more coils provide a flexible and shapeable distal end. Accordingly, the guidewire with its stiffer, stainless steel core extension, its linear elastic central core and its shapeable distal end combines the best qualities of the various materials.

[0041] The foregoing description has been limited to specific embodiments of this invention. It will be apparent, however, that variations and modifications may be made to the invention, including substituting other linear elastic and/or super or non-super elastic materials for those specifically named herein, using coupling members of various shapes and materials, using shaping ribbons of various cross-sectional shapes and materials, with the attainment of some or all of its advantages. Therefore, it is the object of the appended claims to cover all such variations and modifications as come within the true spirit and scope of the invention.

What is claimed is:

1. A composite guidewire including:

a central core of linear elastic material, the central core having a distal portion and a proximal portion;

a coupling tube or coil extending over the proximal portion of the central core, the coupling tube or coil having a distal end and a proximal end;

a shaping ribbon of a shapeable material, the ribbon attaching to a distal portion of the central core and extending beyond the distal end of the central core;

an elongated coil engaged over the distal portion of the central core, the elongated coil having a distal end that attaches to the distal end of the shaping ribbon and a proximal end that attaches to the coupling tube or coil, and

an atraumatic tip attached to the distal ends of the coil and the shaping ribbon.

2. The composite guidewire of claim 1 further including a core extension of a relatively stiff material, the core extension having a distal end that joins to a proximal end of the central core through the coupling tube.

3. The composite guidewire of claim 2 wherein the proximal end of the elongated coil attaches to the distal end of the coupling tube.

4. The composite guidewire of claim 3 wherein the central core and the core extension have tapered ends that fit within the coupling tube or coil and the space between the tapered ends and the inner diameter of the coupling tube or coil is filled with an adhesive.

5. The composite guidewire of claim 4 wherein the proximal end of the coupling tube or coil abuts the distal end of the core extension at the point where the end of the core extension tapers to approximately the size of the inner diameter of the coupling tube or coil.

6. The composite guidewire of claim 5 wherein the distal end of the coupling tube or coil abuts the proximal end of the central core at the point where the end of the core tapers to approximately the size of the inner diameter of the coupling tube or coil.

7. The composite guidewire of claim 2 wherein the elongated coil extends over the coupling tube and attaches at the distal end to the core extension.

8. The composite guidewire of claim 7 wherein the core extension has a tapered distal end and the coil attaches to the core extension at a proximal end of the tapered section.

9. The guidewire of claim 1 wherein a distal end segment of the central core is tapered.

10. The guidewire of claim 9 wherein

the elongated coil is non-radiopaque, and

the guidewire further includes a radiopaque coil engaged over the non-radiopaque coil.

11. The guidewire of claim 9 wherein

the elongated coil is non-radiopaque, and

the guidewire further includes a radiopaque cover engaged over the tip and the distal end of the coil.

12. A composite guidewire including:

a core that includes a first section of linear elastic material and a second section of a relatively stiff material;

a flexible coupling member that extends over a distal segment of the second section and a proximal segment of the first section, the member attaching to a proximal section of the first section of the core and a tapered distal section of the second section of the core;

a shaping ribbon of a shapeable material that attaches to a distal portion of the first section of the core, the shaping ribbon extending beyond the distal end of the first section;

a coil engaged over a distal segment of the first core section, the coil having a distal end that attaches to a distal end of the shaping ribbon, and

a tip that attaches to the distal ends of the coil and the wire.

13. The composite guidewire of claim 12 wherein space between the coupling member and the ends of the first and second sections of the core that extend within the coupling member is filled with an epoxy adhesive.

14. The composite guidewire of claim 12 wherein the coil extends over the flexible coupling member, the coil attaching to the core extension at a proximal end of the tapered distal section of the core extension.

15. The composite guidewire of claim 12 wherein the proximal end of the core is tapered.

16. The guidewire of claim 12 wherein the coil is radiopaque.

17. The guidewire of claim 12 wherein

the coil is non-radiopaque, and

the guidewire further includes a radiopaque coil engaged over the non-radiopaque coil.

18. The guidewire of claim 12 wherein

the coil is non-radiopaque, and

the guidewire further includes a radiopaque plastic cover engaged over the tip and the distal end of the coil.

19. The guidewire of claim 15 wherein the ends of the coupling member abut tapered portions of the distal and proximal ends of the first and second sections, respectively.

20. A composite guidewire including:

a central core of a linear elastic material;

a core extension of a relatively stiff material;

a flexible coupling member that extends over a distal segment of the core extension and a proximal segment of the central core, the coupling member

attaching to a tapered proximal section of the central core at a point where the section has an outer diameter that corresponds to the inner diameter of the coupling member,

attaching to a tapered distal section of the core extension at a point where the section has an outer diameter that corresponds to the inner diameter of the coupling member; and

being filled with an adhesive to retain the ends and provide a joint between the central core and the core extension;

a shaping ribbon of a shapeable material that attaches to a distal portion of the central core, the shaping ribbon extending beyond the distal end of the first section;

a coil engaged over a distal segment of the first core section, the coil having a distal end that attaches to a distal end of the shaping ribbon, and

an atraumatic tip that attaches to the distal ends of the coil and the wire.

21. The composite guidewire of claim 20 wherein the linear elastic material is a Nitinol alloy that at body temperature remains in a single phase under the levels of stress associated with guidewire use.

22. The composite guidewire of claim 20 wherein the flexible coupling member is a coupling tube made of linear elastic material, super elastic material, or stainless steel.

23. The composite guidewire of claim 20 wherein the flexible coupling member is a coupling coil made of stainless steel.

24. The composite guidewire of claim 20 wherein the coil attaches at a proximal end to the distal end of the coupling member.

25. The composite guidewire of claim 20 wherein the coil extends over the coupling tube and attaches to the core extension at a proximal end of the tapered distal portion.

* * * * *

专利名称(译)	具有线性弹性远端部分的复合导丝		
公开(公告)号	US20040193073A1	公开(公告)日	2004-09-30
申请号	US10/403848	申请日	2003-03-31
[标]申请(专利权)人(译)	DEMELLO RICHARD中号 飞行BRUCE		
申请(专利权)人(译)	DeMello RICHARD M. 飞行BRUCE		
当前申请(专利权)人(译)	DeMello RICHARD M. 飞行BRUCE		
[标]发明人	DEMELLO RICHARD M FLIGHT BRUCE		
发明人	DEMELLO, RICHARD M. FLIGHT, BRUCE		
IPC分类号	A61M25/01 A61B5/00 A61M25/00 A61M25/09		
CPC分类号	A61M2025/09083 A61M25/09		
外部链接	Espacenet USPTO		

摘要(译)

复合导丝包括由"线性弹性"材料制成的中心芯，其在体温下在受到导丝共有的应力范围时不会表现出屈服点和/或变化相。由较硬材料（例如不锈钢）制成的芯延伸部通过连接管连接到中心芯，连接管可以由超弹性材料，线性弹性材料或不锈钢制成。耦合管安装在芯延伸部的锥形远端和中心芯的近端上，该近端可以但不必是锥形的。连接管的近端邻接芯延伸部的锥形部分，其中该部分的外径与连接管的内径大致相同，因此管保持抵抗轴向移动。连接管的内径和配合在管内的端部之间的空间填充有粘合剂，以形成坚固而灵活的接头，可传递相当大的扭矩而不会出现故可以是不透射线的细长线圈安装在中心芯的远端部分上。线圈可以通过例如粘合剂，钎焊或焊接在近端处附接到联接管的远端，使得线圈和联接管沿着芯的整个长度为线性弹性芯提供支撑。线圈可以替代地在耦合管上延伸，使得线圈附接到芯延伸部的远端。由可弯曲材料（例如不锈钢）制成的成形带连接到中心芯的远端部分并延伸超过芯的端部，以为导丝提供可成形的远端。无创伤尖端装配在导丝的端部上，并通过钎焊，焊接或粘合剂附接到线圈和成形带，以为导丝提供缓冲端。适当时，相对较短的不透射线外线圈可以定位在细长线圈上，以提供对导丝远端的可视性。