GUIDEWIRE DEVICE AND METHOD

Inventor: Timothy J. Claude, Coon Rapids, MN (US)

Correspondence Address:
Beck & Tysver, PLLC.
Suite 100
2900 Thomas Avenue South
Minneapolis, MN 55416 (US)

Appl. No.: 09/888,147
Filed: Jun. 22, 2001

Related U.S. Application Data
Non-provisional of provisional application No. 60/213,813, filed on Jun. 23, 2000.

Publication Classification
Int. Cl. 7 .......................... B21F 29/00
U.S. Cl. .......................... 74/62; 264/295; 140/30

ABSTRACT
The present invention is a multi-layer guidewire which has a first core metal and a secondary metal formed on the outer periphery of the core. During manufacture the composite structure is twisted providing superior mechanical properties to the finished guidewire.
GUIDEWIRE DEVICE AND METHOD

FIELD OF THE INVENTION

[0001] The present invention relates generally to guidewires used for interventional procedures, more particularly to a guidewire and guidewire construction technology that permits improved performance of the interventional device.

BACKGROUND OF THE INVENTION

[0002] Superalistic nitinol guidewires are well known in the art. These devices may be coated with plastic material. One example is the well known Terumo Gliedewire™. Stainless steel guide wire are also known in the art.

[0003] In devices where the nitinol core provides the bulk of the mechanical properties of the guidewire the operator “feel” is reduced because the nitinol never deforms plastically and always is attempting to straighten out. This property of the traditional Nitinol guidewire is undesirable. The present invention is a two metal guidewire with a nitinol core.

SUMMARY

[0004] The interventional device is made from a core with a secondary layer of metal encapsulating the primary core. The core and the secondary metal are twisted during manufacture and heat treated to form a high performance interventional device such as a guide wire.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] Throughout the various figures of the drawing like reference numerals indicate identical structure where:

[0006] FIG. 1 is a cross-section of a guidewire made in accordance with the invention;

[0007] FIG. 2 is a cross section of an interventional device and

[0008] FIG. 3 is a schematic diagram depicting the manufacturing process.

DETAILED DESCRIPTION

[0009] The concept of operator “feel” is difficult to describe and more difficult to quantify. However, in the field of interventional cardiology it is widely recognized that solid nitinol guidewires react differently in vessels than more conventional stainless steel guidewires. Although nitinol guidewires excel at such properties as “push” and “torque” ability, the drag on the wire as well as the ability to feel the tip is reduced when compared to stainless steel wires. For this reason there is a continuing need to improve guidewires.

DETAILED DESCRIPTION OF THE INVENTION

[0010] The invention is disclosed in the context of a guide wire which is a common interventional device. It should be appreciated that a similar construction for any interventional device.

[0011] FIG. 1 shows a guidewire 10 having a super elastic nitinol core 12 surrounded by a cladding 14 of stainless steel or other metal. Material of this type can be prepared by drawing clad material through progressively smaller dies. This process is well known in the industry. The distal tip of the device 16 may include a coil 20 placed over a centerless ground taper 22 which exposes the nitinol core 12. The coil is attached by a weld glue or solder joint 24. The atrumatic tip 26 may be formed of the core material or it may be a separate piece 28.

[0012] FIG. 2 shows the cross section of the wire where D is the total diameter. It is preferred to have the cladding depth range between about 5% and 25% of the diameter D. The optimal dimension of cladding stainless steel onto nitinol is difficult to determine analytically, but it is believed that on a standard 0.014 to 0.018 guidewire approximately 10 to 15 percent of the total diameter should be stainless steel. In general it is easier to make thick clad material which may influence the design choice.

[0013] FIG. 3 shows a schematic representation of the two metal material that has been twisted as indicated by arrow 42 resulting in a twist 40 in the wire.

[0014] Although stainless steel material is preferred as the clad, other metals may be used as a substitute for stainless steel. In each instance, however, the core should be super elastic nitinol. A non-exhaustive list of alternative cladding materials includes titanium, tungsten, MP35N, gold and platinum.

[0015] Returning to the process of treating the coaxial wire it has been determined that a twist of five to 12 turns per inch followed by a heat soak at 900°F. for 5 to 20 minutes simultaneously results in both stress relief for the stainless steel layer and straightening or set the nitinol wire. The heater 45 depicts the heat treatment process. In general there

What is Claimed

1. In interventional device comprising:
   an elongate body having a distal end and a proximal end;
   a first interior core member formed from super elastic nitinol and a second layer of a metal which is not nitinol.
2. The device of claim 1 wherein said second layer material is selected from the group comprising:
   elgiloy, MP35N, gold, platinum, silver tungsten, and stainless steel.
3. The device of claim 1 further comprising:
   a distal coil mounted to the distal tip of said elongate body forming a guidewire.
4. An interventional device according to claim 1 having a nitinol core and a stainless steel second layer wherein said second layer represents between 5 and 25 percent of the diameter of the device.
5. A method of making a guidewire comprising the steps of:
   drawing a bimetal clad wire and subsequently twisting the wire while heating it for a fixed period of time.
6. The process of claim 5 wherein said heat range extends between 500°F. and 1,200°F. for between four minutes and thirty minutes.

* * * * *