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PATENT
9438-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: **JAMES E. JERVIS**

Examiner: **R. A. Hafer**

Serial No.: **08/483,291**

Group Art Unit: **331**

Filing Date: **June 7, 1995**

For: **MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS**

Pasadena, California

AMENDMENT

Assistant Commissioner for Patents
Washington, D. C. 20231

Sir:

In response to the Office Action of October 29, 1996, please amend the above-identified Application as follows:

IN THE SPECIFICATION

At page 6, line 4, after the description of Figures 3-6 added by the Preliminary Amendment, please add the following:

--Figure 7 shows a guide catheter, transport catheter, and compacted wire coil stent according to the present invention.--

At page 17, at the end of line 23 insert: --According to Dotter et al., Radiology 147: 259-260, a compacted nitinol coil is readily positioned in a narrowed

arterial segment and then expanded to its original form with a luminal diameter approximately equal to that of the adjacent, relatively normal, blood vessel. Expansion of the coil anchors it against the slightly stretched, but otherwise intact, surrounding blood vessel. Several means have been found to facilitate the placement of the nitinol coil stent. One of the simplest involves the use of conventional catheterization techniques to position a large-bore guide catheter 102 (as shown in Fig. 7) close to the site of intended stent 103 placement. The coil 103 is wedged-loaded over the inner end of an inner coaxial transport catheter 104 that has a closed tip and multiple side holes evenly spaced within the surrounding nitinol coil stent.

C2 cont.

According to Cragg et al., Radiology 147: 261-262, straightened nitinol coils were passed through a 10-F Teflon catheter in the abdominal aorta. The nitinol coils were fastened to a threaded guiding wire to allow accurate placement after being deposited in the aorta. Once the wire was extruded from the catheter, precise placement of the newly formed coil was accomplished by advancing or withdrawing the guide wire in the aorta. Detachment of the coil was achieved by unscrewing the guide wire from the distal end of the coil. After coil placement, the catheter and guide wire were withdrawn and the arteriotomy was closed.--

DRAWINGS

Please add Fig. 7 to the drawings.

IN THE CLAIMS

Cancel claims 11-20, 22, and 24, without prejudice to presenting these claims in a continuation application.

Claim 23, line 2, delete "graft".

Claim 25, line 2, delete "the" (first occurrence).

Please amend claim 21 as follows:

~~21~~. (Amended) A medical device for insertion into a mammalian body, the device comprising

(a) [(i)] a hollow placement device; [and]

(b) [(ii)] a memory alloy element formed at least partly from pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about body temperature such that it has a stress-induced martensitic state and an austenitic state, the memory alloy element having (i) a deformed shape when the alloy is in its stress-induced martensitic state and (ii) a different unstressed shape when the alloy is in its austenitic state; and

(c) a guide wire;

the memory alloy element being within the hollow placement device, and the placement device being guidable by the guide wire, the hollow placement device stressing the memory alloy element at a temperature greater than the A_s of the alloy so that the memory alloy element is in its deformed shape,

wherein the memory alloy element can be extruded from the hollow placement device by the guide wire at a temperature greater than the A_s of the alloy to transform at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape to its unstressed shape, and wherein the [device is adapted] alloy is selected so that the transformation can occur without any change in temperature of the placement device or the memory alloy element.

C3 cont.

Please add the following claims to the application.

~~26~~ 6. A medical device which comprises:

(a) a stent for endarterial placement within a human body so that the stent is substantially at human body temperature, the stent comprising a shape memory alloy which displays stress-induced martensite behavior at body temperature; and

(b) a restraint holding the stent in a deformed configuration at a temperature less than the body temperature of the human for endarterial positioning of the stent within the human body in its deformed configuration, the deformation occurring through the formation of stress-induced martensite;

C4

wherein the stent is sufficiently deformed that when the stent is at human body temperature removal of the restraint from the stent, without change in temperature of the device, releases at least a portion of the stent from its deformed configuration.

~~27~~ 7. A device as claimed in ~~26~~ 6, in which the restraint is hollow, and the stent is positioned at least partially within the restraint.

8
~~28.~~ A device as claimed in claim 6 ~~26~~ or 7 ~~27~~, in which the restraint is a catheter.

9
~~29.~~ A device as claimed in claim 6 ~~26~~ or 7 ~~27~~, in which the stent has a transverse dimension and a longitudinal dimension, and wherein the stent is deformed by its transverse dimension being reduced, and wherein the restraint prevents transverse expansion of the stent.

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~~30.~~ The device of claim 6 ~~26~~, wherein the shape memory alloy element is sufficiently deformed that removal of the restraint from the shape memory alloy releases at least a portion of the shape alloy element from its deformed configuration without change in state of the restraint.

C4 Cont.

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~~31.~~ A medical device suitable for placement within a mammalian body for treatment of the mammalian body, the device comprising:

(a) a stent formed at least partly from a pseudoelastic shape-memory alloy, the alloy having a reversible stress-induced martensitic state and an austenitic state, the memory alloy element having (i) a deformed shape when the alloy is in its stress-induced martensitic state and (ii) a different, unstressed shape; and

(b) restraining means engaging and stressing the stent at a temperature less than the body temperature of the mammal and greater than the A_s of the alloy for positioning the stent within the mammalian body while the stent is in its deformed shape;

wherein the alloy is selected so that removal of the restraining means from the stent at a temperature greater than the A_s of the alloy when the device is placed within

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