



PATENT  
Attorney Docket Number 9438-1

*4-14-98*  
*SM*  
*#13*  
*& Declaration*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: JAMES E. JERVIS

Examiner: Justine Yu

Serial No.: 08/483,291

Group Art Unit: 3301

Filed: June 7, 1995

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

**RESPONSE**

BOX AF  
Assistant Commissioner for Patents  
Washington, D. C. 20231

Sir:

The following remarks are submitted in response to the final Office Action, Paper Number 11, mailed September 18, 1997. Additional documents accompanying this response include the following: (1) Declaration of Dr. Lee Middleman under 37 C.F.R. §1.132; (2) a copy of U.S. Patent No. 5,597,378, to Jervis, entitled "Medical Devices Incorporating SIM Alloy Elements"; (3) a Petition for a Three-Month Extension of Time under 37 C.F.R. §1.136(a); (4) a Conditional Notice of Appeal; and (5) an Associate Power of Attorney giving the undersigned authority to prosecute the subject application.

**REMARKS**

**STATUS OF THE CLAIMS**

Claims 21, 23, and 25-46 are presently pending in the subject application. Reconsideration and reexamination of these claims is respectfully requested.

**CLAIM REJECTIONS**

Claims 21, 23, 25, and 26-46 were rejected under 35 U.S.C. §103(a), as being unpatentable over U.S. Patent No. 4,512,338 to Balko et al. ("Balko") in view of Seader Encyclopedia of Chemical Technology publication ("Seader"), and U.S. Patent No. 4,485,805 to Foster, Jr. ("Foster"). Claims 21 and 23 were rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1 and 2 of U.S. Patent No. 5,231,989 to Middleman et al. ("the '989 patent"). In addition, Claims 21 and 23 were rejected under 35 U.S.C. §102(e), as being anticipated by, or in the alternative, under 35 U.S.C. §103(a), as being obvious over U.S. Patent No. 5,231,989 to Middleman et al.

Applicant respectfully traverses these rejections for the following reasons and for reasons supported by the accompanying expert declaration of Dr. Lee Middleman under 37 C.F.R. §1.132 ("Middleman Decl."). Evidence in the form of affidavits or declarations submitted under 37 C.F.R. §1.132 must be considered by the Examiner, if timely submitted. See M.P.E.P. §716.01. The Middleman Declaration submitted herewith is timely, as it is being submitted with a first response after final rejection for the purpose of overcoming a new ground of rejection made in the final rejection. See M.P.E.P. §716.01.

In view of the reasons discussed below and the accompanying declaration, Applicant respectfully requests that the rejections of claims 21, 23, and 25-46 be withdrawn and that these claims be allowed.

### **THE PRESENT INVENTION**

The present invention is directed to a species of a very basic improvement in medical devices. Prior to the present invention, shape memory alloys have been known to be used in medical devices. The difficulty with shape memory alloys is that to get a change in shape, one of three techniques needed to be used: (a) keep the device cold until it is to be used; (b) externally heat the device for use; or (c) rely on heating from body warmth so that the device would change its shape.

All of these alternatives have significant disadvantages, including lack of reproducibility, difficulty of use in the operating room, additional steps in use and the length of time required to have the device warm up to change shape. It is well known to one skilled in the art that the longer a patient is on the operating table, the greater the chance of complications that may result from an operation.

Applicant's present invention is a fundamental invention that uses stress-induced martensite material in place of conventional shape memory alloy material. For this very basic invention, Applicant has already been awarded by the U.S. Patent Office the following U.S. patents: (1) U.S. Patent No. 5,597,378, entitled "Medical Devices Incorporating SIM Alloy Elements"; (2) U.S. Patent No. 5,190,546, entitled "Medical Devices Incorporating SIM Alloy Elements"; (3) U.S. Patent No. 5,067,957, entitled "Method of Inserting Medical Devices Incorporating SIM Alloy Elements"; and,

(4) U.S. Patent No. 4,665,906, entitled "Medical Devices Incorporating SIM Alloy Elements." At least some of these patents have claims broader than claims presented in the present application.

In particular, the present invention is directed to a species of Applicant's basic invention, namely, a medical device for insertion into a mammalian body, preferably in the form of a stent. The device comprises a hollow placement device, a memory alloy element formed at least partly from pseudoelastic shape-memory alloy, and a guide wire. The alloy displays reversible stress-induced martensite (SIM) at about body temperature such that it has a stress-induced martensitic state and an austenitic state. The memory alloy element has a deformed shape when the alloy is in its stress-induced martensitic state, and a different unstressed shape when the alloy is in its austenitic state. The memory alloy element is positioned within the hollow placement device, and the placement device is guidable by the guide wire. The hollow placement device stresses the memory alloy element at a temperature greater than the  $A_s$  (temperature at which the alloy starts to revert back to austenite) of the alloy so that the memory alloy element is in its deformed shape. 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. The alloy is selected so that the transformation can occur without any change in temperature of the placement device or the memory alloy element.

The medical device incorporating SIM alloy elements of the present invention provides significant advantages over known medical devices, including those disclosed in the cited references. The present invention discloses a memory alloy formed at least partly from a pseudoelastic shape memory alloy that displays reversible stress-induced martensite at about body temperature, and the

present invention requires no temperature change to effect a change in state of the shape memory alloy. Thus, none of the disadvantages associated with heating the shape memory alloy with body heat alone or with external heating sources exist with the present invention. In addition, the simplicity of the present invention, where the device attains its desired configuration without the requirement of any external heating or cooling, provides predictability and ease of operation.

**REJECTION OVER BALKO, SEADER, and FOSTER**

Applicant initially submits that the cited Balko reference was previously before the Patent Office and claims broader than those presented herewith were allowed by the Patent Office, i.e., in U.S. Patent No. 5,597,378, to Jervis, entitled "Medical Devices Incorporating SIM Alloy Elements," the parent case of the subject application. A copy of U.S. Patent No. 5,597,378 is enclosed herewith. The claims presented herein are due to a species election requirement in the parent application, and Applicant submits that if the generic invention is nonobvious, then the species must similarly be nonobvious. Moreover, the Examiner relies on the secondary references of Seader for teaching that nitinol has pseudoelastic properties and Foster for teaching a stylet (guide wire). Along with Balko, teachings that nitinol has pseudoelastic properties and teachings of a guide wire were also already considered by the U.S. Patent Office in allowing claims broader than those presented herein.

The Office Action sets forth at page 2 that Balko shows a nitinol (SMA) wire formed graft structure 22 which is placed inside the sheath head 50 (hollow placement device) and that Balko lacks the description of the nitinol which is a pseudoelastic SMA, but that the teaching on page 733 of Seader discloses that the nitinol has the superelastic (pseudoelastic) behavior, and therefore, it is obvious that the nitinol has the pseudoelastic properties. In addition, the Office Action sets forth at

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