

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**



DECLARATION OF DR. LEE MIDDLEMAN UNDER 37 CFR 1.132

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

Sir:

I, Dr. Lee M. Middleman, hereby declare as follows:

BACKGROUND

1. I am an expert in material use and selection of materials for medical devices, and I have special knowledge of stress-induced martensite ("SIM") alloy elements.
2. Attached as Exhibit A, I enclose a copy of my curriculum vitae, a list of United States patents for which I am an inventor, and a list of publications I have authored or co-authored.
3. I have received seven patents relating to the use of materials in medical devices, all of which relate to the use of SIM material.



Corporation except on an occasional consulting basis for which I am compensated at my usual consulting rate.

8. I am being compensated at my usual consulting rate by Medtronic, Inc., for the consulting work I have performed in preparing this Declaration.

#### MATERIALS REVIEWED

9. In preparation for this declaration, I reviewed the above-identified patent application and pending claims, the office action dated September 18, 1997 for this application, U.S. Patent No. 4,512,338 to Balko et al. ("Balko"), U.S. Patent No. 4,485,805 to Foster, Jr. ("Foster"), my own U.S. Patent No. 5,231,989 to Middleman et al. ("my '989 patent"), and the Seader article from the Encyclopedia of Chemical Technology publication ("Seader").

#### CONCLUSIONS

10. I wish in this declaration to correct some misconceptions that appear in the office action dated September 18, 1997. In short, I conclude that the Patent Office is incorrect in stating that the claims of the subject Jervis application are obvious in view of Balko, Foster and Seader, and that they are obvious in view of claims 1 and 2 of my '989 patent. I have many technically based reasons for this conclusion, which I will now present.

11. First, Balko does not disclose a memory alloy formed at least partly from a pseudoelastic shape memory alloy that displays reversible stress-induced martensite at about body temperature. I find no suggestion or teaching in Balko, Seader, or Foster to make the nitinol disclosed in Balko from a stress-induced martensite alloy. Although nitinol can exhibit the

properties of an SIM material, it can do so only if it undergoes a treatment process to make it exhibit the properties of an SIM material. This process requires an extensive, time consuming, and expensive procedure. Where is the suggestion in Balko or any of the other references to use nitinol exhibiting SIM behavior rather than less expensive conventional Nitinol? There is no such suggestion, and any such idea can only come from hindsight.

12. Even if the nitinol in Balko were to exhibit SIM properties, there is no suggestion or teaching in the references that the SIM phenomenon is to occur in the temperature range around the body temperature of a mammal. Nitinol can be treated to exhibit SIM properties in selected temperature ranges as low as 0 degrees Celsius or as high as 60 degrees Celsius. For the nitinol to be effective in a medical device, the SIM behavior must be exhibited at temperatures which a mammalian body can tolerate (typically 35 degrees Celsius to 40 degrees Celsius). No such teaching is provided in the cited references.

13. Further, Balko requires a temperature change to effect a change in state utilizing SMA materials (see col. 5, lines 57-67). The temperature change results from body heating alone, or body heating in combination with external heating. There is no suggestion in Balko or the other references to use nitinol without a temperature change, whether it be by heating the nitinol with body heat alone, or whether it be by heating the nitinol with body heat and an external heating source.

14. The Jarvis invention has significant practical advantages compared to what is taught by Balko. For the Balko device, a doctor has to rely on heating the nitinol for it to work. If the doctor relies solely on body heating, this slows up the surgical procedure. Needless to say, anything that slows up a medical procedure is undesirable in that the chance for infection and the

chance for adverse patient reactions increase as the length of a medical procedure increases. Also, a device that relies on <sup>d</sup>by heating to change shape exhibits inconsistent performance because of the dependence on heating by the body, which rate of heating can differ from patient-to-patient and from operating room to operating room. I know from personal experience with sutures made of SMA materials that inconsistent heating made the sutures difficult to use in an operating room. If the doctor has to rely on heating the nitinol by means of an external heating source, an additional step is added to the procedure and the possibility of overheating and injury is increased. If electric heating is used, there is a potential for electrical shock or an electric burn to the patient. In spite of these disadvantages of the Balko procedure, there is no suggestion in Balko or the other references of a medical device where transformation can occur without a change in temperature.

*Lum*

15. In view of the differences discussed above, it would not have been obvious at the time the invention was made in 1983 to have converted the nitinol of Balko into an SIM material and to have removed the heating step.

16. I am the inventor of the subject matter claimed in United States Patent Number 5,231,989, ("my '989 patent"), issued on August 3, 1993, entitled "Steerable Cannula," and cited in the office action dated September 18, 1997, in the subject application.

17. The device in claims 1 and 2 of my '989 patent functions very differently than the device claimed in the present Jarvis application and does not render it obvious. I made my invention long after Jarvis made his invention, and in fact, Jarvis Patent Number 4,665,906 is cited as prior art on the cover page of my '989 patent. The device in my '989 patent uses an elastic member made of a SIM material to bend or unband a bendable elongated tube ("transforming the

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