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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

May 15, 2009

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS OF:

APPLICATION NUMBER: *07/956,653*
FILING DATE: *October 02, 1992*
PATENT NUMBER: *5,597,378*
ISSUE DATE: *January 28, 1997*

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

P. SWAIN
Certifying Officer

SERIAL NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT	EXAMINER
07/966,653	10/02/92	606	28	3301	Kenealy
	RULE 60				

APPLICANTS

JAMES E. JERVIS, ATHERTON, CA.

CONTINUING DATA********

VERIFIED

THIS APPLN IS A DIV OF 07/682,243 04/09/91 PAT 5,190,546
WHICH IS A DIV OF 07/252,919 09/27/88 PAT 5,067,957
WHICH IS A CON OF 07/177,817 03/30/88 ABN
WHICH IS A CON OF 07/047,824 05/08/87 ABN
WHICH IS A CON OF 06/865,703 05/21/86 PAT 4,665,906
WHICH IS A CON OF 06/541,852 10/14/83 ABN

5597378

FOREIGN/PCT APPLICATIONS********

VERIFIED

NOTE - DISCLAIMER
The term of this patent subsequent to 5/19/04 has been disclaimed

FOREIGN FILING LICENSE GRANTED 10/28/92

Foreign priority claimed	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
35 USC 119 conditions met ☐ yes ☐ no	AS FILED → CA	1	1	1	$2,190.00	9438
and Acknowledged Examiner's Initials						

REY G. SHELDON
ELDON & MAK
55 S. LAKE AVENUE - 9TH FLOOR
ASADENA, CA 91101

ISSUE FEE and FILE

L DEVICES INCORPORATING SIM ALLOY ELEMENTS

U.S. DEPT. of COMM.-Pat. & TM Office — PTO-436L (rev. 10-78)

ATION
Y

ANCE MAILED	PREPARED FOR ISSUE	CLAIMS ALLOWED
1-05	David J. Kenealy, Assistant Examiner; Docket Clerk	Total Claims: 40; Print Claim: 1
SSUE FEE: Date Paid	ROBERT A. HAFER, S.P.E., ART UNIT 331, Primary Examiner	DRAWING: Sheets Drwg.: 2 (3); Figs. Drwg.: 4 (6); Print Fig.: 4 (5)
	ISSUE CLASSIFICATION: Class 606; Subclass 28	ISSUE BATCH NUMBER: 1111

Label

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PATENT APPLICATION SERIAL NO. 07/956653

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

160 MG 10/19/92 07956653 1 101 2,190.00 CK 9438

PTO-1556
(5/87)

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21 — 10/956653 A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No. 9438

Anticipated Classification of this application:

Class _____ Subclass _____

Prior application:

Examiner: K. Rooney

Art Unit: 3301

Box Patent Application
Commissioner of Patents and Trademarks
Washington, D.C. 20231

TRANSMITTAL OF FILING UNDER 37 CFR 1.60(b)

WARNING: *A c-i-p (continuation-in-part) **cannot** be filed under 37 CFR 1.60.*

WARNING: *Filing under 37 CFR 1.60 is permitted **only** if filed by the same or less than all the inventors named in the prior application.*

WARNING: *The filing of an application as the United States stage of an International Application requires an oath or declaration. 37 CFR 1.61(a)(4).*

WARNING: *The claims of this new application may be finally rejected in the first Office action where all claims of the new application are drawn to the same invention claimed in the earlier application and would have been properly finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. MPEP § 706.07(b).*

This is a request for filing a

☐ Continuation

☒ Divisional

application under 37 CFR 1.60, of pending prior application
serial no. 0 7 / 682,243 filed on 4/9/91
(*date*)

of James E. Jervis
(*inventor(s)*)

for MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS
(*title of invention*)

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this 37 CFR 1.60 request and the documents referred to as attached therein are being deposited with the United States Postal Service on this date Oct. 2, 1992 in an envelope as "Express Mail Post Office to Addressee" service under 37 CFR 1.10, Mailing Label Number GB595993035US addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

(Type or print name of person mailing paper)

K. Ward

(Signature of person mailing paper)

NOTE: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. (37 CFR 1.10(b)).

NOTE: 37 CFR 1.60 permits the omission of a declaration only if the prior application was complete as set forth in 37 CFR 1.51(a), namely, the prior application comprised at least (1) a specification, including a claim or claims; (2) a declaration; (3) drawings when necessary; and (4) the prescribed filing fee. Accordingly, as presently worded, 37 CFR 1.60 does not permit this procedure to be used where the prior application is pending but only the processing and retention fee required by 37 CFR 1.21(l) is paid or where the declaration was not filed.

1. Copy of Prior Application as Filed Which is Attached

NOTE: Under 37 CFR 1.60 practice signing and execution of the application by the applicant may be omitted provided the copy is supplied by and accompanied by a statement by the applicant or his or her attorney or agent that the application papers comprise a true copy of the prior application as filed and that no amendments referred to in the declaration filed to complete the prior application introduced new matter therein.

NOTE: This statement need not be verified if made by an attorney registered to practice before the PTO. (37 CFR 1.60(b)).

☒ I hereby verify that the attached papers are a true copy of what is shown in my records to be the above identified prior application, including the oath or declaration originally filed (37 CFR 1.60).

The copy of the papers of prior application *as filed* which are attached are as follows:

☒ 19 page(s) of specification

☐ _____ page(s) of claims

☒ 1 page(s) of abstract

☒ 1 sheet(s) of drawing

(Also complete part 6 below if drawings are to be transferred)

☒ 2 pages of declaration and power of attorney

If the copy of the declaration being filed does not show applicant's signature indicate thereon that it was signed and complete the following:

☐ in accordance with the indication required by 37 CFR 60(b) my records reflect that the original signed declaration showing applicant's signature was filed on _____

☐ the amendment referred to in the declaration filed to complete the prior application and I hereby state, in accordance with the requirements of 37 CFR 1.60(b), that this amendment did not introduce new matter therein.

2. Amendments

WARNING: *"The claim of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application." MPEP § 706.07(b).*

☐ Cancel in this application original claims _____ of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

☒ A preliminary amendment is enclosed. (Claims added by this amendment have been properly numbered consecutively beginning with the number next following the highest numbered **original** claim in the prior application.)

NOTE: Only amendments reducing the number of claims or adding a reference to the prior application (Rule 1.78(a)) will be entered before calculating the filing fee and granting the filing date. 37 CFR 1.60(b).

NOTE: "When filing under Rule 1.60 retain at least one original claim from the patent application to assure a complete application." Notice of March 3, 1986 (1064 O.G. 37-38).

3. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary).

(check the next item, if applicable)

☐ There is provided herewith a Petition To Suspend Prosecution For The Time Necessary to File An Amendment (New Application Filed Concurrently).

4. Information Disclosure Statement

(check this item, if applicable)

☒ An information disclosure statement is submitted herewith.

5. Fee Calculation (37 CFR 1.16)

CLAIMS AS FILED (INCLUDING PRELIMINARY AMENDMENT)

Number filed	Number Extra		Rate	Basic Fee 37 CFR 1.16(a) $690.00
Total Claims (37 CFR 1.16(c))	52 −20= 32	×	$ 20.00	640
Independent Claims (37 CFR 1.16(b))	8 −3= 5	×	$ 72.00	360
Multiple dependent claim(s), if any (37 CFR 1.16(d))	5	×	$220.00	1100

☐ Fee for extra claims is not being paid at this time. (37 CFR 1.16(d))

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency. 37 CFR 1.16(d).

Filing Fee Calculation $ 2,190

6. Small Entity Status

☐ A verified statement that this filing is by a small entity:

☐ is attached

☐ has been filed in the parent application and such status is still proper and desired (37 CFR 1.28(a))

Filing Fee Calculation (50% of above) $ _____

NOTE: Any excess of the full fee paid will be refunded if a verified statement is filed within 2 months of the date of timely payment of a full fee then the excess fee paid will be refunded on request. 37 CFR 1.28(a).

*NOTE: 37 CFR 1.28(a), last sentence states: "Applications filed under § 1.60 or § 1.62 of this part **must** include a reference to a verified statement in a parent application if status as a small entity is still proper and desired."*

7. Drawings

WARNING: ***Do not*** *check the following box if prior case is not to be abandoned.*

☐ Transfer the drawings from the prior application to this application and, subject to item 17 below, abandon said prior application as of the filing date accorded this application. A duplicate copy of this request is enclosed for filing in the prior application file. *(May only be used if signed by (1) applicant, (2) assignee of record or (3) attorney or agent of record authorized by 37 CFR 1.138 and before payment of issue fee.)*

NOTE: "A registered attorney or agent acting under the provisions of § 1.34(a), or of record, may also expressly abandon a prior application as of the filing date granted to a continuing application when filing such a continuing application." 37 CFR 1.138.

☐ Transfer the following sheet(s) of drawing from the prior application to this application _____

NOTE: Transferred sheets must be cancelled in prior application. 37 CFR 1.88.

☐ A **copy** of the amendment cancelling these sheets of drawing in the prior application is attached

☐ New drawings are enclosed

☐ formal

☐ informal

WARNING: *DO NOT submit original drawings. A high quality copy of drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards of § 1.84. If corrections to the drawings are necessary, they should be made to the original drawings and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1090 O.G. 57-62).*

NOTE: "Identifying indicia such as the serial number, group art unit, title of the inventor, attorney's docket number, inventor's name, number of sheets, etc. not to exceed 2¾ inches (7.0 cm.) in width may be placed in a centered location between the side edges within three fourths inch (19.1 mm.) of the top edge. Either this marking technique on the front of the drawing or the placement, although not preferred, of this information and the title of the invention on the back of the drawings is acceptable." Proposed 37 CFR 1.84(1). Notice of March 9, 1988 (1090 O.G. 57-62).

8. Priority—35 U.S.C. 119

☐ Priority of application serial no. 0 /_____ filed on _____ in _____ is claimed under 35 U.S.C. 119. (*country*)

☐ The certified copy has been filed in prior U.S. application serial no. 0 /_____ on _____

☐ The certified copy will follow.

9. Relate Back—35 U.S.C. 120

☐ Amend the specification by inserting before the first line the sentence:

"This is a

☐ continuation

☐ divisional

of copending application(s)

☐ Serial number 0 /_____ filed on _____"

☐ International Application _____ filed on _____ and which designated the U.S."

NOTE: The proper reference to a prior filed PCT application which entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application which designated the U.S.

10. Inventorship Statement

*NOTE: If the continuation or divisional application is filed by less than all the inventors named in the prior application a statement **must** accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation or divisional application. 37 CFR 1.60(b) [emphasis added].*

(complete appropriate items (a) and (b))

(a) With respect to the prior copending U.S. application from which this application claims benefit under 35 USC 120 the inventor(s) in this application is (are):

(complete applicable item below)

☒ the same

☐ less than those named in the prior application and it is requested that the following inventor(s) identified above for the prior application be deleted:

_____

(Type name(s) of inventor(s) to be deleted)

(b) The inventorship for all the claims in this application are

☒ the same

☐ not the same, and an explanation, including the ownership of the various claims at the time the last claimed invention was made, is submitted.

11. Assignment

☒ The prior application is assigned of record to Raychem Corporation

☐ an assignment of the invention to _____

_____

is attached. A separate "ASSIGNMENT COVER LETTER ACCOMPANYING NEW PATENT APPLICATION" is also attached.

NOTE: "If an assignment is submitted with a new application, send two separate letters - one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

12. Fee Payment Being Made At This Time

☐ Not Enclosed

☐ No filing fee is submitted. *(This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently).*

☐ Enclosed

☒ basic filing fee	$ 690
☐ recording assignment ($40.00; 37 CFR 1.21(h))	$ _____
☐ processing and retention fee ($130.00; 37 CFR 1.53(d) and 1.21(l))	$ _____
X Additional Claims	$ 1500

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78 indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid or else the processing and retention fee of § 1.21(l) must be paid within 1 year from notification under § 53(d).

Total fees enclosed $ 2,190

13. Method of Payment of Fees

☒ enclosed is a check in the amount of $ 2,190

☐ charge Account No. _____ in the amount of $_____. A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that is clear for which purpose the fees are paid. 37 CFR 1.22(b).

14. Authorization To Charge Additional Fees

WARNING: *If no fees are being paid on filing do not complete this item.*

WARNING: *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claim charges are authorized.*

☒ The Commissioner is hereby authorized to charge the following additional fees which may be required by this paper and during the entire pendency of the application to Account No. 19-2090

☒ 37 CFR 1.16 (a), (f) or (g) (filing fees)

☒ 37 CFR 1.16 (b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)) it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☐ 37 CFR 1.17 (application processing fees)

WARNING: *While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a) this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a request or petition for extension is filed." [emphasis added]. Notice of November 5, 1985 (1060 O.G. 27).*

☐ 37 CFR 1.18 (issue fee at or before mailing Notice of Allowance, pursuant to 37 CFR 1.311(b)).

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b)).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying or at the time of paying . . . issue fee." From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

15. Power of Attorney

☒ The power of attorney in the prior application is to

Jeffrey G. Sheldon	27,953
Attorney	Reg. No.

a. ☐ The power appears in the original papers in the prior application.

b. [X] Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.

c. [ ] A new power has been executed and is attached.

d. [X] Address all future communications to

Jeffrey G. Sheldon, Esq. (818) 796-4000
Sheldon & Mak
225 S. Lake Avenue - 9th Floor
Pasadena, CA 91101

(Item d may only be completed by applicant, or attorney or agent of record)

16. Maintenance of Copendency of Prior Application

*(This item must be completed and the papers filed in the **prior** application if the period set in the prior application has run)*

[ ] A petition, fee and response has been filed to extend the term in the pending prior application until _____.

*NOTE: The PTO finds it useful if a **copy** of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the Continuation Application. Notice of November 5, 1985 (1060 O.G. 27).*

[ ] A **copy** of the petition for extension of time in the prior application is attached.

17. Conditional Petition for Extension of Time in Prior Application

(complete this item and file conditional petition in the prior application if previous item not applicable)

[ ] a conditional petition for extension of time is being filed in the pending parent application.

*NOTE: The PTO finds it useful if a **copy** of the petition filed in the prior application extending the term for response is filed with the paper constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).*

[ ] A **copy** of the conditional petition for extension of time in the prior application is attached.

18. Abandonment of Prior Application (if applicable)

***WARNING:** (Do not complete this item if the application being filed is a divisional of the prior application which is not being abandoned)*

NOTE: "A registered attorney or agent acting under the provisions of § 1.34(a), or of record, may also expressly abandon a prior application as of the filing date granted to a continuing application when filing such a continuing application." 37 CFR 1.138.

[ ] Please abandon the prior application at a time while the prior application is pending or when the petition for extension of time or to revive in that application is granted and when this application is granted a filing date so as to make this application copending with said prior application.

19. Notification In Parent Application of the Filing of This Continuation Application

☐ A notification of the filing of this continuation is being filed in the parent application from which this application claims priority under 35 USC § 120.

I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

10/2/92
Date

Jeffrey G. Sheldon
Type or print name of person signing

Signature

Sheldon & Mak
225 S. Lake Avenue
Pasadena, CA 91101
P.O. Address of Signatory

Tel. No.: (818) 796-4000

Reg. No. 27,953
(if applicable)

☐ Inventor
☐ Assignee of complete interest
☐ Person authorized to sign on behalf of assignee
☒ Attorney or agent of record
☐ Filed under Rule 34(a)

(Complete the following if applicable)

Raychem Corporation
Type name of assignee

300 Constitution Drive
Address of assignee

Menlo Park, CA 94025

Title of person authorized to sign on behalf of assignee

Assignment recorded in PTO on _____

Reel _____ Frame _____

☐ Plus ASSIGNMENT (DOCUMENT) COVER LETTER ACCOMPANYING NEW PATENT APPLICATION

U.S. Serial No:

Filed: October 14, 1983

07/956653

a1 73

MP0884-US1

CONFORMED COPY

MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

James E. Jervis

ABSTRACT OF THE DISCLOSURE

Medical devices which are currently proposed to use elements made from shape memory alloys may be improved by the use of stress-induced martensite alloy elements instead. The use of stress-induced martensite decreases the temperature sensitivity of the devices, thereby making them easier to install and/or remove.

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to medical devices incorporating shape memory alloys, and to improvements therein.

Introduction to the Invention

Materials, both organic and metallic, capable of possessing shape memory are well known. An article made of such materials can be deformed from an original, heat-stable configuration to a second, heat-unstable configuration. The article is said to have shape memory for the reason that, upon the application of heat alone, it can be caused to revert, or to attempt to revert, from its heat-unstable configuration to its original, heat-stable configuration, i.e. it "remembers" its original shape.

Among metallic alloys, the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state with a change in temperature. This transformation is sometimes referred to as a thermoelastic martensitic transformation. An article made from such an alloy, for example a hollow sleeve, is easily deformed from its original configuration to a new configuration when cooled below the temperature at which the alloy is transformed from the austenitic state to the martensitic state.

The temperature at which this transformation begins is usually referred to as M_s and the temperature at which it finishes M_f. When an article thus deformed is warmed to the temperature at which the alloy starts to revert back to austenite, referred to as A_s (A_f being the temperature at which the reversion is complete) the deformed object will begin to return to its original configuration.

Many shape memory alloys (SMAs) are known to display stress-induced martensite (SIM). When an SMA sample exhibiting stress-induced martensite is stressed at a temperature above M_s (so that the austenitic state is initially stable), but below M_d (the maximum temperature at which martensite formation can occur even under stress) it first deforms elastically and then, at a critical stress, begins to transform by the formation of stress-induced martensite. Depending on whether the temperature is above or below A_s, the behavior when the deforming stress is released differs. If the temperature is below A_s, the stress-induced martensite is stable; but if the temperature is above A_s, the martensite is unstable and transforms back to austenite, with the sample returning (or attempting to return) to its original shape. The effect is seen in almost all alloys which exhibit a thermoelastic martensitic transformation, along with the shape memory effect. However, the extent of the temperature range over which SIM is seen and the stress and strain ranges for the effect vary greatly with the alloy.

In copending and commonly assigned U.S. Patent Application ~~(Docket No. MP0873-US1)~~ now U.S. Patent no. 4,503,767 to Quin, the disclosure of which is incorporated herein by reference, a nickel/titanium/vanadium alloy having SIM over a wide temperature range is disclosed.

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Shape memory alloys have found use in recent years in, for example, pipe couplings (such as are described in U.S. Pat. Nos. 4,035,007 and 4,198,081 to Harrison and Jervis), electrical connectors (such as are described in U.S. Pat. No 3,740,839 to Otte & Fischer), switches (such as are described in U.S. Patent No. 4,205,293), actuators, etc.

Various proposals have also been made to employ shape memory alloys in the medical field. For example, U.S. Pat. No. 3,620,212 to Fannon et al. proposes the use of an SMA intrauterine contraceptive device, U.S. Pat. No. 3,786,806 to Johnson et al. proposes the use of an SMA bone plate, U.S. Pat. No. 3,890,977 to Wilson proposes the use of an SMA element to bend a catheter or cannula, etc.

These medical SMA devices rely on the property of shape memory to achieve their desired effects. That is to say, they rely on the fact that when an SMA element is cooled to its martensitic state and is subsequently deformed, it will retain its new shape; but when it is warmed to its austenitic state, the original shape will be recovered.

However, the use of the shape memory effect in medical applications is attended with two principal disadvantages. First, it is difficult to control the transformation temperatures of shape memory alloys with accuracy as they are usually extremely composition-sensitive, although various techniques have been proposed (including the blending by ~~powder~~ powder metallurgy of already-made alloys of differing transformation temperatures: see U.S. Pat. No. 4,310,354 to Fountain et al.). Second, in many shape memory alloys there

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is a large hysteresis as the alloy is transformed between austenitic and martensitic states, so that reversing of the state of an SMA element may require a temperature excursion of several tens of degrees Celsius. The combination of these factors with the limitation that (a) it is inconvenient to have to engage in any temperature manipulation, and (b) human tissue cannot be heated or cooled beyond certain relatively narrow limits (approximately 0° - 60°C for short periods) without suffering temporary or permanent damage is expected to limit the use that can be made of SMA medical devices. It would thus be desirable to develop a way in which the advantageous property of shape memory alloys, i.e. their ability to return to an original shape after relatively substantial deformation, could be used in medical devices without requiring the delicacy of alloying control and/or the temperature control of placement or rempval needed by present shape memory alloy devices.

DESCRIPTION OF THE INVENTION

Summary of the Invention

I have discovered that if, in a medical device containing a shape memory alloy element which uses the shape memory property of that alloy, an element which shows the property of stress-induced martensite is used instead, an improved device results.

Accordingly, this invention provides a medical device intended for use within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature, which device comprises a shape memory alloy element, the improvement in which comprises the substitution of an alloy element which displays stress-induced martensite at said body temperature for the shape memory alloy element.

Brief Description of the Drawing

Figures 1 and 2 illustrate the stress-strain behavior of an alloy which exhibits constant stress versus strain behavior due to stress-induced martensite.

Detailed Description of the Preferred Embodiments

The invention will be discussed first by introducing the concept of stress-induced martensite and the effect achievable by its use, and then by examples showing how SIM alloy elements can be substituted for conventional SMA elements in medical devices to achieve the beneficial effect of the invention.

The Figures illustrate the phenomenon of stress-induced martensite by means of stress-strain curves. In both Figure 1 and Figure 2, the alloy is at a temperature between M_s and M_d so that it is initially austenitic; and it will be assumed for the puposes of this discussion that M_s is equal to M_f, and A_s equal to A_f. Figure 1 shows the case when the temperature is below A_s, so that any martensite formed by the applied stress is stable; while Figure 2 shows the case where the temperature is above A_s, so that austenite is the only stable phase at zero stress.

In Figure 1, when a stress is applied to the alloy, it deforms elastically along the line OA. At a critical applied stress, σ_M, the austenitic alloy begins to transform to (stress-induced) martensite. This transformation

takes place at essentially constant stress until the alloy becomes fully martensitic at point B. From that point on, as further stress is applied, the martensite yields first elastically and then plastically (only elastic deformation is shown at point C). When the stress is released, the martensite recovers elastically to point D, at which there is zero residual stress, but a non-zero residual strain. Because the alloy is below A_s, the deformation is not recoverable until heating above A_s results in a reversion to austenite. At that point, if the sample is unrestrained, the original shape will be essentially completely recovered: if not, it will be recovered to the extent permitted by the restraint. However, if the material is then allowed to re-cool to the original temperature at which it was deformed (or a temperature where SIM behavior of this type is seen), the stress produced in the sample will be constant regardless of the strain provided that the strain lies within the "plateau" region of the stress-strain curve. That is, for a ~~strain~~ stress between ε_B and ε_D, the strain will be σ_M. This means that a known, constant force (calculable from σ_M) can be applied over a wide (up to 5% or more for certain Ni/Ti alloys) strain range. Thus, though this resembles the conventional shape memory effect, because the alloy shows SIM and is below A_s a constant force can be achieved.

In Figure 2, when a stress is applied to the alloy, it deforms elastically along line OA, then by SIM along line AB, and by deformation of the martensite to point C, just as in Figure 1. However, the stress-strain behavior on unloading is significantly different, since the alloy is above A_s

and the stable phase is therefore austenite. As the stress is removed, the alloy recovers elastically from C to D; then, at a critical stress, σ_A, the alloy reverts to austenite without requiring a change in temperature. Thus reversion occurs at essentially constant stress. Finally if the stress is removed from the reverted austenite, it recovers elastically along line ED. The recoverable deformation associated with the formation and reversion of stress-induced martensite has been referred to as pseudoelasticity. While σ_M may be comparatively high, e.g. 50 ksi, σ_A is usually substantially lower, e.g. less than 10 ksi; thereby creating a constant-force spring with an effective working range of about 5% ($\epsilon_B - \epsilon_A$). The shape change available in the SMA is thus mechanically, rather than thermally, actuated and controlled, permitting a greater control over a device incorporating it..

Suitable alloy for this invention i.e. those displaying stress-induced martensite at temperatures near mammalian body temperature (35°-40°C), may be selected from known SMAs by those of ordinary skill in ~~the art~~ The art having regard to this disclosure by ~~testing~~ testing for the existence of the SIM effect at the desired temperature. A particularly preferred alloy is the nickel/titanium/vanadium alloy of U.S. Patent Application No. ~~(Docket No. MP0873-US1)~~ now U.S. Patent No 4,505,767, referred to previously.

Inv A37

Inv D17 The invention will now be discussed in detail by some Examples of the use of an SIM alloy.

Example I. Heart Valves

Akins, in U.S. Patent No. 4,233,690, the disclosure of which is incorporated herein by reference, describes the use of a shape memory alloy ring to hold a sewing cuff to the body of an artifical heart valve. The ring is made in the austenstic phase, cooled to the martensitic phase, deformed, placed around the valve body, and heated or allowed to warm to cause reversion to the austenitic phase and recovery of the ring into engagement with the valve body.

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However, this technique has not found commercial acceptance. Present medical technique requires that the valve body be capable of being rotated relative to the cuff, thereby enabling the surgeon to set the rotational orientation of the valve after it has been sewn into place. This is desirable because the techniques used make it difficult to visualize or accomplish optimal orientation during initial placement.

In order to accomplish the desired torque control to permit the desired rotation and yet ensure a firm hold of the cuff on the valve body, precise control of the pressure exerted on the valve body by the ring is needed. This is difficult because there are substantial manufacturing tolerances in the valve body which may be made, for example, of pyrolytic graphite or ceramics, etc. Because the austenite stress-strain curve is extremely steep, it is not considered practical to use the simple shape memory technique proposed by Akins. Indeed, Akins does not even address the issue of rotation of the cuff with respect to the valve body.

However, if an SIM alloy is used instead of conventional shape memory, the process may be considerably simplified.

First, if the alloy has a stress-strain curve like that of Figure 1, the alloy ring may be made just as for Akins. The ring is then expanded from its initial austenitic state by the formation of SIM. When the ring is placed about the valve body, it needs only to be heated above A_f and allowed to cool to its original temperature for the ring to

engage the valve body with a constant force, even if the valve body has a deviation from the specified size. The torque may thus be controlled to the desired level despite manufacturing tolerances.

Second, if the alloy has a stress-strain curve like that of Figure 2, the ring may be expanded, placed over the valve body, and the stress released all at the same temperature. Because the austenitic phase is stable, the stress-induced martensite spontaneously reverts to austenite until recovery is restrained by the ring engaging the valve body. Because the reversion to austenite takes place at constant stress, a constant force (and hence constant torque) may be obtained regardless of manufacturing tolerances. Close temperature control is not required, either; and the fact that the patient in a heart valve replacement operation is conventionally cooled as much as 15°C or so below normal body temperature does not affect the operation of the ring.

To control the torque at a sufficiently low level, it may be desirable for the alloy ring to be other than a solid ring, such as, for example, a continuous helical spring, a flat zigzag spring, etc. Such variations permit the achievement of a greater range of movement with constant force and a reduction in the force exerted by the ring on the valve body, since the ring recovers in a bending mode rather than in tension.

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Example II. Catheters And Cannulas

Wilson, in U.S. Patent No. 3,890,977, the disclosure of which is incorporated herein by reference, discloses a catheter or cannula (both being included hereinafter in the word "catheter") made of, or containing, an SMA element to cause all or a portion of the catheter to deploy in a useful form once introduced into a living body.

However, again this device has not been commercialized. Possible defects of the device which have prevented commercialization include (i) the inability to slowly emplace the catheter in a desired position when the transition temperature of the alloy is below body temperature (since the SMA element will attempt to revert to its original shape as it reaches body temperature), thus limiting the ability of the physician to place the device carefully and precisely; or alternatively, if the transition temperature of the alloy is above body temperature, the requirement that the device be heated to a temperature above body temperature to cause recovery and that the device be placed so as not to change shape again when it re-cools (since the body temperature is below the transition temperature); (ii) the inability to remove the device easily; and (iii) the need for controlled temperature storage to prevent premature reversion to austenite of the SMA, with consequent shape change.

The issue of removal of a catheter is especially significant, and not addressed by Wilson. Consider, for example, a tracheal puncture catheter. This should be

straight for easy insertion into the trachea through a puncture into the front of the neck, but should curve after insertion so that the flow of air or oxygen through the catheter passes axially down the trachea rather than impinging on the surface of the trachea and damaging it. If a shape memory catheter is used as contemplated by Wilson, it would presumably become austenitic and bend after insertion (see Figures 1a and 1b, and corresponding text, of Wilson). But removal would require either cooling to below the transition temperature (which could easily mean cooling to so low a temperature that the tracheal tissue is damaged), removal in the bent shape (presumably damaging tissue), or forcing the austenitic SMA to straighten to permit direct removal (unlikely to be satisfactory since the austenitic alloys e.g. of Ni/Ti may have yield strengths of 100 ksi or more, and force sufficient to cause plastic deformation would be required).

If an SIM element is used instead, however, removal can be accomplished almost as easily as insertion. If the catheter is made in a bent shape (as in Wilson), it can be straightened by insertion of a straight pin down the catheter axis, the catheter deforming by the formation of stress-induced martensite. Insertion of the catheter into the trachea is accomplished while the catheter is straight, at whatever rate is desired (permitting easy and accurate placement), and the pin is gradually withdrawn to permit the catheter to take up its desired shape as the martensite reverts to austenite. [It is assumed here that the stress-strain curve of the alloy at the temperature of use is of the form of Figure 2, so spontaneous reversion occurs on removal of the stress induced by the pin]. When removal is desired, it may be achieved simply by the gradual insertion of the pin, straightening the catheter and permitting easy withdrawal. Insertion of the catheter into the body and pin removal may, of course, take place simultaneously if desired, as may pin reinsertion and removal of the catheter from the body.

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Example III. IUDS

Fannon et al., in U.S. Patent No. 3,620,212, the disclosure of which is incorporated herein by reference, discloses an intrauterine contraceptive device (an IUD) proposed to be formed of a shape memory alloy. The device is suggested to be deformed in the martensitic phase (the transition temperature being below the temperature of the uterus), and the deformed device insulated with, e.g., wax and inserted. Removal is contemplated only by using two SMA elements in opposition, the higher temperature one being martensitic at body temperature but strong enough so that, if heated, it will overcome the lower temperature element and deform the IUD back to a removable shape. The heating contemplated is electrical. The storage problem discussed in Example II also exists here, so that the device must be stored below its transition temperature.

By the use of an SIM element, however, these disadvantages may be overcome. Again, assume that the alloy is SIM psuedoelastic, i.e. that it has the stress-strain curve of Figure 2. Then an IUD may be formed into the desired shape in the austenitic state, and deformed by compression into a tubular placement device (the deformation being such that the strain levels lie within the "plateau" of the stress-strain curve). When the placement device is inserted into the uterus, the IUD may be deployed by extrusion of the IUD from the placement device. Deployment is then controlled but immediate, so that the physician may satisfy himself with placement. Removal is the reversal of placement: the placement device is inserted into the uterus, the IUD deformed by withdrawal into the placement device, and the placement device withdrawn. Temperature control is not required.

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Example IV. Bone Plates

Johnson et al., in U.S. Patent No. 3,786,806, the disclosure of which is incorporated herein by reference, propose the use of Ni/Ti SMA bone plates in fracture fixation. The plate is deformed in its martensitic state, screwed to the two ends of the bone it is desired to compress together, and warmed (or allowed to warm) to the austenitic state, when the plate contracts, compressing the bone ends together.

Because of the high elastic moduli of the austenitic shape memory alloys, it will be difficult to control the amount of force which may be applied by a bone plate of the type proposed by Johnson et al., and precision placement of the bone ends and elongation of the plate will be required.

If, however, an SIM pseudoelastic bone plate is used, it will be easily possible to elongate the plate and fasten it to the bone ends without requiring high precision. Because of the comparatively large (e.g. 5%) strain range at essentially constant stress, the force which will be put on the bone ends to compress them will be readily adjustable (by the size of the plate, for example) and will be insensitive to precise placement of the bone ends and/or elongation of the plate. Also, the recovery of the plate, since it is controlled by mechanical restraint, may be as gradual as desired, achieving excellent force and time control, and permitting the surgeon to make adjustments as desired.

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Example V. Marrow Nails

Baumgart et al., in U.S. Patent No. 4,170,990, the disclosure of which is incorporated herein by reference, discloses the use of the two-way shape memory effect (where an SMA element exhibits a first shape in the austenitic state and a second in the martensitic state, and spontaneously changes between the two shapes with a change in temperature) in, inter alia, marrow nails (see Figures 1a through 1e, and corresponding text, of Baumgart et al.).

The method proposed, however, requires the use of a wide temperature range in order to cause the phase change which is the origin of the two-way shape memory effect (5°C to 60°C for the water used to cool or heat the nail). In addition, it requires the manufacture of two-way shape memory elements, which is generally more complex than the manufacture of conventional shape memory elements; and precise control of the ~~transition~~ temperature is required.

However, if an SIM pseudoelastic alloy element is employed, these disadvantages may be overcome. If internal tangs, which may be gripped by an inserted tool, are provided within a marrow nail of the type shown in Figure 1a of Baumgart et al., then the nail may be radially compressed by the application of stress by such a tool. When the nail is released by the tool, it will expand to fill the bone channel with a constant force (not readily available by Baumgart et al.); and it may be withdrawn by the reverse procedure.

Example VI. Dental Arch Wire

Andreasen, in U.S. Patent No. 4,037,324, the disclosure of which is incorporated herein by reference, proposes the use of dental arch wires made of Ni/Ti alloys instead of conventional 18-8 stainless steel wires. The wires are stated to be of lower elastic modulus and higher elastic limit than stainless steel, which is stated to be advantageous. Heat recovery of an SMA wire is also suggested as a technique for orthodonture.

The technique of using the conventional shape memory effect is not believed to have found clinical application, possibly because such a technique would require rapid placement of the wire in its martensitic state to avoid premature recovery, and would result in rapid recovery with extremely high forces, which would be painful for the patient.

The use of a wire which displays lower elastic modulus and higher elastic limit than stainless steel has found some application, however. Otsuka et al. in Metals Forum, v. 4, pp. 142-52 (1981) have suggested that this behavior may be the result of elasticity enhanced by cold working and martensite-to-martensite psuedoelasticity in an alloy which has a transition temperature below body temperature. The alloy, then, is martensitic rather than austenitic in its undeformed state.

While the use of an enhanced elasticity wire may offer some advantages over the more usual stainless steel wire, it remains the situation that the amount of motion in the teeth that may be produced by an arch wire without further adjustment

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is largely limited by the pain tolerance of the patient (since the force applied by the arch wire is proportional to the deformation of the wire). However, if an SIM pseudoelastic wire is used, it can exert a relatively constant force (chosen by the dentist to be sufficient to cause tooth movement but not painful) over a strain range of up to 5%. The load may be applied mechanically, and is thus more readily established, and no precise temperature control of the alloy is needed as would be required for the shape memory effect.

Example VII. Coil Stents and Filters

The use of tubular coiled wire stent grafts has been discussed in the medical literature since 1969. Although the coils helped maintain patency of the vessels in which they were placed, they were difficult of insertion unless narrow enough to significantly narrow the lumen of the vessel. Recently it has been proposed, see Radiology, v. 147, pp. 259-60 and pp. 261-3 (1983), the disclosures of which are incorporated herein by reference, to use SMA wire to form these tubular coils. The wire, which has a transformation temperature below body temperature, is introduced through a catheter after being straightened in its martensitic state. When the wire is heated, the coil re-forms.

Because of the difficulty of controlling the transformation temperature accurately, it has proved necessary to cool the straightened wire during insertion and/or to heat the wire to form the coil after insertion. These procedures add to the complexity of the operation.

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If an SIM pseudoelastic wire is used to form the coil, which is then isothermally deformed by loading into a catheter, then the need for temperature control is avoided. The wire remains straight when in the catheter, but re-forms the coil spontaneously when it is extruded from the catheter. Accurate placement is thus readily obtainable, since there is no urgency as might be required with a conventional shape memory effect element.

It has similarly been proposed to use SMA wire to form a filter for emplacement by catheter in the vena cava to trap blood clots. The filter is formed in the austenitic state, the wire straightened in the martensitic state and inserted, and the filter re-forms on warming. Just as for the coil stents discussed above, the use of an SIM pseudoelastic wire would greatly simplify manufacture and insertion of such a vena cava filter, permitting accurate placement with no need for urgency or temperature manipulation.

Example VIII. Bone Staples, Clips, etc.

Bone staples are frequently used to hold fragments of fractured bone together when the fracture is fixed, and may be used in some cases as a replacement for bone plates in the same situation. Sometimes the staples are inserted into drilled holes, sometimes merely driven into the bone directly.

It would be desirable to have a bone staple which provided a controlled force between the tines which would tend to hold the staple in place. Shape memory alloys have been proposed for this application, but again the problem of accurate placement while operating quickly enough to prevent the shape change associated with the martensite-to-austenite transition and/or the need for temperature control complicate their use.

If an SIM alloy is used, these disadvantages may be readily overcome. If the alloy is below A_s, it may be emplaced in the martensitic state. Brief heating will then be required to cause it to become austenitic, but on re-cooling to body temperature, a constant force can be achieved. If the alloy is above A_s, the staple can be held deformed by a moderate force, then released after insertion to also provide an accurately-known force. In either event, removal is easier than if the alloy is purely austenitic, as discussed above for Examples II and V, for example.

Similarly, SIM alloy (especially alloy which is pseudoelastic, above A_s at its utilization temperature) may be used to manufacture vascular clips, etc. The alloy element here acts as a constant force spring over a wide strain range (greater than conventional elastic metals), resulting in ease of use.

From the foregoing, it is clear that, in a situation where narrow temperature differences are available or preferable, as often is the case in medical applications, mechanically constrained shape change is a much more useful solution than heat actuated shape change. It offers a degree of control heat actuation does not, it offers easier alloy composition control, it eases mating part tolerance requirements, and it offers simple mechanical reversal at minimal stress levels, all without heating, cooling or insulation complications.

It will be obvious to those skilled in the art, having regard to this disclosure, that other variations on this invention beyond those specifically exemplified here, and other medical devices making use of stress-induced martensite, may be made. Such variations are, however, to be considered as coming within the scope of this invention as limited solely by the following claims.

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I claim:

1. In a medical device intended for use within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature, which device comprises a shape memory alloy element, the improvement which comprises the substitution of an alloy element which displays stress-induced martensite at said body temperature for the shape memory alloy element.

2. The device of claim 1 which is a heart valve, the alloy element being a ring employed to hold a sewing cuff onto the valve body.

3. The device of claim 1 which is a catheter, the alloy element being the catheter or a part thereof which causes the catheter to assume a bent shape.

4. The device of claim 3 which is a tracheal catherter.

5. The device of claim 1 which is an intrauterine contraceptive device.

6. The device of claim 1 which is a bone plate.

7. The device of claim 1 which is a marrow nail.

8. The device of claim 1 which is a dental arch wire.

9. The device of claim 1 which is a bone staple.

10. The device of claim 1 which is a clip.

Add 96

Add B7

+ D6 Add E57

20

DECLARATION AND POWER OF ATTORNEY (Page 1)

Raychem Case No.

MP0884-US1

As a below named inventor, I hereby declare that:
my residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: Medical Devices Incorporating SIM Alloy Elements

the specification of which
X is attached hereto
____ was filed on _____ as Application Serial No. _____
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with 37 CFR §1.56(a).

I hereby claim foreign priority benefits under 35 U.S.C. §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent of inventor's certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATIONS

Application Number	Country	Date Of Filing	Priority Claimed
NONE			Yes__ No__
			Yes__ No__

I hereby claim the benefit under 35 U.S.C.§ 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose material information as defined in 37 CFR §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

PRIOR UNITED STATES APPLICATIONS

Application Number	Date Of Filing	Status
NONE		Pending__ Patented__ Abandoned__
		Pending__ Patented__ Abandoned__

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Herbert G. Burkard, Reg. No. 24,500
and James W. Peterson, Reg. No. 26,057

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at (415)361-5864

Address all correspondence to: Patent Department
Raychem Corporation
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Menlo Park, CA 94025

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF SOLE OR FIRST INVENTOR	INVENTOR'S SIGNATURE	DATE
JAMES E. JERVIS	James E. Jervis	10/14/85
RESIDENCE Atherton, California	CITIZENSHIP U.S.A.	
POST OFFICE ADDRESS 496 Walsh Road, Atherton, CA 94025		

FULL NAME OF SECOND JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

FULL NAME OF THIRD JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
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FULL NAME OF FOURTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

FULL NAME OF FIFTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	)	Group Art Unit: 331
JAMES E. JERVIS	)	
Serial No.: 252,019	)	
Filed: September 27, 1988	)	
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	)	Pasadena, California

ASSOCIATE POWER OF ATTORNEY

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

Please recognize Jeffrey G. Sheldon, Registration No. 27,953, of Sheldon & Mak as associate attorney with power to inspect and copy the record of the above-identified application and to make corrections and additions thereto.

Please address all communications to:

SHELDON & MAK
201 South Lake Avenue, Suite 800
Pasadena, California 91101
(818) 796-4000

Respectfully submitted,

By Herbert Burkard
Herbert Burkard
Reg. No. 24,500

Date

RAYCHEM CORPORATION
300 Constitution Drive
Menlo Park, California 94025
(415) 361-3338

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U.S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231, ON

April 9, 1990

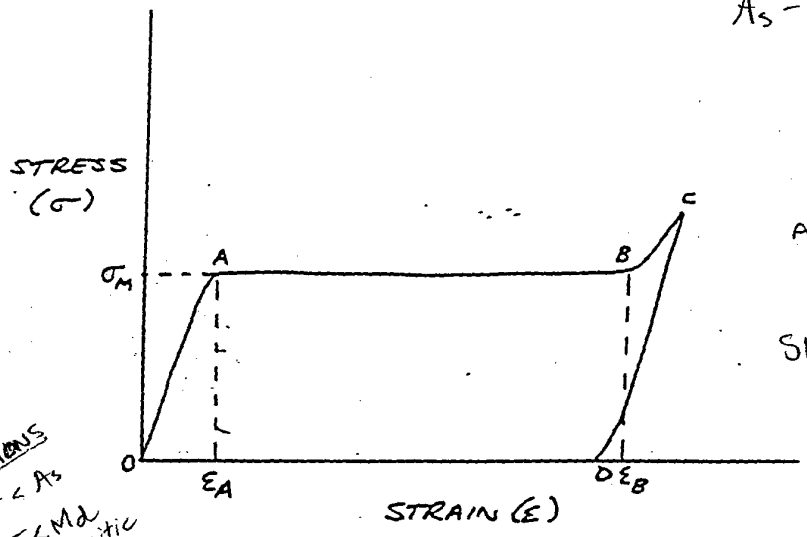
4-9-90
(DATE SIGNED)

606
78

A_s - temperature @ which alloy begins to revert back to austenite (and retain its original shape).

A_f - temp @ completion of this process

SIM - Stress-induced Martensite

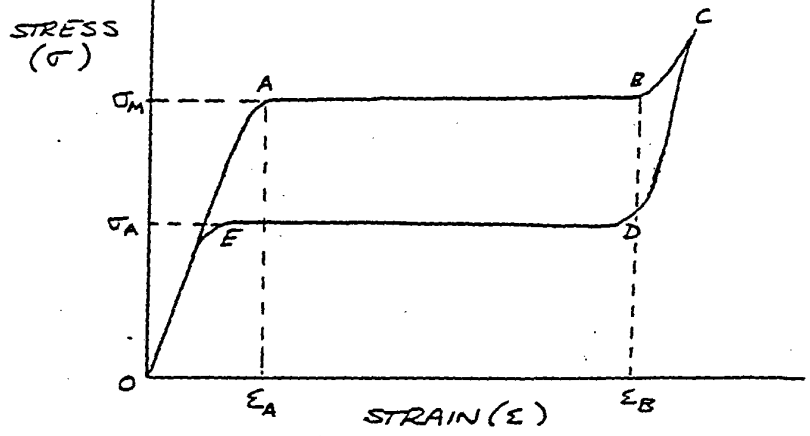


CONDITIONS
$T < A_s$
$M_s < T < M_d$
∴ austenitic

FIGURE 1

CONDITIONS
same as FIG 1
BUT $T \geq A_s$ ∴ UN stable martensite formed @ yielding

FIGURE 2



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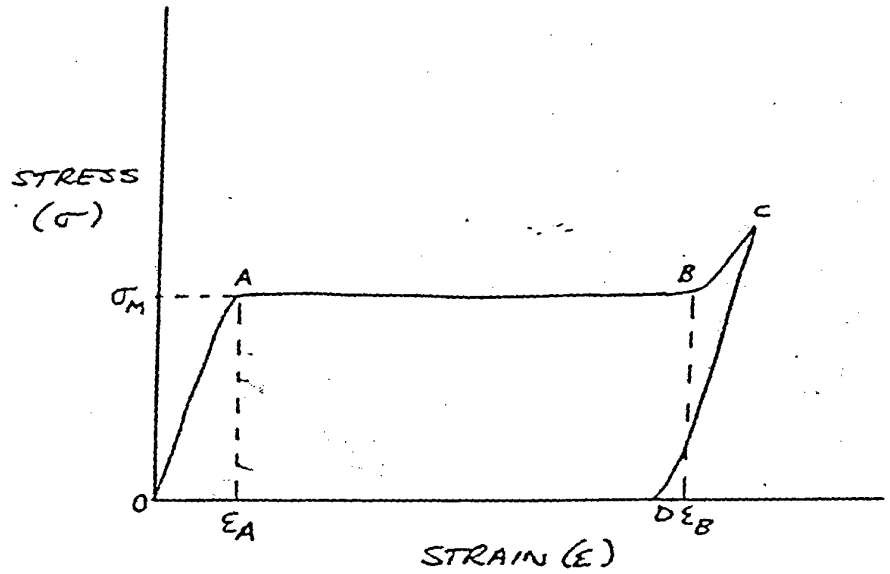
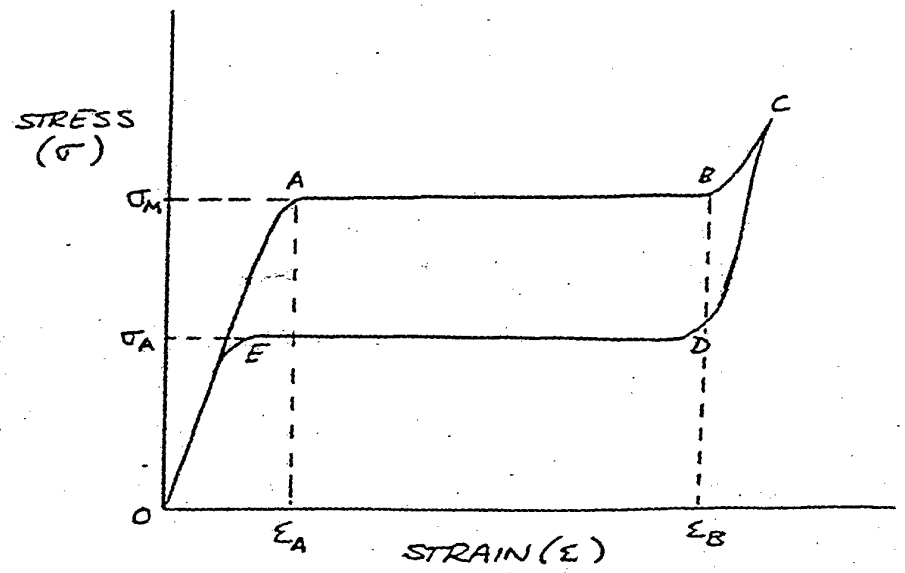


FIGURE 1

FIGURE 2

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07/956653

P Wright 12-23-92 2/Pre A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	)	Group Art Unit:
	)	
JAMES E. JERVIS	)	Examiner:
	)	
Divisional of	)	
Serial No. 07/682,243	)	
	)	
Filed: Herewith	)	
	)	
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	)	

PRELIMINARY AMENDMENT AND INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents and Trademarks
Washington, D. C. 20231

Sir:

Please amend the above-identified patent application as follows:

IN THE SPECIFICATION

Page 2, before the heading "Background of the Invention", insert:

a1

-- CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of application Serial No. 682,243 filed on April 9, 1991, now U.S. Patent No. 5190546, which is a divisional of Serial No. 252,019 filed on September 27, 1988, now U.S. Patent No. 5,067,957, which is a

continuation of Application Serial No. 177,817 filed March 30, 1988, now abandoned; which is a continuation of Application Serial No. 047,824 filed May 8, 1987, now abandoned; which is a continuation of Application Serial No. 865,703 filed May 21, 1986, now U.S. Patent No. 4,665,906; which is a continuation of Application Serial No. 541,852 filed October 14, 1983, now abandoned.

Page 3, line 28, after Quin insert -- now U.S. Patent No. 4,505,767 --.

Page 4, line 26, delete "power" and insert -- powder --.

Page 6, line 4, after "martensite," please insert -- Fig. 3 is a front plan view of a bone implant, namely a nail. --.

Page 7, line 19, delete "E_D" and insert -- E_A--.

Page 7, line 19, delete "strain" and insert -- stress --.

Page 8, line 20, delete "theart" and insert -- the art --.

Page 8, line 21, delete "tsting" and insert -- testing --.

Page 8, line 24, after "(Docket No. MP0873-US1)" insert -- now U.S. Patent No. 4,505,767 --.

Page 8, between lines 24 and 25, insert the following paragraph:

-- The following table sets forth transformation temperature data for alloys disclosed in US-4505767:

TABLE

Composition (atomic percent)

Ni	Ti	V	M_s	A(90)
49.50	43.50	7.00	-107	-88
50.00	44.00	6.00	-96	-84
49.00	43.00	8.00	-83	-61
50.00	45.00	5.00	-42	-33
49.00	45.00	6.00	-35	-12
50.50	48.00	1.50	-32	-6
48.50	44.50	7.00	-30	-13
50.00	46.00	4.00	-11	7
48.50	45.00	6.50	-10	15
49.00	45.50	5.50	-10	14
48.00	44.25	7.75	-7	8
48.50	45.50	6.00	-5	27
41.50	38.50	20.00	-2	86
46.50	43.50	10.00	-1	50
36.25	33.75	30.00	0	42
49.50	46.00	4.50	6	35
48.00	46.00	6.00	12	36
47.75	45.75	6.50	20	54

47.50	45.50	7.00	26	58
48.50	46.50	5.00	27	58
45.00	45.00	10.00	30	71
47.50	46.50	6.00	32	71
46.50	46.50	7.00	34	70

Page 11, line 17, delete "by" and insert -- be --.

Page 13, line 9, delete "it".

Page 14, line 12, delete "whch" and insert -- which --.

Page 14, line 9, after "together." insert -- The Johnson et al. bone plate is of generally oblong configuration, overlaps a bone fracture and is secured by two screws to one portion of the bone and by two other screws to the other portion of the bone --.

Page 15, line 8, before "marrow nails" insert -- implants, such as --.

Page 15, line 9, insert after "Baumgart et al." -- Marrow nails according to Baumgart et al. comprise a tube of memory alloy which has been split along its longitudinal axis and which may have a circular, elliptical, clover-leaf or other rotation preventing cross section, which may also be variable along the axis of the nail. A prepared marrow nail having a

a5 cont reduced diameter is loosely inserted into a slightly, or not at all, pre-drilled marrow channel of a bone which has been broken or fractured. By means of a heating probe the marrow nail is heated and thus expands. This achieves a relative fixing of the two bone ends along the marrow channel axis. Compression of the fracture is effected by the available muscle tension. If it should be necessary, the marrow nail may also be additionally prestretched along its longitudinal axis so that it is additionally compressed in the longitudinal direction when heated. In this case it is necessary, however, to anchor the nail at both of its ends which anchoring can be effected, for example, by sprockets or teeth on the outer surface of the nail. --.

Page 15, line 17, delete "tranisition" and insert -- transition --.

IN THE CLAIMS

Cancel Claims 1 to 10.

Add new Claims 11 to 53 as follows:

a6 11. A medical device for use within a mammalian body, or in such proximity to a mammalian body that the device is

25

substantially at body temperature, the device comprising an element which comprises a shape memory alloy which:

(a) displays stress induced martensite behavior at body temperature; and

(b) has an A(90) temperature of not more than 0°C.

12. A device as claimed in claim 11, which includes a restraint by means of which the shape memory alloy element is held in a deformed configuration to allow it to be positioned within or in proximity to a mammalian body, the deformation occurring through the formation of stress induced martensite.

13. A device as claimed in claim 12, in which the restraint is hollow, and the shape memory alloy element is deformed in such a way that it is compressed transversely, and is positioned within the restraint, the restraint preventing transverse expansion of the element.

14. A device as claimed in claim 13, in which the restraint is a catheter.

15. A device as claimed in claim 13, in which the shape memory alloy element is an intrauterine contraceptive device.

16. A device as claimed in claim ~~14~~ 13, in which the shape memory alloy element is a filter for a blood vessel.

17. A device as claimed in claim 12, in which the shape memory alloy element is tubular, and the restraint is positioned within the shape memory alloy element to deform it.

18. A device as claimed in claim 17, in which the shape memory alloy element is a tracheal catheter.

19. A medical device which comprises:

(a) an element for use within a mammalian body or in such proximity to a mammalian body that the device is substantially at body temperature, the element comprising a shape memory alloy which displays stress induced martensite behavior at body temperature; and

(b) a restraint by means of which the shape memory alloy element is held in a deformed configuration to allow it to be positioned within or in proximity to a mammalian body, the deformation occurring through the formation of stress-induced martensite;

wherein the device is adapted so that removal of the restraint from the shape memory alloy element, without change in temperature of the device, releases at least a portion of the element from its deformed configuration.

20. A device as claimed in Claim ~~19~~, in which the restraint is hollow, and the shape memory alloy element is positioned at least partially within the restraint.

~~21~~. A device as claimed in Claim ~~20~~, in which the restraint is a catheter.

~~22~~. A device as claimed in Claim ~~20~~, in which the shape memory alloy element is an intrauterine contraceptive device.

~~23~~. A device as claimed in Claim ~~21~~, in which the shape memory alloy element is a filter for a blood vessel.

~~24~~. A device as claimed in Claim ~~19~~, in which the shape memory alloy element is tubular, and the restraint is positioned within the shape memory alloy element to deform it.

25. A device as claimed in Claim 20, in which the shape memory alloy element is deformed in such a way that its transverse dimension is reduced, the restraint preventing transverse expansion of the element.

26. The device of Claim 19 wherein removal of the restraint from the shape memory alloy releases at least a portion

A4 Cont of the shape memory alloy element from its deformed configuration without change in state of the restraint.

27. A medical device suitable for placement within or proximate to a mammalian body for treatment of the mammalian body, the device comprising (i) a restraining means and (ii) a memory alloy element formed at least partly from a 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;

the restraining means engaging and stressing the memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element is in its deformed shape;

wherein the restraining means is adapted to be removed from the memory alloy element at a temperature greater than the As of the alloy when the device is placed within or proximate to the mammalian body 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 toward its unstressed shape, and wherein the device is adapted so that the

transformation can occur without any change in temperature of the restraining means or the memory alloy element.

Q6 cont

28. A medical device for treatment of a mammalian body, the device comprising (i) a hollow restraining member and (ii) a memory alloy element formed at least partly from a 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;

the memory alloy element being within the restraining member, the restraining member engaging and stressing the memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element is in its deformed shape;

wherein the restraining member and the memory alloy element are movable relative to each other to transform at least a portion of the alloy from its stress-induced martensitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the device is adapted so that the transformation can

occur without any change in temperature of the restraining member or the memory alloy element.

29. The medical device of Claim 28 wherein the restraining member is a tube and the memory alloy element is axially slidable within the tube, and wherein the device is adapted so that relative axial movement between the tube and the memory alloy element extends at least a portion of the memory alloy element beyond the tube and thereby transforms the memory alloy element toward its austenitic state.

~~30~~. The device of Claim ~~27~~ wherein the memory alloy element can be extruded completely out of the tube for deployment in the mammalian body.

~~31~~. A medical device for treatment of a mammalian body, the device comprising (i) a restraining member and (ii) a hollow memory alloy element formed at least partly from a 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;

the restraining member being within the hollow memory alloy element and engaging and stressing the memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element is in its deformed shape;

wherein the restraining member and the memory alloy element are movable relative to each other to transform at least a portion of the alloy from its stress-induced martensitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the ~~device is adapted so~~ alloy is selected that the transformation can occur without any change in temperature of the restraining member or the memory alloy element.

~~32.~~ 13. The device of Claim ~~31~~ wherein the memory alloy element is a tube and the restraining member is axially slidable within the tube, and wherein the ~~device is adapted so~~ tube is sufficiently long that relative axial movement between the tube and the restraining ~~means~~ members extends at least a portion of the tube beyond the restraining means and thereby transforms the tube toward its austenitic shape.

33. A medical device for insertion into a mammalian body, the device comprising (i) a restraining member and (ii) a

hollow catheter formed at least partly from a 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 catheter having (i) an easily inserted 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;

the restraint ~~externally~~ or internally engaging and stressing the catheter at a temperature greater than the As of the alloy so that the catheter is in its easily inserted shape;

wherein disengagement of the restraining member from the catheter at a temperature greater than the As of the alloy transforms at least a portion of the alloy from its stress-induced martensitic state to its austenitic state so that the catheter transforms from its easily inserted shape toward 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 restraining member or the catheter.

~~14~~ 16. The medical device of Claim ~~13~~ 15 wherein the catheter is a cannula.

35. A medical device for insertion into a ~~mammalian~~ human body, the device comprising (i) a straight pin and (ii) a catheter formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about human body temperature such that it has a stress-induced martensitic state and an austenitic state, the catheter having (i) a straight shape when the alloy is in its stress-induced martensitic state and (ii) a curved unstressed shape when the alloy is in its austenitic state;

the straight pin engaging and stressing the inside of the catheter at a temperature greater than the As of the alloy so that the catheter is in its straight shape;

wherein withdrawal of the pin from the catheter at a temperature greater than the As of the alloy transforms at least a portion of the alloy from its stress-induced martensitic state to its austenitic state so that the catheter transforms from its straight shape to its curved shape, and wherein the ~~device is adapted~~ alloy is selected so that the transformation can occur without any change in temperature of the pin or the catheter.

36. The medical device of Claim ~~35~~ 17 wherein the catheter is a tracheal insertion catheter.

37. A medical device for insertion into a mammalian body, the device comprising (i) a hollow placement device and (ii) a memory alloy element formed at least partly from a 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;

the memory alloy element being within the hollow placement device, the hollow placement device stressing the memory alloy element at a temperature greater than the As 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 at a temperature greater than the As 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.

38. The medical device of Claim 37 wherein the memory alloy element is an intrauterine contraceptive device.

39. The device of Claim 37 wherein the memory alloy element is a stent graft.

40. The device of Claim 37 wherein the memory alloy element is a filter for trapping blood clots.

~~41~~. The invention of Claim ~~27~~ wherein the transformation of the alloy occurs without any change in the state of the restraining means.

~~42~~. The invention of Claim ~~28~~, ~~31~~ or ~~33~~ wherein the transformation of the alloy occurs without any change in the state of the restraining ~~means~~ member.

43. The invention of Claim 37 wherein the transformation occurs without any change in the state of the placement device.

~~44~~. The invention of Claim ~~35~~ wherein the transformation of the alloy occurs without any change in the state of the pin.

A4 Cont

~~45.~~ 22 The invention of Claim ~~27~~ 9, ~~28~~ 10 or ~~31~~ 13 wherein the memory alloy element exerts constant stress during its transformation.

~~46.~~ 23 The invention of Claim ~~33~~ 15 or ~~35~~ 17 wherein the catheter exerts constant stress during its transformation.

~~47.~~ 24 The medical device of Claim ~~27~~ 9 wherein the removal of the restraining means from the memory alloy element causes at least a portion of the alloy to transform to its austenitic state.

~~48.~~ 25 The medical device of Claim ~~28~~ 10, ~~31~~ 13, ~~33~~ 15 wherein relative movement of the restraining member and the memory alloy element causes at least a portion of the alloy to transform to its austenitic state.

~~49.~~ 26 The device of Claim ~~47~~ 24 wherein the alloy is selected

D ~~device is adapted~~ so that engaging the restraining means with the memory alloy element after removal results in the memory alloy element transforming toward its deformed shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

9/6 cont put 077

50. The device of Claim 48 wherein the device is adapted so that (i) the restraining member can be completely disengaged and separated from the memory alloy element, and (ii) engaging the restraining member with the memory alloy element after separation results in the memory alloy element transforming towards its deformed shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

51. The device of Claim 33 wherein the device is adapted so that (i) the restraining member can be completely disengaged and separated from the catheter, and (ii) re-engaging the restraining member with the catheter after separation results in the catheter transforming toward its easily inserted shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

52. The device of Claim 35 wherein the device is adapted so that (i) the pin can be completely disengaged and separated from the catheter, and (ii) re-engaging the restraining means with the memory alloy element after separation results in the catheter transforming toward its deformed shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

53. The device of Claim 36 wherein the device is adapted so that (i) the placement device can be completely disengaged and separated from the catheter, and (ii) re-engaging the placement device with the catheter after separation results in the catheter transforming toward its deformed shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

REMARKS

Entry of the amendments is respectfully requested. All the amendments to the specification and drawings are the same as were made in the parent application.

INFORMATION DISCLOSURE STATEMENT

Attached hereto are copies of Forms PTO-1449. These forms list all the references cited in the parent application. Copies of the references are available in the file of the parent application. It is believed that these cited references are relevant to claims pending in the present application for the same reason as discussed in the parent application. Not all of these references are relevant to the newly filed claims.

If the Examiner would like a further description, or copies of any of the references, please call the undersigned. In

view of the bulk of the references, and the fact that they are available in the file of the parent application, Applicant does not desire to overload the Patent Office files with duplicate copies of references. However, if the Examiner has a need for the copies, applicant would be most happy to provide them.

Respectfully submitted,

SHELDON & MAK

DATED: 10/2, 1992

By _____
Jeffrey G. Sheldon
Reg. No. 27,953

SHELDON & MAK
225 South Lake Avenue - 9th Floor
Pasadena, California 91101
(818) 796-4000

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72.00 102
QW 2/10/93
9438

#3/Re B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Group Art Unit: 3301
JAMES E. JERVIS	
Serial No. 07/956,653	
Filed: October 2, 1992	
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	

PRELIMINARY AMENDMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

IN THE CLAIMS

Please add the following claim:

54. A method for compressing two ends of a mammalian bone together at body temperature, the method comprising the steps of:

(a) providing a bone plate formed from a pseudoelastic shape-memory alloy, wherein the shape-memory alloy can display reversible stress-induced martensite at about body temperature such that the shape-memory alloy has a stress-induced martensitic state and an austenitic state, the bone plate being (i) elongated when the alloy is in its stressed-induced martensitic state and (ii) shortened when the alloy is in its austenitic state;

(b) stressing the bone plate at a temperature greater than the As of the alloy for placing the alloy in its

stress-induced martensitic state and elongating the bone plate;

(c) attaching the stressed and elongated bone plate to the two ends of the bone at a temperature greater than the As of the alloy; and

(d) releasing the stress from the bone plate so that at least a portion of the alloy transforms from its stress-induced martensitic state to its austenitic state so that the bone plate compresses the two ends of the bone together at essentially constant stress.

REMARKS

The above claim was submitted in an Amendment after Allowance dated July 7, 1992, in the parent application Serial No. 07/682,243. However, the Patent and Trademark Office did not enter the Amendment in the parent case on the basis that the claim was not prosecuted during the pendency of the application.

Respectfully submitted,

SHELDON & MAK

DATED: 12/30/92

By _____
Jeffrey G. Sheldon
Reg. No. 27,953

225 S. Lake Avenue - 9th Floor
Pasadena, California 91101
(818) 796-4000

AMENDMENT COVER SHEET

DOCKET NO. 9438

Part of #3

IN RE APPLICATION OF: James E. Jervis

SERIAL NO.: 07/956,653 FILED: October 2, 1992

FOR: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

HONORABLE COMMISSIONER OF
PATENTS AND TRADEMARKS

Washington, D.C. 20231

Sir:

Transmitted herewith is a paper in the above-identified application. Any necessary extension of time period set for this paper is hereby requested.

☐ No additional fee is required.

☐ The fee has been calculated as shown below:

☐ EXTENSION FEE

	RATE Non-Small Entity	RATE Small Entity	FEE
FIRST MONTH AFTER TIME PERIOD SET	110.00	55.00	$
SECOND MONTH AFTER TIME PERIOD SET	360.00	180.00	$
THIRD MONTH AFTER TIME PERIOD SET	840.00	420.00	$
FOURTH MONTH AFTER TIME PERIOD SET	1,320.00	660.00	$

☐ TOTAL EXTENSION FEE $ _____

☒ FEE FOR EXTRA CLAIMS added by Amendment in this response:

	Column 1 Number of Claims after Amendment	Column 2 Number Previously Paid for	Column 3 Number of Extra Claims	RATE Non-Small Entity	RATE Small Entity	FEE
TOTAL CLAIMS	53	MINUS ** 52	* = 1	x 20	x 10	$ 20
INDEPENDENT	9	MINUS *** 8	* = 1	x 72	x 36	$ 72
First presentation of multiple dependent claim				+ 220	+ 110	$

TOTAL FEE FOR EXTRA CLAIMS $ 92.00

* If the entry in Column 1 is less than the entry of Column 2, write "0" in Column 3.
** If the number of Total Claims previously paid for is less than 20, write "20" in this space.
*** If the number of Independent Claims previously paid for is less than 3, write "3" in this space.

☒ Enclosed is the fee of $ 92.00 by Check No. 3645

☐ Please charge Deposit Account No. 19-2090 in the amount of $ _____

☒ The Commissioner is hereby authorized to charge payment of any additional fees, in particular the following fees, associated with this communication, or credit any overpayment to Deposit Account No. 19-2090:

Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
Any patent application processing fees under 37 C.F.R. § 1.17

Date: 12/30/92

SHELDON & MAK

By: Jeffrey G. Sheldon

Reg. No.: 27,953

CERTIFICATE OF MAILING:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on 12/30/92.

Kira P. Lunk
Signature

Kira P. Lunk
Typed or Printed Name of Person Mailing Paper or Fee

Avenue
ia 91101
13) 681-9000

PC20\FORMS\PATENTS\AMEND.CS

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
07/956,653	10/02/92	JERVIS	J	9438

EXAMINER
KENEALY, D

JEFFREY G. SHELDON
SHELDON & MAK
225 S. LAKE AVENUE - 9TH FLOOR
PASADENA, CA 91101

ART UNIT	PAPER NUMBER
3301	4

DATE MAILED: 02/22/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 1 month(s), ___ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 11-54 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☑ Claims 1-10 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☐ Claims _____ are rejected.

5. ☐ Claims _____ are objected to.

6. ☑ Claims 11-53 & 54 are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev.9-89)

The drawings are objected to under 37 C.F.R. § 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the IUD, the tubular structure, the catheter, the filter for a blood vessel, the tracheal catheter, etc., must be shown or the feature canceled from the claim. No new matter should be entered. It is difficult to interpret the claims without a drawings, especially in the instance of claim 25 which claims a transverse dimension without any antecedent basis and has no drawing for reference.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 11-53, drawn to medical devices incorporating SIM alloy elements, classified in Class 606, subclass 78.

II. Claim 54, drawn to a method for compressing two mammalian bones together, classified in Class 606 and Class 128, subclass 898.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (M.P.E.P. § 806.05(e)). In this case the apparatus as claimed can be used to practice another and

materially different process such as contraception or catheterization.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: where the shape memory alloy is an IUD, a stent graft, a blood filter a catheter and a tracheal catheter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 12,19 and 37 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or

identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

It should be noted that most of the claims subsequent to claim 41 are functional in nature and it is difficult for this examiner to comprehend what structure is being claimed with the limitations presented. Claims 49-53 all contain the term "adapted" which has little meaning in terms of patent language used for claiming a structural item.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Kenealy whose telephone number is (703) 308-2680.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

DK
David Kenealy
February 21, 1993

ROBERT A. [illegible]
S.P.E.
ART UNIT 331

200.00 126 Rp331

9438

#5 4-5-93 Prior Art

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Group Art Unit: 3301
JAMES E. JERVIS	)	Examiner:
Serial No.: 07/956,653	)	
Filed: October 2, 1992	)	
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	)	Pasadena, California

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Dear Madam/Sir:

Attached hereto are PTO-1449 forms listing documents believed relevant to the subject application. It is respectfully requested that these documents be considered by the Examiner and an initialed copy of each form be returned to the undersigned.

Enclosed is check no. 3875 for $200, the fee due under 37 C.F.R. § 1.17(p).

Enclosed please find (1) references cited by the Japanese Patent Office in a counterpart Japanese application, (2) Opposition papers and references cited to a counterpart European patent application, and (3) EPO Search Report and references cited therein.

Please note that U.S. Patent 5,190,546 is a parent of the present application, E.P.O. 0145166 is a European Patent Office counterpart application, and Japanese Patent Kokai 100956/1985 is the Japanese counterpart application. These

references have the same inventor as the present application. Hence, these references are not prior art.

It should be noted that the word "prior" has been deleted from the form.

It is believed that this disclosure complies with the requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98, and the Manual of Patent Examining Procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be called so that any deficiencies can be remedied.

A copy of each document is enclosed.

Some of the documents may have markings thereon. No significance is meant to be attached to the markings.

With regard to any translation provided herewith, the undersigned does not know how and who made the translations. Therefore, no representation is being made as to the accuracy of any translation.

These documents are not necessarily analogous.

Respectfully submitted,

SHELDON & MAK

Dated: 3/12/93

By _____
Jeffrey G. Sheldon
Reg. No. 27,953

225 South Lake Avenue
Ninth Floor
Pasadena, California 91101
(818) 796-4000

Encls.

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U. S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D. C. 20231 ON

Melissa Alexander
3-12-93
(DATE SIGNED)

PC20\AKJ\PATENT\9438-1.IDS

FORM PTO-1449 — U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

LIST OF ART CITED BY APPLICANT
(Use several sheets if necessary)

ATTORNEY DOCKET NO.: 9438 | SERIAL NO.: 07/956,653

APPLICANT: JAMES E. JERVIS

FILING DATE: OCTOBER 2, 1992 | GROUP: 3301

U.S. PATENT DOCUMENTS

Examiner Initial		DOCKET NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
DJK	AA-1	4 3 1 0 3 5 4	01/12/82	FOUNTAIN, ET AL.	~	~	
DJK	AB-1	4 4 9 0 1 1 2	09/02/82	TANAKA	433	20	
DJK	AC-1	5 1 9 0 5 4 6	03/02/93	JERVIS	606	78	
	AD-1						
	AE-1						
	AF-1						
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	AH-1						
	AI-1						
	AJ-1						
	AK-1						

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		DOCKET NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
DJK	AL-1	0 1 4 0 6 2 1	05/08/85	E.P.O.	—	—		
	AM-1	0 1 4 5 1 6 6	4/19/85 ~~1985~~	E.P.O.	—	—	✓	
	AN-1	1 0 0 9 5 6	6/4/85 ~~1985~~	JAPAN APPLICATION	—	—	✓	
	AO-1	1 6 0 0 0 0 0	10/14/81	GREAT BRITAIN	F16L	21/00		
DJK	AP-1	DE 28 02 5 7 1 C2	12/14/78	GERMANY	C22F	1/00		

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

DJK	AQ-1	Brief communication dated August 13, 1991, in German.
DJK	AR-1	Communication pursuant to Article 115(2) EPC and Opposition papers dated September 28, 1992.
DJK	AS-1	Communication of a Notice of Opposition dated August 7, 1990. Opposition papers in German.

EXAMINER: Kercal — DATE CONSIDERED: 6/13/93

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

US005190546A

United States Patent [19]

Jervis

[11] Patent Number: 5,190,546

[45] Date of Patent: Mar. 2, 1993

[54] MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

[75] Inventor: James E. Jervis, Atherton, Calif

[73] Assignee: Raychem Corporation, Menlo Park, Calif.

[21] Appl. No. 682,243

[22] Filed: Apr. 9, 1991

Related U.S. Application Data

[60] Division of Ser. No. 252,019, Sep. 27, 1988, Pat. No. 5,067,957, which is a continuation of Ser. No. 177,817, Mar. 30, 1988, abandoned, which is a continuation of Ser. No. 47,324, May 8, 1987, abandoned, which is a continuation of Ser. No. 865,703, May 21, 1986, Pat. No. 4,665,906, which is a continuation of Ser. No. 541,852, Oct. 14, 1983, abandoned.

[51] Int. Cl.[5] A61B 17/58

[52] U.S. Cl. 606/78; 606/60; 606/62; 606/68, 606/200; 606/108; 128/833

[58] Field of Search 606/60, 62, 67, 68, 606/69-76, 78, 108; 128/833

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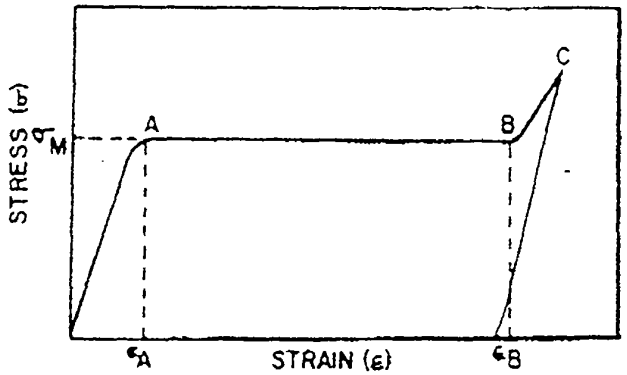
Primary Examiner—Robert A. Hafer
Assistant Examiner—Kevin G. Rooney
Attorney, Agent, or Firm—Jeffrey G. Sheldon

[57] ABSTRACT

Medical devices which are currently proposed to use elements made from shape memory alloys may be improved by the use of stress-induced martensite alloy elements instead. The use of stress-induced martensite decreases the temperature sensitivity of the devices, thereby making them easier to install and/or remove.

40 Claims, 2 Drawing Sheets



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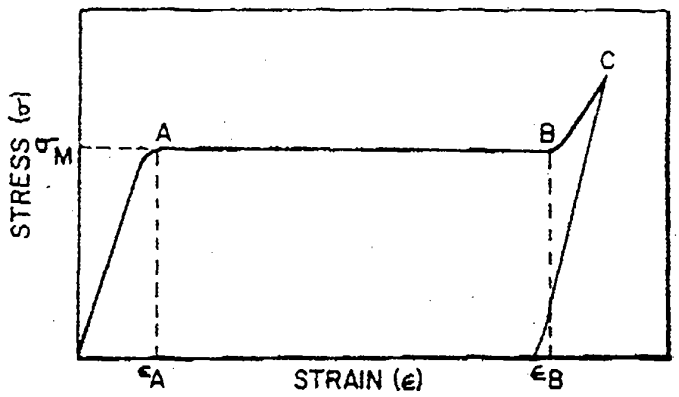
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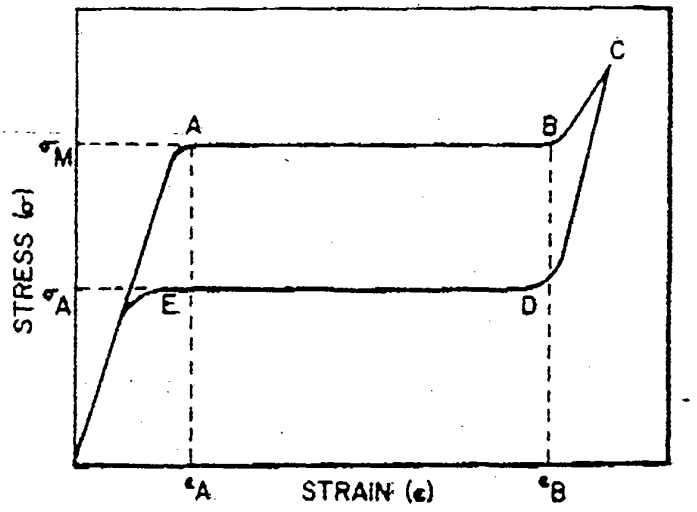
σ_M
A
B
C
ϵ_A
STRAIN (ε)
ϵ_B

FIG. 1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σ_M
σ_A
A
B
C
D
E
ϵ_A
STRAIN (ε)
ϵ_B

FIG. 2

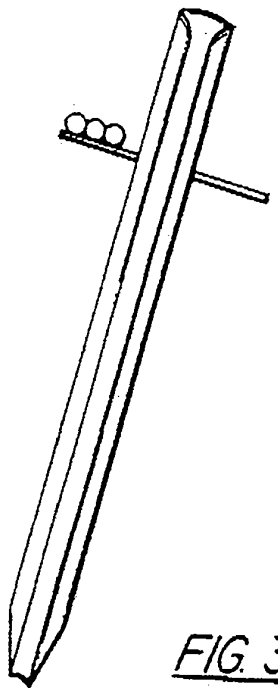

FIG. 3

MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of application Ser. No. 252,019 filed Sept. 27, 1988, now U.S. Pat. No. 5,067,957, which is a continuation of application Ser. No. 177,817 filed Mar. 30, 1988, now abandoned; which is a continuation of application Ser. No. 047,824 filed May 8, 1987, now abandoned; which is a continuation of application Ser. No. 865,703 filed May 21, 1986, now U.S. Pat. No. 4,665,906; which is a continuation of application Ser. No. 541,852 filed Oct. 14, 1983, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to medical devices incorporating shape memory alloys, and to improvements therein.

2. Introduction to the Invention

Materials, both organic and metallic, capable of possessing shape memory are well known. An article made of such materials can be deformed from an original, heat-stable configuration to a second, heat-unstable configuration. The article is said to have shape memory for the reason that, upon the application of heat alone, it can be caused to revert, or to attempt to revert, from its heat-unstable configuration to its original, heat-stable configuration, i.e. it "remembers" its original shape.

Among metallic alloys, the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state with a change in temperature. This transformation is sometimes referred to as a thermoelastic martensitic transformation. An article made from such an alloy, for example a hollow sleeve, is easily deformed from its original configuration to a new configuration when cooled below the temperature at which the alloy is transformed from the austenitic state to the martensitic state. The temperature at which this transformation begins is usually referred to as M_s and the temperature at which it finishes M_f. When an article thus deformed is warmed to the temperature at which the alloy starts to revert back to austenite, referred to as A_s (A_f being the temperature at which the reversion is complete) the deformed object will begin to return to its original configuration.

Many shape memory alloys (SMAs) are known to display stress-induced martensite (SIM). When an SMA sample exhibiting stress-induced martensite is stressed at a temperature above M_s (so that the austenitic state is initially stable), but below M_d (the maximum temperature at which martensite formation can occur even under stress) it first deforms elastically and then, at a critical stress, begins to transform by the formation of stress-induced martensite. Depending on whether the temperature is above or below A_s, the behavior when the deforming stress is released differs. If the temperature is below A_s, the stress-induced martensite is stable; but if the temperature is above A_s, the martensite is unstable and transforms back to austenite, with the sample returning (or attempting to return) to its original shape. The effect is seen in almost all alloys which exhibit a thermoelastic martensitic transformation, along with the shape memory effect. However, the extent of the temperature range over which SIM is seen and the stress and strain ranges for the effect vary greatly with the alloy.

In the commonly assigned Quin U.S. Pat. No. 04505767, the disclosure of which is incorporated herein by reference, a nickel/titanium/vanadium alloy having SIM over a wide temperature range is disclosed.

Shape memory alloys have found use in recent years in, for example, pipe couplings (such as are described in Harrison and Jervis U.S. Pat. Nos. 4,035,007 and 4,198,081), electrical connectors (such as described in Otte and Fischer U.S. Pat. No. 3,740,839), switches (such as are described in U.S. Pat. No. 4,205,293), actuators, etc.

Various proposals have also been made to employ shape memory alloys in the medical field. For example, Fannon et al. U.S. Pat. No. 3,620,212 proposes the use of an SMA intrauterine contraceptive device, Johnson et al. U.S. Pat. No. 3,786,806 proposes the use of an SMA bone plate, Wilson U.S. Pat. No. 3,890,977 proposes the use of an SMA element to bend a catheter or cannula, etc.

These medical SMA devices rely on the property of shape memory to achieve their desired effects. That is to say, they rely on the fact that when an SMA element is cooled to its martensitic state and is subsequently deformed, it will retain its new shape; but when it is warmed to its austenitic state, the original shape will be recovered.

However, the use of the shape memory effect in medical applications is attended with two principal disadvantages. First, it is difficult to control the transformation temperatures of shape memory alloys with accuracy as they are usually extremely composition-sensitive, although various techniques have been proposed (including the blending by powder metallurgy of already-made alloys of differing transformation temperatures; see Fountain et al. U.S. Pat. No. 4,310,354). Second, in many shape memory alloys there is a large hysteresis as the alloy is transformed between austenitic and martensitic states, so that reversing of the state of an SMA element may require a temperature excursion of several tens of degrees Celsius. The combination of these factors with the limitation that (a) it is inconvenient to have to engage in any temperature manipulation, and (b) human tissue cannot be heated or cooled beyond certain relatively narrow limits (approximately 0°-60° C. for short periods) without suffering temporary or permanent damage is expected to limit the use that can be made of SMA medical devices. It would thus be desirable to develop a way in which the advantageous property of shape memory alloys, i.e. their ability to return to an original shape after relatively substantial deformation, could be used in medical devices without requiring the delicacy of alloying control and/or the temperature control of placement or removal needed by present shape memory alloy devices.

DESCRIPTION OF THE INVENTION

Summary of the Invention

I have discovered that if, in a medical device containing a shape memory alloy element which uses the shape memory property of that alloy, an element which shows the property of stress-induced martensite is used instead, an improved device results.

Accordingly, this invention provides a medical device intended for use within a mammalian body, or in such proximity to a mammalian body that the device is

substantially at body temperature, which device comprises a shape memory alloy element, the improvement in which comprises the substitution of an alloy element which displays stress-induced martensite at said body temperature for the shape memory alloy element

BRIEF DESCRIPTION OF THE DRAWING

FIGS. 1 and 2 illustrate the stress-strain behavior of an alloy which exhibits constant stress versus strain behavior due to stress-induced martensite.

FIG. 3 is a front plan view of a bone implant, namely a nail.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention will be discussed first by introducing the concept of stress-induced martensite and the effect achievable by its use, and then by examples showing how SIM alloy elements can be substituted for conventional SMA elements in medical devices to achieve the beneficial effect of the invention.

The Figures illustrate the phenomenon of stress-induced martensite by means of stress-strain curves. In both FIG. 1 and FIG. 2, the alloy is at a temperature between M_f and M_d so that it is initially austenitic; and it will be assumed for the puposes of this discussion that M_s is equal to M_f, and A_s equal to A_f. FIG. 1 shows the case when the temperature is below A_s, so that any martensite formed by the applied stress is stable; while FIG. 2 shows the case where the temperature is above A_s, so that austenite is the only stable phase at zero stress.

In FIG. 1, when a stress is applied to the alloy, it deforms elastically along the line OA. At a critical applied stress, σ_M, the austenitic alloy begins to transform to (stress-induced) martensite. This transformation takes place at essentially constant stress until the alloy becomes fully martensitic at point B. From that point on, as further stress is applied, the martensite yields first elastically and then plastically (only elastic deformation is shown at point C). When the stress is released, the martensite recovers elastically to point D, at which there is zero residual stress, but a non-zero residual strain. Because the alloy is below A_s, the deformation is not recoverable until heating above A_s results in a reversion to austenite. At that point, if the sample is unrestrained, the original shape will be essentially completely recovered: if not, it will be recovered to the extent permitted by the restraint. However, if the material is then allowed to re-cool to the original temperature at which it was deformed (or a temperature where SIM behavior of this type is seen), the stress produced in the sample will be constant regardless of the strain provided that the strain lies within the "plateau" region of the stress-strain curve. That is, for a strain between ϵ_B and ϵ_A the stress will be σ_M. This means that a known, constant force (calculable from σ_M) can be applied over a wide (up to 5% or more for certain Ni/Ti alloys) strain range. Thus, though this resembles the conventional shape memory effect, because the alloy shows SIM and is below A_s a constant force can be achieved.

In FIG. 2, when a stress is applied to the alloy, it deforms elastically along line OA, then by SIM along line AB, and by deformation of the martensite to point C, just as in FIG. 1. However, the stress-strain behavior on unloading is significantly different, since the alloy is above A_s and the stable phase is therefore austenite. As the stress is removed, the alloy recovers elastically from O to D; then, at a critical stress, σ_A, the alloy reverts to austenite without requiring a change in temperature. Thus reversion occurs at essentially constant stress. Finally if the stress is removed from the reverted austenite, it recovers elastically along line EO. The recoverable deformation associated with the formation and reversion of stress-induced martensite has been referred to as pseudoelasticity. While σ_M may be comparatively high, e.g. 50 ksi, σ_A is usually substantially lower, e.g. less than 10 ksi; thereby creating a constant-force spring with an effective working range of about 5% ($\epsilon_B - \epsilon_A$). The shape change available in the SMA is thus mechanically, rather than thermally, actuated and controlled, permitting a greater control over a device incorporating it.

Suitable alloy for this invention i.e. those displaying stress-induced martensite at temperatures near mammalian body temperature (35°–40° C.), may be selected from known SMAs by those of ordinary skill in the art, having regard to this disclosure by testing for the existence of the SIM effect at the desired temperature. A particularly preferred alloy is the nickel/titanium/-vanadium alloy of U.S. Pat. No. 4,505,767 referred to previously.

The following table sets forth transformation temperature data for alloys disclosed in U.S. Pat. No. 4,505,767:

TABLE

Composition (atomic percent)				
Ni	Ti	V	M	A(90)
49.50	43.50	7.00	−107	−38
50.00	44.00	6.00	−96	−84
49.00	43.00	8.00	−83	−61
50.00	45.00	5.00	−42	−33
49.00	45.00	6.00	−35	−12
50.50	48.00	1.50	−32	−6
48.50	44.50	7.00	−30	−13
50.00	46.00	4.00	−11	7
48.50	45.00	6.50	−10	15
49.00	45.50	5.50	−10	14
48.00	44.25	7.75	−7	8
48.00	45.50	6.00	−3	27
41.50	38.50	20.00	−2	86
46.50	43.50	10.00	−1	50
36.25	33.75	30.00	0	42
49.50	46.00	4.50	6	35
48.00	46.00	6.00	12	36
47.75	45.75	6.50	20	54
47.50	45.50	7.00	26	58
48.50	46.50	5.00	27	58
45.00	45.00	10.00	30	71
47.50	46.50	6.00	32	71
46.50	46.50	7.00	34	70

The invention will now be discussed in detail by some examples of the use of an SIM alloy.

EXAMPLE I

Heart Valves

Akins U.S. Pat. No. 4,233,690, the disclosure of which is incorporated herein by reference, describes the use of a shape memory alloy ring to hold a sewing cuff to the body of an artificial heart valve. The ring is made in the austenitic phase, cooled to the martensitic phase, deformed, placed around the valve body, and heated or allowed to warm to cause reversion to the austenitic phase and recovery of the ring into engagement with the valve body.

However, this technique has not found commercial acceptance. Present medical technique requires that the valve body be capable of being rotated relative to the cuff, thereby enabling the surgeon to set the rotational orientation of the valve after it has been sewn into place. This is desirable because the techniques used make it difficult to visualize or accomplish optimal orientation during initial placement.

In order to accomplish the desired torque control to permit the desired rotation and yet ensure a firm hold of the cuff on the valve body, precise control of the pressure exerted on the valve body by the ring is needed. This is difficult because there are substantial manufacturing tolerances in the valve body which may be made, for example, of pyrolytic graphite or ceramics, etc. Because the austenite stress-strain curve is extremely steep, it is not considered practical to use the simple shape memory technique proposed by Akins. Indeed, Akins does not even address the issue of rotation of the cuff with respect to the valve body.

However, if an SIM alloy is used instead of conventional shape memory, the process may be considerably simplified.

First, if the alloy has a stress-strain curve like that of FIG. 1, the alloy ring may be made just as for Akins. The ring is then expanded from its initial austenitic state by the formation of SIM. When the ring is placed about the valve body, it needs only to be heated above A_f and allowed to cool to its original temperature for the ring to engage the valve body with a constant force, even if the valve body has a deviation from the specified size. The torque may thus be controlled to the desired level despite manufacturing tolerances.

Second, if the alloy has a stress-strain curve like that of FIG. 2, the ring may be expanded, placed over the valve body, and the stress released all at the same temperature. Because the austenitic phase is stable, the stress-induced martensite spontaneously reverts to austenite until recovery is restrained by the ring engaging the valve body. Because the reversion to austenite takes place at constant stress, a constant force (and hence constant torque) may be obtained regardless of manufacturing tolerances. Close temperature control is not required, either, and the fact that the patient in a heart valve replacement operation is conventionally cooled as much as 15° C. or so below normal body temperature does not affect the operation of the ring.

To control the torque at a sufficiently low level, it may be desirable for the alloy ring to be other than a solid ring, such as, for example, a continuous helical spring, a flat zigzag spring, etc. Such variations permit the achievement of a greater range of movement with constant force and a reduction in the force exerted by the ring on the value body, since the ring recovers in a bending mode rather than in tension.

EXAMPLE II

Catheters and Cannulas

Wilson U.S. Pat. No. 3,890,977, the disclosure of which is incorporated herein by reference, discloses a catheter or cannula (both being included hereinafter in the word "catheter") made of, or containing, an SMA element to cause all or a portion of the catheter to deploy in a useful form once introduced into a living body.

However, again this device has not been commercialized. Possible defects of the device which have prevented commercialization include (i) the inability to slowly emplace the catheter in a desired position when the transition temperature of the alloy is below body temperature (since the SMA element will attempt to revert to its original shape as it reaches body temperature), thus limiting the ability of the physician to place the device carefully and precisely; or alternatively, if the transition temperature of the alloy is above body temperature, the requirement that the device be heated to a temperature above body temperature to cause recovery and that the device be placed so as not to change shape again when it re-cools (since the body temperature is below the transition temperature); (ii) the inability to remove the device easily; and (iii) the need for controlled temperature storage to prevent premature reversion to austenite of the SMA, with consequent shape change.

The issue of removal of a catheter is especially significant, and not addressed by Wilson. Consider, for example, a tracheal puncture catheter. This should be straight for easy insertion into the trachea through a puncture into the front of the neck, but should curve after insertion so that the flow of air or oxygen through the catheter passes axially down the trachea rather than impinging on the surface of the trachea and damaging it. If a shape memory catheter is used as contemplated by Wilson, it would presumably become austenitic and bend after insertion (see FIGS. 1*a* and 1*b*, and corresponding text, of Wilson). But removal would require either cooling to below the transition temperature (which could easily mean cooling to so low a temperature that the tracheal tissue is damaged), removal in the bent shape (presumably damaging tissue), or forcing the austenitic SMA to straighten to permit direct removal (unlikely to be satisfactory since the austenitic alloys e.g. of Ni/Ti may have yield strengths of 100 ksi or more, and force sufficient to cause plastic deformation would be required).

If an SIM element is used instead, however, removal can be accomplished almost as easily as insertion. If the catheter is made in a bent shape (as in Wilson), it can be straightened by insertion of a straight pin down the catheter axis, the catheter deforming by the formation of stress-induced martensite. Insertion of the catheter into the trachea is accomplished while the catheter is straight, at whatever rate is desired (permitting easy and accurate placement), and the pin is gradually withdrawn to permit the catheter to take up its desired shape as the martensite reverts to austenite. [It is assumed here that the stress-strain curve of the alloy at the temperature of use is of the form of FIG. 2, so spontaneous reversion occurs on removal of the stress induced by the pin]. When removal is desired, it may be achieved simply by the gradual insertion of the pin, straightening the catheter and permitting easy withdrawal. Insertion of the catheter into the body and pin removal may, of course, take place simultaneously if desired, as may pin reinsertion and removal of the catheter from the body.

EXAMPLE III

IUDS

Fannon et al. U.S. Pat. No. 3,620,212, the disclosure of which is incorporated herein by reference, discloses an intrauterine contraceptive device (an IUD) proposed to be formed of a shape memory alloy. The device is suggested to be deformed in the martensitic phase (the transition temperature being below the temperature of the uterus), and the deformed device insulated with, e.g., wax and inserted. Removal is contemplated only

by using two SMA elements in opposition, the higher temperature one being martensitic at body temperature but strong enough so that, if heated, it will overcome the lower temperature element and deform the IUD back to the removable shape. The heating contemplated is electrical. The storage problem discussed in Example II also exists here, so that the device must be stored below its transition temperature.

By the use of an SIM element, however, these disadvantages may be overcome. Again, assume that the alloy is SIM pseudoelastic, i.e. that it has the stress-strain curve of FIG. 2. Then an IUD may be formed into the desired shape in the austenitic state, and deformed by compression into a tubular placement device (the deformation being such that the strain levels lie within the "plateau" of the stress-strain curve). When the placement device is inserted into the uterus, the IUD may be deployed by extrusion of the IUD from the placement device. Deployment is then controlled but immediate, so that the physician may satisfy himself with placement. Removal is the reversal of placement: the placement device is inserted into the uterus, the IUD deformed by withdrawal into the placement device, and the placement device withdrawn. Temperature control is not required.

EXAMPLE IV

Bone Plates

Johnson et al. U.S. Pat. No. 3,786,806, the disclosure of which is incorporated herein by reference, propose the use of Ni/Ti SMA bone plates in fracture fixation. The plate is deformed in its martensitic state, screwed to the two ends of the bone it is desired to compress together, and warmed (or allowed to warm) to the austenitic state, when the plate contracts, compressing the bone ends together. The Johnson et al. bone plate is of generally oblong configuration, overlaps a bone fracture and is secured by two screws to one portion of the bone and by two other screws to the other portion of the bone.

Because of the high elastic moduli of the austenitic shape memory alloys, it will be difficult to control the amount of force which may be applied by a bone plate of the type proposed by Johnson et al., and precision placement of the bone ends and elongation of the plate will be required.

If, however, an SIM pseudoelastic bone plate is used, it will be easily possible to elongate the plate and fasten it to the bone ends without requiring high precision. Because of the comparatively large (e.g. 5%) strain range at essentially constant stress, the force which will be put on the bone ends to compress them will be readily adjustable (by the size of the plate, for example) and will be insensitive to precise placement of the bone ends and/or elongation of the plate. Also, the recovery of the plate, since it is controlled by mechanical restraint, may be as gradual as desired, achieving excellent force and time control, and permitting the surgeon to make adjustments as desired.

EXAMPLE V

Marrow Nails

Baumgart et al. U.S. Pat. No. 4,170,990, the disclosure of which is incorporated herein by reference, discloses the use of the two-way shape memory effect (where an SMA element exhibits a first shape in the austenitic state and a second in the martensitic state, and spontaneously changes between the two shapes with a change in temperature) in, inter alia, marrow nails (see FIGS. 1a through 1e, and corresponding text, of Baumgart et al.). Marrow nails according to Baumgart et al. comprise a tube of memory alloy which has been split along its longitudinal axis and which may have a circular, elliptical, clover-leaf or other rotation preventing cross section, which may also be variable along the axis of the nail. A prepared marrow nail having a reduced diameter is loosely inserted into a slightly, or not at all, pre-drilled marrow channel of a bone which has been broken or fractured. By means of a heating probe the marrow nail is heated and thus expands. This achieves a relative fixing of the two bone ends along the marrow channel axis. Compression of the fracture is effected by the available muscle tension. If it should be necessary, the marrow nail may also be additionally prestretched along its longitudinal axis so that it is additionally compressed in the longitudinal direction when heated. In this case it is necessary, however, to anchor the nail at both of its ends which anchoring can be effected, for example, by sprockets or teeth on the outer surface of the nail.

The method proposed, however, requires the use of a wide temperature range in order to cause the phase change which is the origin of the two-way shape memory effect (5° C. to 60° C. for the water used to cool or heat the nail). In addition, it requires the manufacture of two-way shape memory elements, which is generally more complex than the manufacture of conventional shape memory elements; and precise control of the transition temperature is required.

However, if an SIM pseudoelastic alloy element is employed, these disadvantages may be overcome. If internal tangs, which may be gripped by an inserted tool, are provided within a marrow nail of the type shown in FIG. 1a of Baumgart et al., then the nail may be radially compressed by the application of stress by such a tool. When the nail is released by the tool, it will expand to fill the bone channel with a constant force (not readily available by Baumgart et al.); and it may be withdrawn by the reverse procedure.

EXAMPLE VI

Dental Arch Wire

Andreasen U.S. Pat. No. 4,037,324, the disclosure of which is incorporated herein by reference, proposes the use of dental arch wires made of Ni/Ti alloys instead of conventional 18-8 stainless steel wires. The wires are stated to be of lower elastic modulus and higher elastic limit than stainless steel, which is stated to be advantageous. Heat recovery of an SMA wire is also suggested as a technique for orthodonture.

The technique of using the conventional shape memory effect is not believed to have found clinical application, possibly because such a technique would require rapid placement of the wire in its martensitic state to avoid premature recovery, and would result in rapid recovery with extremely high forces, which would be painful for the patient.

The use of a wire which displays lower elastic modulus and higher elastic limit than stainless steel has found some application, however. Otsuka et al in Metals Forum, v. 4, pp. 142-52 (1981) have suggested that this behavior may be the result of elasticity enhanced by cold working and martensite-to-martensite pseudoelasticity in an alloy which has a transition temperature

below body temperature. The alloy, then, is martensitic rather than austenitic in its undeformed state.

While the use of an enhanced elasticity wire may offer some advantages over the more usual stainless steel wire, it remains the situation that the amount of motion in the teeth that may be produced by an arch wire without further adjustment is largely limited by the pain tolerance of the patient (since the force applied by the arch wire is proportional to the deformation of the wire). However, if an SIM pseudoelastic wire is used, it can exert a relatively constant force (chosen by the dentist to be sufficient to cause tooth movement but not painful) over a strain range of up to 5%. The load may be applied mechanically, and is thus more readily established, and no precise temperature control of the alloy is needed as would be required for the shape memory effect.

EXAMPLE VII

Coil Stents and Filters

The use of tubular coiled wire stent grafts has been discussed in the medical literature since 1969. Although the coils helped maintain patency of the vessels in which they were placed, they were difficult of insertion unless narrow enough to significantly narrow the lumen of the vessel. Recently, it has been proposed, see Radiology, v 147, pp. 259–60 and pp. 261–3 (1983), the disclosures of which are incorporated herein by reference, to use SMA wire to form these tubular coils. The wire, which has a transformation temperature below body temperature, is introduced through a catheter after being straightened in its martensitic state. When the wire is heated, the coil re-forms.

Because of the difficulty of controlling the transformation temperature accurately, it has proved necessary to cool the straightened wire during insertion and/or to heat the wire to form the coil after insertion. These procedures add to the complexity of the operation.

If an SIM pseudoelastic wire is used to form the coil, which is then isothermally deformed by loading into a catheter, then the need for temperature control is avoided. The wire remains straight when in the catheter, but re-forms the coil spontaneously when it is extruded from the catheter. Accurate placement is thus readily obtainable, since there is no urgency as might be required with a conventional shape memory effect element.

It has similarly been proposed to use SMA wire to form a filter for emplacement by catheter in the vena cava to trap blood clots. The filter is formed in the austenitic state, the wire straightened in the martensitic state and inserted, and the filter re-forms on warming. Just as for the coil stents discussed above, the use of an SIM pseudoelastic wire would greatly simplify manufacture and insertion of such a vena cava filter, permitting accurate placement with no need for urgency or temperature manipulation.

EXAMPLE VIII

Bone Staples, Clips, etc.

Bone staples are frequently used to hold fragments of fractured bone together when the fracture is fixed, and may be used in some cases as a replacement for bone plates in the same situation. Sometimes the staples are inserted into drilled holes, sometimes merely driven into the bone directly.

It would be desirable to have a bone staple which provided a controlled force between the tines which would tend to hold the staple in place. Shape memory alloys have been proposed for this application, but again the problem of accurate placement while operating quickly enough to prevent the shape change associated with the martensite-to-austenite transition and/or the need for temperature control complicate their use.

If an SIM alloy is used, these disadvantages may be readily overcome. If the alloy is below A_S, it may be emplaced in the martensitic state. Brief heating will then be required to cause it to become austenitic, but on recooling to body temperature, a constant force can be achieved. If the alloy is above A_S, the staple can be held deformed by a moderate force, then released after insertion to also provide an accurately-known force. In either event, removal is easier than if the alloy is purely austenitic, as discussed above for Examples II and V, for example.

Similarly, SIM alloy (especially alloy which is pseudoelastic, above A_S at its utilization temperature) may be used to manufacture vascular clips, et. The alloy element here acts as a constant force spring over a wide strain range (greater than conventional elastic metals), resulting in ease of use.

From the foregoing, it is clear that, in a situation where narrow temperature differences are available or preferable, as often is the case in medical applications, mechanically constrained shape change is a much more useful solution than heat actuated shape change. It offers a degree of control heat actuation does not, it offers easier alloy composition control, it eases mating part tolerance requirements, and it offers simple mechanical reversal at minimal stress levels, all without heating, cooling or insulation complications.

It will be obvious to those skilled in the art, having regard to this disclosure, that other variations on this invention beyond those specifically exemplified here, and other medical devices making use of stress-induced martensite, may be made. Such variations are, however, to be considered as coming within the scope of this invention as limited solely by the following claims.

I claim:

1. A method of forming an attachment to a bone, which comprises positioning in an aperture in the bone an element formed at least partially from a shape memory alloy which displays stress induced martensite behavior at body temperature, the element being so positioned that it is deformed by the walls of the aperture by the formation of stress-induced martensite, and thereby exerts a force outwardly on the walls of the aperture.

2. A method as claimed in claim 1, in which the aperture is formed before the element is positioned.

3. The method of claim 1 wherein the step of positioning takes place at a temperature greater than the A_S of the alloy.

4. The method of claim 1 wherein substantially all of the formation of martensite results from deformation of the element, and not from any change in temperature of the element.

5. A method for installing a bone attachment into a bone of a mammalian body such that the device is substantially at body temperature, the method comprising the steps of:

(a) providing a bone attachment device at least partly formed from a pseudoelastic shape-memory alloy, wherein the shape-memory alloy can display reversible stress-induced martensite at about body temperature such that the shape-memory alloy 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 stressed-induced martensitic state and (ii) a different unstressed shape when the allow is in its austenitic state;

(b) deforming the bone attachment device with a tool at a temperature greater than the As of the alloy for placing the alloy in its stress-induced martensitic state and the bone attachment device in its deformed shape;

(c) inserting and positioning the bone attachment device into a channel in the bone at a temperature greater than the As of the alloy while the bone attachment remains in its deformed shape; and

(d) while maintaining the temperature of the bone attachment device above the As of the alloy, releasing the bone attachment device from the tool so that at least a portion of the alloy transforms from its stress-induced martensitic state so that the bone attachment device transforms from its deformed shape toward its unstressed shape to fill the bone channel and exert a constant force, wherein substantially all of the transformation occurs from releasing the bone attachment device from the tool and not from any change in temperature of the bone attachment device or the tool.

6. The method of claim 5 wherein the bone attachment device is a marrow nail.

7. The method of claim 5 or 6 comprising the additional steps, after step (d), of (e) deforming the device with the tool at a temperature greater than the As of alloy so that at least a portion of the alloy transforms from its austenitic state so that the bone attachment device transforms into its deformed shape; and (f) withdrawing the deformed bone attachment device from the bone without changing the temperature of the device.

8. The method of claim 5 wherein the bone attachment device is a bone staple.

9. A method for installing an implant into a bone in a mammalian body comprising the steps of:

(a) drilling a channel in the bone;

(b) selecting a bone implant comprised of a 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 bone implant having (i) an insertable shape suitable for insertion into the channel when the alloy is in its stress-induced martensitic state and (ii) a second different shape when the alloy is in its austenitic state, the bone implant being in its second shape; and

(c) inserting the bone implant into the channel and stressing the bone implant so that the alloy transforms toward its stress-induced martensitic state and the bone implant transforms to its insertable shape.

10. The method of claim 9 wherein the bone implant is inserted into the channel and stressed at a temperature greater than the As of the alloy.

11. The method of claim 9 wherein substantially all of the transformation of the bone implant to its insertable shape occurs from inserting and stressing the bone implant, and not from any change in temperature of the bone implant.

12. The method of claim 9 wherein the bone implant that is selected is a marrow nail.

13. The method of claim 9 comprising the additional step, after step (c), of:

(d) causing the stress on the implant to be released so that the alloy transforms toward its austenitic state and the implant transforms toward its second shape.

14. The method of claim 9 comprising the additional step, after step (c), of:

(d) causing the stress on the implant to be released so that the implant exerts constant force in the channel.

15. The method of claim 13 or 14 including the additional step, after step (d), of stressing the implant so that the alloy transforms toward its stress-induced martensitic state and the implant transforms toward its insertable shape, and thereafter withdrawing the installed implant from the channel.

16. The method of claim 15 wherein the implant is a marrow nail.

17. A bone implant sized for insertion into a channel in a bone in a mammalian body, the bone implant being comprised of a 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 bone implant having (i) an insertable shape for insertion into the bone when the alloy is in its stress-induced martensitic state and (ii) a second, different, non-insertable shape when the alloy is in its austenitic state.

18. The bone implant of claim 17 wherein the bone implant is a nail.

19. The bone implant of claim 18 wherein the nail has a tine.

20. A method for holding onto a bone in a mammalian body comprising the steps of:

(a) drilling a hole into the bone;

(b) selecting a bone-holding device comprised of a 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 device 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, the bone-holding device being in its unstressed shape; and

(c) inserting the device into the hole and deforming the device to its deformed shape so that the alloy transforms toward its stress-induced martensitic state.

21. The method of claim 20 wherein the device is a bone staple.

22. The method of claim 20 wherein the step of selecting comprises selecting a device having a tine.

23. The method of claim 20 wherein the step of inserting the device and deforming the device takes place at a temperature greater than the As of the alloy.

24. The method of claim 20 wherein substantially all of the transformation of the alloy results from inserting the device and deforming the device, and not from any change in temperature of the device.

25. The method of claim 20 wherein the bone holding device is a bone nail.

26. The method of claim 25 wherein the nail has a tine.

27. A method for removing from a mammalian body a medical device comprising a memory alloy element at least partly formed from a 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 device having (i) a removable shape when the alloy is in its stress-induced martensitic state and (ii) a different non-removable shape when the alloy is in its austenitic state, the device being positioned in a mammalian body and being in its non-removable shape, the method comprising the steps of:

(a) stressing the device so that the alloy transforms toward its stress-induced martensitic state and the device transforms to its removable shape, without changing the temperature of the device; and

(b) withdrawing the transformed device from the mammalian body.

28. The method of claim 27 wherein both steps (a) and (b) take place at a temperature greater than the A_s of the alloy.

29. The method of claim 27 wherein the medical device is a bone implant.

30. The method of claim 29 wherein the medical device is a marrow nail.

31. The method of claim 29 wherein the medical device is a bone staple.

32. The method of claim 27 wherein the medical device is an intrauterine contraceptive device.

33. The method of claim 27 wherein the medical device is a filter for a blood vessel.

34. The method of claim 27 wherein the medical device is tubular.

35. The method of claim 34 wherein the medical device is a catheter.

36. The method of claim 35 wherein the medical device is tracheal catheter.

37. An article formed at least partially from a shape memory alloy which displays stress-induced martensite behavior at human body temperature, the article adapted to be positioned in an aperture in a bone of a human body so that the article is deformed by the walls of the aperture by the formation of stress-induced martensite, and thereby exerts a force outwardly on the wall of the aperture.

38. A bone plate for compressing two ends of a fractured mammalian bone together, the bone plate being formed at least partly from a 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 bone plate being (i) elongated when the alloy is in its stress-induced martensitic state and (ii) shortened when the alloy is in its austenitic state;

the bone plate being provided with means for securing the bone plate to both ends of a fractured bone.

39. The method of claim 9 wherein the step of stressing of the bone implant is performed before placement of the bone implant into the channel in the bone.

40. The method of claim 20 wherein the step of deforming the device is performed before the device is inserted into the hole.

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

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APPLICANT: JAMES E JERVIS

FILING DATE: OCTOBER 2, 1992 | GROUP: 3301

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	AN-2 ✓	5 0 9 5 1	3/1983	JAPAN			✓	
	AO-2	56 2 8 9 8 0	7/1981	JAPAN			✓	
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AS-2	Mazer, "Therapeutic Embolization of the Renal Artery with Gianturco Coils: Limitations and Technical Pitfalls," Radiology, 138:37-46 (Jan. 1981)

EXAMINER Kenealy DATE CONSIDERED 6/17/93

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ENGLISH TRANSLATION OF JAPANESE PATENT KOKAI PUBLICATION NO. 41546/1983

APPLICATION NO.: 140477/1981
APPLICATION DATE: SEPTEMBER 7, 1981

KOKAI DATE: MARCH 10, 1983

APPLICANT: SUWA-SEIKOSHA

INVENTORS: Susumu TANAKA, Takehiko OOSAKU, & Kumahide SUMIDA

CLAIMS:

1. A device for orthodonture, orthodontic load of which corresponds to and changed by a temperature difference between a temperature corresponding to body temperature and a temperature generated by applying a temperature stimulating material to a buccal cavity.

2. The device for orthodonture according to claim 1, which comprises an alloy mainly consisting of a metal compound of Ni-Ti.

3. The device for orthodonture according to claim 2, wherein a temperature at which reverse martensite transformation of the Ni-Ti alloys finishes is lower than the body temperature.

IN THE DESCRIPTION:

Page 282, lower left column, lines 13 to 19

The super elasticity has completely different mechanism and properties from proportional elasticity found in conventional metallic materials. Even when it is deformed by about 8 %, it super elastically reverts to its original shape.

Page 283, upper left column, line 10 to upper right column, line 6

Metallic materials having super elastic effect and shape memory effect include an alloy mainly consisting of Ni-Ti metal compound, Cu-Zn, Cu-Zn-X (wherein X is Si, Sn Al or the like), Cu-Al-Ni, Au-Cd, Ag-Cd, Ni-Al. Cu-Au-Zn, Cu-Sn, etc. These alloys are super lattice alloys which exhibit martensite transformation, namely thermoelastic transformation. Super elasticity utilizes, as motive force, stress-induced martensite transformation caused in a temperature rage higher than the martensite transformation temperature of these alloys and its reverse transformation. Generally, this transformation has small hysterisis of forward and reverse transformations between a mother phase (austenite phase) and a martensite phase, and is crystallographically reversible. "Crystallographically reversible" means that not only the alloy reverts to its crystal structure of the mother phase but also the orientation of the crystal reverts to its original orientation.

SIM

ENGLISH TRANSLATION OF JAPANESE PATENT KOKAI PUBLICATION NO. 50951/1983

APPLICATION NO.: 150425/1981
APPLICATION DATE: SEPTEMBER 22, 1981

KOKAI DATE: MARCH 25, 1983

APPLICANT: SUWA-SEIKOSHA

INVENTOR: Susumu TANAKA

CLAIMS:

1. A bracket for orthodonture, which comprises a substrate member which is attached to a tooth body and a wire supporting member which grips and support a wire, wherein the wire supporting member is imparted with elastic deformation ability.

2. The bracket for orthodonture according to claim 1 wherein the wire supporting member is imparted with deformation ability due to super elasticity.

3. The bracket for orthodonture, wherein the at least the wire supporting member is made of an alloy mainly consisting of a metal compound of Ni-Ti.

IN THE DESCRIPTION:

Page 302, lower left column, line 11 to lower right column, line 6

Metallic materials having super elastic effect and shape memory effect include an alloy mainly consisting of

Ni-Ti metal compound, Cu-Zn, Cu-Zn-X (wherein X is Si, Sn Al or the like), Cu-Al-Ni, Au-Cd, Ag-Cd, Ni-Al. Cu-Au-Zn, Cu-Sn, etc. These alloys are super lattice alloys which exhibit martensite transformation, namely thermoelastic transformation. Super elasticity utilizes, as motive force, stress-induced martensite transformation caused in a temperature rage higher than the martensite transformation temperature of these alloys and its reverse transformation. Generally, this transformation has small hysterisis of forward and reverse transformations between a mother phase (austenite phase) and a martensite phase, and is crystallographically reversible. "Crystallographically reversible" means that not only the alloy reverts to its crystal structure of the mother phase but also the orientation of the crystal reverts to its original orientation.

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APPLICANT: JAMES E. JERVIS

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	AM-3	57 7 5 6 4 7	5/1982	JAPAN	—		✓	
	AN-3	57 9 5 4 5 2	6/1982	JAPAN	—		✓	
	AO-3							
	AP-3							

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	FILING DATE: OCTOBER 2, 1992	GROUP: 3301

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		DOCKET NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
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	AM							
	AN							
	AO							
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MAK	AS-4	Wayman, "Some Applications of Shape-Memory Alloys," Journal of Metals, June, 1980, pp. 129-137.

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SIM
AS-4

Some Applications of Shape-Memory Alloys

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And the LORD said unto Moses, "What is that in your hand?" And he said, "A rod."

Then HE said, "Cast it on the ground." And he cast it on the ground and it became a serpent; and Moses fled from it.

And the LORD said unto Moses, "Put forth thine hand and take it by the tail." And he put forth his hand and caught it, and it became a rod in his hand.

OLD TESTAMENT
Exodus, Chapter 4:2-4

SUMMARY

Uses or potential uses of shape memory alloys fall into industrial, energy, and dental/medical categories. These various applications are considered after a brief discussion of the nature of the shape memory effect and other interesting properties in shape memory alloys. Most applications involve NiTi-type and Cu-based alloys, the latter being relatively inexpensive to produce and fabricate into numerous forms.

NATURE AND MECHANISTICS OF THE SHAPE MEMORY EFFECT

The shape-memory effect (SME) can be described as follows: basically, an object in the low-temperature, martensitic condition when it is deformed and the stress then removed will regain its original shape when heated. Strains typically 6–8% may be completely recovered. The process of regaining the original shape is associated with the reverse transformation of the deformed martensitic phase to the higher temperature parent phase.

Many materials are now known to exhibit the shape-memory or "marmem" (*mar*tensite *mem*ory) effect; a partial list includes the alloy systems Cu-Zn, Cu-Zn-Al, Cu-Zn-Ga, Cu-Zn-Sn, Cu-Zn-Si, Cu-Al-Ni, Cu-Au-Zn, Cu-Sn, Au-Cd, Ni-Ti, Ni-Ti-X (X = ternary element), Ni-Al, and Fe-Pt. These alloys are all ordered (both parent and martensite) and exhibit a crystallographically reversible, thermoelastic martensitic transformation.

Substantial progress has recently been made in understanding the nature of SME. As is well known, a crystal of the parent phase will transform into many orientations (plates or variants) of martensite on cooling. Ideally, a single crystal of the parent phase will form 24 orientations of martensite on cooling between the M_s and M_f temperatures. But when this multi-orientation configuration of martensite is deformed, a single orientation of martensite eventually results because of twinning and the movement of certain martensite interfaces. It has been shown that the twins which form in the martensite are simply other orientations (variants) of martensite; thus twinning can convert one orientation of martensite to another. The same thing happens when martensite/martensite interfaces move under stress: one orientation grows at the expense of another. In the final analysis, the single remaining orientation of martensite is the variant whose "shear" or shape deformation will permit the maximum elongation of the specimen in the direction of the tensile axis.

Although the original single crystal of the parent phase transforms into many (up to 24) orientations of martensite, the reverse does not occur. Instead, the single crystal of martensite obtained from deformation below the M_s temperature transforms, on heating, to a single orientation of the parent phase. This is a consequence of the relative symmetries involved and the necessity to maintain ordering. In other words, the highly symmetric (usually cubic) parent phase has many crystallographically equivalent principal axes for the lattice change (Bain distortion) which will thus lead to the many variants of martensite which are observed. On the other hand, the relatively unsymmetric martensite (e.g., monoclinic in Cu-Zn-Al alloys) does not enjoy such a multiplicity of choices, and only a single variant of the parent is usually nucleated during the reverse martensite-to-parent transformation. In essence, the single crystal of martensite "unshears" to form a single crystal of the parent, and this "unshearing" during reverse transformation restores the specimen to its original shape. This sequence is metallographically depicted in Figure 1.

The above account appears to be generally valid, irrespective of the alloy system or martensite crystal structure.

OTHER INTERESTING PROPERTIES OF MARMEM ALLOYS

Shape-memory alloys have interesting properties and characteristics in addition to the shape-memory effect, *per se*. As will be described later, excessively deformed (some 30% strain, and well beyond the limit of shape-memory recoverable strain) martensitic NiTi alloys have unusual elastic properties. When many of the martensitic Cu-based alloys are continually deformed beyond the single-crystal martensite stage, a new martensite phase is generated, i.e., a stress-induced martensite-to-martensite transformation occurs. This successive mode of martensite deformation allows recoverable strains of more than 17%. Shape-memory alloys are also excellent damping materials. The relative ease of movement of internal boundaries, such as martensite-martensite boundaries, under a small stress is strongly attenuating. Finally, a "two-way" shape memory can be programmed into various memory alloys by appropriate stress and/or thermal cycling. Once this conditioning has been achieved, a specimen will spontaneously "bend" when the parent transforms into martensite, and "unbend" to the initial shape during the reverse transformation.

INDUSTRIAL APPLICATIONS OF SHAPE-MEMORY ALLOYS

Fasteners and Couplings

One of the earliest widespread applications of SME was Raychem Corporation's (Menlo Park, Calif.) introduction of tubing or pipe couplings which shrink during heating. Typical of such NiTi-type couplings are those used for connecting aircraft hydraulic lines. The couplings are expanded ~4% in the martensitic condition at liquid-nitrogen temperature, then placed around the tubes to be joined. During warming to room temperature, they contract, producing a tight seal. The use of such fittings avoids metallurgical degradation which can result from welding or brazing, and avoids damage to the aircraft "skin." Over 300,000 such high-performance connectors have been used in U.S. Navy aircraft, with no reported failures.

Similar NiTi-type fixtures have been used extensively for plumbing on submarines and surface ships during the past five years by the British Royal Navy, and within the past two years by the U.S. Navy for a variety of surface ships; an example is shown in Figure 2.

The size of NiTi-type fittings has been increased considerably recently, and fittings which join carbon-steel subsea pipe up to six inches in diameter have been installed successfully at depths up to 300 ft using saturation diving techniques, taking a pre-chilled fitting down in the diving chamber. For broken subsea piping, SME fittings are justified by speed and ease of installation compared with other techniques and by no necessity to rely on operator skill.

Raychem has also developed a "Cryocon" shape-memory type electrical connector particularly suited for multiconnector electrical plugs.

Extensive research and development on NiTi and NiTiX ternary alloys is also being conducted at the Brown Boveri Research Center in Baden, Switzerland.

Raychem recently introduced a new line of Cu-based alloy heat-shrinkable fittings in addition to other fasteners and devices. These devices can be provided in the field in the (deformed) martensitic condition at room temperature and applied simply by heating them with a propane torch. Figures 3-5 are examples showing a coupling, retainer, and clamp; and Figures 6 and 7 are photographs of a clamp and a seal made of a Cu-based SME alloy. Figure 8 shows a clamp and expander, demonstrating that the engineering parameters for the Cu alloys have been well worked out. Additional fasteners, clamps, plugs, rivets, etc., will undoubtedly appear in the near future, including plugs for nuclear reactors which will eliminate welding.

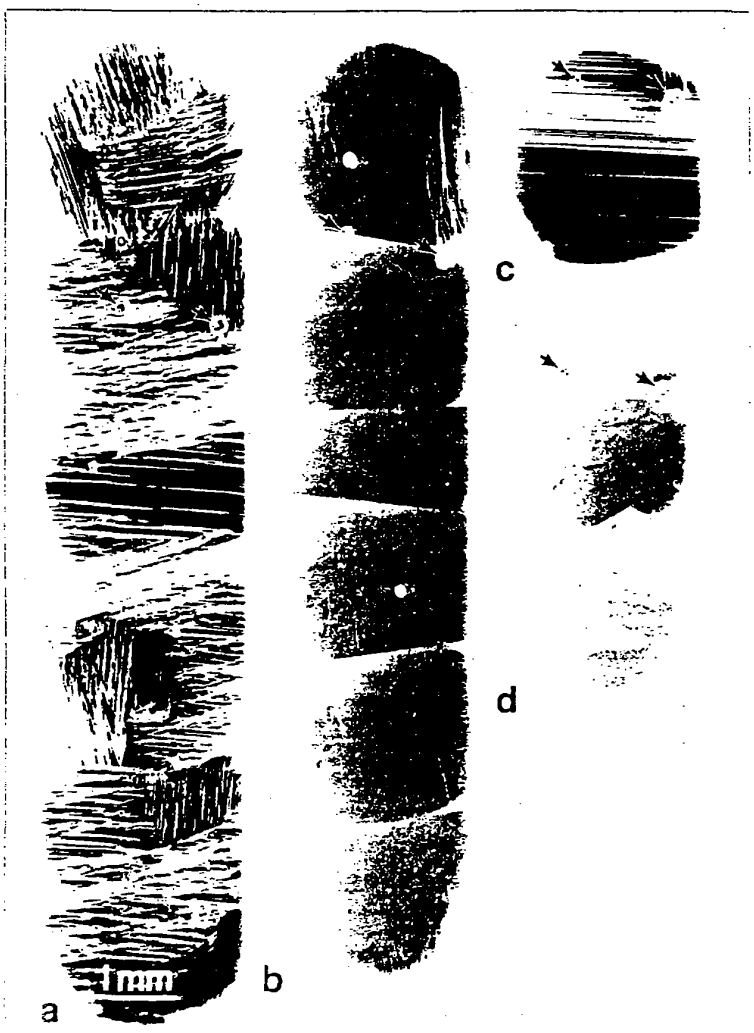

Figure 1. Optical micrographs showing a) numerous orientations of martensite in as-transformed Cu-Zn-Ga alloy, b) the "coalescence" of variants upon stressing, c) nucleation of only a single variant of the parent phase during heating, and d) the original single crystal of the parent phase.

Figure 2. Bank of hydraulic piping on the USS Peleliu installed with heat-shrinkable NiTi-type couplings. (Courtesy Raychem Corp.)

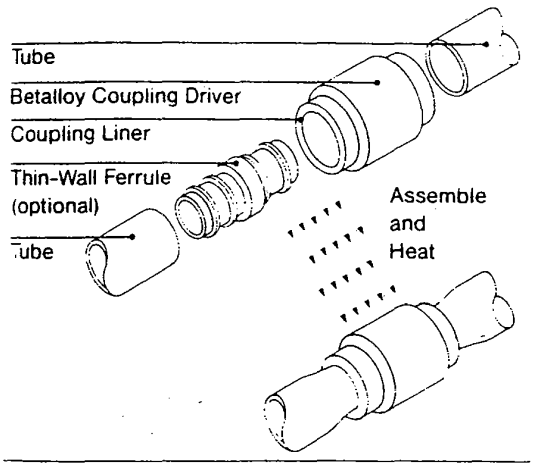

Figure 3. Tube or pipe coupling made from Cu-based shape-memory alloy. (Courtesy Raychem Corp.)

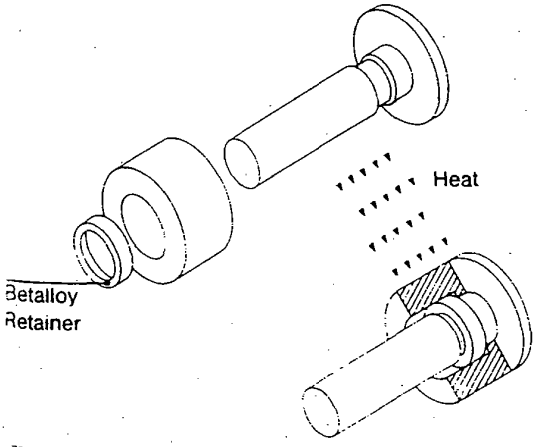

Figure 4. Retainer made from Cu-based shape-memory alloy. (Courtesy Raychem Corp.)

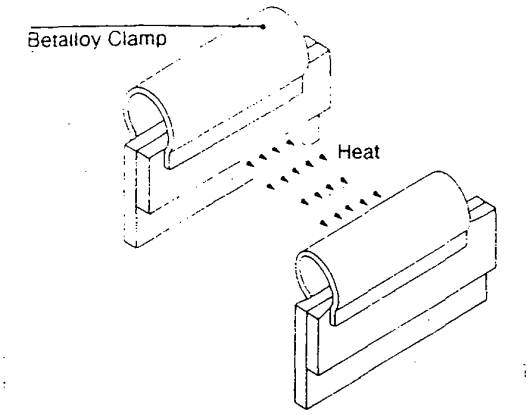

Figure 5. Clamp or crimp made from Cu-based shape-memory alloy. (Courtesy Raychem Corp.)

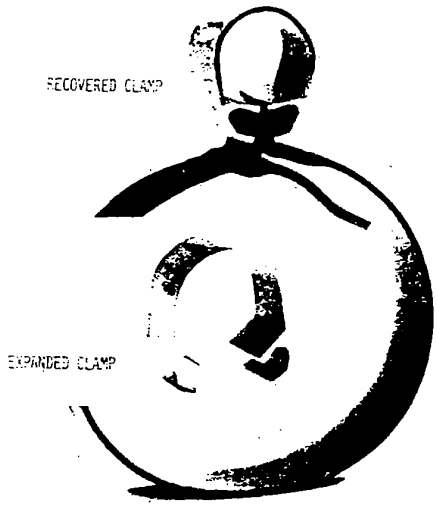

Figure 6. Clamp made from Cu-based shape-memory alloy. (Courtesy Raychem Corp.)

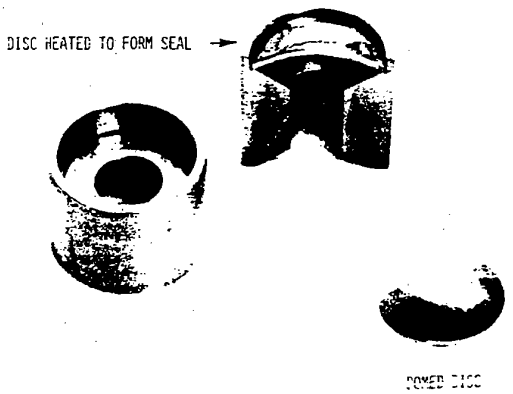

Figure 7. Disc seal made from Cu-based shape-memory alloy. (Courtesy Raychem Corp.)

Numerous patents have also been filed for various SME devices not yet been marketed, such as mechanisms for platform motion, pumps for fluids, and thermal warning devices which can be attached to containers used for shipping refrigerated biological materials such as human blood.

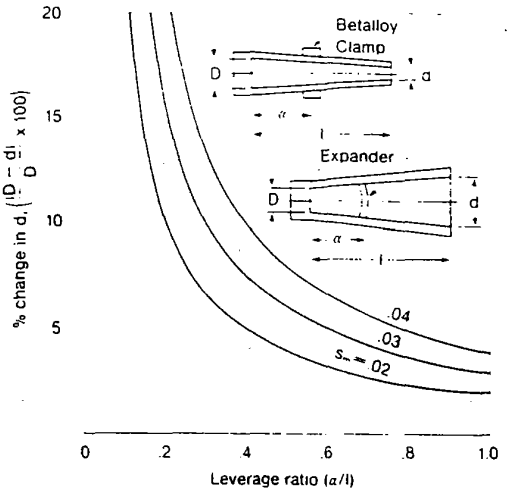

Figure 8. Clamp and expander made from Cu-based shape-memory alloy. (Courtesy Raychem Corp.)

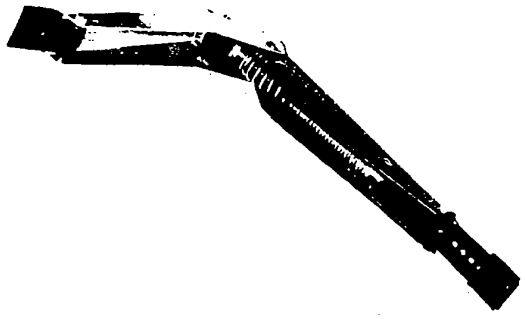

Figure 9. Greenhouse window control incorporating a Cu-based shape-memory alloy. (Courtesy Delta Memory Metal Co.)

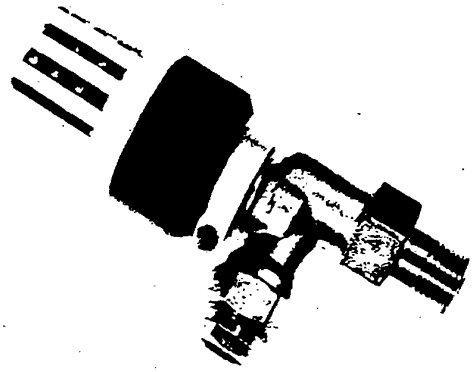

Figure 10. Thermostatic radiator valve incorporating Cu-based shape-memory alloy actuator spring. (Courtesy Delta Memory Metal Co.)

Thermomechanical and Thermostatic Devices

Substantial efforts in developing Cu-based shape-memory alloys have been made by the Delta Memory Metal Company (Suffolk, England). They have developed a range of Cu-Zn-Al SME alloys with emphasis on thermostats, controls for heating and cooling equipment, automotive control devices, and actuators for equipment ranging from greenhouse windows to fire doors. Many of these prototypes have been cycled a half-million times or so with no observable fatigue, "creep," or change in deflection characteristics.

Figure 9 shows an actuator for greenhouse windows, basically a spring-loaded hinge containing a bias spring and a SME spring. Below 18°C, the SME spring is in the contracted (martensitic) condition and the window is closed. When the temperature rises, the shape-memory spring overcomes the restraining bias spring, and at 25°C the window is fully opened. The window is automatically pulled shut when the temperature falls. As expected, the hysteresis of an unloaded actuator is some 10–15°C, but this can be compensated for by forcing the actuator to work against a bias spring. Delta has proposed similar devices to open fire doors, actuate ventilators in factories, open radiator vents in diesel trucks, and control vents in warm-air heating systems.

Another SME spring-actuator/bias-spring device is thermostatic radiator valve for residential hot-water heating systems (Figure 10). As the temperature in a room increases, the actuator expands, overcomes the force of the bias spring, and closes the port of the valve on the hot water line of the radiator system. The temperature can be adjusted by rotating the top head assembly, which alters the compression of the bias spring. Such regulators are comparatively inexpensive and have a much faster system response time. With a proper bias spring, thermal hysteresis can be held to 1.2C°. There is a remote-control version of these valves.

Another Delta device, an automotive clutch fan (Figure 11), uses an SME actuator in the form of a helical spring which is biased against a set of four steel leaf springs. The SME actuator coil engages a clutch which turns an automotive engine fan when the "air-off" temperature exceeds a certain value, typically 53°C; the actuator closes the clutch plate until the temperature is under control. At low temperatures, the fan idles at ~250 rpm. At higher temperatures, the clutch fan speeds up sufficiently to cool the engine assembly. If this speed is less than engine speed, the clutch fan will slip. Thus the fan does only as much work as required and, accordingly, saves energy. Such a device has been road tested for 20,000 miles, and indications are that it would operate an additional 60,000 miles. The clutch fan was proposed in order to reduce engine noise (at idling) and fuel consumption (because it removes the energy loss from the fan when it is not required to cool the engine).

Another automotive application of Cu-type SME alloys concerns the carburetor. In this case, atmospheric pollution is minimized and fuel consumption optimized by compensating for fuel viscosity. A simple jet made of a Cu-Zn-Al SME alloy is inserted in a Stromberg-type carburetor. As the fuel warms, an orifice reduces in size and thus meters the correct fuel volume. Figure 12 shows the performance of such a jet. Note particularly the reduction in CO emission at high fuel temperatures.

A further automotive application, also concerning the carburetor, is to use a Cu-type SME actuator to close a "cold start" choke at a predetermined time after an engine has started. The SME actuator is energized by heat from an electrical source, causing the actuator to close the choke.

Figure 13 shows a room-temperature thermostat control designed by Delta. This control consists of an SME actuator spring and bias spring mounted to a standard microswitch, with a simple adjustment for temperature. A similar thermostatic principle is involved in the use of an SME element to switch off electrically-operated tea kettles once the wa-

boils. If the kettle boils dry or is not filled, the SME element is heated, switching off the kettle.

Other examples of Cu-Zn-Al SME devices are the tubular and coil-type torsion actuators shown in Figures 14 and 15 in the "closed" and "open" positions. A somewhat similar line of Cu-Zn-Al SME devices is being developed by N.V. Bekaert in Zwevegen, Belgium, but they have not yet been introduced in the U.S.

The above discussion emphasizes many existing thermomechanical and thermostatic applications of Cu-based SME alloys. More will surely follow, considering the inexpensiveness of such brasses and their ease of fabrication. However, such alloys are subject to aging effects and cannot cyclically operate indefinitely when the "upper" temperature is ~150°C or more. The nature of the aging effects which cause deterioration of the shape memory remains to be determined. Higher operating temperatures are expected in the future through alloy development.

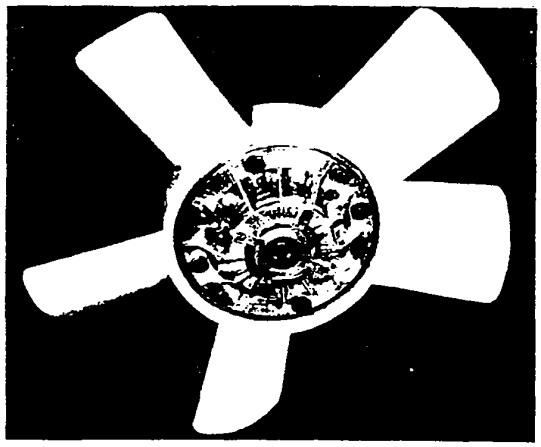

Figure 11. Automotive clutch fan with heat-energized actuator made from a Cu-based shape-memory alloy. (Courtesy Delta Memory Metal Co.)

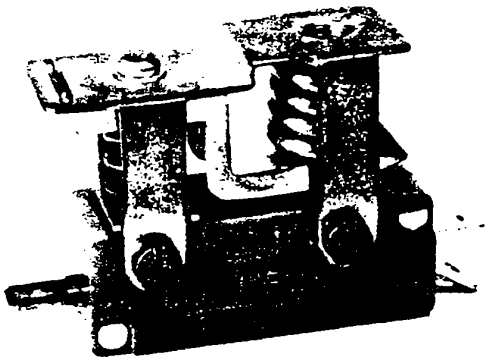

Figure 13. Room-temperature thermostat control using a Cu-based shape-memory alloy spring. (Courtesy Delta Memory Metal Co.)

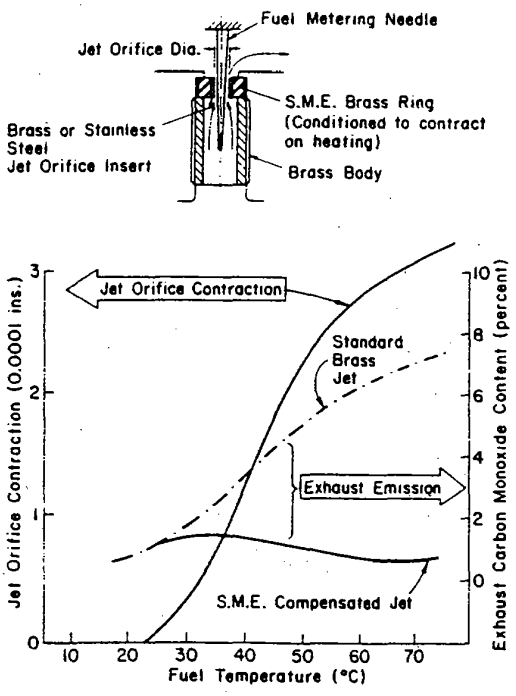

Figure 12. Carburetor jet assembly with variable orifice controlled by a Cu-based shape-memory alloy. Note the reduction of CO emission by using the SME compensated jet. (Courtesy Delta Memory Metal Co.)

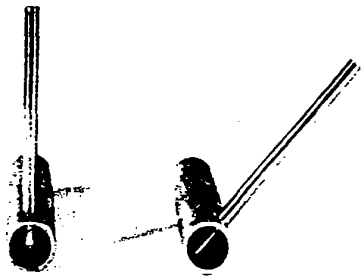

Figure 14. Tubular torsion actuator made from Cu-based shape-memory alloy. (Courtesy Delta Memory Metal Co.)

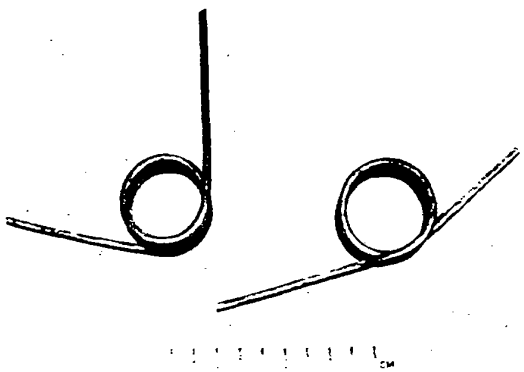

Figure 15. Coil-type torsion actuator made from Cu-based shape-memory alloy. (Courtesy Delta Memory Metal Co.)

Recording Pen Drive Unit

The Foxboro Company (Foxboro, Mass.) has developed a simplified servomechanism to drive recording pens and indicating-pointer assemblies. The servodrive unit (Figure 16) contains a NiTi wire maintained under tensile stress. The input signal is converted to a current which is induced into the SME wire, the thus-heated wire changes its length and moves a connected lever. This device eliminates many moving parts and is extremely reliable. Over 500,000 such units have been produced since their introduction in 1972.

ENERGY APPLICATIONS

That large stresses are generated during the shape-memory effect has been known for some time. For example, in NiTi alloys stresses as high as 100,000 psi are created by the reverse transformation of the deformed martensite to the memory configuration during heating. Such stresses are an order of magnitude higher than those necessary to deform the martensite at lower temperatures. Thus, heat can be used to create a mechanical force which can do work. Figure 17 illustrates the principle involved.

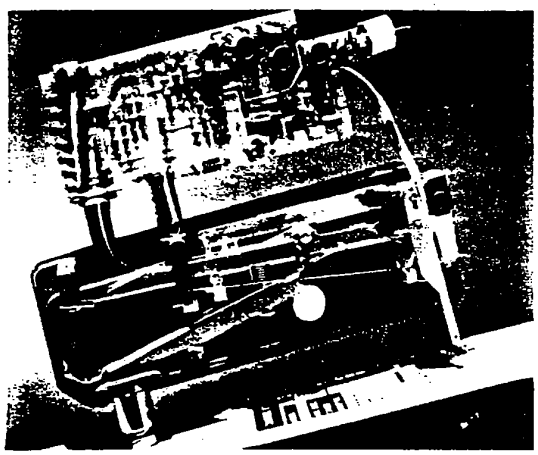

Figure 16. Servodrive unit using NiTi wire actuator. (Courtesy Foxboro Co.)

Numerous heat engines built in the past few years typically operate between two fixed temperatures (usually maintained by two water reservoirs) and have modest efficiencies of 4–6% when operated at room temperature and above. They are consequently well suited to extract heat from "low-grade" energy sources such as industrial coolant water, discharge water from nuclear reactors, geothermal sources, and solar heated masses.

DENTAL AND MEDICAL APPLICATIONS

Orthodontic Dental Arch Wires

Unitek Corporation (Monrovia, Calif.) now extensively markets an orthodontic dental arch wire made from a NiTi alloy. This arch wire, attached to bands on the teeth, is now replacing the traditional stainless steel arch wire in many cases. Since its introduction about 2½ years ago, over 5,000 of the estimated 6,500 orthodontists in the U.S. have used this device for straightening teeth.

In contrast to the other SME devices mentioned in this report, the dental arch wire is used in the martensitic condition. Because the martensitic wires have been plastically deformed to more than 30%, however, they exhibit an unusual springback and rubberlike character. After a 90° bend test, the coldworked NiTi wires will almost completely unbend, in contrast to similar stainless steel wires which remain bent at a 45° angle. Figure 18 shows the results of comparative bend tests, and Figure 19 shows how the NiTi arch wires are tied into malposed teeth.

It is claimed that using NiTi arch wires offers advantages, such as fewer arch wire changes during treatment, a greater working range (and thus fewer arch wire adjustments), less patient discomfort, and shorter treatment time.

Blood Clot Filters

A *vena cava* filter using a NiTi alloy has been evaluated by Dr. M. Simon of the Harvard Medical School and other colleagues. The device they propose is a new method for trapping "wandering" blood clots. A chilled, initially straight NiTi wire (martensitic condition) assumes a complex filter shape as it warms to body temperature (parent phase condition) after being placed into the *vena cava* (a large vein which returns blood to the heart) by a catheter inserted in a vein in the arm. A straight martensitic wire obtains a complex cross sectional shape once ejected from the catheter into the warm body, a process schematically shown in Figure 20.

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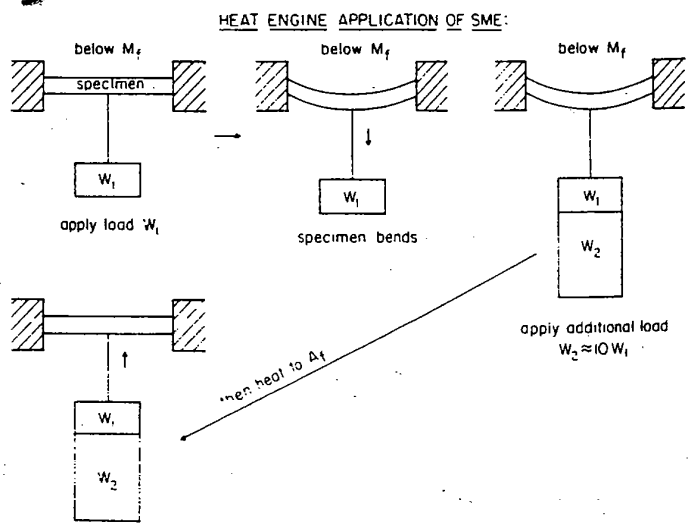

Figure 17. Schematic of heat engine application of a shape-memory alloy.

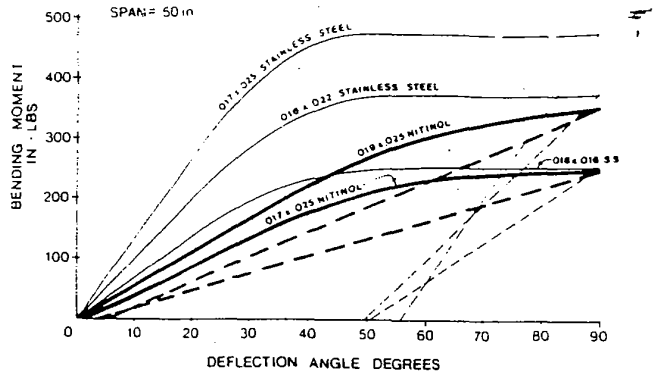

Figure 18. Bend tests comparing cold-worked stainless steel and coldworked NiTi martensitic alloy. (Courtesy G.F. Andreasen.)

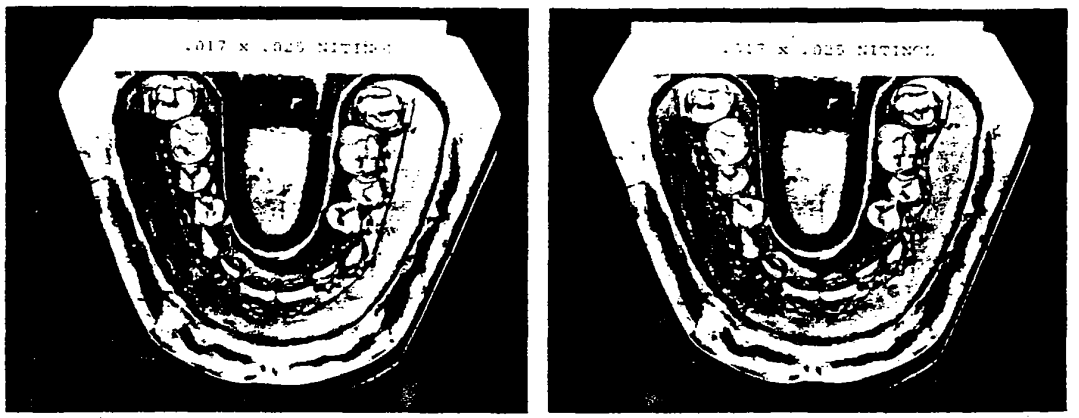

Figure 19. NiTi dental arch wire before (above) and after (below) being fastened to malposed teeth. (Courtesy G.F. Andreasen.)

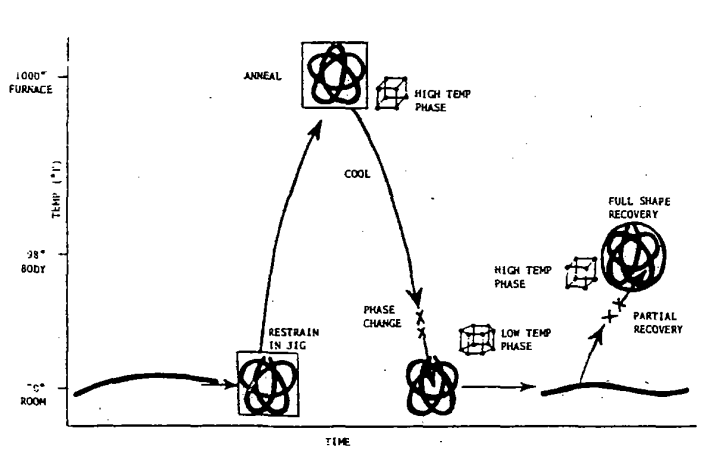

Figure 20. Schematic of *vena cava* filter operation. (Courtesy M. Simon.)

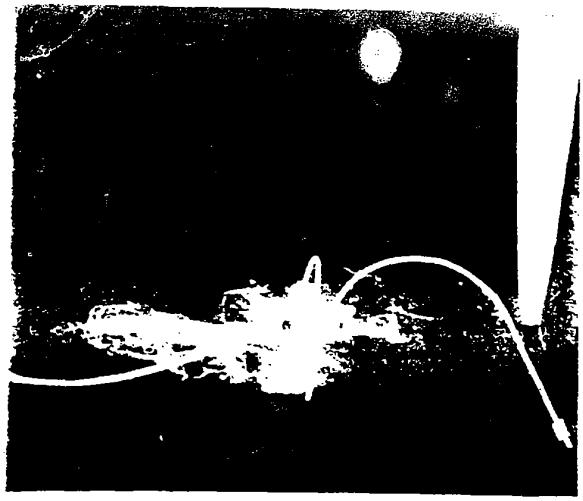

Figure 21. Radiograph showing placement of *vena cava* filter in a dog. (Courtesy M. Simon.)

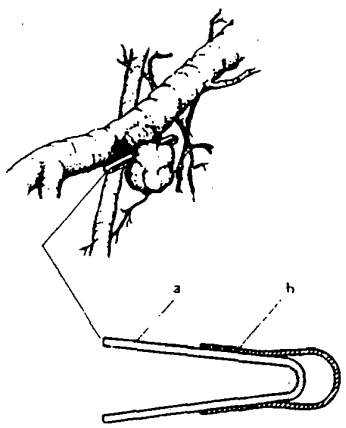

Figure 22. Composite aneurism clip; a.) of Ag; b.) of NiTi. (Courtesy T. Honma.)

Figure 23. Prototype artificial heart using NiTi contractile elements. (Courtesy P.N. Sawyer.)

Such devices can prevent 95% of clots formed in the legs, pelvis, or thighs, and which later dislodge, from reaching the heart/lung region and causing a pulmonary embolism. The NiTi filter offers several advantages, such as avoiding anticoagulant drugs (dangerous when internal bleeding may occur) and surgery, both risky procedures, and requiring only a local anesthetic. Such devices promise greater safety, simplicity, and speed of introduction.

Experiments on dogs have been very encouraging and those involving humans are anticipated soon. Figure 21, a radiograph of an NiTi filter implanted into the *vena cava* of a dog, clearly shows the trapped embolus at one side of the filter.

Intracranial Aneurism Clips

Aneurism clips or clamps used to tie off unwanted bulges which form in arteries have to be easily applied and removed. After experimenting with different versions of metallic aneurism clips, Honma and colleagues in Japan reported on a basic silver clip straddled by a supplementary clip made of NiTi. Such composite clips, as shown in Figure 22, met all mechanical conditions for practical use and could be removed easily by local heating.

Artificial Hearts

Dr. Philip Sawyer and associates at the State University of New York conceived the intriguing idea of using NiTi SME alloys to act as prosthetic muscles when heat pulsed, and they have proposed using NiTi wire strands as a contractile artificial muscle for an artificial heart. They claim that NiTi alloys are a potentially practical means of obtaining proximate contractility of the chamber wall and a satisfactory beginning towards developing an artificial muscle "skin-activated" cardiac chamber. The wire strands were initially constructed using "muscle groups" which were anchored to the exterior of the chamber in various configurations to attempt to replicate the contractility of the left heart ventricle.

Such artificial hearts are envisioned to be activated by electrical heating and programmed timing cycles involving various groups of contractile elements. Using NiTi elements attached to an elastomer chamber, significant pumping speeds were obtained. Such devices have pumped water up a 160 cm gradient 12–15 times per minute.

Sawyer and colleagues suggest that the next critical step is an evaluation *in vivo* following the implantation of such devices in dogs and calves. This is a novel, exciting possibility for applying an SME alloy. Figure 23 shows a prototype artificial heart with elastomer pumping elements activated by bands of NiTi wires.

Orthopedic Devices

Workers at the Polytechnic Institute of New York (see Castleman et al.) have suggested the manufacture of bone plates from NiTi alloys for the compression fixation of bone fractures. A "preprogrammed" NiTi implant would be fastened to a fractured bone on each side of the fracture. Raising the plate temperature locally some 10–15F° above body temperature would cause the shape memory to contract the plate and fit the ends of the fractured bone securely together. Such a process would involve a much simpler surgical procedure than is now common, using implants made of vitallium and other alloys with "static" dimensions. However, recognizing the possible bioincompatibility of NiTi alloys, these workers carried out a tissue response study by implanting NiTi bone plates in dogs. No adverse tissue reactions, loss of implant material to surrounding tissue, corrosion effects, or contamination of body organs by implant materials were found, leading to the conclusion that NiTi alloys are sufficiently compatible with dog tissue to warrant further investigation as a biomaterial.

Another evaluation of NiTi alloys for orthopedic implants was conducted by Dr. James Hughes of the University of Mississippi. He also prepared bone plates (Figure 24) and

confirmed the biologic acceptability of NiTi alloys. Hughes also suggested a new type of hip prosthesis and intramedullary rod. Instead of cement to hold the stem of the prosthesis in place, the metallic components within the bone are firmly fixed by the gripping segments of NiTi in the stem of the prosthesis.

Another proposed orthopedic device involves using NiTi alloys in a Harrington rod for straightening a bent spinal column.

SOME FURTHER APPLICATIONS

A few additional applications of SME alloys can be briefly mentioned. A U.S. patent has been obtained for a variety of intrauterine contraceptive devices (IUDs) fabricated from NiTi SME alloys. A Cu-Zn SME alloy has been proposed for manufacturing integrated circuit packages with SME used in making contacts. Finally, researchers at the Polytechnic Institute of New York have developed "blind plugs" of NiTi to be used as remotely activated, internally placed seals for old gas lines under streets in New York City.

CLOSURE

The previous discussion suggests that, from a metallurgical point of view, shape-memory alloys are reasonably well understood. Some of the many existing and proposed applications of this new class of materials have been described, and this admittedly nonexhaustive discussion indicates a remarkable variety of new things that can be done with these materials. Since the shape-memory effect is an intrinsic consequence of martensitic transformations, this type of phase change, once thought to be of interest only for quenched steels, takes on new dimension and importance. Many new developments and applications are expected now that the Biblical "serpent" has been tamed.

ACKNOWLEDGMENTS

I would like to thank many friends and colleagues for providing information and photographs. They are too numerous to mention individually, but their contributions are identified in the text. I am particularly indebted to Dr. Tsugio Tadaki for translating this report into Japanese; thanks are also due Dr. Morris Simon for providing the Biblical description of the shape-memory effect. I wish to acknowledge the support of the National Science Foundation, the Materials Research Laboratory at the University of Illinois, and the Army Research Office.

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Company Brochures

Raychem Corporation, Menlo Park, California, 94025. *Couplings, Clamps, Plugs, Electrical Connectors.*

Delta Memory Metal Company, Ipswich, Suffolk, IP2 0EG, England, *Manual on the Design of Shape Memory Effect Actuators.*

Unitek Corporation, Monrovia, California, 91016. *Brochure on NiTi Dental Archwires.*

Foxboro Corporation, Foxboro, Massachusetts, 02035. *Technical Information Sheets on Nitinol Pen Drive Unit*

Figure 24. Radiograph showing bone plate made from NiTi alloy attached to a bone. (Courtesy James Hughes.)

ABOUT THE AUTHOR

C.M. Wayman received a PhD in metallurgy from Lehigh University in 1957; he then joined the University of Illinois where he has been Professor of Metallurgy since 1964. An acknowledged expert in the field of martensitic transformation, he has written a book on the crystallography of martensitic transformations, contributed chapters to 10 others, and has authored or co-authored some 170 papers on martensitic transformations, thin films, and electron microscopy.

In 1969 he was Visiting Professor at the University of Cambridge, England, and also NATO Lecturer, Guggenheim Fellow, and an Overseas Fellow of Churchill College. In 1978, he received the TMS-AIME Mathewson Gold Medal for "outstanding contributions to the study of thermoelastic martensitic transformations in alloys." A member of numerous committees in technical societies, he is also a noted lecturer and has presented keynote lectures on martensitic transformations, the shape-memory effect and its applications.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY DOCKET NO.: 9438	SERIAL NO.: 07/956,653
LIST OF ART CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT: JAMES E. JERVIS	
	FILING DATE: OCTOBER 2, 1992	GROUP: 3301

U.S. PATENT DOCUMENTS

Examiner Initial		DOCKET NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCKET NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	AL							
	AM							
	AN							
	AO							
	AP							

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

DRC	AQ-5	Physik in Unserer Zeit, 1977, Nr. 2, Verlag Chemie GmbH, Seite 33, and translation thereof.
	AR-5	
	AS-5	

EXAMINER Renealy DATE CONSIDERED 6/13/93

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

GP 331
QW 4-6-93
9438

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#6/C

In re Application of:	Group Art Unit: 331
JAMES E. JERVIS	Examiner: David Kenealy
Serial No.: 07/956,653	
Filed: October 2, 1992	
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	Pasadena, California

fee OK

RESPONSE TO OFFICE ACTION

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Dear Madam/Sir:

In response to the Office Action of February 22, 1993, please amend the above-identified patent application as follows:

IN THE SPECIFICATION

In the Cross-reference section of the Preliminary Amendment, in the blank line after "U.S. Patent No.," please insert --5,190,546--.

Page 6, line 4, delete the language --Fig. 3 is a front plan view of a bone implant, namely a nail.--, as inadvertently added by the preliminary amendment. (There is no Figure 3 in the application as filed.)

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C

Page 6, line 4, after "martensite." please add:

--Figure 3 is a side elevation view of a partial section of a catheter of the present invention in a stressed configuration.

C1

Figure 4 is a side elevation view of the catheter of Figure 3 in an unstressed configuration.--

IN THE DRAWINGS

Please add Figures 3 and 4 to the drawings.

IN THE CLAIMS

Please amend the following claim:

25. (once amended) A device as claimed in claim 20, the device having a transverse dimension, [in which] wherein the shape memory alloy element is deformed by the restraint, in such a way that its transverse dimension is reduced [, the restraint preventing] and transverse expansion of the element is obstructed.

33

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Office Action mailed on February 22, 1993, applicant elects, the claims of Group I as defined by the Examiner, namely claims 11-53.

PROVISIONAL ELECTION

The Office Action also requires a provisional election between the claims directed to an IUD, a stent graft, a blood filter, a catheter, and a tracheal catheter.

Applicant provisionally elects the catheter, with traverse. The generic and species claim directed to catheters are: 11-14, 17-21, 24-37, and 41-53.

Applicant respectfully submits that no election is required between tracheal catheters and catheters, because "tracheal catheters" are as their name suggests, merely species of catheters, namely those catheters that are inserted into the throat of a patient. This relationship is evident from the fact that Claim 36, which is directed to tracheal catheters, depends upon Claim 35 which is directed to the generic catheters. Thus, Applicant has included Claims 18 and 36, which are directed to tracheal catheters, in the list defined above.

Applicant respectfully traverses this election requirement. Restriction is proper only when two or more independent and distinct inventions are claimed in one application. 35 U.S.C. § 121; 37 C.F.R. § 1.142. The IUD, stent graft, blood filter, and catheter devices are not independent because they have common design and operational features. The relationship between the devices is evident from the structure of the claims. Many of the claims to these devices were drafted as claims which are dependent upon independent claims which recited common structural and operational features. For example, Claim 14 (directed to a catheter), claim 15 (IUD), Claim 16 (blood filter), and Claim 18 (tracheal catheter) are all dependent on Claim 11 which recites common structural features. Similarly, Claims 38 (IUD), 39 (stent graft) and 40 (blood filter) are all dependent upon independent Claim 37 which has common design elements. Thus, these devices are connected in both design and operation.

Furthermore, if the Examiner requires election, is it the Examiner's position that these devices are patentably distinct, i.e., novel and non-obvious over each other as claimed? If they are not patentably distinct as claimed, a restriction requirement is improper. M.P.E.P. § 802.01.

Finally, Applicant wishes to direct the Examiner's attention to U.S. Patent No. 5,190,546, in which allowed Claim nos. 29-36 are directed to methods of using a bone implant,

marrow nail, bone staple, IUD, blood filter, tubular device, catheter, and a tracheal catheter, respectively. Since these claims directed to separate devices were allowed in the parent application, Applicant respectfully submits that these claims should all be examined here.

REMARKS

Figures 3 & 4 show a catheter with a tubular structure in the stressed and unstressed configurations, respectively. These drawings were added pursuant to the request of the Examiner. Both Figures 3 and 4 are merely copies of the drawings shown in U.S. Patent 3,890,977 to Wilson (Figures 1a and 1b in the Wilson patent). These figures are expressly incorporated by reference in the specification, on page 12, lines 7-8. Hence, no new matter is added.

Since applicant has provisionally elected the catheter species, applicant believes that it is not necessary at the present time to submit drawings showing the IUD or the filter for a blood vessel. Applicant will submit such drawings if and when it is determined that the generic claim is allowable.

CLAIM 25

As per the Examiner's request, claim 25 was amended to provide antecedent basis for "transverse dimension."

CLAIMS 41-44

The Office Action also objects to claims subsequent to claim 41 on grounds that these claims are "functional in nature, and it is difficult for this Examiner to comprehend what structures being claimed with the limitations being presented."

Applicant respectfully submits that claims 41-44 merely impose a limitation that the restraining means, placement device, or pin, does not change in state. Such limitations are allowed in claims. See, In re Bankowski, 318 F.2d 778, 138 U.S.P.Q. 75 (C.C.P.A. 1963) (limitation that virus propagating medium is "devoid of avian tissue" held not objectionable); Johns-Manville Corp. v. Guardian Indus. Corp., 586 F.Supp. 1034 (E.D. Mich. 1983), aff'd, 770 F.2d 178 (Fed. Cir. 1985), (limitation in claim of "without using hot gas blast continuation" allowed); In re Duva, 387 F.2d 402, 156 U.S.P.Q. 90 (C.C.P.A. 1967) (limitation that read "absent sufficient CN ions to prevent decomposition" held proper).

USE OF "ADAPTED"

The Office Action also states that the term "adapted" present in claims 49-53 has "little meaning in terms of patent language used for claiming a structural item." This rejection is respectfully traversed.

Applicant has identified over 25 issued patents where the term "adapted" has been used for claiming a structural item. A partial listing of these issued patents includes: U.S. Patent 4,386,477 ("tube adapted to be inserted"); U.S. Patent 4,386,486 ("adapted to fit within the eye of an anchor insert. . .adapted to engage the anchor insert. . .adapted to receive"); U.S. Patent 4,386,646 ("adapted to be mounted"); U.S. Patent 4,431,111 ("adapted to engage"); U.S. Patent 4,431,155 ("adapted to receive").

Thus, applicant respectfully submits that the term "adapted" has widespread use for claiming a structural item, and consequently, should be allowed by the Examiner.

CONCLUSION

For the reasons given above, entry of the amendments and allowance of the claims is respectfully requested.

Respectfully submitted,

SHELDON & MAK

Dated: 3/22/93 By _____

Jeffrey G. Sheldon
Reg. No. 27,953

225 S. Lake Avenue
Ninth Floor
Pasadena, CA 91101
(818) 796-4000

"EXPRESS MAIL" MAILING LABEL NO. TB309073644US. DATE OF DEPOSIT: March 22, 1993. I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS" MAIL POST OFFICE TO ADDRESSEE SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231 BY MELISSA ALEXANDER

Melissa Alexander

Fig. 4

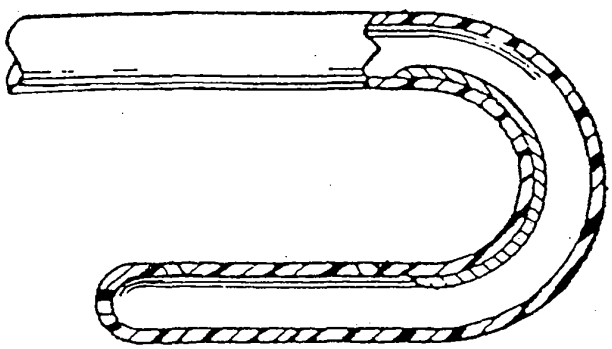
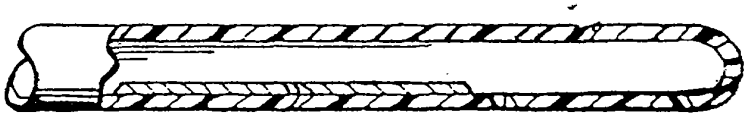


Fig. 3

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AMENDMENT COVER SHEET

DOCKET NO. 9438

33 C Kisonaly

IN RE APPLICATION OF: JAMES E. JERVIS

SERIAL NO.: 07/956,653 FILED: OCTOBER 2, 1992

FOR: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is a paper in the above-identified application. Any necessary extension of time period set for this paper is hereby requested.

☒ No additional fee is required.

☐ The fee has been calculated as shown below:

☐ EXTENSION FEE

	RATE Non-Small Entity	RATE Small Entity	FEE
FIRST MONTH AFTER TIME PERIOD SET	110.00	55.00	$
SECOND MONTH AFTER TIME PERIOD SET	360.00	180.00	$
THIRD MONTH AFTER TIME PERIOD SET	840.00	420.00	$
FOURTH MONTH AFTER TIME PERIOD SET	1,320.00	660.00	$

☐ TOTAL EXTENSION FEE $ _____

☐ FEE FOR EXTRA CLAIMS added by Amendment in this response:

	Column 1 Number of Claims after Amendment	Column 2 Number Previously Paid for	Column 3 Number of Extra Claims	RATE Non-Small Entity	RATE Small Entity	FEE
TOTAL CLAIMS		MINUS **	* =	x 20	x 10	$
INDEPENDENT		MINUS ***	* =	x 72	x 36	$
First presentation of multiple dependent claim				+ 220	+ 110	$

TOTAL FEE FOR EXTRA CLAIMS $ _____

* If the entry in Column 1 is less than the entry of Column 2, write "0" in Column 3.
** If the number of Total Claims previously paid for is less than 20, write "20" in this space.
*** If the number of Independent Claims previously paid for is less than 3, write "3" in this space.

☐ Enclosed is the fee of $ _____ by Check No. _____

☐ Please charge Deposit Account No. 19-2090 in the amount of $ _____

☒ The Commissioner is hereby authorized to charge payment of any additional fees, in particular the following fees, associated with this communication, or credit any overpayment to Deposit Account No. 19-2090:

Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
Any patent application processing fees under 37 C.F.R. § 1.17

Date: 3/22/93

SHELDON & MAK

By: _____
Reg. No. 27,953

"EXPRESS MAIL" mailing label number TB309073644US
Date of Deposit March 22, 1993
I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Melissa Alexander
Signature

Melissa Alexander
Typed or Printed Name of Person Mailing Paper or Fee

225 South Lake Avenue
Suite 900
Pasadena, California 91101
(818) 796-4000 (213) 681-9000

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$200/126

GP 3301

Terminally

9438

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#1 HW 4-28-93 Prior art

In re Application of: 33X	Group Art Unit: 3301
JAMES E. JERVIS	Examiner:
Serial No.: 07/956,653	
Filed: October 2, 1992	
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	Pasadena, California

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Dear Madam/Sir:

Attached hereto is a PTO-1449 form listing documents believed relevant to the subject application. It is respectfully requested that this document be considered by the Examiner and an initialled copy of this form be returned to the undersigned.

It should be noted the word "prior" has been deleted from the form.

It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.56 and the Manual of Patent Examining procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be called so that any deficiencies can be remedied.

050 MS 04/19/93 07956653 1 126 200.00 CK

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These documents are not necessarily analogous art.

Enclosed is check no. 3929 for $200, the fee due under 37 C.F.R. § 1.17(p).

Respectfully submitted,

SHELDON & MAK

Dated: 4/2/93

By _____
Jeffrey G. Sheldon
Reg. No. 27,953

225 South Lake Avenue
Ninth Floor
Pasadena, California 91101
(818) 796-4000

Encls.

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U.S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. ON 4-2-93

BY: MELISSA ALEXANDER _____

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FORM PTO-1449 — U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NO. 9438 | SERIAL NO. 07/956,653

APPLICANT: James E. Jervis

FILING DATE: October 2, 1992 | GROUP: 3301

LIST OF ART CITED BY APPLICANT

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Examiner Initial		DOCKET NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
DSK	AA	4 1 9 8 0 8 1	04/15/80	HARRISON, ET AL.	—	—	
DSK	AB	4 5 0 5 7 6 7	03/19/85	QUIN	—	—	
DSK	AC	4 9 2 5 4 4 5	05/15/90	SAKAMOTO, ET AL.	—	—	
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	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCKET NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	AL							
	AM							—
	AN							
	AO							
	AP							

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

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	AS	
	AT	

EXAMINER: Kenealy — DATE CONSIDERED 6/9/93

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PC20\AKJ\RAYCHEM\PTO-9438.SUP

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/956,653	10/02/92	JERVIS	

EXAMINER	
KENEALY, D	

ART UNIT	PAPER NUMBER
3301	8

DATE MAILED: 06/24/93

F3M1/0624

JEFFREY G. SHELDON
SHELDON & MAK
225 S. LAKE AVENUE - 9TH FLOOR
PASADENA, CA 91101

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 11-54 are pending in the application.
   Of the above, claims 15,16,22,23,38-40 and 54 are withdrawn from consideration.
2. ☑ Claims 1-10 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 11-14,17-21,24-37 and 41-53 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate description of the invention. There is no basis in the specification for the variable "A(90)". In the claims it is not understood what limitation such a variable intends to claim. Although there is an A(90) column in applicant's description of the Quinn 4,505,767 device in the 9/25/92 preliminary amendment, applicant does not describe the characteristics that the variable represents nor the units of measurement.

Claims 11-14,17 and 18 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 13,14,33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite because it contains language concerning transverse compression when there has been no transverse dimension set forth. Without drawings it is difficult to understand such

limitations.

Claim 33 uses incorrect alternative language at line 10 where applicant claims, "the restraint externally OR internally engaging...".

It is requested that applicant use the standard "means for" language when claiming a structure that has a particular function and for which applicant desires broad coverage. For example, in claim 12, a preferable way of claiming the restraint is, "a restraint means for holding the shape memory alloy element in a deformed configuration...". This type of claim language should be used throughout the claims whenever applicant desires a function to have structural weight.

In response to applicant's remarks in the 3/22/93 Office response, this examiner was not stating that "adapted for" language is forbidden in any patent claim. However, such language does not carry with it the patentable weight that positively reciting a structure or its characteristics carries. Applicant is welcome to use "adapted for" language in the claims, but please note that this examiner gives little structural weight to such language.

The drawings are objected to under 37 C.F.R. § 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the restraint, the catheter, the tracheal catheter and the straight pin, must be shown or the feature canceled from the claims. No new matter should be entered.

An election of species restriction is typically accomplished by applicant selecting one of the figured embodiments. Presently applicant does not have a drawing for each of the different embodiments, but has selected to prosecute the group of claims that are directed towards the catheter. It has been determined that claims 11-14,17-21,24-37 and 41-53 all depend from a generic claim. The claims for a tracheal catheter will be included.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 11-14,17-21,24-37 and 41-53 are rejected under 35 U.S.C. § 103 as being unpatentable over Schreck in view of Wilson. Schreck discloses the use of a restraint means, 3 and 7, for holding a shape memory catheter, 4, in a predetermined configuration. A portion of the restraint, 7, is hollow so that the catheter is held within the restraint and compressed "transversely". The catheter displays "stress induced martensite

behavior" at body temperature. It is not known whether the catheter has an A(90) temperature of not more than 0 degrees C due to the insufficiency of the specification. Wilson teaches the use of varying compositions in a shape memory alloy such that the temperature range where the alloy is in its transitional phase can vary between -396 and +331 degrees F. It is believed that the range of transitional temperatures being claimed would have been an obvious characteristic to have included in the material traits of Schreck's catheter in light of the teaching of Wilson because if one had desired a catheter that would return to its original shape at body temperature after being deformed at a temperature below 0 degrees C, one could have looked to Wilson to see that such a temperature range in a shape memory alloy is well known in the art.

Wilson also teaches the use of a curved shape being desirable at the catheter's unstressed state so that it can be placed in certain body regions with greater ease. It is also believed to have been obvious to have had the Schreck device's unstressed state be in a curved configuration instead of just at a larger diameter because if one had wanted to place the device at angle in the human body, one could have looked to Wilson to see how this is done in a shape memory catheter. Item 3 of Schreck could be obviously replaced by a straight pin for design reasons if a fenestration already existed in the area that the catheter is desirably inserted.

It is requested that applicant define more structural

limitations that allow applicant's device to function in the manner described in the claims. Some of applicant's limitations are strictly functional, such as: "can be extruded from the device at a temperature..", "the hollow placement device stressing the memory alloy at a temperature...", "transformation of the alloy occurs without any change in the state..." and more. What are the structural limitations that allow the device to function in these manners and how are they different from the prior art?

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Kenealy whose telephone number is (703) 308-2680.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

David Kenealy
June 13, 1993

MICKEY YU
PRIMARY EXAMINER
ART UNIT 331

FORM PTO-892 (REV. 2-92)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
NOTICE OF REFERENCES CITED		956653	331	8
		APPLICANT(S) Jervis		

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	3890977	6/75	Wilson	604	281	
	B	4411655	10/83	Schreck	604	281	
	C	3868956	3/75	Alfidi	606	78	
	D	4512338	4/85	Balko	606	78	
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L	2114005	8/83	UK	Krupp	606	78		
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

R	
S	
T	
U	

EXAMINER	DATE
Kreat	6/13/93

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

AMENDMENT COVER SHEET

DOCKET NO. 9439/MP0884-US7

340-114 331

IN RE APPLICATION OF: **JAMES E. JERVIS**

SERIAL NO.: **07/956,653**

FILED: **October 2, 1992**

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

#9 RECEIVED
DEC 14 1993
GROUP 330

HONORABLE COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

336

MAIL ROOM NOV 29 1993

Sir:

Transmitted herewith is a paper in the above-identified application. Any necessary extension of time period set for this paper is hereby requested.

[ ] No additional fee is required.

[X] The fee has been calculated as shown below:

[X] EXTENSION FEE	RATE Non-Small Entity	RATE Small Entity	FEE
FIRST MONTH AFTER TIME PERIOD SET	110.00	55.00	$
SECOND MONTH AFTER TIME PERIOD SET	360.00	180.00	$360.00
THIRD MONTH AFTER TIME PERIOD SET	840.00	420.00	$
FOURTH MONTH AFTER TIME PERIOD SET	1,320.00	660.00	$

[X] TOTAL EXTENSION FEE **$360.00**

[ ] FEE FOR EXTRA CLAIMS added by Amendment in this response:

	Column 1 Number of Claims after Amendment	Column 2 Number Previously Paid for	Column 3 Number of Extra Claims	RATE Non-Small Entity	RATE Small Entity	FEE
TOTAL CLAIMS	46	MINUS **	* = 3	x22	x 10	$ 66.00
INDEPENDENT	8	MINUS ***	* = 1	x74	x 36	$ 74.00
First presentation of multiple dependent claim				+ 220	+ 110	$

TOTAL FEE FOR EXTRA CLAIMS **$132.00**

* If the entry in Column 1 is less than the entry of Column 2, write "0" in Column 3.
** If the number of Total Claims previously paid for is less than 20, write "20" in this space.
*** If the number of Independent Claims previously paid for is less than 3, write "3" in this space.

[X] Enclosed is the fee of $~~500~~**.00** by Check No. 4574

[ ] Please charge Deposit Account No. 19-2090 in the amount of $ _____

[X] The Commissioner is hereby authorized to charge payment of any additional fees, in particular the following fees, associated with this communication, or credit any overpayment to Deposit Account No. 19-2090:

Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
Any patent application processing fees under 37 C.F.R. § 1.17

Date: 11/24/93

SHELDON & MAK
By: _____
Jeffrey G. Sheldon, Reg. No.: 27,953

CERTIFICATE OF MAILING: I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D. C. 20231 on November 24, 1993.

Date Signed: 11/24/93 By _____

SHELDON & MAK
225 SOUTH LAKE AVENUE, SUITE 800
PASADENA, CALIFORNIA 91101
(818) 796-4000 - Direct Line: (818) 356-1201

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QW 12-28

9438/MP0884-US7

10/20 attach

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	**Group Art Unit: 3301**
JAMES E. JERVIS	**Examiner: KENEALY, D**
Serial No. 07/956,653	RECEIVED
Filed: October 2, 1992	DEC 14 1993
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	GROUP 330 **Pasadena, California**

AMENDMENT

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U. S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D. C. 20231 ON

November 24, 1993

November 24, 1993 Marilyn Rios
(DATE SIGNED)

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

In response to the Office Action of June 24, 1993, please amend the above-identified application as follows:

IN THE SPECIFICATION

At page 8, between lines 24 and 25, and after the table added by the preliminary amendment filed with the application, please insert:

--The A(90) temperature is the temperature at which the transformation from the martensitic phase to the austenitic phase is 90% complete.--

120 WP 12/13/93 07956653
120 WP 12/13/93 07956653

1 102 74.00 CK
1 103 66.00 CK

At page 6, line 4, after the description of Figures 3 and 4 added by the Amendment of March 22, 1993, please insert:

94

--Fig. 5 is a tracheal catheter, which is curved in its unstressed configuration, partially straightened by a straight pin restraint.

Fig. 6 shows an IUD formed at least partly from a pseudoelastic shape-memory alloy being restrained in a deformed shape by a restraining tube.--

At page 13, line 24, before "When", insert --The IUD has a longitudinal dimension and a transverse dimension.--

IN THE CLAIMS

Please amend the claims as follows:

12. (Amended) A device as claimed in Claim 11, which includes a restraint [by means of which] holding the shape memory alloy element [is held] in a deformed configuration to allow it to be positioned within or in proximity to a mammalian body, the deformation occurring through the formation of stress-induced martensite.

13. (Amended) A device as claimed in claim 12, in which the restraint is hollow, and the shape memory alloy element has a transverse dimension and a longitudinal dimension, and wherein the shape memory alloy element is deformed [in such a way that it is] by being compressed transversely, and is positioned

within the restraint, the restraint preventing transverse expansion of the element.

~~19.~~ (Amended) A medical device which comprises:

(a) an element for use within a mammalian body or in such proximity to a mammalian body that the device is substantially at body temperature, the element comprising a shape memory alloy which displays stress-induced martensite behavior at body temperature; and

(b) a restraint [by means of which] holding the shape memory alloy element [is held] in a deformed configuration to allow it to be positioned within or in proximity to a mammalian body, the deformation occurring through the formation of stress-induced martensite;

wherein [the device is adapted so that] the element is sufficiently deformed that removal of the restraint from the shape memory alloy element, without change in temperature of the device, releases at least a portion of the element from its deformed configuration.

~~25.~~ (Amended) A device as claimed in claim ~~20,~~ in which the shape memory alloy element has a transverse dimension and a longitudinal dimension, and wherein the shape memory alloy element is deformed [in such a way that] by its transverse dimension [is] being reduced, and wherein the restraint [preventing] prevents transverse expansion of the element.

~~26.~~ (Amended) The device of claim ~~19,~~ 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 memory alloy element from its deformed configuration without change in state of the restraint.

27. (Amended) A medical device suitable for placement within or proximate to a mammalian body for treatment of the mammalian body, the device comprising: [(i) a restraining means and (ii)]

(a) a memory alloy element formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying 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) [the] restraining means engaging and stressing the memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element is in its deformed shape;

wherein the alloy is selected so that removal of the restraining means [is adapted to be removed] from the memory alloy element at a temperature greater than the As of the alloy when the device is placed within or proximate to the mammalian body, [to transform] transforms at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape toward its

unstressed shape, [and wherein the device is adapted so that the transformation can occur] without any change in temperature of the restraining means or the memory alloy element <u>being required for the transformation of the alloy</u>.

28. (Amended) A medical device for treatment of a mammalian body, the device comprising: [(i) a hollow restraining member and (ii)]

<u>(a)</u> a memory alloy element formed at least partly from a 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; <u>and</u>

<u>(b) a hollow restraining member with</u> the memory alloy element being within the restraining member, the restraining member engaging and stressing the memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element is in its deformed shape;

wherein the restraining member and the memory alloy element are movable relative to each other to transform at least a portion of the alloy from its stress-induced martensitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the [device is adapted] <u>alloy is selected</u> so that the transformation can occur without any

change in temperature of the restraining member or the memory alloy element.

11 ~~29.~~ (Amended) The medical device of claim 10 ~~28~~ wherein the restraining member is a tube and the memory alloy element is axially slidable within the tube, and wherein the [device is adapted so] memory alloy element is sufficiently long that relative axial movement between the tube and the memory alloy element extends at least a portion of the memory alloy element beyond the tube and thereby transforms the memory alloy element toward its austenitic state.

Claim 31, line 21, change "device is adapted so" to --alloy is selected--.

Claim 32, line 3, change "device is adapted so" to --tube is sufficiently long--.

Claim 33, line 10, delete "externally or internally"; in lines 19-20; and change "device is adapted" to --alloy is selected--.

Claim 35, line 18, change "device is adapted" to --alloy is selected--.

Claim 37, line 21, change "device is adapted to --alloy is selected--.

Claim 49, lines 1-2, change "device is adapted" to --alloy is selected--.

27 ~~50.~~ (Amended) The device of claim ~~48~~ 25 wherein [the device is adapted so that] (i) the restraining member can be completely disengaged and separated from the memory alloy element, and (ii) the alloy is selected so that engaging the restraining member with the memory alloy element after separation results in the memory alloy element transforming towards its deformed shape by reversion to its stress-induced martensitic state.

28 ~~51.~~ (Amended) The device of claim ~~33~~ 15 wherein [the device is adapted so that] (i) the restraining member can be completely disengaged and separated from the catheter, and (ii) the alloy is selected so that reengaging the restraining member with the catheter after separation results in the catheter transforming toward its easily inserted shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

29 ~~52.~~ (Amended) The device of claim ~~35~~ 17 wherein [the device is adapted so that] (i) the pin can be completely disengaged and separated from the catheter, and (ii) the alloy is selected so that reengaging the restraining means with the memory alloy element after separation results in the catheter transforming toward its deformed shape by reversion of at least a

portion of the alloy from its austenitic state to its stress-induced martensitic state.

~~53.~~ 30. (Amended) The device of claim 36 wherein [the device is adapted so that] (i) the placement device can be completely disengaged and separated from the catheter, and (ii) the alloy is selected so that reengaging the placement device with the catheter after separation results in the catheter transforming toward its deformed shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

Please add the following claims to the application:

~~54.~~ 31. The medical device of claim ~~33~~ 15 wherein the restraint externally engages the catheter.

~~55.~~ 32. The medical device of claim ~~33~~ 15 wherein the restraint internally engages the catheter.

~~56.~~ 57. A medical device suitable for placement within or proximate to a mammalian body for treatment of the mammalian body, the device comprising (i) a restraint, and (ii) an element formed at least partly from a pseudoelastic shape-memory alloy,

the alloy displaying reversible stress-induced martensite by virtue of being above its A_s and above its M_s and below its M_d at about body temperature;

such that it has a stress-induced martensitic state and an austenitic state, the element having (i) a deformed shape when the alloy is in its stress-induced martensitic state and (ii) a different unstressed shape;

wherein the restraint is capable both of stressing the element and of being at least partially removed from the element while the device is within or proximate to the said body at the said body temperature and the element is therefore at an operating temperature greater than the A_s and M_s and below the M_d of the alloy,

2nd concl. such removal of the restraint causing at least a portion of the alloy to transform from its stress-induced martensitic state to its austenitic state so that the element spontaneously transforms from its deformed shape toward its unstressed shape,

and such transformation can occur without a change in temperature of the restraint or of the element from the operating temperature.

IN THE DRAWINGS

Please approve new Figures 5 and 6 accompanying this amendment.

REMARKS

Claims 11-56 are pending in this application. Claims 54-56 are added by this amendment. Claim 15, 16, 22, 23, and 38-40 are withdrawn from consideration. Claims 11-14, 17, 18, and

33 were rejected under 35 U.S.C. § 112. The drawings were objected to under 37 C.F.R. § 1.83(a). All of the claims originally submitted were rejected under 35 U.S.C. § 103. Reexamination, reconsideration, and allowance are respectfully requested.

It is noted the Examiner referred to claim 54 in the Office Action. It is believed this was in error in that there was no claim 54 in the application prior to this amendment.

Entry of the amendments is respectfully requested. No new matter is added by the amendments in that they are clearly supported by the specification. In particular, the amendments to the claims are to meet some objections raised by the Examiner. For example, new claims 54 and 55 result from deletion of the alternative language that appeared in claim 33. Claim 56 is similar to a claim undergoing prosecution in Europe based on the present application.

New Fig. 5 is based on Fig. 4, with a pin inserted as described in the specification. Fig. 6 is based on drawings in U.S. Patent No. 3,620,212, which was incorporated by reference at page 13, lines 2-5. The new drawings have been added pursuant to the request of the Examiner to include in the application a drawing showing all features claimed. Since these features are claimed, and the claims are supported by the specification, no new matter is added.

The reference explaining the significant of A(90), which was added to page 8 of the specification, is based on the amendment and declaration filed in great-grandparent Application Serial No. 177,817, filed March 30, 1988, in response to an Office Action filed August 11, 1988. Relevant portions of that amendment and the declaration are provided herewith for the convenience of the Examiner. As is made clear that amendment and declaration, A(90) is an inherent property of the materials listed in the table.

REJECTIONS AND OBJECTIONS UNDER 35 U.S.C. § 112

The specification was objected to as failing to provide an adequate description of "A(90)". By this amendment, that objection has been obviated. This also obviates the rejection of claims 11-14, 17, and 18 under 35 U.S.C. § 112, based on the same grounds.

Claim 13 was objected to because of reference to transverse compression. This objection has been obviated by providing an antecedent basis in claim 13 for a transverse dimension. Moreover, the specification has been amended to make it clear that an IUD has a transverse and longitudinal dimension, which is inherent in such a device.

The rejection to claim 33 has been obviated by removing the alternative language.

Applicant has used "means for" language where appropriate. However, in view of recent decisions by the Federal Circuit, where it is unclear exactly what scope the Federal Circuit will apply to "means for" language, Applicant has elected to use broad language, such as "restraint".

With regard to the use of "adapted for" language, Applicant respectfully disagrees with the Examiner's position that "adapted for" language cannot be considered in determining the patentability of the claimed invention. Nevertheless, to avoid controversy, Applicant has revised the claims, without prejudice, to eliminate the "adapted for" language.

In view of the foregoing remarks, removal of the objections and rejections under 35 U.S.C. § 112 is respectfully requested.

OBJECTION TO THE DRAWINGS

The drawings were objected to for not showing every feature of the invention specified in the claims. The drawings have been amended to specify all such features. Accordingly, approval of the accompanying drawings and removal of the objection are respectfully requested.

REJECTION UNDER 35 U.S.C. § 103

All the claims under consideration were rejected under 35 U.S.C. § 103 as being unpatentable over Schreck U.S. Patent

No. 4,411,655 in view of Wilson U.S. Patent No. 3,890,977. This rejection is respectfully traversed.

This rejection assumes that Schreck's catheter displays "stress-induced martensite behavior". As detailed below, Schreck teaches no such thing. Thus, no prima facie case of obviousness has been made, and the rejection should be withdrawn.

As is made clear throughout the specification, a key feature of the claimed invention is a medical device that comprises an alloy in its stress-induced martensitic state. By way of background, there are two techniques available for transforming an appropriate alloy into the martensitic state. The first technique, which is the common technique, is cooling the material so that martensite forms at M_s under no stress. By the second technique, the same material, martensite can form above M_s if stress is applied, thereby forming "stress-induced martensite". The present invention is directed to use of the unique properties of stress-induced martensite, not martensite formed by cooling.

Contrarily, Schreck only teaches conventional martensite formed by cooling. In particular, Schreck first describes a "one way" mode where "a martensite phase transformation . . . occurs as the specimen is cooled through the appropriate temperature range ($M_s \rightarrow M_f$)." (Column 3, lines 18-20)

Thus, it is clear that in Schreck's "one way" mode, martensite is formed through conventional cooling.

Schreck then goes on to discuss a "two way" or reversible mode. Again, however, martensite is clearly formed by cooling. Schreck states "if a shape-memory alloy is deformed beyond a minimum stained (sic, strained) value while in its martensite phase, the original "parent" shape will be recovered on heating the specimen above the phase change as in the 'one way' effect." (emphasis added; Column 3, lines 32-37) Thus, clearly, Schreck is referring to deformation after the alloy is in its martensite phase, and not the use of stress or deformation to put the alloy into its martensite phase. Thus, Schreck has no teaching of stress-induced martensite.

Moreover, by no stretch of the imagination, can Schreck's elastomeric sleeve be considered to be a restraint that causes stress-induced martensite transformation. As Schreck states at column 2, lines 21-25 "the shape memory alloy cannula may advantageously be encased in elastomeric sleeve whose lumenal diameter is stretched by the SMA material as it equilibrates to the desired temperature." Thus, the elastomeric sheath is deformed by the dilating cannula, not the reverse. There is no suggestion that the sheath could possibly deform the cannula and cause phase transformation, i.e., the formation of stress-induced martensite. Indeed, there is no mention of stress-induced martensite anywhere in Schreck.

Moreover, as specifically recited in many of the claims, such as claims 19, 27, 28, 31, 33, 35, 37, and 56, and the claims dependent therefrom, the changes that take place in the memory alloy element occur "without any change in temperature of the restraining means or the memory alloy element be required for the transformation of the alloy." (This is language quoted from claim 27). This is clearly not what is taught by Schreck, who specifically requires the temperature of the shape-memory alloy change to dilate the cannula (see for example, column 2, line 7-16 of Schreck). This is a significant advantage of Applicant's invention in that recovery is achieved without temperature change. Schreck does not have this feature.

Therefore, for the foregoing reasons, and, in particular, because no prima facie case of obviousness has been made, removal of the rejection under 35 U.S.C. § 103 is respectfully requested.

INFORMATION DISCLOSURE STATEMENT

Applicant has obtained a translation of Oonishi, Clinical Magazine: Orthopedic Surgery, 32, page 1180 (1981) which was listed as one of the references cited to the Examiner as part of the information disclosure statement that accompanied the original application. A copy of the translation is enclosed.

Applicant appreciates the fact that the Examiner considered some of the references cited. However, the Examiner

has not acknowledged considering references that were cited as part of a supplemental information disclosure statement that was mailed April 2, 1993 (copy enclosed), nor references cited in the original application (pages 1-7 of PTO-1449 forms). It is respectfully requested that the Examiner acknowledge consideration of all these references. Copies of these seven pages are provided herewith for the convenience of the Examiner.

If for some reason the Examiner does not have copies of any of these references, please notify the undersigned and courtesy copies will be hand carried to the Examiner. Applicant respectfully requests the Examiner to initial all of the attached forms and return them to the undersigned.

CONCLUSION

For reasons detailed above, it is believed that the present application is in condition for allowance. If for some reason the Examiner considers otherwise, it is respectfully requested that a telephone call be placed to the undersigned to resolve any remaining difficulties. It is the undersigned's experience that such telephone calls can often lead to early disposal of applications.

Respectfully submitted,

SHELDON & MAK

11/24/93
Date

By _____
Jeffrey G. Sheldon, Reg. No. 27,953

225 South Lake Avenue, Suite 900
Pasadena, California 91101 - Phone: (818) 796-4000

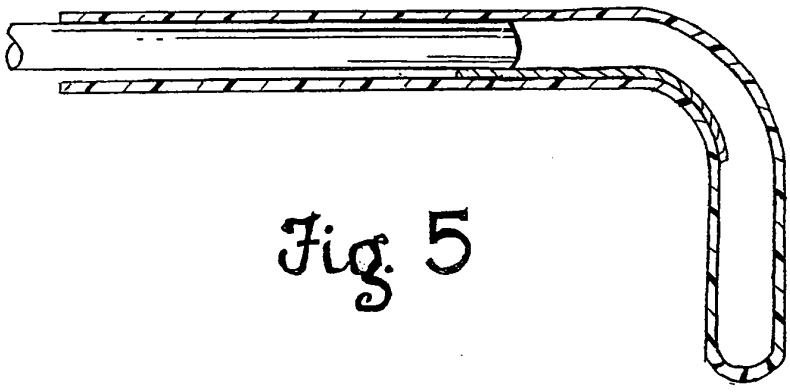

Fig. 5

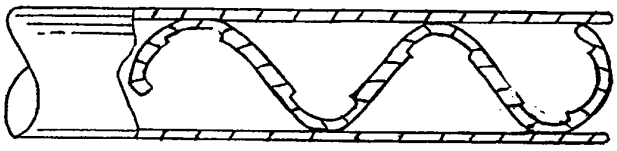

Fig. 6

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

LIST OF ART CITED BY APPLICANT

(Use several sheets if necessary)

ATTORNEY DOCKET NO. 9438	SERIAL NO. 07/956,653
APPLICANT: James E. Jervis	
FILING DATE: October 2, 1992	GROUP: 3301

U.S. PATENT DOCUMENTS

Examiner Initial		DOCKET NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
VJV	AA	4 1 9 8 0 8 1	04/15/80	HARRISON, ET AL.			
VJV	AB	4 5 0 5 7 6 7	03/19/85	QUIN			
VJV	AC	4 9 2 5 4 4 5	05/15/90	SAKAMOTO, ET AL.			
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCKET NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	AL							
	AM							
	AN							
	AO							
	AP							

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	
	AS	
	AT	

EXAMINER Vervack DATE CONSIDERED 3/16/94

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PC20\AKJ\RAYCHEM\PTO-9438.SUP

United States Patent [19]
Quin

[11] Pat Number: 4,505,767
[45] Date of Patent: Mar. 19, 1985

[54] NICKEL/TITANIUM/VANADIUM SHAPE MEMORY ALLOY

[75] Inventor: Mary P. Quin, Redwood City, Calif.

[73] Assignee: Raychem Corporation, Menlo Park, Calif.

[21] Appl. No.: 541,844

[22] Filed: Oct. 14, 1983

[51] Int. Cl.³ C22C 19/00; C22C 30/00

[52] U.S. Cl. 148/402; 148/442; 420/441

[58] Field of Search ..... 148/402, 11.5 F, 11.5 N; 420/442, 441

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3,753,700	8/1973	Harrison et al.	148/402
3,786,806	1/1974	Johnson et al.	128/92 D
3,832,243	8/1974	Donkersloot et al.	148/402
3,890,977	6/1975	Wilson	128/418
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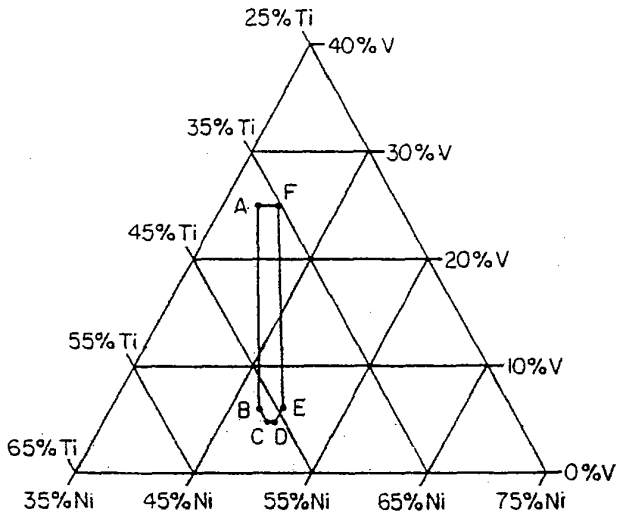
Primary Examiner—Peter K. Skiff
Attorney, Agent, or Firm—Ira D. Blecker; James W. Peterson; Herbert G. Burkard

[57] ABSTRACT

Nickel/titanium alloys having a nickel:titanium atomic ratio between about 1:02 and 1:13 and a vanadium content between about 4.6 and 25.0 atomic percent show constant stress versus strain behavior due to stress-induced martensite in the range from about 0° to 60° C.

8 Claims, 6 Drawing Figures



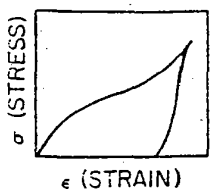


FIG_1A

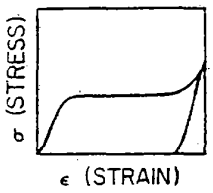


FIG_1B

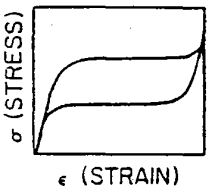


FIG_1C

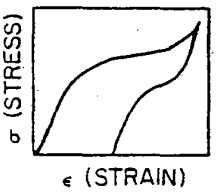


FIG_1D

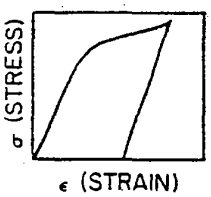


FIG_1E

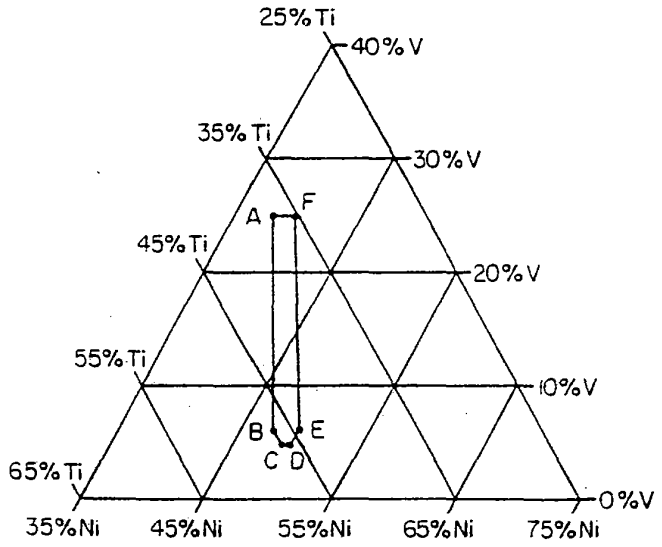


FIG_2

NICKEL/TITANIUM/VANADIUM SHAPE MEMORY ALLOY

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to nickel/titanium shape memory alloys and improvements therein.

Introduction to the Invention

Materials, both organic and metallic, capable of possessing shape memory are well known. An article made of such materials can be deformed from an original, heat-stable configuration to a second, heat-unstable configuration. The article is said to have shape memory for the reason that, upon the application of heat alone, it can be caused to revert, or to attempt to revert, from its heat-unstable configuration to its original, heat-stable configuration, i.e. it "remembers" its original shape.

Among metallic alloys, the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state with a change in temperature. This transformation is sometimes referred to as a thermoelastic martensitic transformation. An article made from such an alloy, for example a hollow sleeve, is easily deformed from its original configuration to a new configuration when cooled below the temperature at which the alloy is transformed from the austenitic state to the martensitic state. The temperature at which this transformation begins is usually referred to as M_s and the temperature at which it finishes M_f. When an article thus deformed is warmed to the temperature at which the alloy starts to revert back to austenite, referred to as A_s (A_f being the temperature at which the reversion is complete) the deformed object will begin to return to its original configuration.

Shape memory alloys (SMAs) have found use in recent years in, for example, pipe couplings (such as are described in U.S. Pat. Nos. 4,035,007 and 4,198,081 to Harrison and Jervis), electrical connectors (such as are described in U.S. Pat. No. 3,740,839 to Otte and Fischer), switches (such as are described in U.S. Pat. No. 4,205,293), actuators, etc.

Various proposals have also been made to employ shape memory alloys in the medical field. For example, U.S. Pat. No. 3,620,212 to Fannon et al. proposes the use of an SMA intrauterine contraceptive device. U.S. Pat. No. 3,786,806 to Johnson et al. proposes the use of an SMA bone plate. U.S. Pat. No. 3,890,977 to Wilson proposes the use of an SMA element to bend a catheter or cannula, etc.

These medical SMA devices rely on the property of shape memory to achieve their desired effects. That is to say, they rely on the fact that when an SMA element is cooled to its martensitic state and is subsequently deformed, it will retain its new shape; but when it is warmed to its austenitic state, the original shape will be recovered.

However, the use of the shape memory effect in medical applications is attended with two principal disadvantages. First, it is difficult to control the transformation temperatures of shape memory alloys with accuracy as they are usually extremely composition-sensitive, although various techniques have been proposed (including the blending by powder metallurgy of already-made alloys of differing transformation temperatures; see U.S. Pat. No. 4,310,354 to Fountain et al.).

Second, in many shape memory alloys there is a large hysteresis as the alloy is transformed between austenitic and martensitic states, so that reversing of the state of an SMA element may require a temperature excursion of several tens of degrees Celsius. The combination of these factors with the limitation that human tissue cannot be heated or cooled beyond certain relatively narrow limits without suffering temporary or permanent damage is expected to limit the use that can be made of SMA medical devices.

In copending and commonly assigned U.S. patent application (Ser. No. 541,844, filed 10/14/83) to Jervis, the disclosure of which is incorporated herein by reference, it is proposed that the stress-induced martensite (SIM) properties of shape memory alloys be employed in SMA medical devices, rather than the use of the shape memory effect.

When an SMA sample exhibiting stress-induced martensite is stressed at a temperature above M_s (so that the austenitic state is initially stable), it first deforms elastically and then, at a critical stress, begins to transform by the formation of stress-induced martensite. Depending on whether the temperature is above or below A_s, the behavior when the deforming stress is released differs. If the temperature is below A_s, the stress-induced martensite is stable; but if the temperature is above A_s, the martensite is unstable and transforms back to austenite, with the sample returning (or attempting to return) to its original shape. The effect is seen in almost all alloys which exhibit a thermoelastic martensitic transformation, along with the shape memory effect. However, the extent of the temperature range over which SIM is seen and the stress and strain ranges for the effect vary greatly with the alloy. For many purposes, it is desirable that the SIM transformation occur at a relatively constant stress over a wide strain range, thereby enabling the creation of, in effect, a constant force spring.

Various alloys of nickel and titanium have in the past been disclosed as being capable of having the property of shape memory imparted thereto. Examples of such alloys may be found in U.S. Pat. Nos. 3,174,851 and 3,351,463.

Buehler et al (Mater. Des. Eng., pp.82-3 (Feb. 1962); J. App. Phys., v.36, pp.3232-9 (1965)) have shown that in the binary Ni/Ti alloys the transformation temperature decreases dramatically and the yield strength increases with a decrease in titanium content from the stoichiometric (50 atomic percent) value. However, lowering the titanium content below 49.9 atomic percent has been found to produce alloys which are unstable in the temperature range of 100° C. to 500° C., as described by Wasilewski et al., Met. Trans., v.2, pp. 229-38 (1971). The instability (temper instability) manifests itself as a change (generally an increase) in M_s between the annealed alloy and the same alloy which has been further tempered. Annealing here means heating to a sufficiently high temperature and holding at that temperature long enough to give a uniform, stress-free condition, followed by sufficiently rapid cooling to maintain that condition. Temperatures around 900° C. for about 10 minutes are generally sufficient for annealing, and air cooling is generally sufficiently rapid, though quenching in water is necessary for some of the low Ti compositions. Tempering here means holding at an intermediate temperature for a suitably long period (such as a few hours at 200°-400° C.). The instability thus makes the low titanium alloys disadvantageous for

shape memory applications where a combination of high yield strength and reproducible M_s is desired.

Although certain cold-worked binary nickel/titanium alloys have been shown to exhibit SIM, these alloys are difficult to use in practice because, in order to obtain the appropriate M_s to give SIM properties at physiologically acceptable temperatures, the alloys must have less than the stoichiometric titanium content. These binary alloys then are (1) extremely composition-sensitive in M_s as referred to above for shape memory; (2) unstable in M_s with aging and sensitive to cooling rate; and (3) require cold-working to develop the SIM, so that any inadvertent plastic deformation is not recoverable simply by heat-treatment; new cold-working is required.

Certain ternary Ni/Ti alloys have been found to overcome some of these problems. An alloy comprising 47.2 atomic percent nickel, 49.6 percent titanium, and 3.2 atomic percent iron (such as disclosed in U.S. Pat. No. 3,753,700 to Harrison et al.) has an M_s temperature near −100° C. and a yield strength of about 70,000 psi. While the addition of iron has enabled the production of alloys with both low M_s temperature and high yield strength, this addition has not solved the problem of instability, nor has it produced a great improvement in the sensitivity of the M_s temperature to compositional change.

U.S. Pat. No. 3,558,369 shows that the M_s temperature can be lowered by substituting cobalt for nickel, then iron for cobalt in the stoichiometric alloy. However, although the alloys of this patent can have low transformation temperatures, they have only modest yield strengths (40,000 psi or less).

U.S. Naval Ordnance Laboratory Report NOLTR 64-235 (August 1965) examined the effect upon hardness of ternary additions of from 0.08 to 16 weight percent of eleven different elements, including vanadium, to stoichiometric Ni/Ti. Similar studies have been made by, for example, Honma et al., Res. Inst. Min. Dress. Met. Report No. 622 (1972) and Proc. Int. Conf. Martensitic Transformations (ICOMAT '79), pp. 259–264; Kovneristii et al., Proc. 4th Int. Conf. on Titanium, v. 2, pp. 1469–79 (1980); and Donkersloot et al., U.S. Pat. No. 3,832,243, on the variation of transformation temperature with ternary additions, also including vanadium. These references, however, do not describe any SIM behavior in the alloys studied.

It would thus be desirable to develop an alloy which exhibits stress-induced martensite in the range from 0° to 60° C. which is preferably of low composition sensitivity for ease of manufacture.

DESCRIPTION OF THE INVENTION

Summary of the Invention

I have discovered that the addition of appropriate amounts of vanadium to nickel/titanium shape memory alloys permits the production of workable alloys exhibiting stress-induced martensite in a physiologically acceptable temperature range, when in the fully annealed condition (i.e. no cold working is required to produce the desired mechanical properties).

This invention thus provides a shape memory alloy consisting essentially of nickel, titanium, and vanadium within an area defined on a nickel, titanium, and vanadium ternary composition diagram by a hexagon with its first vertex at 38.0 atomic percent nickel, 37.0 atomic percent titanium, and 25.0 atomic percent vanadium; its second vertex at 47.6 atomic percent nickel, 46.4 atomic percent titanium, and 6.0 atomic percent vanadium; its third vertex at 49.0 atomic percent nickel, 46.4 atomic percent titanium, and 4.6 atomic percent vanadium; its fourth vertex at 49.5 atomic percent nickel, 45.6 atomic percent titanium, and 4.6 atomic percent vanadium; its fifth vertex at 49.8 atomic percent nickel, 44.0 atomic percent titanium, and 6.2 atomic percent vanadium; and its sixth vertex at 39.8 atomic percent nickel, 35.2 atomic percent titanium, and 25.0 atomic percent vanadium.

BRIEF DESCRIPTION OF THE DRAWING

FIGS. 1A through 1E are typical stress-strain curves for shape memory alloys at various temperatures.

FIG. 2 is a nickel/titanium/vanadium ternary composition diagram showing the area of the alloy of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1A through 1E are typical stress-strain curves for shape memory alloys at various temperatures. Ignoring, for the moment, the difference between M_s and M_d and between A_s and A_f, the behavior of a shape memory alloy may be generally seen to fit with one of these Figures.

In FIG. 1A, T is below M_s. The alloy is initially martensitic, and deforms by twinning beyond a low elastic limit. This deformation, though not recoverable at the deformation temperature, is recoverable when the temperature is increased above A_s. This gives rise to the conventional shape memory effect.

In FIG. 1B, T is between M_s and M_d (the maximum temperature at which martensite may be stress-induced), and below A_s. Here, though the alloy is initially austenitic, stress results in the formation of martensite permitting ready deformation. Because the alloy is below A_s, the deformation is again not recoverable until heating to above A_s results in the transformation back to austenite. If the sample is unrestrained, the original shape will be completely recovered; if not, it will be recovered to the extent permitted by the restraint. However, if the material is then allowed to re-cool to the temperature of deformation, the stress produced in the alloy is constant regardless of the strain provided that the strain lies within the "plateau" region of the stress-strain curve. This means that a known, constant force (calculable from the height of the stress plateau) can be applied over a wide (up to 5% or more) strain range.

In FIG. 1C, T is between M_s and M_d, and above A_f. Here, the stress-induced martensite is thermally unstable and reverts to austenite as the stress is removed. This produces, without heating, what is, in effect, a constant-force spring acting over a strain range which can be about 5%. This behavior has been termed stress-induced martensite pseudoelasticity.

FIG. 1D shows the situation where T is near M_d. Although some stress-induced martensite is formed, the stress level for martensite formation is close to the austenitic yield stress of the alloy and both plastic and SIM deformation occur. Only the SIM component of the deformation is recoverable.

FIG. 1E shows T above M_d. The always-austenitic alloy simply yields plastically when stressed beyond its elastic yield point and the deformation is non-recoverable.

The type of stress-strain behavior shown in these FIGS. 1A through 1E will hereafter be referred to as A- through E-type behavior.

Constant stress over a wide strain range is desirable mechanical behavior for many medical applications. Such a plateau in the stress-strain curve of these alloys occurs over limited temperature ranges above M_s and below M_d.

Such properties are useful for medical products when they occur at temperatures between 0° C. and 60° C., and particularly at 20° C. to 40° C. It has been discovered that certain compositions of Ni/Ti/V alloys exhibit B- or C-style behavior in this temperature range.

Shape memory alloys according to the invention may conveniently be produced by the methods described in, for example, U.S. Pat. Nos. 3,753,700 and 4,144,057. The following example illustrates the method of preparation and testing of samples of shape memory alloys.

EXAMPLE

Commercially pure titanium and vanadium and carbonyl nickel were weighed in proportions to give the atomic percentage compositions listed in Table I (the total mass for test ingots was about 330 g). These metals were placed in a water-cooled copper hearth in the chamber of an electron beam melting furnace. The chamber was evacuated to 10^{-5} Torr and the charges were melted and alloyed by use of the electron beam. The resulting ingots were hot swaged and hot rolled in air at approximately 850° C. to produce strip of approximately 0.025 inch thickness. Samples were cut from the strip, descaled, vacuum annealed at 850° C. for 30 minutes, and furnace cooled.

The transformation temperature of each alloy was determined (on an annealed sample) as the temperature at the onset of the martensite transformation at 10 ksi stress, referred to as M_s (10 ksi).

For a series of samples, stress-strain curves were measured at temperatures between −10° and 60° C. to determine the existence of stress-induced martensite behavior.

TABLE I

Properties of Nickel-Titanium-Vanadium Alloys

Composition Atomic Percent			M_s (10 ksi)	Mechanical Behavior at T
Ni	Ti	V	C	
51.0	45.5	3.5	−196	
48.5	41.5	10.0	−196	
49.5	43.5	7.0	−107	
50.0	44.0	6.0	−96	
49.0	43.0	8.0	−83	
50.0	45.0	5.0	−42	D D
49.0	45.0	6.0	−35	C C C D D
50.5	48.0	1.5	−32*	B D E
45.0	41.0	14.0	−32	C D
48.5	44.5	7.0	−30	C C C D
49.5	45.5	5.0	−13	B C C D
50.0	46.0	4.0	−11*	B D D
48.5	45.0	6.5	−10	B B C D
49.0	45.5	5.5	−10	B B C C D
48.0	44.25	7.75	−7	A/B C C D
48.5	45.5	6.0	−5	A B B C
41.5	38.5	20.0	−2	A A B B B C
46.5	43.5	10.0	−1	A B C
36.25	33.75	30.0	0*	A A B B
49.5	46.0	4.5	6*	B B D·
48.0	46.0	6.0	12	A A/B B B B B B D
47.75	45.75	6.5	20	A A B B
47.5	45.5	7.0	26	A A B B
48.5	46.5	5.0	27	A A B B
45.0	45.0	10.0	30	A A/B B B
47.5	46.5	6.0	32	A B B B B
46.5	46.5	7.0	34	A A B
48.25	46.25	5.5	36	A A B B

* Alloys with an asterisk beside the M_s temperature are not within the scope of the invention, even though the M_s temperature is in the correct range

It can be seen from Table I that alloys with an M_s higher than −40° C. but lower than 20° C. show predominantly B- and C-type behavior at 20° and 40° C. This M_s criterion is not sufficient to ensure a flat stress-strain curve at the desired temperatures, however. A vanadium content of at least 4.6 atomic percent is also necessary, since alloys with 1.5 and 4.0 atomic percent V show D- and E-type behavior at 20° C. and 40° C. The sample with a V content of 4.5 at % shows D-type behavior at 40° C., although B-type at 0° and 20° C. Such an alloy would be marginally useful.

Since the alloy with an M_s of −42° C. has D-type behavior at 0° C., it is expected that alloys with an M_s below −40° C. will show D- or E-type behavior in the temperature range of interest, while alloys with an M_s above 20° C. show A-type behavior over at least half the 0°-60° C. range.

Too much vanadium also leads to undesirable properties, since an alloy with 30 atomic percent vanadium shows a lesser degree of SIM elongation and a much higher yield strength for the SIM transformation than alloys of lower vanadium content. This alloy also showed A-type behavior at 20° C. despite an M_s of −3° C. Such an alloy, with a nearly 1:1:1 composition ratio, is probably not treatable as a Ni/Ti type alloy.

The claimed composition range, based on these data, is shown in FIG. 2, and the compositions at the vertices given in Table II.

TABLE II

Point	Atomic Percent Compositions		
	Nickel	Titanium	Vanadium
A	38.0	37.0	25.0

TABLE I-continued

Point	Atomic Percent Compositions Nickel	Titanium	Vanadium
B	47.6	26.4	26.0
C	49.0	26.4	24.6
D	49.8	45.6	4.6
E	49.8	44.0	6.2
F	39.8	35.2	25.0

The lines AB and BC represent the upper limit of M_c expected to allow the desired behavior, i.e. 20° C. The line AB corresponds approximately to a Ni:Ti atomic ratio of 1.13. The line CD corresponds to the lower limit of vanadium composition: alloys having less vanadium do not exhibit B- or C-type behavior in the desired temperature range even if of the correct M_c. The lines DE and EF represent the lower limit of M_c giving the desired behavior, i.e. −40° C. The line EF corresponds approximately to an Ni:Ti atomic ratio of 1.02. Finally, the line FA represents the upper limit of vanadium content for the desirable SIM properties.

Presently preferred alloys include a region consisting essentially of 47.6–48.8% at % Ni, 45.2–46.4 at % Ti, remainder V around 48.0% Ni, 46.0% Ti, 6.0% V, which alloy has B-type behavior from 10° to 50° C.; and a region having an Ni:Ti atomic ratio between about 1.07 and 1.11 and a vanadium content between 5.25 and 15 atomic percent, which shows C-type behavior at 20° C. and/or 40° C.

In addition to the method described in the Example, alloys according to the invention may be manufactured from their components (or appropriate master alloys) by other methods suitable for dealing with high-titanium alloys. The details of these methods, and the precautions necessary to exclude oxygen and nitrogen either by melting in an inert atmosphere or in vacuum, are well known to those skilled in the art and are not repeated here.

Changes in composition cann occur during the electron-beam melting of alloys: the technique employed in this work. Such changes have been noted by Honma et al., Res. Inst. Min. Dress. Met. Report No. 622 (1972), and others. The composition ranges claimed as a part of this invention are defined by the initial commpositions of alloys prepared by the electron-beam method. However, the invention includes within its scope nickel/titanium/vanadium alloys prepared by other techniques which have final compositions which are the same as the final compositions of alloys prepared here.

Alloys obtained by these methods and using the materials described will contain small quantities of other elements, including oxygen and nitrogen in total amounts from about 0.05 to 0.2 percent. The effect of these materials is generally to reduce the martensitic transformation temperature of the alloys.

The alloys this invention are hot-workable and exhibit stress-induced martensite in the range of 0° to 60° C. in the fully annealed condition.

We claim:

1. A shape memory alloy consisting essentially of nickel, titanium, and vanadium within an area defined on a nickel, titanium, and vanadium ternary composition diagram by a hexagon with its first vertex at 38.0 atomic percent nickel, 37.0 atomic percent titanium, and 25.0 atomic percent vanadium; its second vertex at 47.6 atomic percent nickel, 46.4 atomic percent titanium, and 6.0 atomic percent vanadium; its third vertex at 49.0 atomic percent nickel, 46.4 atomic percent titanium, and 4.6 atomic percent vanadium; its fourth vertex at 49.8 atomic percent nickel, 45.6 atomic percent titanium, and 4.6 atomic percent vanadium; its fifth vertex at 49.8 atomic percent nickel, 44.0 atomic percent titanium, and 6.2 atomic percent vanadium; and its sixth vertex at 39.8 atomic percent nickel, 35.2 atomic percent titanium, and 25.0 atomic percent vanadium.

2. The alloy of claim 1 which has an Ni:Ti atomic ratio between 1.07 and 1.11 and a vanadium content between 5.25 and 15 atomic percent.

3. The alloy of claim 1 which consists essentially of between 47.6 and 48.8 atomic percent nickel, 45.2 and 46.4 atomic percent titanium, and the remainder vanadium.

4. A shape-memory article comprising a shape-memory alloy consisting essentially of nickel, titanium, and vanadium within an area defined on a nickel, titanium, and vanadium ternary composition diagram by a hexagon with its first vertex at 38.0 atomic percent nickel, 37.0 atomic percent titanium, and 25.0 atomic percent vanadium; its second vertex at 47.6 atomic percent nickel, 46.4 atomic percent titanium, and 6.0 atomic percent vanadium; its third vertex at 49.0 atomic percent nickel, 46.4 atomic percent titanium, and 4.6 atomic percent vanadium; its fourth vertex at 49.8 atomic percent nickel, 45.6 atomic percent titanium, and 4.6 atomic percent vanadium; its fifth vertex as 49.8 atomic percent nickel, 44.0 atomic percent titanium, and 6.2 atomic percent vanadium; and its sixth vertex at 39.8 atomic percent nickel, 35.2 atomic percent titanium, and 25.0 atomic percent vanadium.

5. The article according to claim 4 which has an Ni:Ti atomic ratio between 1.07 and 1.11 and a vanadium content between 5.25 and 15 atomic percent.

6. The article according to claim 4 which consists essentially of between 47.6 and 48.8 atomic percent nickel, 45.2 and 46.4 atomic percent titanium, and the remainder vanadium.

7. The article according to claim 4 exhibiting stress-induced martensite.

8. The article according to claim 4 exhibiting stress-induced martensite in the range of 0° to 60° C. when in the fully annealed condition.

* * * * *

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

LIST OF ART CITED BY APPLICANT (Use Several sheets if necessary)

ATTORNEY DOCKET NO. 9438

SERIAL NO. Division of 682,243

APPLICANT JAMES E. JERVIS

FILING DATE Herewith

GROUP 3301 (Prior application)

U.S. PATENT DOCUMENTS

Examiner Initial		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
DJK	AA	3 3 4 8 5 4 8	10-24-67	CHARDACK	128	418	
	AB	3 4 1 6 5 3 1	12-17-68-	EDWARDS	128	348	-
	AC	3 4 1 9 0 1 2	12-31-78	WILLIAMSON	125	350	
	AD	3 5 0 0 8 2 0	3-17-70	T.H.O. ALMEN	128	303	
	AE	3 5 1 6 4 1 2	06-23-70	ACKERMAN	128	418	
	AF	3 5 3 9 0 3 3	11-10-70	TAFEEN	128	221	
	AG	3 6 2 0 2 1 2	11-1971	FANNON, JR.	128	130	
	AH	3 7 2 9 0 0 8	04-24-83	BERKOVITS	128	418	
	AI	3 7 4 0 8 3 9	06-26-73	OTTE, ET AL.	29	628	
	AJ	3 7 8 6 8 0 6	1-1974	JOHNSON, ET AL.	128	92YN	
DJK	AK	3 8 5 7 3 9 1	12-21-74	LERNER	128	127	

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DJK	AM	9 4 0 7 5 9	11-80	SU	128	92YN		
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~~DJK~~	AO	0 1 2 9 6 3 4		EPO				
~~DJK~~	AP	0 1 3 2 5 4 4		EPO				

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DJK	AT	Cragg, et al., Radiology, (April 1983) Vol. 147, pp 261-263

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DSK	AA	3 8 6 8 9 5 6	3-4-75	ALFIDI, ET AL.	128	345	
	AB	3 8 8 9 6 6 6	6-17-75 -	LERNER	128	127	-
	AC	3 8 9 0 9 7 7	6-19-75	WILSON	604	281	
	AD	3 9 3 9 8 2 8	2-24-76	MOHR, ET AL.	128	92B	
	AE	3 9 6 0 1 4 7	6-1-76	MURRAY	128	92B	
	AF	4 0 3 3 3 3 1	7-5-77	GUSS, ET AL.	128	2M	
	AG	4 0 3 5 0 0 7	7-12-77	HARRISON, ET AL.	285	381	
	AH	4 0 3 7 3 2 4	7-1977	ANDREASEN	433	24	
	AI	4 1 4 9 9 1 1	04-17-79	CLABBURN	148	11.5R	
	AJ	4 1 7 0 9 9 0	10-1974	BAUMGART, ET AL.	128	92YN	
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DSK	AL	1 0 0 1 0 3 4	12-7-76	CANADA	128	93		
DSK	AM	1 1 1 0 4 4 7	8-1984	SU	128	92YN		
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DSK	AO	1 4 9 1 6 2 8		GERMANY				
DSK	AP	2 1 0 6 1 9 0	4-7-83	UK				

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DJK	AA	4 2 0 5 2 9 3	5-27-80	MELTON, ET AL.	337	140	
	AB	4 2 3 0 1 2 3	10-28-80-	HAWKINS, JR.	128	658	-
	AC	4 2 3 3 6 9 0	11-1980	AKINS	623	2	
	AD	4 3 0 7 7 2 3	12-29-81	FINNEY	128	349R	
	AE	4 3 1 0 3 5 4	1-12-82	FOUNTAIN, ET AL.	75	211	
	AF	4 3 7 8 8 1 1	4-5-83	LEVITAN	128	757	
	AG	4 4 0 1 4 3 3	8-30-83	LUTHER	604	159	
	AH	4 4 1 1 6 5 5	10-25-83	SCHRECK	604	165	
	AI	4 4 2 5 9 0 8	1-17-84	SIMON	128	1R	
	AJ	4 4 2 7 0 0 0	1-24-84	UEDA	128	6	
DJK	AK	4 4 5 2 2 3 6	6-5-84	UTSUGI	128	4	

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	AN	2 7 0 3 5 2 9	3-8-78	GERMANY			ABSTRACT	
	~~AO~~	~~3 1 4 7 7 2 2~~		~~GERMANY~~				
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	AB	4 4 9 0 1 1 2	12-25-84-	TANAKA, ET AL.	433	20	
	AC	4 4 9 4 5 3 1	1-22-85	GIANTURCO	128	1R	
	AD	4 5 0 5 7 6 7	3-19-85	QUIN	148	402	
	AE	4 5 0 9 5 1 7	4-9-85	ZIBELIN	128	319	
	AF	4 5 1 2 3 3 8	4-23-85	BALKO, ET AL.	128	1R	
	AG	4 5 4 3 0 9 0	9-24-85	McCOY	604	95	
	AH	4 5 5 6 0 5 0	12-3-85	HODGSON, ET AL.	128	1R	
	AI	4 5 8 6 3 3 5	5-6-86	HOSODA, ET AL.	60	528	
	AJ	4 6 0 1 2 8 3	7-22-86	CHIKAMA	128	4	
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DK	AO	5 8 4 1 5 4 6		JAPAN			PARTIAL	
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DJE	AB	3 6 0 5 7 2 5	9-20-71	Bentov	128	2.05R	
	AC	3 7 5 7 7 6 8	9-11-73	Kline	128	2M	
	AD	3 7 8 9 8 4 1	2-5-74	Antoshkiw	128	2.05	
	AE	4 0 8 0 7 0 6	3-28-78	Heilman	29	173	
DJE	AF	4 6 6 5 9 0 6	5-87	Jervis	128	92YH	
	AG						
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	AI						
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DJE	AM	5 9 9 7 1 1 5		JAPAN			Abstract	
DJE	AN	6 0 4 5 3 5 6		JAPAN			X	
DJE	AO	6 2 2 0 8 2 7		JAPAN			Partial	
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Materials Science and Engineering, 48 (1981) 241 - 247

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Variation in the Shape Recovery Temperature in Ni–Ti Alloys

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SUMMARY

In the near-equiatomic Ni–Ti alloy, certain processing factors significantly affect the shape recovery temperature T_f and the extent of shape recovery while others do not. The lowest recovery temperature and the best shape recovery were obtained by annealing between 450 and 500 °C. Varying the annealing temperature resulted in the largest change in these two parameters, causing an increase of 20 °C in T_f and a decrease of 13% in the shape recovery (in one sample batch) if the annealing temperature was increased much above 500 °C. Increasing the maximum strain (in the range between 0% and 8%) induced an increase of 10 °C in T_f at 500 °C with larger increases at other annealing temperatures but without any effect on the extent of shape recovery. Altering the annealing time had a relatively small effect. A recovery-resistant physical constraint raised the effective T_f but if the constraint was maintained at a sufficiently high temperature the transformation occurred, plastic deformation resulted and permanent partial loss of shape memory was suffered.

T_f extrapolates to nearly the same temperature, at zero strain, for all the annealing temperatures near 500 °C. Similarly, the final temperature of the transformation from martensite to β phase (zero strain) is the same for all the annealing temperatures. This strongly suggests that each annealing temperature yields a high temperature B2 phase with a slightly different structure which interacts differently with stress.

Although this study is based on only two batches of Ni–Ti wires of similar composition, it is expected that qualitatively similar variations with processing factors occur in all Ni–Ti alloys which exhibit shape memory.

1. INTRODUCTION

Near-equiatomic Ni–Ti alloys (Nitinol) exhibit shape memory characteristics [1 - 3]. The memory is such that, given the proper conditions, Nitinol objects can be restored thermally to their original shape after being deformed from that shape. The shape recovery takes place over a range of temperatures on heating with maximum or, ideally, complete recovery being reached at a specific temperature T_f.

The high temperature phase in Ni–Ti alloys is reported to be of a CsCl (B2) type, and the martensite is reported to be a monoclinic distortion of the B19 structure [4]. There is also a higher order phase transition from the B2 phase which occurs below a critical temperature T_R. Among many other effects the transition from the B2 phase is characterized by a rapid increase in electrical resistance [4, 5], extra diffraction spots at the one-third positions of the B2 reciprocal lattice [4, 6] and a rhombohedral distortion of the B2 lattice [5, 6]. This transition is pre-empted by the martensitic transformation when $M_s > T_R$ (where M_s is the martensitic transformation temperature); application of factors which lower M_s relative to T_R, such as thermal cycling of the specimen in the transformation range or compositional variations [7], may be necessary to see both transformations. We define the structure below T_R as the R phase and refer to the structure encompassing both the B2 and the R phases as the β phase. Thus martensite may form from the B2 or the R phase depending on the relative temperatures T_R and M_s [5].

The primary mechanism for the shape memory effect is generally considered to be the interaction of stress with the martensitic

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transformation [5, 8 - 11]. Depending on the deformation temperature with respect to M_s, one or more of the following three mechanisms may be operative in Ni–Ti alloys [12]: (1) stress-induced martensite formation from the β phase; (2) reorientation of thermally induced martensite variants through twin-interface motion; (3) variation in twin thickness within individual variant "plates". The B2 $\rightleftarrows$ R transition has been found to contribute to the two-way shape memory [5]. Our recent results [13] show that this transition is probably also a primary shape memory mechanism, although the effect is smaller in magnitude than that due to the martensitic transformation. When T_R is below the final temperature A_f of the transformation from martensite to β phase, the final shape recovery temperature will be determined by the reversion of the last plate of martensite (ideally the first one formed). This situation is generally observed in Ni–Ti alloys. Thus we expect T_f to be closely related to A_f.

The shape memory properties of Ni–Ti alloys are very sensitive to the chemical composition of the alloy. Buehler and Wang [14] have shown that T_f varies in binary Ni–Ti alloys from about −50 to 166 °C. Eckelmeyer [15] has also reported that T_f showed a steep increase (80 °C) as the titanium content changed from about 49.7 to 50.4 at.% and remained constant for further increases in titanium content. Substituting a small percentage of a third element for either nickel or titanium can cause either an increase or a decrease in T_f [15]. The shape memory properties are also sensitive to the methods by which the alloy is processed and heat treated [16]. Cross *et al.* [17] have performed a study on the shape memory response of Ni–Ti rod, wire and foil of varying diameter or thickness. They selected a final annealing temperature of about 500 °C as the optimum for shape memory and reported on the shape recovery as a function of material form (rod, wire or foil) and the amount of strain. The variation in T_f was not documented. Besides the references cited above, we are not aware of any published results which deal quantitatively with the effect of other factors on T_f and shape recovery.

Variables of concern in utilizing the shape memory phenomenon can be divided into two groups: the first group, associated with shape memory in general, includes the final annealing temperature, the annealing time, the amount of strain and the effect of thermal cycling; the second group relates to parameters intrinsic to practical applications such as shape change constraints caused by a storage device and manual handling. Although these were not expected to have as drastic an effect on the recovery temperature as the composition, there are potential applications where strict temperature requirements demand close knowledge and control of all parameters which may together cause unacceptable variations.

2. EXPERIMENTAL PROCEDURES

The materials used in this study were drawn wires approximately 0.020 in in diameter. Two batches numbered A383 and V4865 were chemically analyzed to be of compositions 50.13at.%Ti–49.96at.%Ni and 50.12at%Ti–49.86at.%Ni respectively with a reported estimated error of 0.1%. (The A383 wire was supplied by the Nitinol Technology Center, Naval Surface Weapons Center, White Oaks, MD. It was strand annealed at 500 °C in the as-received condition. The V4865 wire was purchased from the Timet Corporation. In the as-received condition it is totally martensitic.) The procedures used for specimen preparation, electrical resistance measurement and shape recovery experiments were as described in ref. 5. Figure 1 illustrates schematically the shape memory geometry for these experiments. As a shape change parameter we chose the included angle θ between the two arms of the U-shaped specimen. The "fractional shape recovery" was taken to be $(180 - \theta)/180$.

The measurements of the detailed shape recovery, including precise T_f values, were made as a function of annealing temperature and annealing time and for various "straighten-

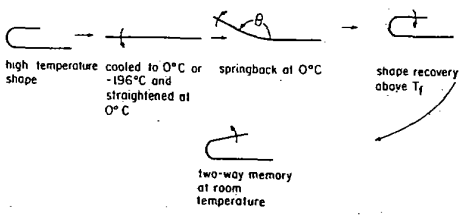

Fig. 1. A schematic sequence of the shape memory experiment.

" strains between 2% and 8%. Earlier empirical observations [16, 17] have indicated that an annealing temperature in the vicinity of 500 °C yields good shape recovery behavior in Ni–Ti alloys. Thus our investigation centered on this temperature region. All specimens, unless otherwise specified, were air cooled after the high temperature anneal by placing the jig over an air vent.

The specimen was straightened at 0 °C. At this temperature the V4865 wire is essentially 100% martensite. For A383 wire the initial state depends on the lowest cooling temperature prior to deformation: (a) 0 °C, 100% R phase; (b) −196 °C, a mixture of R phase and martensite.

3. RESULTS AND DISCUSSION

Although the A383 and V4865 alloys have similar atomic compositions, differences exist in their transformation behavior [5]. For example, in the range of annealing temperature and strain investigated, T_f lies between 30 and 4[illegible]°C for the A383 alloy and between 60 and [illegible]°C for the V4865 alloy. The different recovery temperatures for the two materials are also reflected in the low M_s value (below −10 °C) observed for the A383 alloy compared with that (about 30 °C) for the V4865 alloy. The zero-strain values of M_s and A_f as a function of annealing temperature for an annealing time of 30 min are listed in Table 1. A_f is constant for all the annealing temperatures in each material. Although M_s is also constant for the V4865 alloy, changing the annealing temperature from 500 to 540 °C raises M_s from −25 to −12 °C for the A383 alloy. It was also observed that 100% shape recovery was attained for the A383 alloy for all strains tested compared with 94% for the V4865 alloy at the higher strains of 5% - 8% and annealed at 500 °C. On repeating shape memory cycles up to 10 times, the A383 alloy still achieves 100% recovery while the incomplete shape recovery in the V4865 alloy deteriorates with cycling. The differences in the transformation behavior between the two materials are not clear. Neither optical microscopy nor X-ray diffraction in these wire specimens revealed any noticeable difference in the structure or phases initially present. Processing variables prior to the final anneal (such as in wire drawing etc.) and the impurity content probably cause the differences.

A typical shape recovery curve of a U-shaped specimen consists of an immediate elastic spring-back and then a slow recovery followed by a narrow temperature region of rapid recovery. A description of shape recovery mechanisms has been presented earlier [5]. In this paper we shall concentrate on the experimental variations of T_f and the percentage of shape recovery.

3.1. Variation in the shape recovery temperature

Although the A383 and V4865 alloys show differences in the transformation behavior, both wire batches none the less exhibit similar variations in T_f with annealing temperature and with percentage strain (for a fixed annealing time of 30 min). As shown in Fig. 2, T_f

TABLE 1

The variations in T_R, M_s and A_f at zero strain as a function of annealing temperature for an annealing time of 30 min

Specimen batch	*Annealing temperature* (°C)	T_R (°C)	M_s (°C)	A_f (°C)
A383	500	28	−25	31
	520	25	−20	31
	540	20	−12	31.5
V4865	400	45	31.5	59
	450	40	31.5	60
	500	37 ± 2	31	60
	550	37 ± 2	31	58
	600	37 ± 2	31	61

These values of T_R, M_s and A_f were determined from the electrical resistance measurements on the first thermal cycle after cooling to room temperature from the high temperature annealing treatment.

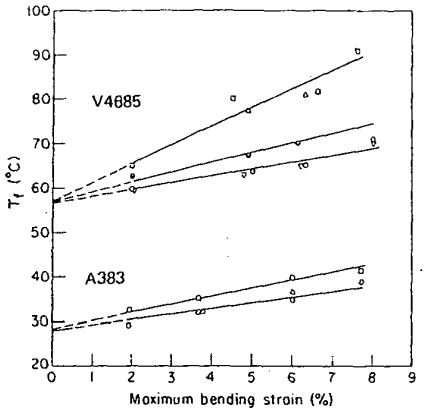

Fig. 2. Variation in the shape recovery temperature T_f with percentage bending strain at different annealing temperatures for an annealing time of 30 min for the V4685 alloy (□, 600 °C; △, 550 °C; ○, 500 °C; ▽, 450 °C; ●, 400 °C) and the A383 alloy (□, 540 °C; △, 520 °C; ○, 500 °C).

increases linearly with increasing strain between 2% and 8% strain with a change of approximately 9 °C for annealing temperatures near 500 °C. Larger increases are caused in samples of the V4865 alloy annealed at other temperatures. External strain (stress) raises M_s and A_f in general, so this result is not unexpected. For a fixed strain, T_f has a minimum for annealing temperatures between 450 and 500 °C, as shown in Fig. 3. Similar variations occur for strains between 2% and 8%.

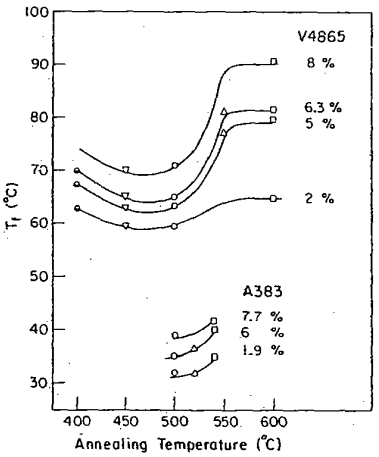

Fig. 3. Variation in shape recovery temperature T_f with annealing temperature at different bending strains for an annealing time of 30 min.

Thus a final anneal near 500 °C yields a low recovery temperature.

The effect of changing the annealing time is shown in Fig. 4 for the V4865 alloy. With the annealing temperature fixed at 500 °C and with 6.3% strain, T_f increases from 65 to 67.5 °C as the annealing time is increased from 30 min to about 1.5 h and remains constant for longer annealing times up to 24 h. (The specimen annealed for 10 min was quenched in water at room temperature.) The perfection of the shape recovery decreases slightly, from 94% to 91%, with increasing annealing time.

Using A383 wire, other parameters were studied to determine their effect on T_f. Cooling to 0 °C (100% R phase) or −196 °C (a mixture of R phase and martensite) prior to straightening at 0 °C resulted in a variation in T_f of only 1 °C. This means that A_f is the same whether the induced strain is a result of stress-induced martensite formation and/or reorientation of martensite variants. Two different cooling rates after the final anneal, air cooling and quenching in iced water, showed less than 1 °C difference in T_f. This indicates that any structural changes which may occur on cooling to the straightening temperature are not diffusion controlled. On cycling the same specimen through the shape memory cycle up to 10 times the T_f values showed a scatter of 1.5 °C. Changing the straightening temperature from 0 to 15 °C and to 24.5 °C (the A383 alloy is 100% R phase at all these temperatures) does not shift T_f by more than 1 °C. The immediate recovery at the higher straightening temperatures is such that the specimen goes directly to the shape

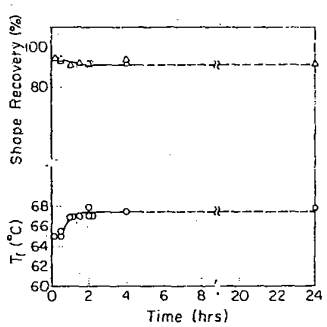

Fig. 4. Variations in T_f and shape recovery with annealing time (batch V4865; 500 °C anneal; 6.3% strain).

It was attained at the same temperature by a specimen that was straightened at 0 °C. Thus these processing parameters seem to have relatively little effect on the recovery behavior.

We now turn to the effect on the wire of physical constraint (as in a storage or application container) while the temperature is raised above the normal A_f, after it has been straightened and placed in the container. The normally occurring shape change is partially constrained by the container. This might result in plastic deformation which will impair shape recovery. In our experiments an initially U-shaped specimen (A383 wire; air cooling at 500 °C for 30 min; 6.0% strain) was straightened at 0 °C and was placed inside a rigid tube $\frac{1}{8}$ in inside diameter, which only allows a small fraction of the shape recovery to occur. The specimen was then heated in water to various temperatures before being pulled from the tube into the water. These experiments are depicted in Fig. 5. Figure 5, curve 1, illustrates the case when the specimen was not constrained. The corresponding electrical resistance curve is also shown. (It should be noted, however, that the resistance measurements here are for the entire length of the wire (approximately 2.5 in) while only about 20% of the wire was actually deformed as part of the U bend. Thus the resistivity changes are underrepresented.)

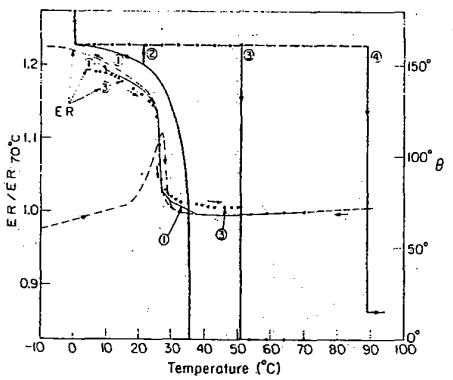

Fig. 5. Effect of a recovery-resistant constraint on T_f and shape recovery (batch A383; 500 °C anneal for 30 min; 6% strain): ---, electrical resistance (ER) at zero strain; curves 1 and 3, correspondence between the electrical resistance and θ changes.

After straightening, the electrical resistance is lower than in the zero-strain curve (broken line) because of the stress formation of martensite, which has a lower intrinsic electrical resistance than the R phase. Between 27 and 37 °C the martensite electrical resistance is higher than that of the R or B2 phase, so curve 1 lies above the zero-strain curve. Above 37 °C (A_f) the transformation of martensite to the B2 phase is completed and the electrical resistance curves show the same temperature variations. If the intermediate temperature is below T_f (about 36 °C), the specimen immediately reverts to the identical (partially recovered) shape that was attained at the same temperature by a specimen which has not been constrained. Under these conditions the ultimate T_f did not vary from the original value by more than 1.5 °C (Fig. 5, curve 2). If the intermediate temperature was above T_f but below about 90 °C, an instantaneous and 100% recovery was obtained. Figure 5, curve 3, illustrates the case when the intermediate temperature is 51 °C. The corresponding electrical resistance curve showed that the electrical resistance remained constant between 37 and 51 °C, indicating that a volume fraction of martensite was prevented from reverting to the B2 phase by the constraint. Once the specimen had been pulled from the rigid tube, the electrical resistance immediately attained the value of the B2 phase at that temperature, so the instantaneous shape recovery was accompanied by the simultaneous reversion of the remaining martensite to the B2 phase. Thus the extra stress caused by the constraint raises the effective T_f. At a temperature of about 90 °C, only 85% recovery was achieved (Fig. 5, curve 4). Further, only incomplete shape recovery was achieved on further cycling at lower intermediate temperatures. Thus at a sufficiently high temperature the external stress due to the constraint is unable to prevent the transformation in the material, which then results in permanent plastic deformation.

This important result indicates that the equilibrium T_f may be exceeded significantly while a shape memory device is constrained without impairing shape recovery. These data also stress the fact that any handling technique likely to cause plastic deformation in the wire should be avoided.

3.2. Variation in the percentage of shape recovery

In the A383 wire, 100% recovery was achieved in all the specimens and conditions tested. The V4865 wire, however, did not show similarly perfect behavior. The variation in percentage shape recovery with annealing temperature and strain is shown in Fig. 6. At a fixed annealing temperature the elastic spring-back is largest at 2% strain while the total shape recovery (spring-back and shape memory) decreases from 100% at 2% strain to approximately 94% for strains between 5% and 8% at an annealing temperature of 500 °C. These results agree qualitatively with those reported by Cross *et al.* [17] on Ni–Ti alloys with a final annealing temperature of 500 °C. Their tests have shown that shape recovery deteriorates with increases in strains up to 18%.

At different annealing temperatures the spring-back is essentially constant for a fixed strain, while the extent of shape recovery has a maximum of 94% between 450 and 500 °C with a slight decrease to 90% at 400 °C and a larger decrease to 81% at 550 and 600 °C. Thus a final annealing temperature near 500 °C gives the best shape recovery as well as a low recovery temperature.

3.3. Further consideration of the annealing treatment

T_f extrapolates to nearly the same temperature at zero strain for all annealing temperatures near 500 °C (Fig. 2). Similarly, A_f at zero strain is the same for all the annealing

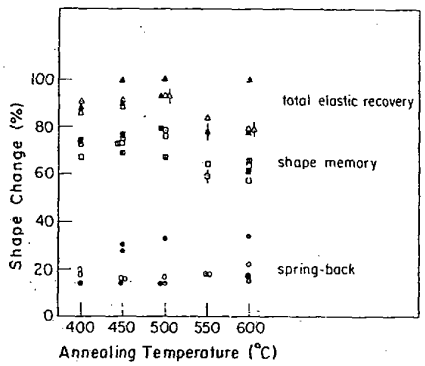

Fig. 6. Percentage shape change as a function of annealing temperature and strain (batch V4865; maximum strains of 8% (▲), 6.3% (△), 5% (△) and 2% (▲); annealing time, 30 min).

temperatures (A_f is about 60 °C for the V4865 alloy and 31 °C for the A383 alloy). This strongly suggests that each different annealing temperature yields a high temperature B2 phase with a slightly different structure (degree of order, defect structure etc.) that interacts differently with stress to yield different (finite strain) T_f values at different strains.

Consideration must therefore be given to the possibility that the annealing temperature affects such structural factors as the degree of long- and short-range order in the mutual arrangement of the nickel and titanium atoms and that subsequent transformations are affected by these factors, particularly in the presence of strain. Similarly, the effect of annealing on defect structures must be considered. For example, the Ni–Ti alloys are subject to contamination by oxygen and nitrogen, which form oxides and nitrides as inclusions. Although inclusions are an integral part of the microstructure in Nitinol alloys [17], their atomic composition, structure and morphology have not been determined. The inclusions may affect the phase transformation and shape changes because of the internal stress modifications which they cause, as a result of interaction with external stress. The influence of annealing temperature on the effect of the inclusions is not clear. A clarification of these effects may lead to a better understanding of the changes caused by the annealing treatment.

4. CONCLUSIONS

We established that certain processing factors affect T_f and the extent of shape recovery significantly while others do not. The lowest recovery temperature T_f and the best shape recovery is obtained by annealing between 450 and 500 °C. Varying the annealing temperature results in the largest change in these two parameters, causing an increase of as much as 20 °C in T_f and a decrease of 13% in shape recovery for the V4865 alloy if the annealing temperature is increased much above 500 °C. Changing the maximum strain (between 2% and 8%) induces a 10 °C variation in T_f at 500 °C with larger increases at other annealing temperatures but without an effect on the extent of shape recovery. Alter-

ing the annealing time has a relatively small effect. At 500 °C and 6.3% strain there is only a maximum of 3 °C change in T_f and a 4% loss in shape recovery for the V4865 alloy. Recovery-resistant stress caused by an external constraint raises the effective T_f but, if maintained at a sufficiently high temperature, the plastic deformation accompanying the transformation under constraint causes permanent partial loss of shape memory.

Although this study is based on only two batches of Nitinol wires of similar compositions, it is expected that qualitatively similar variations occur in all Ni–Ti wires that exhibit shape memory.

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Zur Dwyerschen Skoliosenoperation mittels Drähten aus Memory-Legierungen

Eine experimentelle Studie

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On DWYER'S Scoliosis Operation Using Memory Alloy Wire

Summary. In Dwyer's spinal column correction a titanium cable is stretched from vertebra to vertebra by special clamp and secured to each vertebra with claws and clips. It is suggested to replace the titanium wire with wire consisting of the memory alloy NiTi. This will permit the prestretched wire to be tensioned by heating it to 60 deg C after it has been fixed at its ends in the vertebrae.

The functional principle of the NiTi memory wire was demonstrated in an experiment carried out on a plastic model. This consists of 8 plastic vertebrae with 30 mm sides which are connected by interposed wedge-shaped soft rubber discs, giving the model a curved shape. Memory wire prestretched by 7% is led through eylets on the convex side and fixed at the ends. On being heated (electrically in this experiment for the sake of simplicity), the wire shortens, righting the model so that it assumes a straight shape.

The authors also describe in detail the manufacture of the alloy, i.e. the melting and shaping operations, as well as the properties of the material, that is, the stress-strain and strain-temperature relationships and the transformation temperatures, as well as mechanical problems.

Zusammenfassung. Bei der Dwyerschen Wirbelsäulenkorrektur wird mittels einer Spezialspannzange ein Titankabel von Wirbelkörper zu Wirbelkörper verspannt und an jedem einzelnen mittels Schrauben in Agraffen festgeklemmt. Hier wird vorgeschlagen, das Titankabel durch einen Draht aus Memory-Legierung NiTi zu ersetzen. Dies ermöglicht das Spannen des vorgereckten Drahtes durch einfache Erwärmung auf etwa 60° C, nachdem dieser an den Enden in den Wirbelkörpern verankert wurde.

Die Wirkungsweise des NiTi-Drahtes wurde in einem prinzipiellen Versuch an einem Kunststoffmodell demonstriert. Das Modell besteht aus 8 Kunststoffwirbeln von 30 mm Kantenlänge, die durch dazwischengeklebte keilförmige Weichgummischeiben verbunden sind. Dadurch erhält das Modell eine gekrümmte Form. Der auf der konvexen Seite durch Ösen geführte und an den Enden verankerte Memory-Draht ist um 7% vorgereckt. Er wird in diesem Versuch der Einfachheit halber elektrisch aufgeheizt, verkürzt sich und richtet das Modell in eine gerade Form aus.

In diesem Zusammenhang werden auch ausführlich die Herstellung der Legierung, d. h. Erschmelzen und Umformen, die Eigenschaften, d. h. Spannungs-Dehnungs-Verhalten, Dehnungs-Temperatur-Verhalten und Umwandlungstemperaturen sowie mechanische Probleme beschrieben.

Die Skoliose ist eine Dreh-Seitverbiegung der Wirbelsäule, die auch mit den heute bekannten und angewandten Operationsverfahren nur sehr schwer zu korrigieren ist. Mit den meisten derzeit üblichen Operationsmethoden läßt sich die Seitverbiegung in erstaunlich gutem Maße korrigieren. Die Torsion

Sonderdruckanfragen an: Prof. Dr. F. Baumgart (Adresse siehe oben)

hingegen ist bisher noch nicht oder nur unbefriedigend zu beherrschen. Wird eine dorsale Spondylodese nach Harrington durchgeführt, so resultiert meist ein lordosierender Effekt, wogegen bei der ventralen Wirbelsäulenkorrektur nach Dwyer sich die Kyphose nicht oder nur schwer vermeiden läßt. Dieser kyphosierende Effekt ist im Dorso-Lumbalbereich, wo die Dwyer-Technik auch am erfolgreichsten ist, nur erwünscht. Besonders vorteilhaft ist diese Technik bei rigiden thorakolumbalen und lumbalen Wirbelsäulenverbiegungen Erwachsener sowie bei Lähmungsskoliosen. Sie bilden somit die besten Erfolgschancen für die Dwyersche Operationsmethode. Bei den Skoliosen und Lordosen, die durch Meningomyelozelen oder andere Fehlbildungen im Bereich der dorsalen, lumbalen Wirbelsäule bedingt sind, ist sie sogar die Methode der Wahl.

Um nun die aufwendige und ohnehin schon schwierige Operationsmethode zu vereinfachen, wurde von uns ein Verfahren zur Korrektur der Skoliose im Modell erprobt, das auf die Grundidee von Dwyer zurückgeht.

1. Operationstechnik im Experiment

Nach dem Ausräumen der Bandscheiben wird bei der Dwyerschen Operationsmethode ein Titaniumkabel durch Schraubenköpfe geführt, die in der Mitte ein Loch haben. Diese Schrauben wiederum sitzen in sogenannten Agraffen, die den Wirbelkörper wie eine Klammer fest umschließen. Diese Agraffen haben die Aufgabe, ein seitliches Abrutschen oder Ausbrechen der Schrauben während des Spannvorganges zu verhindern. Bei der Methode nach Dwyer wird das Titaniumkabel mit einer Spezialspannzange von Wirbelkörper zu Wirbelkörper verspannt und jeweils durch Zusammenquetschen des Schraubenkopfes blokkiert.

In unserem weiter unten ausführlich beschriebenen Modellversuch wurde das Titaniumkabel durch einen NiTi-Draht ersetzt, der lediglich an den Neutralwirbeln fixiert wurde. An den übrigen Wirbelkörpern wird der NiTi-Draht durch Ösen geführt, um ein Ausgleiten der Korrektur aus der gewünschten Richtung zu vermeiden. Die Korrekturwirkung wird durch Erwärmen des Drahtes erreicht und ist stufenlos steuerbar. Die genaue Versuchsbeschreibung des Modellversuches ist weiter unten angegeben.

Wir glauben, das Operationsverfahren nach Dwyer durch die Verwendung von NiTi-Drähten noch weiter vereinfachen und verbessern zu können.

Weiterhin wäre auch eine postoperative Nachkorrektur durchaus noch denkbar, da die NiTi-Drähte ja nicht in ihrer vollen Zugkapazität ausgeschöpft werden müssen. Es erscheint z. Z. nicht ausgeschlossen, das Metall z. B. induktiv soweit wieder aufzuheizen, daß sich eine gewisse Nachkorrektur evtl. auch noch post operationem womöglich unter Bildwandlerkontrolle durchführen ließe.

Neben schon anderen von uns beschriebenen Einsatzmöglichkeiten dieses neuen Implantat-Werkstoffes sehen wir in der Verwendung von NiTi-Drähten bei der Dwyerschen Operation eine erhebliche technische Verbesserung einer vielfach mit Erfolg erprobten Operationsmethode. Der Vorteil gegenüber der herkömmlichen Spanntechnik ist die stufenlose Spanntechnik des Drahtes, die eine schonende Korrektur der Wirbelsäule, auch in Etappen, ermöglicht.

2. Herstellung der NiTi-Legierung

Die Legierung NiTi kann grundsätzlich sowohl im Elektronenstrahlofen als auch in einem Vakuuminduktionsofen erschmolzen werden. Da beim Elektronenstrahlofen zu einer bestimmten Zeit immer nur ein geringer Anteil des zu erschmelzenden NiTi-Volumens flüssig ist, kann es vorkommen, daß beim ungleichmäßigen Abschmelzen des Ausgangsmaterials der Gußblock inhomogen wird. Die Inhomogenitäten des Gußblockes können auch durch mehrfaches Umschmelzen im Elektronenstrahlofen nicht beseitigt werden. Legierungsschwankungen von ± 1% zwischen Kopf und Fuß des Ingots waren bei den durchgeführten Versuchen keine Seltenheit.

Günstiger gestaltet sich die Erschmelzung des NiTi im Vakuuminduktionsofen. Probleme der Inhomogenität treten hier praktisch nicht auf, da die Schmelze während des Herstellungsprozesses stetig gut durchgemischt wird.

Nachdem der Gußblock erstarrt und abgekühlt ist, wird er gedrittelt. Das anschließende Warmwalzen selbst bereitet, solange man nicht zu weit von der stöchiometrischen Zusammensetzung entfernt ist, keine Schwierigkeiten. Die Blocksegmente werden in einem elektrischen Kammerofen auf 900°C erwärmt, wobei darauf zu achten ist, daß das Material gut durchgewärmt ist.

Nach jedem Walzstich ist es empfehlenswert, die Bramme im Ofen wieder aufzuwärmen. Gewalzt werden kann mit einem Walzgrad von $\varphi_g \approx 0{,}25$. Höhere Walzgrade können mit großer Wahrscheinlichkeit erreicht werden, wurden aber versuchsmäßig noch nicht erprobt.

Der dem Warmwalzen folgende Kaltwalzvorgang gestaltet sich etwas aufwendiger als der Warmwalzvorgang. Die warmgewalzte Platte kann in den ersten drei Stichen mit einem Umformgrad von $\varphi \approx 0{,}04$ gewalzt werden, wobei nach jedem Stich eine Zwischenglühung zu erfolgen hat. Bei dieser Zwischenglühung wird der in der Niedertemperaturphase vorliegende Werkstoff über seine A_s-Temperatur erwärmt, und die Umformung wird durch den einsetzenden Memory-Effekt weitgehend wieder rückgängig gemacht. Pro Walzzyklus (Kaltwalzen, Zwischenglühung, Abkühlung an Luft) wird dadurch nur ein sehr geringer Umformgrad erreicht. Danach kann der Umformgrad langsam gesteigert werden, ohne daß mit einem Versagen des Werkstoffes gerechnet werden muß.

Die Probleme der Drahtherstellung sind ähnlich wie beim Kaltwalzen. Die warmgewalzten, geschmiedeten oder strangepreßten Rundstäbe können zunächst nur mit einem sehr kleinen Ziehgrad gezogen werden. Hat der Draht bereits mehrere Züge hinter sich, kann der Ziehgrad gesteigert werden

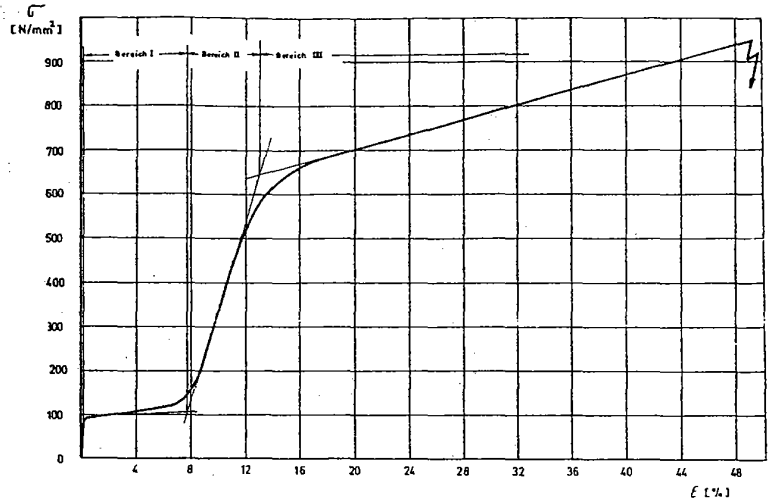

Abb. 1. Spannungs-Dehnungs-Diagramm eines bei 500°C geglühten NiTi-Drahtes bei Raumtemperatur

3. Eigenschaften der erschmolzenen NiTi-Legierung

Um Aussagen über die Eigenschaften der NiTi-Legierung machen zu können, wurden Drähte von 2 mm Ø aus dem Material bei verschiedenen Temperaturen geglüht und dann in der Zerreißmaschine bis zu vorgegebenen plastischen Dehnungen gereckt. Diese verformten Drähte wurden dann bis über die Umwandlungstemperatur erwärmt und die Umwandlungstemperaturen und die Rückdehnung gemessen.

3.1. Das Spannungs-Dehnungs-Diagramm

Abbildung 1 zeigt das typische Spannungs-Dehnungs-Diagramm der NiTi-Legierung. Klar erkennbar gliedert sich die Kurve in drei Bereiche. Vor dem ersten Bereich erfolgt ein linearer Anstieg der Spannung, der durch die elastische Dehnung der Probe hervorgerufen wird.

Die drei Bereiche lassen sich wie folgt deuten:

Bereich I. Sobald eine kritische Spannung überschritten wird, wird das in der Niedertemperaturphase vorliegende, martensitische Gefüge bei günstig orientierten Kristallen in „Verformungsmartensit" umgewandelt. Da für die Bildung des "Verformungsmartensits" nur eine geringe Energie erforderlich ist, wird die Spannung bei größeren Dehnungen nur geringfügig erhöht, so daß die Kurve hier einen sehr flachen Anstieg zeigt.

Bereich II. Die Bildung von „Verformungsmartensit", auf die im Bereich I der größere Anteil der Dehnung zurückzuführen war, ist jetzt weitgehend abgeschlossen. Durch die nun verstärkt einsetzenden Versetzungsbewegungen kommt es zu Versetzungsreaktionen, durch die die Gleitwege verkürzt und die Versetzungen aufgestaut werden. Mit größer werdender Dehnung nimmt die Versetzungsdichte stark zu, was eine erheblich größere Fließspannung als im Bereich I erfordert. Der Werkstoff verfestigt.

Bereich III. Sobald die Versetzungsdichte einen bestimmten Wert erreicht hat, können Schraubenversetzungen quergleiten. Dadurch werden die Versetzungen wieder frei beweglich, und die Kurve nimmt wieder einen flacheren Verlauf. Dieser Bereich wird auch als der „Bereich der dynamischen Erholung" bezeichnet.

3.2. Der Memory-Effekt

Erwärmt man einen plastisch verformten Draht, bis sich das in der Niedertemperaturphase vorhandene, martensitische Gefüge in ein austenitisches umgewandelt hat (Hochtemperaturphase), so nimmt er seine ursprüngliche Gestalt weitgehend wieder an. In Abbildung 2 ist die Abhängigkeit der Rückverformung von der Vorverformung und der Glühtemperatur aufgetragen. Bei den Proben handelt es sich um Drähte, die im letzten Stich um ca. 8% kaltverformt wurden. Aus Abbildung 2 ist ersichtlich, daß die Rückverformung mit steigender Glühtemperatur ansteigt. Bei einer Glühtemperatur von 500°C scheint die Rückverformung unabhängig von der danach erfahrenen plastischen Dehnung am größten zu sein. Das läßt sich dadurch erklären, daß bei dieser Temperatur bereits alle Eigenspannungen, die durch den Herstellungsprozeß in die Proben eingebracht wurden, weitgehend abgebaut sind. Bei niedrigen Glühtemperaturen (s. z. B. 200°C) dürfte das noch nicht der Fall sein, was zu

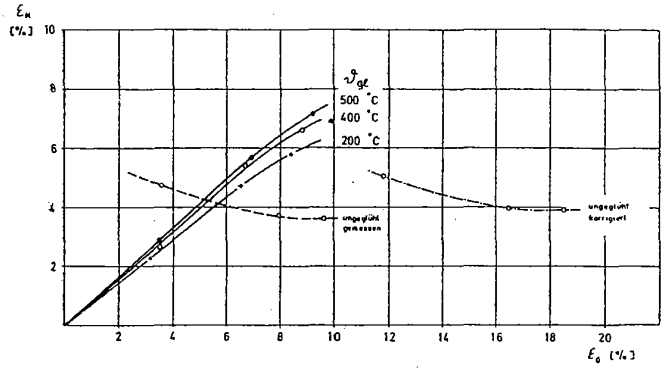

Abb. 2. Abhängigkeit der Rückverformung ε_M von der plastischen Vorverformung ε_0 bei verschiedenen Glühtemperaturen ϑ_{gl} für die Schmelze VIO 1. Die Kurve für den ungeglühten Draht ist unter Berücksichtigung der nach dem letzten Ziehvorgang eingeprägten Dehnung von 8% korrigiert worden

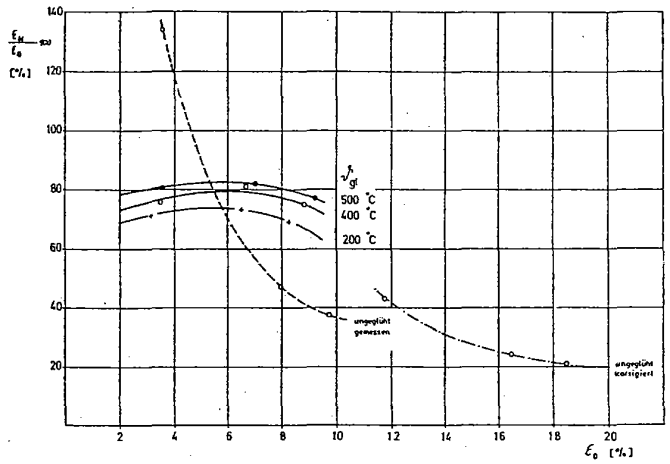

Abb. 3. Abhängigkeit der prozentualen Rückverformung $\varepsilon_M/\varepsilon_0$ von der plastischen Vorverformung ε_0 bei verschiedenen Glühtemperaturen für die Schmelze VIO 1. Korrektur der für die ungeglühte Probe gemessenen Werte entsprechend Abbildung 2

einer Behinderung der Rückdehnung führt. Trägt man die Rückdehnung in Prozent von der plastischen Vorverformung des Drahtes auf, so erhält man Abbildung 3. Wie aus diesem Diagramm ersichtlich, beträgt die Rückdehnung bis zu einer Vorverformung von ca. 7% etwa 80%. Werden 7% Vorverformung überschritten, verringert sich der Rückdehnungsanteil. Dieser Effekt ist zwanglos aus dem Spannungs-Dehnungs-Diagramm erklärbar. Bis etwa 7% plastischer Dehnung resultiert die Verformung zum überwiegenden Teil aus der Bildung von „Verformungsmartensit", der bei Überschreitung der Umwandlungstemperatur in eine austenitische Konfiguration übergeht. Bei größeren plastischen Verformungen erfolgt diese in zunehmendem Maße durch das Wandern von Stufenversetzungen. Der dadurch aufgebrachte Verformungsanteil ist irreversibel.

3.3. Die Umwandlungstemperatur

Nimmt man von einem plastisch verformten NiTi-Draht die Dilatometerkurve $\varepsilon = f(\vartheta)$ auf, so erhält man Abbildung 4. Aus diesem Diagramm können die Umwandlungstemperaturen wie folgt abgelesen werden:

$A_s \approx 45{,}5°C$, $A_f \approx 51°C$. Bei der in Abbildung 4 gezeigten Kurve handelt es sich um einen NiTi-Draht, der bei 400°C geglüht und um 6,68% plastisch gedehnt worden war.

Trägt man die mit Hilfe des Dilatometers bestimmten Umwandlungstemperaturen für verschiedene plastische Dehnungen in Abhängigkeit von der Glühtemperatur auf, so erhält man die in Abbildung 5 dargestellten Kurven. Ausgehend vom ungeglühten Zustand nimmt die Umwandlungstemperatur mit steigender Glühtemperatur rasch ab. Bei einer Glühtemperatur von 200 bis 300°C zeigen die Kurven ein schwaches Minimum, um dann mit höher werdender Glühtemperatur wieder leicht anzusteigen. Aus diesen Diagrammen kann abgeschätzt werden, innerhalb welcher Bereiche die Umwandlungstemperatur durch eine entsprechende Glühbehandlung variiert werden kann.

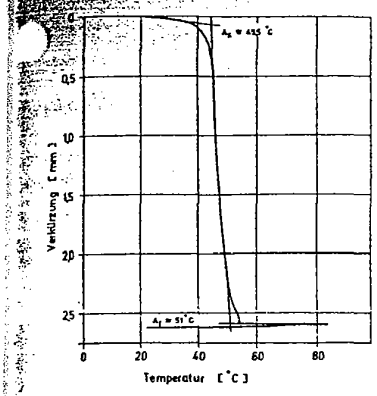

Abb. 4. Dilatometerkurve eines NiTi-Drahtes. $\varepsilon_0 = 6{,}68\%$, $\vartheta_{gl} = 400°C$

Abb. 6. Versuchsaufbau

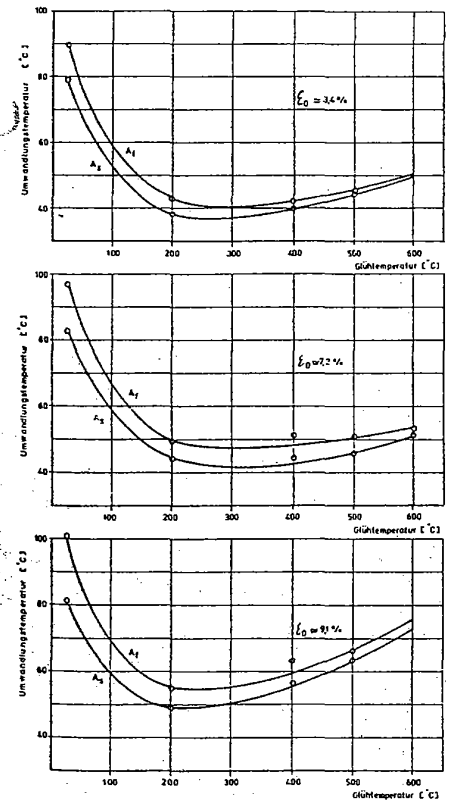

Abb. 5. Abhängigkeit der Umwandlungstemperaturen A_s und A_f von der Glühtemperatur für verschiedene plastische Dehnungen bei der Schmelze VIO 1

4. Modellversuch: Dwyer-Operation

Wie bereits unter Punkt 1 dargelegt, besteht die Möglichkeit, eine Wirbelsäulenkorrektur mittels eines Spanndrahtes vorzunehmen. Es erscheint nun sehr sinnvoll, bei dieser recht aufwendigen Operationstechnik den Spanndraht durch einen Memory-Draht zu ersetzen und dadurch die Operation wesentlich einfacher zu gestalten. In diesem Fall wird ein um ε_0 vorgereckter Memory-Draht im Bereich der Wirbelsäulenverkrümmung an den beiden äußeren Wirbeln befestigt. Durch die anschließende Erwärmung bis über die Umwandlungstemperatur nimmt der Draht seine ursprüngliche Gestalt näherungsweise wieder an und richtet dadurch die deformierte Wirbelsäule wieder gerade. Das Richten der Wirbelsäule kann dabei durch die Wahl einer geeigneten Aufheizgeschwindigkeit sehr schonend erfolgen.

Eine prinzipielle Demonstration dieser Möglichkeit wurde an einem einfachen Modell im Krupp-Forschungsinstitut in Essen durchgeführt. Abbildung 6 zeigt die Versuchsanordnung. Das Modell besteht aus kubischen Kunststoffelementen, die die Wirbel symbolisieren. Sie sind durch dazwischengeklebte Weichgummischeiben miteinander verbunden, die durch ihre Keilform die Verkrümmung des Wirbelsäulenmodells erzeugen. Der Memory-Draht von 2,8 mm Durchmesser ist um $\varepsilon_0 = 7\%$ bleibend vorgereckt, durch in den „Wirbeln" sitzende Ösen gezogen und an den Enden mit Schraubklemmen verankert. Dabei ist darauf zu achten, daß sich der Draht möglichst reibungsfrei durch die Ösen bewegen kann. Prinzipiell

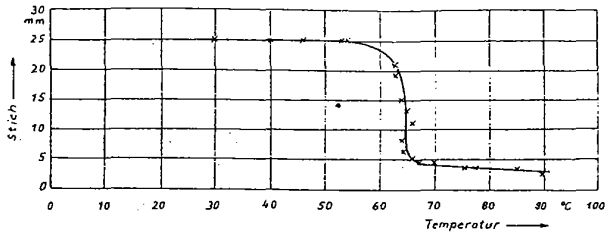

Abb. 7. Veränderung des Stichmaßes in Abhängigkeit von der Temperatur

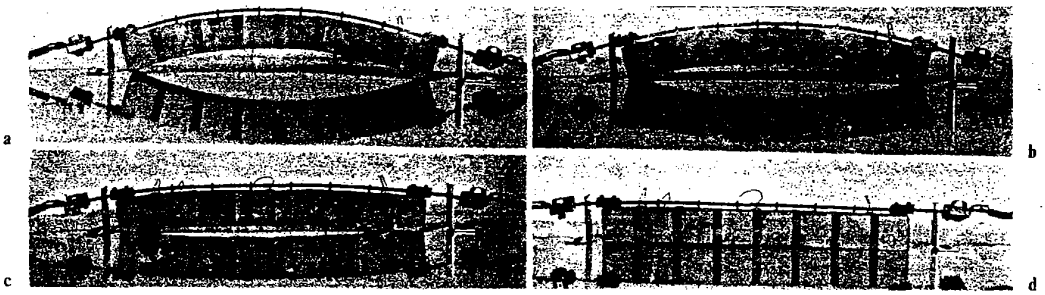

Abb. 8a–d. Versuchsablauf

besteht auch die Möglichkeit, den Draht an den in den Wirbeln befestigten Ösen festzulegen. Diese Methode bringt dann keinen Vorteil, wenn die Wirbelsäule zwischen den beiden äußeren Befestigungspunkten gleichmäßig gerichtet werden soll, d. h. wenn die verkrümmte Wirbelsäule Kreisbogenform aufweist.

Günstig wirkt sich die Festlegung des Memory-Drahtes an allen Wirbeln nur dann aus, wenn der Memory-Draht sich zwischen den einzelnen Fixpunkten um unterschiedliche Wege verkürzen soll, was bei einer vom Kreisbogen stark abweichenden Verkrümmung interessant sein könnte. In diesem Fall sind die einzelnen Drahtabschnitte zwischen den Befestigungspunkten getrennt zu beheizen und die Wärmezufuhr in dem Moment zu unterbrechen, in dem partiell die gewünschte Verkürzung eingetreten ist. Bei dem hier durchgeführten Modellversuch wird der Memory-Draht nur an den beiden äußeren Wirbeln befestigt.

Die Erwärmung des vorgereckten Drahtes erfolgt über eine stufenlos regelbare Widerstandsheizung. Zur Bestimmung der Temperatur wird eine Infrarot-Thermovisionskamera eingesetzt, die es gestattet, berührungslos die Temperatur innerhalb des Gesichtsfeldes zu bestimmen.

Hierzu wird die vom Objekt ausgehende Infrarotstrahlung punktförmig abgetastet, auf einen Detektor fokussiert und in ein elektrisches Signal umgewandelt. Dieses Signal wird auf einem Oszillografen dargestellt, wobei die Abstufung der Grautöne der Temperaturverteilung des Objektes entspricht. Diese Kamera wird übrigens auch in der Medizin eingesetzt, z. B. zur Krebsfrüherkennung. Für die kontinuierliche Registrierung der Temperatur sind am Draht zusätzlich 3 Thermoelemente angebracht, die an einen Punktdrucker angeschlossen sind.

Die ursprüngliche Verformung des Modells — gemessen als Stichmaß in der Mitte — betrug 25 mm. Bei ca. 60°C wurde die Umwandlungstemperatur erreicht, und der Memory-Effekt setzte ein. Diese Umwandlungstemperatur kann durch eine geringe Änderung der Legierungszusammensetzung sowohl nach oben als auch nach unten verschoben werden, vgl. Buehler, Wang. In Abbildung 7 ist die Veränderung des Stichmaßes in Abhängigkeit von der Temperatur aufgetragen. Die Gesamtverformung von 25 auf 4 mm Stichmaß wird bei einer mittleren Drahttemperatur von ca. 65°C erreicht.

Die Verformungsgeschwindigkeit kann über die Wärmeeinbringung in weiten Grenzen gesteuert werden. Im vorliegenden Fall beträgt die interessierende Zeit 15 min, sie kann im Bedarfsfall verlängert oder auch wesentlich verkürzt werden. Eine weitere Steigerung der Temperatur von 67°C auf 90°C erbringt dann keine Vergrößerung des Memory-Effektes mehr. Abbildung 8 zeigt das Modell in verschiedenen Versuchsphasen.

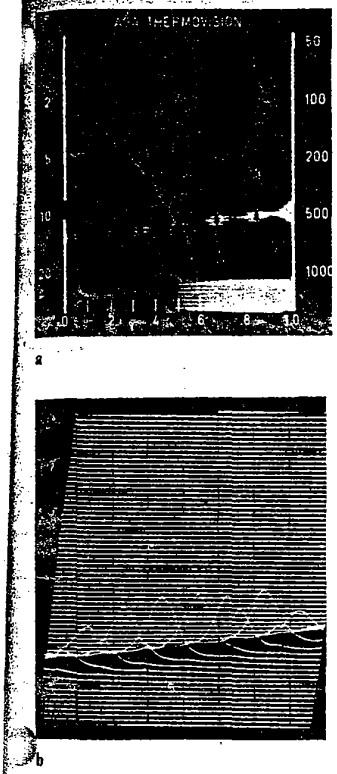

Abb. 9. Temperaturverteilung am Wirbelsäulenmodell. a Thermogramm in der Draufsicht, b Temperaturverteilung längs des Memory-Drahtes

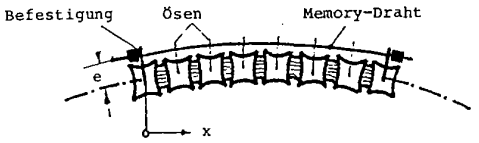

Abb. 10. System Wirbelsäule-Memory-Draht

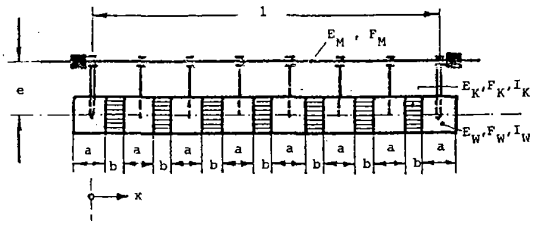

Abb. 11. Rechenmodell

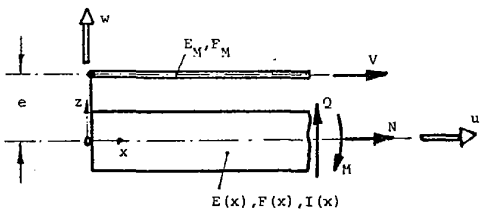

Abb. 12. Bezeichnungen

Durch den Einsatz mehrerer Memory-Drähte kann eine beliebig starke Wirbelsäulenverkrümmung korrigiert werden. Der Mechanismus ist dabei der gleiche wie bei dem hier beschriebenen Modellversuch.

Die mit der Infrarotkamera gemessene Temperaturverteilung ist in den folgenden Abbildungen 9a und b dargestellt. Im Thermogramm (Abb. 9a) ist in der Draufsicht der erwärmte Memory-Draht als helle Linie zu erkennen. Die Köpfe der Ösenschrauben zeichnen sich als einzelne dunkle (kältere) Punkte ab. Die Wärmeableitung in die Kunststoffwürfel ist gering. In der Umgebung der eingeschraubten Ösen ist zwar eine gewisse Temperaturerhöhung festzustellen, die jedoch auf einen recht engen Bereich beschränkt ist. In Abbildung 9b ist die Temperaturverteilung in Amplitudenform längs einzelner Bildzeilen wiedergegeben. Die Temperatur stellt sich über die gesamte Länge recht gleichmäßig ein, so daß davon auszugehen ist, daß der Memory-Effekt auf der gesamten Länge des Drahtes ausgenutzt wird.

5. Mechanische Probleme

5.1. Grundlagen, System und Belastungen

Die Grundlagen für die Berechnung von Memory-Bauteilen wurden von Baumgart, Bensmann und Hartwig ausführlich dargelegt. Hier geht es um die Berechnung eines Systems aus einem einachsig beanspruchten Memory-Draht und einem als elastisch angenommenen Balken (Wirbelsäule) mit veränderlichen Material- und Querschnittswerten (Abb. 10). Von funktionellen Belastungen soll bei dieser Untersuchung zunächst abgesehen werden. Der einzig wirkende Lastzustand ist der durch den Memory-Effekt hervorgerufene Vorspannzustand des Memory-Drahtes. Die Zusammenziehung des Memory-Drahtes bewirkt eine Krümmungsänderung und eine Kompression der Wirbelsäule.

Der Berechnung wird das idealisierte System gemäß Abbildung 11 zugrunde gelegt. Es stimmt mit dem im Experiment untersuchten System praktisch überein. Der Memory-Draht ist nur an den beiden Enden

fest mit dem Stab verbunden, dazwischen wird er in Ösen geführt. Für eine genauere Berechnung müßte die Veränderlichkeit der Querschnitte zusätzlich berücksichtigt werden.

5.2. *Berechnung*

Die Berechnung lehnt sich an die von Baumgart, Bensmann und Hartwig durchgeführte Untersuchung eines Stabsystems aus einem Memory-Stab und einem elastischen Stab an.

Für die Überlegungen wurden die in Abbildung 12 eingetragenen Bezeichnungen benutzt. Es wird davon ausgegangen, daß das System als schwach gekrümmter Balken betrachtet werden kann.

Das Biegemoment M als Funktion der Koordinate x ist beim Wirken der Vorspannkraft V im Memory-Draht bei einer konstanten Exzentrizität e des Drahtes gegenüber der Schwerachse des Stabes: $M = -V \cdot e = \text{const.}$

Die Längskraft N ist

$N = -V = \text{const.}$

während keine Querkraft Q vorhanden ist:

$Q = 0$

Dabei ist angenommen, daß die Stützung des Memory-Drahtes nicht in äquidistanten (reibungsfreien) Ösen, sondern kontinuierlich erfolgt.

Legt man die Querschnittswerte und die Kombination von 8 Kunststoff„wirbeln" mit 7 Gummi„knorpel"-Scheiben gemäß Abbildung 11 zugrunde, dann ergibt sich die für die Erzeugung der Vorspannkräfte V erforderliche einzuprägende Relativverkürzung Δu im Memory-Draht zu

$$\Delta u = \int_0^l \frac{V\,dx}{E_M F_M} + \int_0^l \frac{V\,dx}{E(x)F(x)} + \int_0^l \frac{Ve^2\,dx}{E(x)J(x)}$$

$$\Delta u = V\left[\frac{l}{e_M F_M} + \frac{7a}{E_w}\left(\frac{1}{F_w} + \frac{e^2}{J_w}\right) + \frac{7b}{E_K}\left(\frac{1}{F_K} + \frac{e^2}{J_K}\right)\right]$$

Für die Verschiebung Δw in der Mitte des Balkens gegenüber der Anfangsauslenkung relativ zur Sehne hat man in gleicher Weise bei Annahme eines zur Stelle $x = l/2$ symmetrischen Systems

$$\Delta w = -Ve\int_0^{l/2} \frac{x\,dx}{E(x)J(x)}$$

$$\Delta w = -\frac{Ve}{8}\left[\frac{a(49a+48b)}{E_w J_w} + \frac{b(50a+49b)}{E_K J_K}\right]$$

Für einen zahlenmäßigen Überschlag wurden die folgenden Werte eingesetzt:

$E_w = 1.000.000\ \text{N/cm}^2 = 10.000\ \text{N/mm}^2$ (Kunststoff, Holz)
$F_w = 30 \cdot 30 = 900\ \text{mm}^2$
$J_w = \frac{1}{12} 30^4 = 67.500\ \text{mm}^4$
$E_K = 0{,}43\ \text{N/mm}^2$ (in einem Druckversuch gemessener Materialwert)
$F_K = 900\ \text{mm}^2$
$J_K = 67.500\ \text{mm}^4$
$a = 30\ \text{mm}$
$b = 8\ \text{mm}$
$e = 19{,}5\ \text{mm}$
$E_M = E_l = 35.000\ \text{N/mm}^2$
$F_M = \frac{\pi}{4} \cdot 2{,}8^2 = 6{,}16\ \text{mm}^2$

Man sieht leicht, daß die Anteile aus den „Wirbeln" gegenüber denen aus dem „Knorpel" wegen des erheblichen Unterschiedes der Elastizitätsmoduli in diesem Falle zu vernachlässigen sind.

Man erhält:

$$\Delta u = V\left[\frac{7 \cdot 38}{35000 \cdot 6{,}16} + \frac{7 \cdot 30}{10000}\left(\frac{1}{900} + \frac{19{,}5^2}{67500}\right) + \frac{7 \cdot 8}{0{,}43}\left(\frac{1}{900} + \frac{19{,}5^2}{67500}\right)\right]$$

$$\Delta u = V\left[0{,}0012 + 0{,}0001 + 0{,}8783\right]\frac{\text{mm}}{\text{N}} = V \cdot 0{,}8796\,\frac{\text{mm}}{\text{N}}$$

und

$$\frac{\Delta u}{l} = \frac{V}{F_M} \cdot 204 \cdot 10^{-4}\,\frac{\text{mm}^2}{\text{N}}$$

$$\Delta w = -V \cdot \frac{19{,}5}{8}\left[\frac{30(49 \cdot 30 + 48 \cdot 8)}{10000 \cdot 67500} + \frac{8(50 \cdot 30 + 49 \cdot 8)}{0{,}43 \cdot 67500}\right]$$

$$\Delta w = -V \cdot (0{,}0002 + 1{,}2711) = -V\ 1{,}2713\,\frac{\text{mm}}{\text{N}}$$

Der Draht ist um 7% bleibend vorgereckt. Man hat also eine Anfangsdehnung von $\varepsilon_0 = 0{,}07$.

Man kann sich leicht überlegen, daß

$$\frac{\Delta u}{l} = \varepsilon_M(\sigma, \varepsilon_0) = \frac{V}{F_M} \cdot 204 \cdot 10^{-4}\,\frac{\text{mm}^2}{\text{N}} = \sigma \cdot 204 \cdot 10^{-4}\,\frac{\text{mm}^2}{\text{N}}$$

sein muß. Dabei ist $\varepsilon_M(\sigma, \varepsilon_0)$ eine für eine bestimmte Legierung aus Versuchen ermittelbare Kurvenschar für die Memoryrückdehnung als Funktion der Lastspannung σ und der Anfangsdehnung ε_0. Wir nehmen für diesen Fall an, daß die Spannung σ sehr klein ist, so daß keine Behinderung des Memory-Effektes erfolgt und daß bei dieser Legierung bei Lastfreiheit ($\sigma = 0$) eine 80%ige Rückverformung erfolgt, d. h.

$\varepsilon_M(\sigma, \varepsilon_0) \approx 0{,}8\ \varepsilon_0 = 0{,}056$

Damit läßt sich leicht errechnen

$$\sigma = \frac{0.056}{204 \cdot 10^{-4}}\ \frac{\text{N}}{\text{mm}^2} = 2{,}75\ \frac{\text{N}}{\text{mm}^2}$$

und eine Vorspannkraft von

$V = \sigma\ F_M = 2{,}75 \cdot 6{,}16 = 16{,}9\ \text{N}$

Damit ergibt sich eine Stichänderung von

$\Delta w = -16{,}9\ \ 1{,}2713 = -21{,}5\ \text{mm}$

Dies stimmt recht gut mit den gemessenen Werten überein.

Der nach Abschluß der Erwärmung verbleibende Spannungszustand sieht also im Versuchsmodell größenordnungsmäßig so aus:

im Memory-Draht

$\sigma = 2{,}75\,\frac{\text{N}}{\text{mm}^2}$ Zugspannung

in der „Wirbelsäule"

$$\sigma = \frac{V}{F} \pm \frac{Ve}{W} = -V \cdot \left(\frac{1}{a^2} \pm \frac{6e}{a^2}\right) = -\frac{V}{a^2}\left(1 \pm 6\frac{e}{a}\right)$$

$$= -\frac{16{,}9}{900}\left(1 \pm 6 \cdot \frac{19{,}5}{30}\right) = \begin{cases} -0{,}0920\ \text{N/mm}^2, \text{ Druck,} \\ +0{,}0545\ \text{N/mm}^2, \text{ Zug.} \end{cases}$$

Man sieht, daß die Beanspruchungen sehr gering sind, was auf die große Nachgiebigkeit der Gummischeiben zurückzuführen ist. Auf der ursprünglich

konkaven Seite treten Zugspannungen auf, während e dem Memory-Draht zugewandte Seite Druckspannungen aufweist.

6. Abschließende Bemerkungen

Der beschriebene Versuch zeigt, daß es möglich ist, Krümmungsänderungen an der Wirbelsäule durch Memory-Spanndrähte vorzunehmen. Die Vorteile bei dieser neuartigen Technik sind das Entfallen jeglicher Spannvorrichtung und die schonende Auslösung durch Erwärmen des Drahtes. Der Draht braucht nur an den beiden Enden der Spannstrecke hinreichend verankert zu werden, an den Zwischenwirbeln genügen u. U. leichte Führungsösen, so daß der Umfang des Eingriffs reduziert wird. Die bei dieser Maßnahme auftretenden Spannungen in der Wirbelsäule sind relativ gering.

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苦労しました！　ゴム金属

——超弾性 Ni-Ti 合金をメガネフレーム用ワイヤへ応用開発——

古河電気工業　中央研究所　鈴木　雄一

メガネのフレームは構造的にいくつかのタイプに分けられるが，これらの内で，レンズに溝（グルーブ）を切ってワイヤをかけ，レンズを吊って固定するタイプのものは，軽くて，視野が広いなど，機能的にきわめてすぐれたフレームである．デザイン的な面からも，レンズ下部のリムがほとんど見えないため，いわゆるリムレスフレームと同じ外観を有し，誰にもフィットしやすいファッション性の高いフレームであるといわれている．特に，プラスチックレンズと組み合わせると，軽量という利点が生かされ，より効果的である．プラスチックレンズで高いシェアをもつ，㈱諏訪精工舎が新しいメガネフレームの開発に当って，このタイプのフレームに着目したのは主にこのような理由からであった．

ところが，ワイヤで吊るタイプのフレームはワイヤの材質に問題があった．従来，このタイプのフレームには，通常の金属製のワイヤ（たとえば，ニッケルクロム合金）や，合成樹脂のワイヤなどが用いられていたが，いずれも，レンズを拭く時や，冬場レンズが縮んだ時に外れやすいとか，長期間使用するとのびてしまうとか，いろいろと問題があり，その機能上の利点を生かせないのが実状であった．レンズを吊るワイヤはレンズの収縮やフレームの変形に追従する弾力と，長時間の使用に対してもクリープなどでゆるまない耐久性を備えていなければならない．通常の金属バネ材では前者の，合成樹脂では後者の点で十分でなかった．ワイヤは，さらに，キズがつきにくく，耐食性にすぐれ，外観的にも美しい，といったメガネフレーム材としての一般的な要件も満足しなくてはならない．これらの多くの条件を満たすワイヤ材を選択することは困難な課題であった．

㈱諏訪精工舎では，新しいフレームを開発するに際して，まず，このワイヤ材の選定に力を注ぎ，いくつかの材質については実際に試作をするなど，積極的な調査検討を行なった．経過の詳細は割愛するが，結局，超弾性 Ni-Ti 合金のワイヤがあらゆる面から最適であるという結論にいたった．

1.　ゴムのように元にもどる超弾性合金

超弾性とは，弾性限界をはるかにこえ，降伏領域におよぶ変形が，変形応力を除くと変形前のひずみゼロの状態にもどってしまう現象である（図1）．通常の金属材料では弾性限以下のひずみは除荷時に完全に元にもどるが，ひずみが弾性限をこえると応力を除いてもひずみは完全に消失せず永久変形が残る．したがって，たかだか

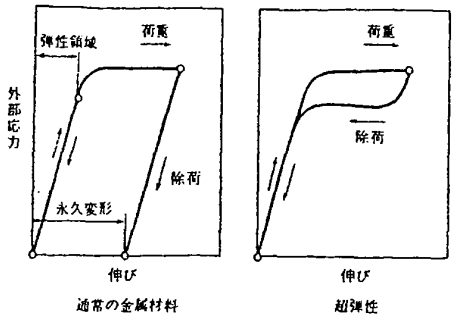

図1　超弾性材と通常の金属材料の比較

0.5%程度のひずみしか元にもどらない．超弾性合金では降伏点をこえ，降伏領域の終点近くまで変形しても，たとえば Cu-Al-Ni 合金の単結晶では実に 10 %をこえる変形ひずみが除荷時に完全に元にもどってしまう．超弾性といわれる所以である．超弾性はこのような変形挙動から，擬弾性，ゴム弾性ともよばれる．

超弾性を示す合金は，現在，Au-Cd, Cu-Al-Ni, Ni-Ti 合金など十数種類が知られているが，それらの合金の多くは単結晶でないと超弾性を示さない．工業上，実用的な多結晶材では変形ひずみが超弾性ひずみにいたる前に，つまり，降伏点をこえる前に粒界で破断してしまう．多結晶ですぐれた超弾性特性を示すのは，今のところ，Ni-Ti 合金のみである．また，この合金はチタン並みのきわめて良好な耐食性をもち，応力腐食割れの心配もないこともあって，超弾性材料として最も有望視されている．メガネフレーム材としては，さらに，軽量で，金属光沢面の美観にすぐれているなどの利点があげられる．

ところが，開発を始めた当時，Ni-Ti 合金の超弾性に関する研究報告は，同じ合金の形状記憶効果にくらべて極端に少なく，わずかに，本間[1] と Wasilewski[2] が独立に発表した2件の報告があるだけであった．この2つの報告は簡単なもので，データも少なかったため，超弾性 Ni-Ti 合金の開発は，まず合金組成を見つけることから始めなければならなかった．

一方，超弾性現象については，Au-Cd, Cu-Al-Ni 合金などで1950年代から多くの研究が行なわれてきており，1970年代のはじめにはこの現象が形状記憶効果と同じく熱弾性型マルテンサイト変態によっておこること，マルテンサイト変態温度と密接な関係があることなどが判明していた．これらの理論によれば，Ni-Ti 合金もマルテンサイト逆変態温度 (A_f 点) を使用温度よりやや低い温度に設定してやれば超弾性特性を示すことが予想された．しかし，Ni-Ti 合金のマルテンサイト変態温度は組成 (Ni wt%) が0.1%ずれただけで，約10℃も変化するため，変態温度の制御が非常にむずかしいことが知られており，所定の変態温度をもつ合金の調製が実用化への第1の関門であった．

2.　超弾性 Ni-Ti 合金の細線を作る

当社では以前から，超弾性や形状記憶効果とはまったく別に，Ni-Ti 合金の高温相 (母相) の特徴であるすぐれた耐食性と耐摩耗性に着目し，すでに昭和45年にこれを改良した摺動部材用合金 (FAEDIC-NT®) の商品化に成功していた．FAEDIC-NT は主に化学プラント機器の部品として製造販売を続けているが，最近では，原子力発電所の炉水浄化系ポンプ部品として採用され，高い評価を受けている．これら FAEDIC-NT の製造技術特に溶解鋳造技術はほとんど超弾性材に応用できたので，均質で健全な合金鋳塊を作ることは比較的容易であった．マルテンサイト変態温度の制御，つまり合金組成制御はかなり難航したが，示差走査熱量計 (DSC) による測定精度の向上，溶解法の改良などにより，±5℃以内にコントロールできるまでになった．

超弾性合金線製造の第2の関門は伸線加工であった．Ni-Ti 合金は金属間化合物でありながら冷間で塑性加工ができるまれな材料であるといわれているが，実際にこれを加工してみると，加工硬化が非常に大きくなかなか加工がむずかしい材料であることがわかる．形状記憶効果を示す組成範囲の Ni-Ti 合金もかなり伸線加工がむずかしいが，超弾性材は Ni 量がわずかに多いだけなのにこれより大幅に加工が困難である．このような材料を，焼付，ビビリ，断線などなしに能率的に伸線するためには，ダイス形状，潤滑，熱処理(中間焼なまし)，整直など多くの点に高度な技術が必要であった．

これらの技術のベースになったのは，当社で主にエレクトロニクス関係向けに製造販売しているチタン細線の製造技術および設備であった．フレーム用ワイヤの場合，超弾性特性だけでなく，通常より高い線径精度と真直度が要求されていたが，数次の設備および加工条件の改良により，図2のような特性の Ni-Ti 細線を作ることができた．現在では，線径が0.1 mm までの超弾性 Ni-Ti 線を精度よく製造することができる．これらの Ni-Ti 線は熱処理のやり方によって図3のようなややなだらかな超弾性特性をもたせることができる．

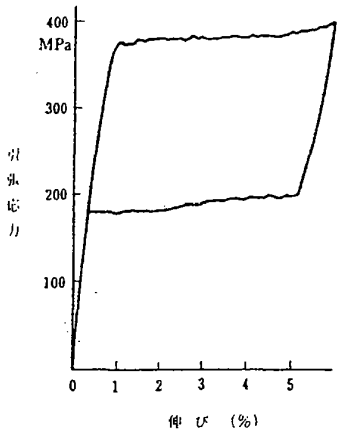

図2 Ni-Ti 合金線の超弾性特性①

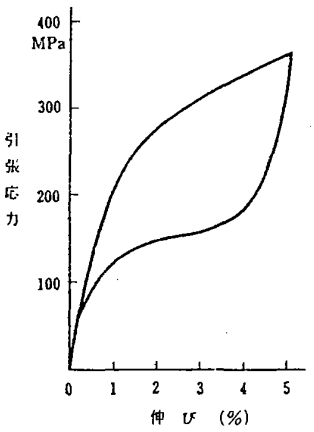

図3 Ni-Ti 合金線の超弾性特性②

使用にもゆるまないなど，このタイプのフレームのこれまでの欠点をすべて解決したといってよいであろう．デザインは写真に示すとおりで非常に好評である．

4. バネ材として広い応用分野

超弾性 Ni-Ti 合金は通常の金属材料と比較すると桁違いに大きな復元能力をもつので，メガネフレームばかりでなく，バネ材として大きな期待がもたれている．最近は線材以外に板材，条材に対する要求がふえており，これらの内ではマイクロモーター，コンピューター周辺機器などの小型精密機器関係が有望である．超弾性バネは本質的に非線形バネであるため，当然この非線形性を生かした使い方が考えられるが，通常のバネと同じ設計法が適用できないので，現在は，バネ加工，熱処理法などとともに超弾性バネ素子（コイルバネ，ヘリカルバネなど）の設計法が検討されている．

超弾性 Ni-Ti 合金の特殊な用途として医療機器への応用がある．Ni-Ti 合金は耐食性が良いうえに，生体に対する適合性（バイオコンパティビリティー）が非常に良く，生体に埋め込んで使用できるので，インプラント材としての応用が考えられている．形状記憶効果 Ni-Ti 合金の医療への応用研究は割合と進んでいるが，超弾性については研究が始められたばかりである．現在，骨

3. ビスタ「リムライトフレーム」

超弾性 Ni-Ti 線材の開発と併行して，㈱諏訪精工舎ではこれを使用したフレームの開発が進められた．超弾性線をフレーム用ワイヤとして実用するためには，たとえば，好ましい光沢を与える磨き方，弾力を適正に整える熱処理法など多くの問題を解決しなければならなかったが，特に苦労したのは，ワイヤ端部をフレーム上部に固定する方法であった．ワイヤと他の部品が溶接できれば問題はないのであるが，これは Ni-Ti 合金の性質から不可能であった．ろう付は可能ではあるが，繰り返し変形に弱くなり良い結果は得られなかった．このため時計製造で培った精密加工技術を応用して機械的な固定法をいろいろと改良した結果，カシメとネジ止めを併用する方式で解決することができた（図4）．また，レンズに溝（グルーブ）を切る新しい装置もあわせて開発された．

このようにしてできあがったフレーム（ビスタ「リムライトフレーム」[10]）は，レンズが伸び縮みしたり，強い力がかかっても，超弾性ワイヤがレンズをしっかり保持し，また，長期間の

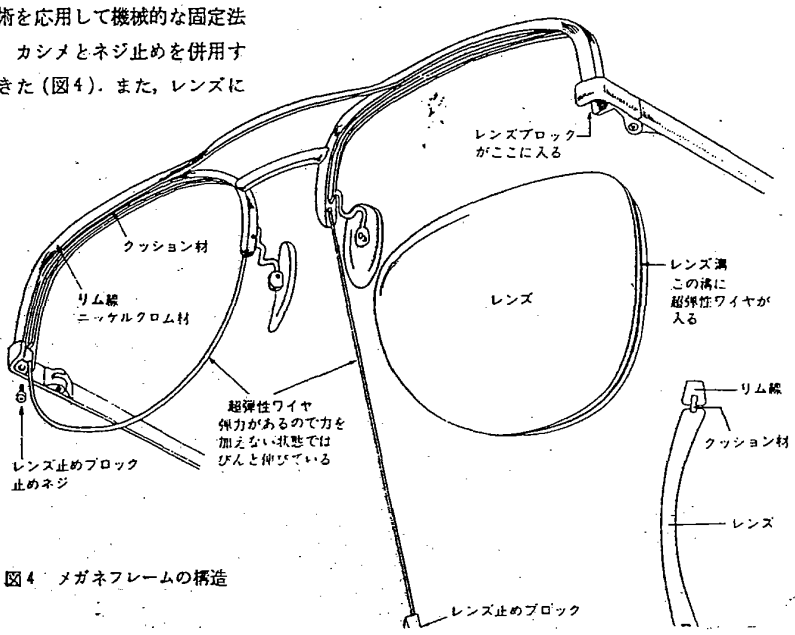

図4 メガネフレームの構造

の固定，結束などの整形外科関係の研究が，形状記憶効果の応用と併行して国立大阪南病院と大阪府立工業技術研究所で，歯列矯正をはじめとする歯科関係の研究が東京医科歯科大学で進められており，その成果の一部はすでに学会で発表されている．

一方，大学の金属系研究室を中心に，Ni-Ti 合金の超弾性に関する基礎的な研究が行なわれており，最近の宮崎ら[3]の報告に見られるように，その変形挙動，温度依存性などが次第に解明されつつある．

超弾性 Ni-Ti 合金は，小規模な製造が始められたばかりで，まだ実用化の例も少ないが，5％をこえるひずみがゴムのように完全に元にもどるという性質は，金属バネ材として画期的なものであり，今後の広範な応用が期待される．

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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

		DOCKET NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
DSK	AL	0 7 3 3 0 8	9-3-83	EPO				X
	AM	0 7 9 4 8 6	10-22-82	EPO				X
	AN	0 1 0 2 6 8 5	5-27-83	EPO				
	AO	1 5 9 9 5 6 4	8-21-70	FRANCE				X
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論　文

歯科理工学雑誌 Vol. 23 No. 61 (1982)

新しい超弾性 NiTi 矯正用ワイヤーの研究

(第 1 報) 引張および曲げ試験*

渡　辺　勝　久**

Studies on New Superelastic NiTi Orthodontic Wire

(Part 1) Tensile and Bend Test

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NiTi alloy has attracted the most public interest in recent years. This alloy has two unique properties, one is "shape memory effect" and the other is "outstanding elasticity". NiTi wire with the property of outstanding elasticity suggested it could be useful in orthodontics.

Recently new NiTi alloy which had other characteristics of "superelasticity" was developed. In this study, new superelastic NiTi wire was examined to evaluate for use in orthodontics, in tensile and bend tests, compared with stainless steel, Co-Cr alloy and work hardened NiTi wire.

The results obtained are as follows;

(1) New superelastic NiTi wire showed unique stress-strain curve with a plateau from the strain of 2% to 5%, the unique deformation behavior was caused by stress induced transformation, and returned to almost zero strain as stress was reduced.

(2) New superelastic NiTi wire showed an elongation of about 11%. In the cyclic tensile tests to the strain of 8%, new superelastic NiTi wire showed little permanent deformation of 0.5% after 10 cycles.

(3) In bend tests, new superelastic NiTi wire showed lower than half load compared with stainless steel and Co-Cr alloy wires. Its permanent deformation was very little after 2 mm deflection.

(4) The load-deflection curve of new superelastic NiTi wire showed almost constant load in the wide range of deflection.

The results of this study indicate that new superelastic NiTi wire must be considered as a promising candidate for orthodontic arch wire.

I. 緒　　言

歯科矯正臨床において，不正咬合を積極的に矯正治療する方法として，フルバンドシステムが一般的に使用されている．しかし，従来のフルバンドシステムに使用するアーチワイヤーは，ステンレススチールや Co-Cr 基合金のものが主に用いられてきたが，これらは弾性率が高く，少量の変形で永久ひずみが生じるという欠点がある．このため，口腔内への装着に際しては，ワイヤーを歯列に適合させて屈曲する必要があり，適切な矯正力を得るためには，アーチワイヤーの屈曲とデザインに熟練

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と工夫を必要としている[1~3].

最近，NiTi ワイヤーが注目をあつめている．米国では非常に弾力性のある NiTi ワイヤーが市販され，これに関する矯正学的また理工学的研究が G. F. Andreasen らにより報告されている[4~6].

NiTi 合金は普通の合金とは異なり，Ni と Ti が原子比で 1：1 の割合で結びついた金属間化合物であるが，特異な性質を持っており，加工が可能で，しかも形状記憶効果という特殊な現象を示す[7,8]．これは一定の温度以下の温度で変形した後，これを逆変態温度以上に加熱すると変形前の元の形状に戻る現象である．逆変態点以上の高温相は CsCl 型体心立方構造になっており，機械的性質および耐食性に優れている．そこで逆変態温度を室温以下に抑えさらに加工を加えることによって弾性を増すことができる．現在市販されている NiTi 合金ワイヤーはこの加工硬化型のワイヤーであると考えられる[9]．また，この NiTi 合金は組成や加工および熱処理により大きく性質が変化するという特徴があり，適当な条件の下では，超弾性という特殊な性質を示すことが判ってきた[10].

本研究は，新しく開発された超弾性という特殊な性質を示す NiTi ワイヤーについて，引張および歯列を模した 3 点曲げ試験を行い，理工学的見地から矯正用ワイヤーとしての考察を試みた．なお従来から用いられているステンレススチール，Co-Cr 基合金および加工硬化 NiTi ワイヤーについても同様に実験を行ない比較検討した．

II. 実験材料および実験方法

実験材料は φ0.4 mm (0.016″) の超弾性型 NiTi ワイヤー，加工硬化型 NiTi ワイヤー，2 種類の市販ステンレススチールワイヤー，3 種類の市販 Co-Cr 基合金ワイヤーを使用した．なお Co-Cr 基合金については，メーカーの指示に熱処理を施すことが記されているため，ここでは 500℃の電気炉内で 1 分間の熱処理を行った．

1. a 引張試験

本研究では φ 0.4 mm の細いワイヤーの引張試験を行うために，図 1 のように 20×80 mm の鉄板の間にエポキシ樹脂接着剤 (Araldite Standard, Ciba-Geigy) によりワイヤーを接着した．鉄板には φ 8 mm の穴をあけ，特別に作製した専用チャックにより試験機に装着をして試験した．

試験機は万能試験機 Instron Model 1102 を使用し，クロスヘッドスピード 1 mm/min にて行った．同時に正確な応力-ひずみ曲線を求めるために，精密伸び計 (Instron Strain Gage Extensometer G 51-17 MA ゲージ長 10 mm) を図 1 に示すように試験片部に取付け，引張荷重に対応する伸びを測定し，レコーダーで自動記録した．以上の方法および測定によって応力-ひずみ曲線を求めた．

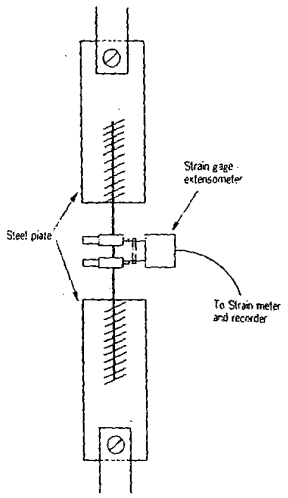

図 1 引張試験模式図

1. b 引張繰返し試験

上記の引張試験と同様な方法により NiTi ワイヤーを一定量引張った後に，除荷を行い応力が 0 となるまで戻すという操作を繰返して試験した．前記の引張試験の結果から判断して，超弾性型 NiTi については伸び 8% まで，加工硬化型 NiTi では伸び 4.8% までの試験を 10 回繰返した．

2. 曲げ試験

矯正用ワイヤーの曲げに対する変形量と荷重の関係を調べて比較を行うために，新しくワイヤー曲げ試験機を作製して試験を行った．この曲げ試験機は犬歯から小臼歯部分の歯列矯正を想定して，図 2 に示すように，直径

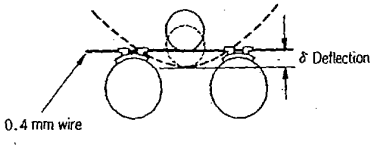

図 2 曲げ試験模式図

7 mm の金属製丸棒を，中心間距離 14 mm で植立固定し，支点間に渡したワイヤーの中央を直径 5 mm の丸棒で変位させ荷重を測定できるように設計を行った．支点

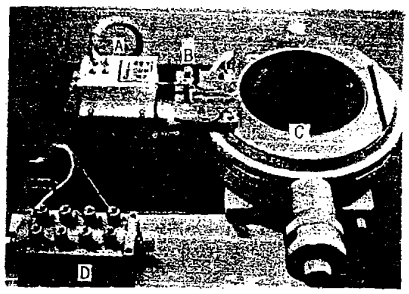

図 3　矯正ワイヤー用に試作した微小3点曲げ試験機
A：ロードセル
B：3点曲げ試験部
C：移動ステージ
D：ゲージボックス

の丸棒には，ダイレクトボンディング用金属ブラケット (0.018″×0.025″ slot) を瞬間接着材により接着固定して，ワイヤーの支持点とした．なお曲げ試験機は図3のように万能投影機のステージ (Nikon 社製) に支点部分を固定し，ステージを移動させることにより変位を与えることができるようにした．ステージの移動はマイクロメーターにより 1/1 000 mm まで読取ることが可能で，変位は 50 μ/30 sec で行った．荷重はロードセル (東洋ボールドウィン社，容量 1 000 gf) によりレコーダーで自動記録した (図 3)．試験は一定の変位量に達するまでワイヤーに変位を加えて行き，引続いて変位を減少させ荷重が0となるまでの一連のサイクルを測定した．

試験の条件は，表1に示した通りである．ワイヤーの

表 I　3点曲げ試験条件

試験条件	Bracket 種類	Bracketでの固定	変位量
(a)	Single	無	2 mm
(b)	Single	有	2 mm
(c)	Siamese	無	2 mm
(d)	Siamese	有	2.7～3 mm

支持点として，Single type と Siamese type の2種類のダイレクトボンディング用金属ブラケット (小臼歯用) を使用し，ブラケットの固定には歯科矯正用リングレットを用いた．

III. 実験結果

1.a　引張試験

引張試験での応力-ひずみ曲線は，図4に示した．ステンレススチールは弾性率が 17～20×10³ kg/mm² と高く，伸びは 1.2～1.6%，引張強さはステンレススチールAが 233.3 kg/mm²，ステンレススチールBが 182 kg/mm² であった．次に Co-Cr 基合金は弾性率 20～23×10³ kg/mm²，熱処理を行わないものは引張強さ 150～185 kg/mm²，伸びは 2.4～3% であったが，熱処理を行うと引張強さ 160～200 kg/mm² と上昇をし，反対に伸びは 1.8～2% 程度と減少した．

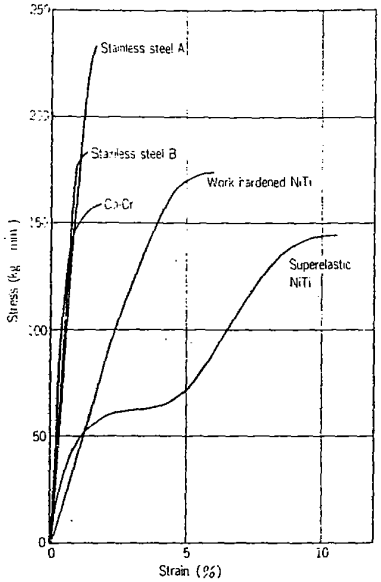

図 4　各種ワイヤーの応力-ひずみ曲線

以上のワイヤーに比べ NiTi ワイヤーは明らかに低い弾性率と大きな伸びを示した．加工硬化型 NiTi は弾性率 5～6×10³ kg/mm² とフレキシブルで，ほぼ直線的な挙動を示し約 6% まで伸びた．一方超弾性型 NiTi は他種のワイヤーとは異なり，中央に平坦な部分をもつ応力-ひずみ曲線を示した．すなわち伸び 2% までは弾性率 8×10³ kg/mm² を示すが，2% を過ぎると 5% あたりまで応力は増加せず，ほぼ一定の値となった．伸び 5% を過ぎてから再び応力が増加しはじめ右上がりの曲線を示し，伸び 11% で破断した．

1.b　繰返し引張試験

NiTi ワイヤーに対して行った繰返し引張試験の結果はそれぞれ，図5と図6に示した．超弾性型 NiTi は図5のように，引張試験において観察された曲線途中の平坦部が，荷重を減少していく際にも現れた．1回目の永久変形は 0.3% であり，10 回繰返した後の永久変形は 0.5% と，ほとんど変らなかった．加工硬化型 NiTi は 10 回繰返した後は永久変形 0.75% であった．

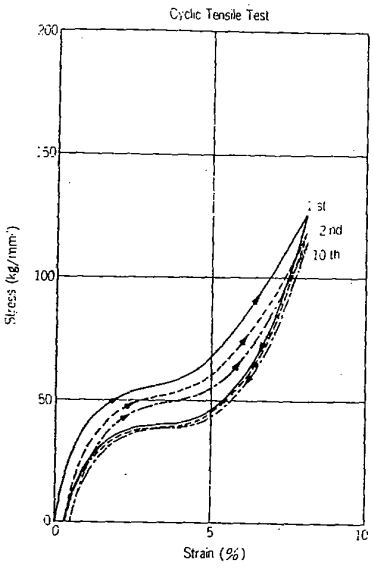

図 5　超弾性 NiTi ワイヤーのひずみ 8% まで繰返し引張試験したときの応力-ひずみ曲線

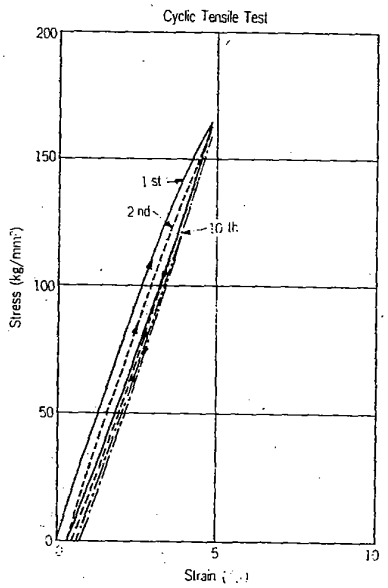

図 6　加工硬化 NiTi ワイヤーのひずみ 4.8% まで繰返し引張試験したときの応力-ひずみ曲線

2. 曲げ試験

条件 (a)（single bracket 使用，bracket でのワイヤーの固定をしない.）

この条件での実験結果は図 7～図 13 に変位量と荷重で示した．超弾性型 NiTi は変位量が 1 mm を超えると，荷重の増加率が低下し，曲線は次第に平坦となった．変位 2 mm での荷重は 200 g であった．変位量を 2 mm から漸次減少させた時にも，変位量 2 mm から 1 mm までは荷重の変化が少なく，永久変形は 0.01 mm 以下であった．

加工硬化型 NiTi は変位に対する荷重の増加がほぼ直

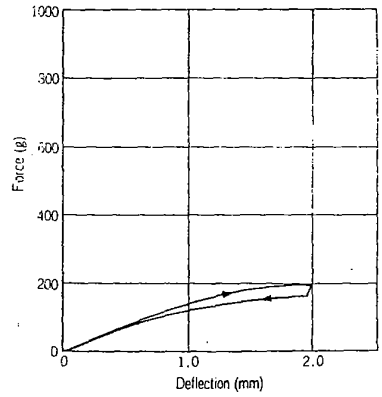

図 7　3 点曲げ試験による超弾性 NiTi ワイヤーの荷重-変位曲線
(single bracket を使用して bracket での固定は行わなかったもの)

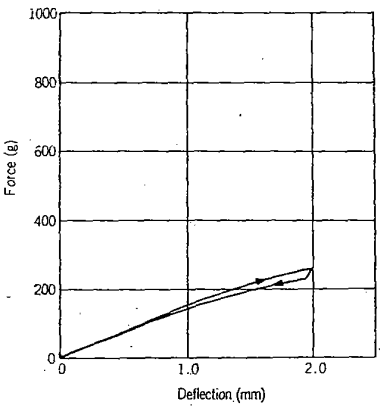

図 8　3 点曲げ試験による加工硬化 NiTi ワイヤーの荷重-変位曲線
(single bracket を使用して bracket での固定は行わなかったもの)

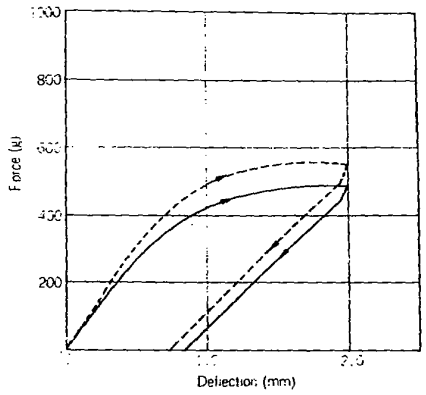

図 9　3点曲げ試験による Co-Cr 基合金ワイヤーAの荷重-変位曲線
破線で表わしたものは熱処理を施したワイヤー
(single bracket を使用して bracket での固定は行わなかったもの)

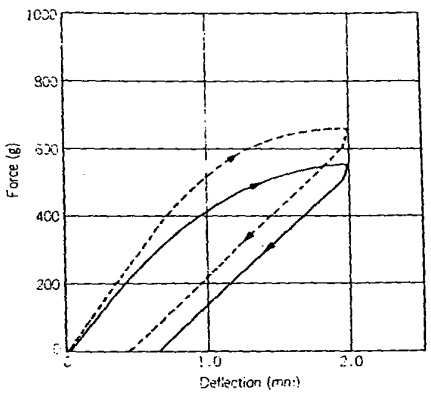

図 11　3点曲げ試験による Co-Cr 基合金ワイヤーCの荷重-変位曲線
破線で表わしたものは熱処理を施したワイヤー
(single bracket を使用して bracket での固定は行わなかったもの)

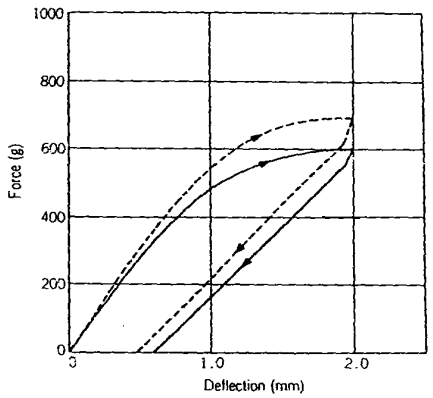

図 10　3点曲げ試験による Co-Cr 基合金ワイヤーBの荷重-変位曲線
破線で表わしたものは熱処理を施したワイヤー
(single bracket を使用して bracket での固定は行わなかったもの)

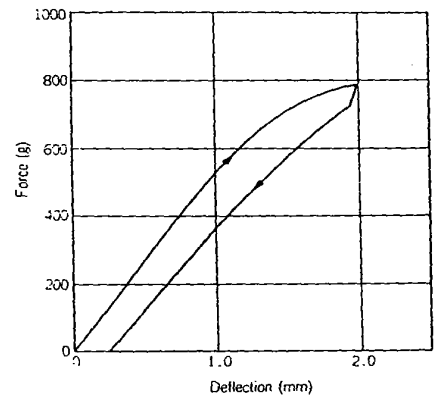

図 12　3点曲げ試験によるステンレススチールワイヤーAの荷重-変位曲線
(single bracket を使用して bracket での固定は行わなかったもの)

線を示し，変位 1.7 mm を過ぎたあたりからやや増加率が低下を示した．そして変位 2 mm で荷重 258 g を示した．変位減少時も直線的に荷重を減じ，永久変形は 0.030 mm であった．

一方，Co-Cr 基合金は変位 2.0 mm における荷重と永久変形量にかなりの差があったが，3種ともほとんど同様の曲線を示した．点線で示したものが熱処理を行った試料である．最初は直線的に荷重が上昇したが，途中から荷重の増加率は低下し始めた．2 mm 変位での荷重は 580～700 g であった．変位を減少していくと荷重はほぼ直線的に減少し，永久変形は 0.45～0.8 mm とかなり大きな値を示した．

ステンレススチールは Co-Cr 基合金と似たような曲線を示した．ステンレススチールAは変位 2 mm での荷重は 785 g，永久変形は 0.23 mm であったが，ステンレススチールBは変位 2 mm で荷重 690 g，永久変形は 0.63 mm と大きな差を示した．しかし，両方のワイヤーとも変位を減少していくと，S字に近い直線を示した．

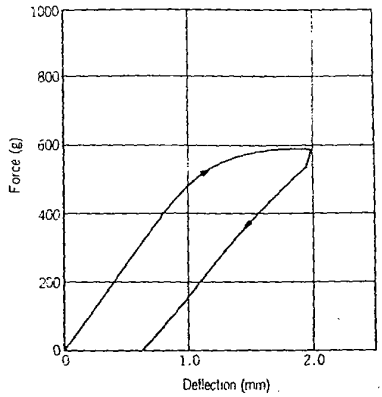

図 13　3点曲げ試験によるステンレススチールワイヤーBの荷重-変位曲線
(single bracket を使用して bracket での固定は行わなかったもの)

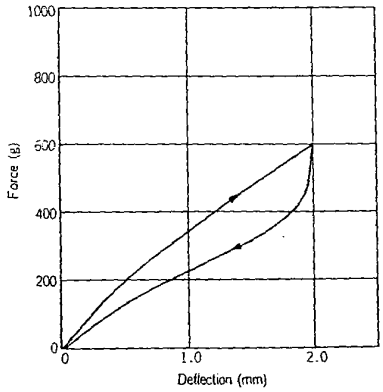

図 15　3点曲げ試験による加工硬化 NiTi ワイヤーの荷重-変位曲線
(single bracket を使用して bracket でワイヤーを固定したもの)

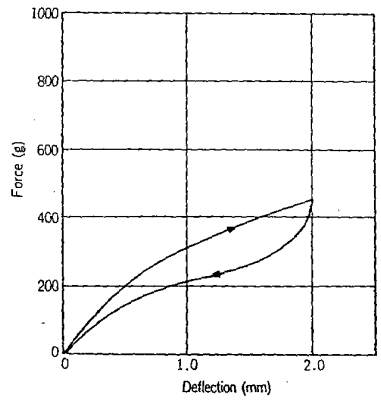

図 14　3点曲げ試験による超弾性 NiTi ワイヤーの荷重-変位曲線
(single bracket を使用して bracket でワイヤーを固定したもの)

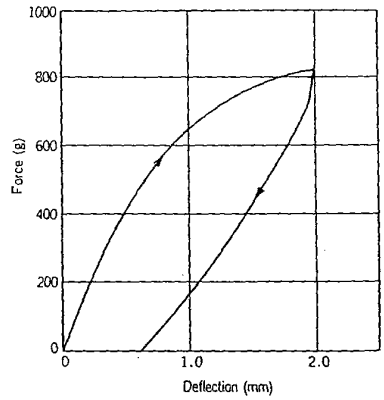

図 16　3点曲げ試験による熱処理を施した Co-Cr 基合金ワイヤーAの荷重-変位曲線
(single bracket を使用して bracket でワイヤーを固定したもの)

条件 (b)　(single bracket 使用, リングレットによりワイヤーを固定)

これらの結果は図14～図20に示した. 超弾性型 NiTi は変位開始後に変位約 0.4 mm から徐々に荷重の増加率が低下し始め, 変位約 0.7 mm からは荷重の増加率が一定となった. 2 mm 変位での荷重は 460 g を示した. 変位を減少させると 1.5 mm から 0.5 mm の間では, ほぼ一定の荷重の部分があらわれた. 永久変形は 0.030 mm を示した.

加工硬化型 NiTi は超弾性型と同様に変位 0.5 mm で増加率の変化を示した. しかし, 超弾性型に比べると変化は少なかった. 変位 2 mm では 600 g の荷重を示した. 変位を減少させると, 最初急激に荷重が低下したが, その後は, ほぼ一定に荷重も減少し, 永久変形は 0.038 mm であった.

Co-Cr 基合金は条件 (a) とほぼ同様な荷重の増加を示した. 2 mm 変位における荷重は 800 g から 900 g であった. 変位を減少すると, 荷重は直線的な減少はせず, 減少率を徐々に低下させる傾向を示した. また永久変形は 0.38 mm から 0.6 mm であった.

ステンレススチールBは引張試験や条件 (a) において Co-Cr 基合金に似た性質を示したが, この試験でも Co-

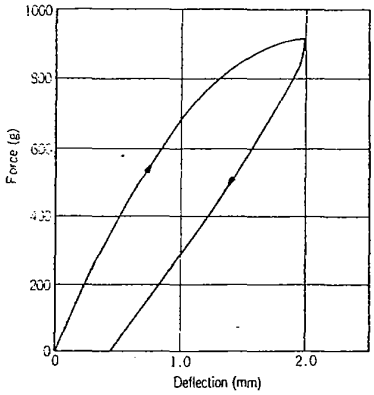

図 17　3点曲げ試験による熱処理を施した Co-Cr 基合金ワイヤーBの荷重-変位曲線
(single bracket を使用して bracket でワイヤーを固定したもの)

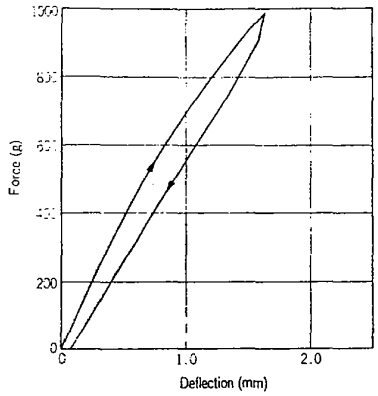

図 19　3点曲げ試験によるステンレススチールワイヤーAの荷重-変位曲線
(single bracket を使用し bracket でワイヤーを固定したもの)

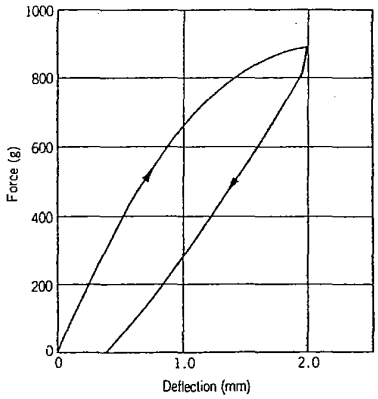

図 18　3点曲げ試験による熱処理を施した Co-Cr 基合金ワイヤーCの荷重-変位曲線
(single bracket を使用して bracket でワイヤーを固定したもの)

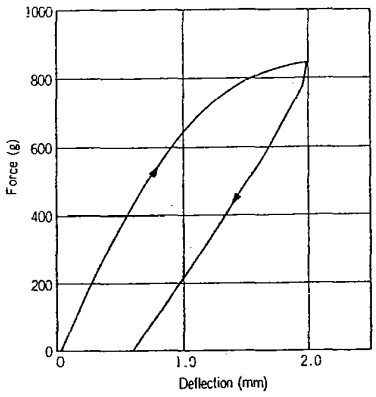

図 20　3点曲げ試験によるステンレススチールワイヤーBの荷重-変位曲線
(single bracket を使用し bracket でワイヤーを固定したもの)

Cr 基合金に近い曲線を示した．2 mm 変位での荷重は 840 g，永久変形は 0.63 mm であった．一方ステンレススチールAは変位 1.7 mm でロードセルの容量 1 000 g に達したため，2 mm まで変位を与えることができなかった．

条件 (c)　(siamese bracket 使用，bracket での固定をしない．)

この結果は図 21 に示した．超弾性型 NiTi は変位 1 mm 程度から荷重の増加率が鈍くなり，変位 1.5 mm を過ぎると荷重の増加率は非常に低下した．この挙動は変位を減じたときにも現われ，変位 2 mm から 1 mm までは荷重の変化が少ない曲線となった．一方，加工硬化型 NiTi はほぼ直線的な挙動を示し，超弾性型とは異なる曲線を示した．

条件 (d)　(siamese bracket 使用，bracket 部でリングレットによりワイヤーを固定した．)

この条件での結果は図 22 に示した．変位約 0.5 mm までは超弾性型 NiTi のほうがやや高い荷重を示した．しかし，超弾性型はその後荷重増加率が低下して，曲線はやや平坦な傾向を示し出した．加工硬化型 NiTi は途中やや荷重増加率が低下したものの，ほぼ直線的に荷重が増加し，変位 2.7 mm で荷重は 1 000 g まで達した．

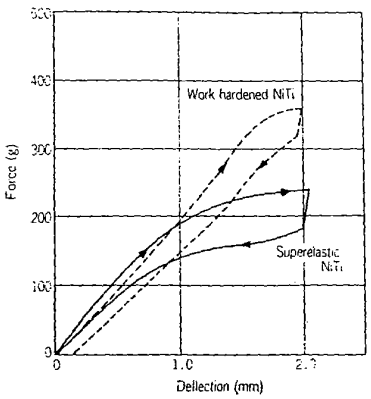

図 21　3点曲げ試験による超弾性 NiTi と加工硬化 NiTi ワイヤーの荷重-変位曲線 (siamese bracket を使用して bracket での固定は行わなかったもの)

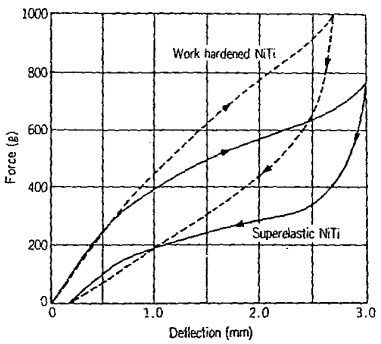

図 22　3点曲げ試験による超弾性 NiTi と加工硬化 NiTi ワイヤーの荷重-変位曲線 実線で表わしたものが超弾性 NiTi (siamese bracket を使用して bracket でワイヤーを固定した)

変位を減少してゆくと，両ワイヤーとも最初急に荷重を減じたが，超弾性型は変位 2.5 mm から荷重の変化が少なくなり，変位 0.8 mm までは非常にゆるやかな荷重の減少を示した．一方，加工硬化型は急激な荷重の減少を示した後は，直線的な荷重の減少を示した．

IV. 考　　察

超弾性型 NiTi ワイヤーの歯科矯正用アーチワイヤーとしての適性を検討するため，引張試験，3点曲げ試験を行ない理工学的な見地から検討を試みた．その結果，超弾性型 NiTi ワイヤーは非常に興味ある特性を示し，歯科矯正用ワイヤーとして優れた性質を有することが示唆された．以下に，現在矯正ワイヤーとして用いられているステンレススチール，Co-Cr 基合金，加工硬化型 NiTi ワイヤーと比較しながら，超弾性 NiTi 合金ワイヤーの特性について見ていくことにする．

1. 引張試験

まず引張試験における応力-ひずみ曲線図から見ていくことにする．一般に金属材料の応力-ひずみ線図は，まず連続的な弾性変形とそれに引続いて起る塑性変形から成っている．弾性変形の範囲では外力を除くとひずみは消失して変形前の形状に戻る．弾性限を超えるとひずみは急に増加し始めるが，弾性範囲を超えたひずみは応力を除いても，永久変形として残留する．矯正用ワイヤーとしての使用を考えた場合，利用できる範囲はこの弾性限度内であり，この弾性限度のひずみ量が大きく取れるほど優れた矯正用ワイヤーということになる．また応力-ひずみ曲線の勾配，すなわち弾性率も矯正用ワイヤーとして重要な要因である．図4においてステンレススチールや Co-Cr 基合金ワイヤーのように弾性率が高ければ，わずかなひずみ量に対して大きな応力を生じてしまい，また逆にほんのわずかにひずみ量が減少した場合でも応力は大きく減少し，歯科矯正においては荷重の変動が大き過ぎ，そのためにはループを作るとか様々な工夫が必要になってくる[11,12]．

加工硬化型 NiTi ワイヤーの場合，応力-ひずみ線図は直線的であるが，弾性限度は約 4% であり，ステンレススチールや Co-Cr 基合金よりも広いひずみの範囲まで応用でき，しかも弾性率が約 1/4 と低く，ひずみ量が大きくなっても応力はあまり増加しないという特徴がある．すなわち矯正用ワイヤーとしてはより望ましい材料ということになると考えられる．

新しく開発された超弾性型 NiTi ワイヤーの場合，他の種類のワイヤーとは，異なった応力-ひずみ曲線を示す．伸び 1% までは直線的な弾性変形を示した後に応力はほぼ一定値となり，それが約 4% まで続いた後に再び応力は上がり始め約 8% まで直線領域を示して，10% あたりから再び曲り始めて伸び 11% で破断に至る．伸び 1% までの直線部分は通常の弾性変形によるものであるが，1% 以上の変形は，一般の金属材料に見られるような転位のすべりによる塑性変形やそれに伴なう加工硬化とはまったく異なったメカニズムによるもの，すなわち応力誘起変態という特殊な変形機構による見かけ上の降伏現象である[10]．このことは図5に示した繰返し引張試験の結果から明らかである．すなわち超弾性型 NiTi ワイヤーを伸び 8% まで引張った後に伸びを減少させていくと，増加のときと同様に応力がほぼ一定となる部分があらわれ，ほぼ元の位置まで戻ってくる．一定となる応力はひずみの増加時に比べて若干小さい値となるが，この

特徴のある変形挙動を超弾性と称している．

超弾性は，最近注目をあびている形状記憶効果と同様，熱弾性型マルテンサイト変態すなわち変態温度と逆変態温度の差の少ないマルテンサイト変態に起因することが知られるようになった．形状記憶効果というのは，一定の変態温度以下で変形させた後に，逆変態温度以上に加熱すると変形前の元の形状に復帰する現象を言う．変態点以下での変形は一般の金属材料とは異なり転位のすべりによる変形ではなく，応力が加わると結晶が部分的にマルテンサイト変態を起しながら変形が進行する．これを逆変態以上の温度に加熱すると，マルテンサイト変態していた部分がもとの CsCl の結晶構造にもどるために，全体として元の形状に復帰するというものである[7~9]．超弾性型 NiTi 合金の場合は逆変態温度（Af 点）を室温よりも低くしてあるために，室温では形状記憶効果が起らないが，荷重をかけていくと応力により変態が誘起され，見掛け上は変形が起るが，周囲の温度が Af 点以上なので温度を加えなくても応力を減じるとすぐ逆変態が起り元に戻るというわけである[10]．このようにして伸び 1% から 4% までは変形が進むが，4% 以上となると次第にこの応力誘起変態も起り難くなり，さらに変形させるためにはより多くの応力を必要とするようになる．伸び 4% から 8% にかけて直線的に応力が増加するのはこのためであると考えられる．

超弾性型 NiTi 合金は破断するまでの伸びが約 11% ある．しかも繰返し引張試験において 8% 前後の変形でもほとんど元に戻り，10 回の繰返しの後においても生じた永久変形量は 0.5% というこれまでの金属材料では到底想像できないような大きな復元力を持っている．また現在市販されている加工硬化型の NiTi に比較すると，1% までの少ないひずみ量がそれ以上増すと応力がほとんど一定となるという特質を持っている．この超弾性型 NiTi の矯正用ワイヤーへの応用を考えた場合，変位が次第に減じた場合でもほぼ一定の復元力を有するという特徴があり，現在市販されている NiTi ワイヤーよりも一歩進んだ材料であると考えられる．引張試験でこのような結果が得られたことから，次に実際の矯正用ワイヤーとして必要な曲げ試験について検討することとした．

2. 曲げ試験

フルバンドシステムにより歯科矯正治療を行う時，アーチワイヤーの弾力は個々の歯に複雑に作用して歯の移動が行われる．しかし複雑な力も局所的に考えると，3点曲げ試験に置き換えることができると考えられる．矯正用ワイヤーの曲げに対する性質を試験するとき，なるべく臨床に近づけた結果を得るために，特に小臼歯部分を想定して試験機を考案した．今回の曲げ試験では，3点曲げ試験を行い，ワイヤー中央部に変位を与えその時の荷重を測定した．また最大変位を与えた後，引続き変位を減少させてゆき，歯の移動に伴う荷重の減弱という変化も同時に記録し，一連のサイクルとして測定した．

条件 (a) (single braket を使用して bracket でのワイヤーの固定をしない．)

single bracket はその支持面がワイヤーと平行して一致するため，ワイヤーの中央部分に変位を与える時，支点間の距離に変化を生じないという特徴がある．このため，この条件では支点となる bracket でのワイヤーの固定は行わず基本的な3点曲げ試験により，ワイヤーの性質の比較を行った．

超弾性型および加工硬化型 NiTi は曲げ試験での永久変形が非常に少なかった．ステンレススチールおよび Co-Cr 基合金の場合は，3点曲げにより変位を与えていくと，ある荷重まで増加した後に塑性変形を生じるため，荷重が増加しなくなるところがある．このため変位を 2 mm より減少させると，塑性変形したぶんだけ永久変形として残留することになり，直線的に荷重が減少する．しかも変位量 2 mm のときの荷重はかなり高い値を示し，このままの弾力を矯正力として使用するには高過ぎる値と考えられる[13]．

超弾性型 NiTi の場合，変位を増加しても荷重の増加は除々に少なくなるという Co-Cr 基合金と似た曲線を示した（図 7）．しかし変位を減少してゆくと，Co-Cr 基合金のように直線的な荷重の減少は示さず，変位を増した時と同じ曲線を示した．荷重の増加が徐々に低下し平坦な曲線となるのは，塑性変形が生じているのではなく，応力誘起変態による超弾性の発現のためである．一方，加工硬化型 NiTi はほぼ直線的に荷重が上昇し，また変位を減少していくと，直線的に荷重が減少している（図 8）．

条件 (b) (single bracket を使用してリングレットによりワイヤーを固定した．)

アーチワイヤーとして実際に口腔内で使用するときは，ワイヤーをブラケットに固定して用いる．つまりワイヤーの弾力を歯に伝えるためには，ブラケットでの固定が必要となる．この固定のためには金属製の細い線（結紮用線）を用いることが多いが，結紮の強さによりブラケット部分のワイヤーに加わる力が異なると，ブラケットでのワイヤーの滑り等に差が生じ，結果に差が出る原因となる．このため，固定にはリングレットを使用し，条件を一定に揃え，しかも実際の使用状態に近い条件で比較検討した．

超弾性型 NiTi は変位を加えてゆくと約 0.5 mm から荷重の増加率が低下するが，その後は一定の増加率で

荷重が増し，加工硬化型 NiTi とやや似た曲線を示した．変位を減少した場合もやや似た曲線であったが，超弾性型 NiTi は変位量が 1 mm 前後において超弾性により発現したものと考えられる平坦な部分があらわれた．この超弾性が発現したと考えられる部分では，変位量が変っても荷重の変化が少ないため，実際に歯の移動を行うとき，歯が移動してもワイヤーの矯正力が減弱しないことが考えられる．矯正力として望ましい力は持続する力である[2]．超弾性型 NiTi を利用することにより，今までのアーチワイヤーでは得られなかった歯の移動に伴っても減弱の少ない矯正力が得られると考えられる．

支点を固定することにより，どのワイヤーの試験結果も条件 (a) より荷重が著しく上昇している．特にステンレススチール A は 2 mm 変位させる前に 1000 g に達してしまった．また Co-Cr 基合金も同様に高い荷重を示した．あまり強い力は逆にスムーズな歯の移動を阻害すると言われている[4]．このためアーチワイヤーの屈曲を行い，各種のループ等により緩和で持続性のある矯正力を得られるように細工が行われている[11,12]．超弾性型 NiTi ワイヤーの場合は，2 mm の変位を与えたときの荷重は Co-Cr 基合金の半分以下で，また永久変形も非常に少ない．しかも超弾性による減弱の少ない力を示すので，あらかじめ理想的な歯列の形態にワイヤーを作っておくことにより，スムーズな歯の移動が達成されるのではないかと考えられる．

条件 (c) (siamese bracket を使用して bracket での固定をしない．)

この条件では支持のツメが 4 本に分かれた siamese bracket を使用した．このブラケットはツメが曲面上にあるために，ワイヤーの曲げを行うに従い，ごくわずかに支点間の距離が縮小する特徴がある．

超弾性型 NiTi は変位を減少してゆくと，やはり超弾性による平坦な部分を持つ曲線を示した．一方加工硬化型 NiTi は直線的な変化を示し，荷重の変化の大きな曲線を示した．

条件 (d) (siamese bracket を使用して，bracket 部でリングレットによりワイヤーを固定した．)

この条件では今までワイヤーの変位を 2 mm までで終了していたものを，超弾性型は 3 mm までの変位にした．試験結果は条件 (b) と同様に超弾性型 NiTi と加工硬化型 NiTi はやや似た曲線を示した．これは，ワイヤーを固定することにより，ブラケットにおけるワイヤーの滑りが制限されたことなどが考えられる．しかし，変位を減少する時，変位 2 mm から 1 mm までの荷重の減少を比較すると，加工硬化型 NiTi が 220 g であるのに対して超弾性型 NiTi は 100 g と少ないことがわかる．固定を行うことにより超弾性の現われる部分が明確ではない．超弾性型 NiTi が持続的な力を発揮することは図 22 により明らかである．

以上の結果から超弾性型 NiTi の歯科矯正用ワイヤーとしての適性を考えると，次のようなことがいえる．超弾性型 NiTi は従来の矯正ワイヤーにはない．広い変位量にわたって一定の荷重が得られるという超弾性と，大きな変形を与えても永久変形が非常に少ないという特徴をもっている．これらを利用してアーチワイヤーとして使用すると，矯正力としては理想的ということができる持続的な力が得られることが考えられる．

V. 結　　論

新しく開発された超弾性型 NiTi 合金ワイヤーについて引張および曲げ試験を行ない，歯科矯正用ワイヤーとしての適性について検討した．比較のために現在歯科矯正用として用いられているステンレススチール，Co-Cr 基合金，および加工硬化型 NiTi ワイヤーについても合わせて検討を試みた．この研究で得られた主な結果はおよそ次のとうりである．

1) 引張試験において，超弾性型 NiTi ワイヤーは一般の金属材料とはかなり異なった応力-ひずみ曲線を示した．ひずみ 2% から 5% の間では，ひずみ量は増加するが応力はほぼ一定となり，この範囲においてはひずみを減少させていった場合でもやや低い応力で一定値を示すという特殊な変形挙動を示した．

2) 超弾性型 NiTi の破断までの伸びは約 11% であるが，伸び 8% までの繰返し引張試験の後でも永久変形は 0.5% とわずかであった．これらの特殊な変形挙動は応力誘起変態に基づくものである．

3) 曲げ試験において，超弾性型 NiTi ワイヤーは Co-Cr 基合金やステンレススチールワイヤーと比較して，大きな変位量を与えても荷重が少なく，また永久変形が非常に少ないという特性を示した．

4) 超弾性 NiTi ワイヤーは曲げ試験において，変位量が減少しても荷重の変化は少なく，広い変位量にわたって一定の荷重が得られるという特性を示した．

以上より超弾性 NiTi は変化の少ない持続的な力を発揮することができ，しかも永久変形が少ないという特徴をもつことから，矯正用ワイヤーとして非常に優れた性質をもつものと考えられる．

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同種移植による抗腫瘍抵抗性

同種移植を行なうことによって腫瘍の成長遅延および退縮さえも起こることが偶然的に知られるようになったのはよほどに古い時期のことと思われる。一時期流行をみた白血球輸血もある種の同種移植であろうが，抗腫瘍抵抗性の獲得に至るのに必要な条件および抗腫瘍性の成立機序そのものがまったく不明であったため，現在ではあまり行なわれなくなっているようである。

1975年 G. Parmiani らはマウスに同種移植を行なうと抗腫瘍抵抗性が誘導されることを発表した。その後，彼らはマウスの同種主要組織適合抗原（H-2 抗原）と腫瘍特異的移植抗原（TSTA）との間に交叉反応が起こるためであることを示した。この H-2 抗原と TSTA との交叉反応は腫瘍免疫学の分野のみならず，現代の免疫遺伝学の主要なテーマとなった「自己とは何か？」という古くて新しい問題への扉のひとつを開くことになった。同じころわが国においても，小林博らはラットの系において抗腫瘍抵抗性が誘導されることを別個に観察し，immunological xenogenization として追及を始めた。マウスに比べてラットでは免疫遺伝学そのものが未成熟なこともあって，必ずしも十分な解析がなされたとはいえない現状である。小林らによれば，同種移植による抗腫瘍抵抗性の成立には長期のメモリーがなく，特異性もみられないことから，NK 細胞によって抗腫瘍抵抗性が発現する可能性を示唆している。ウイルスおよびハプテンによる xenogenization の試みもみられるようである。

私たちはマウスの系において同種移植の組み合わせをかえ，どのような H-2 抗原の組み合わせで移植を行なうと強い抗腫瘍抵抗性が誘導されるかを決定した。H-2 抗原をコードする遺伝子領域内の亜領域がそれぞれ異なる C 57 BL/10 系 congenic マウスを移植の donor として用いて，どの亜領域が異なることが必要なのかをみると，K, A, B および J 亜領域が一致して I, C, S および D 亜領域が異なっていた（あくまでも遺伝子レベルでの事実であって細胞表面における抗原分子のレベルとは異なる）。また，抗腫瘍抵抗性の発現機序については，私たちの系ではキラー T 細胞を effector としていたことを示した。

同種移植による抗腫瘍抵抗性がヒトの悪性腫瘍に対して試みられる日がくるかもしれないが，現在はなおいっそうの基礎実験を必要としている段階であると思われる。ヒトへの応用は社会的および法的問題を含んでいるようである。

（群馬・千木良正俶）

整形トピック

TiNi 合金は強度や耐食性にすぐれ，熱弾性型マルテンサイト変態をし，記憶処理を行なえば「形状記憶効果（shape memory effect）」が得られる。また，変態温度（Af 点）より少し上の温度で変形させても，応力を除けばゴムのように元の形状にもどる「擬弾性的性質」がある。特に，応力誘起マルテンサイト変態とその逆変態に起因するものを「超弾性（superelasticity）」とよぶ。超弾性も形状記憶効果も，ともに逆変態が形状回復の駆動力になっていて，そのどちらが起きるかは変形温度と Af 点との相対関係で定まる。二つの現象にとってもっとも基本的なことは，逆変態が結晶学的にまったく可逆的に行なわれているということである。すなわち，マルテンサイトが母相の方位を覚えているのである。形状記憶合金と並んで，超弾性 TiNi 合金を整形外科領域に応用すれば，従来の金属の諸欠点を改善しうる。

超弾性 TiNi 線は不銹鋼線よりもたわみやすく，除荷すれば完全に元の形状にもどるために，従来の捻り法による結合は不可能である。したがって，TiNi 線を同種金属パイプに通し，パイプをかしめる「かしめ法」を応用した。「かしめ法」を従来の不銹鋼線に応用しても従来の捻り法の2倍以上の締結力が得られ，すぐれた締結法である。締結操作として，まず，金属パイプを通した TiNi 線を馬蹄形締結器具を用いて強い張力でもって締めつけた後，我々が試作した先端をV型にした「かしめ器」で金属パイプと TiNi 線を圧迫変形させ，TiNi 線がパイプ内ですべらないように圧着する。

超弾性 TiNi 線のひっ張り試験結果では，曲線の形は温度に著しく依存しているが，この合金のマルテンサイト変態の特性温度（Ms, Mf, As, Af）と密接に関係している。Ms より上の温度でひっ張ったとき，弾性変形に伴う直線領域に続いて降伏が起こり，みかけのうえでは塑性変形している。しかし，この変形は応力誘起マルテンサイト変態によるもので，このマルテンサイトは Af より上では応力ゼロの状態で熱力学的に不安定であるから，除荷すれば逆変態が起こって母相にもどる。この合金はその逆変態が結晶学的に可逆的だから，母相の元の方位にもどって塑性ひずみが完全に消失する。したがって，手術時に超弾性 TiNi 線を強く締結すれば，術後，骨接合部の骨吸収により接合部がわずかに弛んでも，応力誘起マルテンサイト変態により線が弛むことがない。

従来の AO プレートによる骨接合を行なえば，皮質骨の海綿骨化の結果，プレート除去後に再骨折の危険性があり，また，プレートの折損など AO プレートの問題点は周知のとおりである。この AO プレート材に超弾性 TiNi 合金を用いれば，生物学的になじみがあるばかりでなく，TiNi 合金は従来の金属に比較して，骨の弾性に近づき，生体力学的にもなじみがあり，また外力によりプレートが変形しても，外力が除かれると完全に元の形状にもどり，皮質骨の海綿骨化やプレートの折損が起こりにくくなるであろう。また，人工関節に応用すれば，特に骨セメントを使用しない場合，ステムの弛みや，折損が減少するであろう。

形状記憶効果と超弾性を同時に応用すれば，さらに応用範囲が拡大され，夢ある合金である。現在，大阪府立工業技術研究所および古河電気工業(株)の協力を得て，応用開発をすすめている。

（大阪・大西啓靖）

超弾性的性質のある TiNi 合金

<経験と考察> Yoshiyasu Donishi, Clinical Medicine : Orthopaedic Surg. y, 32 at p. 1180 (1987)

骨 Paget 病におけるウナギカルシトニンの治療効果

Effects of synthetic eel calcitonin in patients with Paget's disease of bone

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杉浦　昌　梅沢健司*

はじめに

骨 Paget 病は 1877 年 Sir James Paget[1] により詳細に報告された骨疾患である．本症の本態は骨組織の remodeling の過程，すなわち骨形成と骨吸収が病的に亢進した状態であるとされているが，その病因についてはいまだ定説が得られていない．そのために治療も対症的なものにならざるをえず，種々な薬剤の投与が試みられてきた．1967 年カルシトニン（以下 CT と略す）が本症に有効であると報告されて以来[1]，本症の CT 治療に関する報告があい次いでなされるようになった．筆者らは骨 Paget 病 5 症例に対して合成ウナギ CT による治療を行ない，その効果について検討したので報告する．

症　例

1. 臨　床　像

症例は表 1 に示す 5 症例である．男 1 例，女 4 例で，平均年令は 58.6 才である．主訴は頭痛，腰痛，股関節痛などであるが，顔貌の著しい変化や頭部の変形を他人に指摘されたり，他科にて骨 X 線像の異常陰影を発見されて当科へ紹介された例もある．

診断は，血液・尿生化学検査にて血清 alk. p-ase 値の上昇と尿中 OH-proline 量の増加，骨 X 線像上果状，限局性の骨硬化像と骨梁の粗大，不整化（症例 2，3，5）や頭蓋骨の内外板の肥厚（症例 1，3），cotton wool appearance（症例 4），osteoporosis circumscripta（症例 5）などの特有な所見（図 1），骨生検組織像で既存骨梁の破壊吸収後の新旧骨質の接合によるモザイク構造（図 2），^{99m}Tc 骨 scintigram での異常集積像（図 3）などにより行なった．

a. 内外板の肥厚（症例 3）．　b. Cotton wool appearance（症例 4）．　c. Osteoporosis circumscripta（症例 5）．

図 1. 頭蓋骨 X 線像．

Key words: Paget's disease of bone, calcitonin

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AR

Figure 3. Case 1. Photomicrograph of the polypectomy specimen. Note the branching core of smooth muscle fibers in a treelike pattern in the lamina propria (H&E, original magnification ×17).

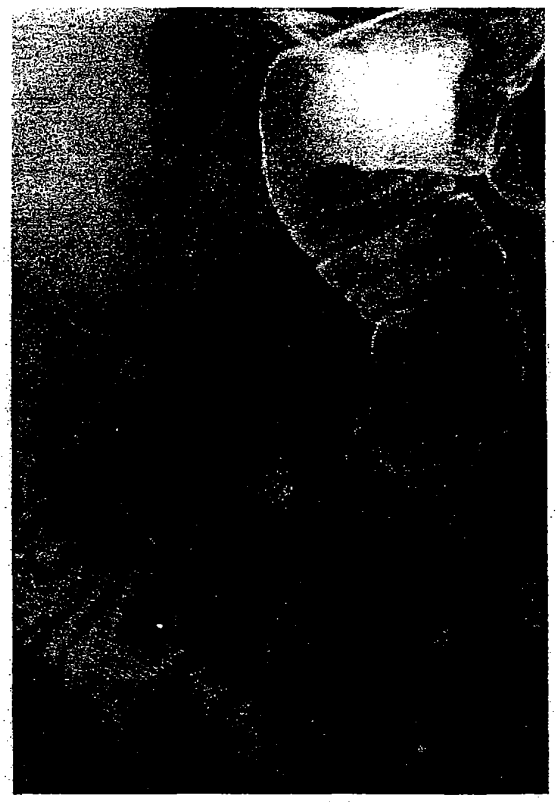

Figure 4. Case 2. Radiographic appearance of a multilobulated polyp in the second to third portion of the duodenum; the head measures 25 × 20 mm in size, and the stalk measures 53 mm in length.

mucocutaneous pigmentation and family history, and suggested that these were incomplete forms of the syndrome. A recent report[4] gave some support to their concept by the finding of a solitary hamartoma in a resected specimen of ileum.

Paterlini et al.[5] in 1983 succeeded in performing endoscopic polypectomy of multiple jejunal polyps in a patient with Peutz-Jeghers syndrome who had undergone surgical segmental resection of the jejunum. In the literature, there have been only two cases of hamartoma detected endoscopically in the distal duodenum.[2,6] One polyp was removed by endoscopic polypectomy.[2]

Because of the difficulty of inserting the conventional duodenofiberscopes into the distal duodenum and upper jejunum, endoscopic excision of polypoid lesions in these areas has rarely been reported. We recently described the advantages of jejunal endoscopy with a long duodenofiberscope,[3] which was successfully used for the excision of these solitary hamartomas in the distal duodenum.

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Variable stiffening device for colonoscopy

To the Editor:

It is apparent to most endoscopists who perform colonoscopy on a regular basis that it is sometimes difficult to perform colonoscopy where there is formation of loops in the sigmoid, transverse colon, or even the descending colon. The more redundant the colon and the less stiff the scope, the more frequent this problem would be. Some endoscopists have already used various devices such as biopsy forceps to

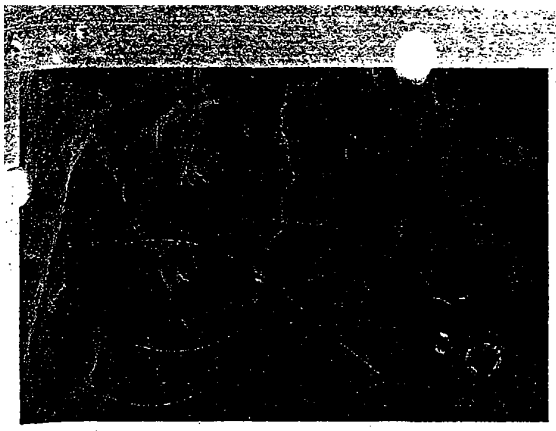

Figure 1. Prototype variable stiffening device SVSC-1 (Wilson-Cook Medical, Inc.) for colonoscopy.

stiffen the colonoscope. As the colonoscope becomes older with more frequent uses and more torqueing, the insertion tube becomes more flexible; it then becomes more difficult to perform colonoscopy since the critical stiffness is lost.

Various ways to introduce stiffening into the scope, including external stiffeners such as splints, have not received widespread acceptance. Patients with redundant sigmoid colons, redundant colons in general, long colons, and large dilated atonic colons, and those with megacolon are especially difficult to treat. To provide for a stiffening device, it was thought best that the stiffener might have the additional luxury of being variably stiff. This would allow different degrees of stiffness for different settings and different endoscopists.

For the past 2 years, we have been experimenting with different types of cables to be used through the biopsy forceps of a standard colonoscope. A prototype stiffening device, SVSC-1 (Wilson-Cook Medical Inc., Winston-Salem, N.C.) through an Olympus CF10L colonoscope was used in 25 patients (Fig. 1). The patients were selected when routine colonoscopy was not easily performed.

The SVSC-1 was successful in providing colonoscopy to the cecum in 22 of 25 patients (88%). It was thought that the stiffening device was helpful in proceeding with more rapid colonoscopy where the procedure might have been prolonged without the use of the stiffener.

Although we do not have a control group, it was thought subjectively that the stiffener provided a great improvement in forward motion in cases where the colonoscope was thought to be too limp or the colon itself was thought to be too redundant.

This type of variable stiffener can be expanded to other types of endoscopy, including in the very flexible upper endoscopes that require further stiffening to intubate the pylorus and even in intubation of other structures that are routinely performed by the gastrointestinal endoscopist (e.g. choledochoscopy, stent placement, etc.). It is thought that a variable stiffening device will provide many more applications in the future in all fields of endoscopy.

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Pyelo-choledochal fistula secondary to pancreatic carcinoma

To the Editor:

The presence of spontaneous fistulization between the biliary system and the gastrointestinal tract is an uncommon complication of neoplasms. Fistulizations are exceptional when one of the organs is not digestive.

We encountered a 55-year-old man, who was a heavy smoker and moderate drinker. He was admitted to the hospital with a 1-month history of upper abdominal pain, progressive jaundice, dark urine, and pale stools.

Abdominal sonography displayed dilation of the intrahepatic and common bile ducts and gallbladder. In addition, CT demonstrated a mass in the head of the pancreas and dilation of the main pancreas duct, and the common bile duct was sharply interrupted at the level of the pancreatic mass.

ERCP was performed and showed a long, irregular stenosis in the intrapancreatic portion of the common bile duct and a small fistula between the bile duct and the right renal pelvis. The ureter was filled with the contrast that was introduced into the common bile duct. There was a significant dilation of the common hepatic and intrahepatic bile ducts (Fig. 1). A subsequent abdominal radiograph showed the bladder to be filled with contrast. Urinalysis confirmed the presence of bile.

The patient underwent surgical exploration that disclosed unresectable pancreatic carcinoma. A choledochojejunostomy was performed. The patient died 1 month later.

Figure 1. ERCP showing fistula between the common bile duct and the right renal pelvis (arrow).

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY DOCKET NO. 9438	SERIAL NO. Division of 682,243
LIST OF ART CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT: James E. Jervis	
	FILING DATE: Herewith	GROUP: 3301 (prior application)

U.S. PATENT DOCUMENTS

Examiner Initial		DOCKET NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCKET NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
~~DJK~~	AL	58 1 3 3 2 2 5		JAPAN			X	
DJK	AM	3 0 8 6 3 8 4	1-24-85	AUSTRALIA			X	
~~DJK~~	~~AN~~	~~8 3 0 1 5 7 6~~		~~AUSTRALIA~~			~~X~~	
	AO							
	AP							

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	
	AS	
	AT	

EXAMINER [signature] DATE CONSIDERED 3/6/94

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner,
See p. 10 of Amendment re Part of #10
SN 956653

MPO884-US4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	)	Group Art Unit: 331
James E. Jervis	)	Examiner: C. Sam
Serial No. 177,817	)	Raychem Corporation 300 Constitution Drive
Filed: March 30, 1988	)	Menlo Park, CA 94025
For: Medical Devices Incorporating SIM Alloy Elements	)	August 11, 1988

RESPONSE TO OFFICE ACTION

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This is a response to the office action dated August 5, 1988. Reexamination is requested in view of the following amendments and remarks.

REQUEST FOR WITHDRAWAL OF FINALITY OF REJECTION

The present application was filed as a continuation application claiming priority under 35 USC §120 from US patent applications nos. 06/541852 and 07/047824. As filed, the application contained claims identical to those contained in application serial no. 07/047824 and rejected in an office action in that application dated September 30, 1987. It was the intention to amend the present application, by submitting new claims in a preliminary amendment.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner of Patents and Trademarks, Washington, D.C. 20231, on 8/11/88
(Date of Deposit)
Tami Haskins
Name of applicant, assignee, or Registered Rep.
Tami Haskins
Signature

In order to provide the Examiner with all the information that the might require in order to consider the issues presented in the amendment, it was thought prudent to submit a declaration under 37 CFR §1.132 by a technical expert. This was completed and signed at the beginning of August.

It is sincerely regretted that compilation of the papers to be submitted has meant that the preliminary amendment has not been filed before receipt of the first office action.

In accordance with MPEP 706.07 (e), it is requested that the finality of the rejection of this application be withdrawn. The general policy of the Patent Office of rejecting a continuation application in the first office action in the situation outlined in MPEP 706.07 (b) is recognized. However, in the present case, the delay in filing a preliminary amendment arose from efforts to make more clear the issues presented in the amendment.

Furthermore, the rationale behind the policy of final rejecting applications is to further the interest of the public that prosecution of an application be confined to as few actions as is consistent with a thorough consideration of its merits (see MPEP 706.07). It is respectfully submitted that the examination, to which the present application was subjected for the purposes of the outstanding office action, did not involve the consideration of merits not considered previously in connection with the application from which priority is claimed. The merits are now presented for consideration, unfortunately and regretably after receipt of the first office action. In view of the bona fide reasons for the delay in filing the amendment and of the nature of

the examination to which the application has been subjected, it is respectfully requested that the finality of the rejection be withdrawn and that the amendments now submitted be entered and considered. While refusal to enter the amendments would be contrary to the interest of the applicants, it is believed that it would also be contrary to the interest of the public since the required further continuation application would prolong prosecution of this case yet further. It is believed that this should be avoided, and that, in the present circumstances, to do so by withdrawing the finality of the rejection is consistent with the provisions of the MPEP and the Code of Federal Regulations.

AMENDMENTS

The Examiner is requested to amend the specification as follows:

In the Description:

Page 2, before the heading "Background of the Invention", insert:

-- CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of copending commonly assigned application serial no. 047,824, filed May 8, 1987, which is a continuation of application serial no. 865,703, filed May 21, 1986 now US Patent No. 4665906, which is a continuation of application serial no. 541852 filed October 14, 1983 now abandoned. --

A2 Page 3, line 28, after Quin insert --now U.S. Patent No. 4,505,767--.

A3 Page 4, line 26, delete "power" and insert --powder--.

A4 Page 7, line 19, delete "E_D" and insert --E_A--.

A5 Page 7, line 19, delete "strain" and insert --stress--.

A6 Page 8, line 20, delete "theart" and insert--the art--.

A7 Page 8, line 21, delete "tsting" and insert --testing--.

A8 Page 8, line 24, after "(Docket No. MP0873-US1)" insert --now U.S. Patent No. 4,505,767--.

A9 Page 11, line 17, delete "by" and insert --be--.

A10 Page 13, line 9 delete "it".

A11 Page 14, line 12, delete "whch" and insert --which--.

A12 Page 15, line 17, delete "tranisition" and insert --transition --.

A13 Page 8, between lines 24 and 25, insert the following paragraph:

~~A14~~ --The following table sets forth transformation temperature data for alloys disclosed in US-4505767:

TABLE

Composition (atomic percent)

Ni	Ti	V	M_S	A(90)
49.50	43.50	7.00	-107	-88
50.00	44.00	6.00	-96	-84
49.00	43.00	8.00	-83	-61
50.00	45.00	5.00	-42	-33
49.00	45.00	6.00	-35	-12
50.50	48.00	1.50	-32	-6
48.50	44.50	7.00	-30	-13
50.00	46.00	4.00	-11	7
48.50	45.00	6.50	-10	15
49.00	45.50	5.50	-10	14
48.00	44.25	7.75	-7	8
48.50	45.50	6.00	-5	27
41.50	38.50	20.00	-2	86
46.50	43.50	10.00	-1	50
36.25	33.75	30.00	0	42
49.50	46.00	4.50	6	35
48.00	46.00	6.00	12	36
47.75	45.75	6.50	20	54
47.50	45.50	7.00	26	58
48.50	46.50	5.00	27	58
45.00	45.00	10.00	30	71
47.50	46.50	6.00	32	71
46.50	46.50	7.00	34	70--

In the Claims:

Cancel claims 1 to 10.

Add new claims 11 to 28 as follows:

-- 11. A medical device for use within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature, the device comprising an element which comprises a shape memory alloy which:

(a) displays stress induced martensite behavior at body temperature; and

(b) has an A(90) temperature of not more than 0°C.

12. A device as claimed in claim 11, which includes a restraint by means of which the shape memory alloy element is held in a deformed configuration to allow it to be positioned within or in proximity to a mammalian body, the deformation occurring through the formation of stress induced martensite.

13. A device as claimed in claim 12, in which the restraint is hollow, and the shape memory alloy element is deformed in such a way that it is compressed transversely, and is positioned within the restraint, the restraint preventing transverse expansion of the element.

14. A device as claimed in claim 13, in which the restraint is a catheter.

15. A device as claimed in claim 13, in which the shape memory alloy element is an intrauterine contraceptive device.

16. A device as claimed in claim 14, in which the shape memory alloy element is a filter for a blood vessel.

17. A device as claimed in claim 12, in which the shape memory alloy element is tubular, and the restraint is positioned within the shape memory alloy element to deform it.

18. A device as claimed in claim 17, in which the shape memory alloy element is a tracheal catheter.

19. A medical device for use within a mammalian body or in such proximity to a mammalian body that the device is substantially at body temperature, the device comprising an element which comprises a shape memory alloy consisting essentially of nickel, titanium and vanadium within an area defined on a nickel, titanium, and vanadium ternary composition diagram by a hexagon with its first vertex at 38.0 atomic percent nickel, 37.0 atomic percent titanium, and 25.0 atomic percent vanadium; its second vertex at 47.6 atomic percent nickel, 46.4 atomic percent titanium, and 6.0 atomic percent vanadium; its third vertex at 49.0 atomic percent nickel, 46.4 atomic percent titanium, and 4.6 atomic percent vanadium; its fourth vertex at 49.8 atomic percent nickel, 45.6 atomic percent titanium, and 4.6 atomic percent vanadium; its fifth vertex at 49.8 atomic percent nickel, 44.0 atomic percent titanium, and 6.2 atomic percent vanadium; and its sixth vertex at 39.8 atomic percent nickel, 35.2 atomic percent titanium, and 25.0 atomic percent vanadium.

20. A medical device which comprises:

(a) an element for use within a mammalian body or in such proximity to a mammalian body that the device is substantially at body temperature, the element comprising a shape memory alloy which displays stress induced martensite behavior at body temperature; and

(b) a restraint by means of which the shape memory alloy element is held in a deformed configuration to allow it to be positioned within or in proximity to a mammalian body, the deformation occurring through the formation of stress-induced martensite.

21. A device as claimed in claim 20, in which the restraint is hollow, and the shape memory alloy element is deformed in such a way that it is compressed transversely, and is positioned within the restraint, the restraint preventing transverse expansion of the element.

22. A device as claimed in claim 21, in which the restraint is a catheter.

23. A device as claimed in claim 21, in which the shape memory alloy element is an intrauterine contraceptive device.

24. A device as claimed in claim 22, in which the shape memory alloy element is a filter for a blood vessel.

25. A device as claimed in claim 20, in which the shape memory alloy element is tubular, and the restraint is positioned within the shape memory alloy element to deform it.

26. A method of medical treatment which comprises:

(a) providing a device comprising an element which comprises a shape memory alloy which displays stress induced martensite behavior at body temperature, the element being restrained in a

deformed configuration against a stress which induces the formation of stress induced martensite;

(b) positioning the device so that the shape memory alloy element is within a mammalian body or in such proximity to a mammalian body that the element is substantially at body temperature; and

(c) allowing the element to transform from the deformed configuration, the transformation occurring substantially at body temperature.

27. A method as claimed in claim 26, in which the shape memory alloy element is held in the deformed configuration by a restraint, and the method includes the step of removing the restraint to allow the element to transform from the deformed configuration.

28. A method as claimed in claim 26, in which transformation of the shape memory alloy element causes one or more parts of the body in contact with the element to be displaced.--

REMARKS

Amendments to the description:

The description has been amended by incorporating a cross-reference to related applications and to correct typographical errors.

Information concerning alloys disclosed in US-4509767 has been incorporated in the description on page 8. The

disclosure of US-4505767 is incorporated in the present specification by the reference thereto on page 3 at line 28. Specifically, several alloys are disclosed in Table I in column 6 of the incorporated document, each alloy having characteristic thermomechanical properties. In particular, the M_S temperature (which is the temperature at which transition of the alloy from martensitic phase to austenitic phase starts) is specified for each alloy. Each alloy inherently also has a characteristic A(90) temperature (which is the temperature at which the transformation from martensitic phase to austenitic phase is 90% complete). It is appropriate to define alloys which are preferred for use in the device of the present invention in terms of their A(90) temperature since, for the alloy to be capable of being deformed by the formation of martensite under stress, it is necessary for the alloy initially to be at least partially, preferably completely, in the austenitic phase. Like the M_S temperature, the A(90) temperature is an inherent characteristic of the alloys disclosed in US-4505767, so that the disclosure therein of alloys having the compositions set forth in Table I represents also the disclosure of alloys having the A(90) values set forth in the table to be included on page 8 of the description.

The table incorporated on page 8 sets out M_S and A(90) data for the alloys disclosed in US-4505767. The data is the subject of a 37 CFR §1.132 declaration submitted herewith. It is believed that amendment of the description by inclusion of the data set out in the table does not involve the addition of subject matter.

Amendments to the claims:

MPO884-US4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	)	Group Art Unit: 331
	)	
James E. Jervis	)	Examiner: C. Sam
	)	
Serial No. 177,817	)	Raychem Corporation
	)	300 Constitution Drive
Filed: March 30, 1988	)	Menlo Park, CA 94025
	)	
For: Medical Devices Incorporating SIM Alloy Elements	)	August 1, 1988

DECLARATION UNDER 37 CFR §1.132

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Thomas W. Duerig of 41618 Mission Creek Drive, Fremont, CA 94539 hereby declare as follows:

1. I hold a BS Degree in physics from Lehigh University, and ME and Ph.D Degrees in metallurgy from Carnegie-Mellon University. I have worked in the field of shape memory alloys for eight years.

2. For the last five years, I have been employed by Raychem Corporation of 300 Constitution Drive, Menlo Park, California 94025-1164 in its metals division to develop inter alia shape memory alloys and devices employing such alloys.

3. US Patent No. 4505767 relates to shape memory alloys which consist essentially of nickel, titanium and vanadium

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on 8/11/88 (Date of Deposit)
Tammi Haskins
Name of applicant, assignee, or Registered Representative

and which were developed by Mary P. Quin who, at the time, was also employed by Raychem Corporation in the metals division.

4. The compositions, and aspects of the thermomechanical behavior, of certain Ni-Ti-V alloys are disclosed in Table I in column 6 of US-4505767. The disclosed alloys have characteristic martensite-austenite transformation temperatures of which the M_S temperatures are set forth in the table.

5. The table which forms part of this declaration sets forth M_S and A(90) temperatures for alloys disclosed in Table I of US-4505767. The A(90) temperature is the temperature at which the transformation from the martensite phase to the austenite phase is 90% complete. Like the M_S temperature, the A(90) temperature is an inherent characteristic of the alloys disclosed in US-4505767, so that the disclosure therein of alloys having the compositions set forth in Table I represents also the disclosure of alloys having the A(90) values set forth in the table below.

6. The data included in the table below have been compiled by me from technical records of the metals division of Raychem Corporation, which were compiled during the development of the alloys which form the subject of US-4505767.

I declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under the provisions of 18 U.S.C.

1001 and that such willful false statements may jeopardize the validity of any patent issuing upon the application.

FURTHER DECLARANT SAYETH NOT.

Thomas W. Lee

Declared at Menlo Park, California
on Aug 9, 1988.

TABLE

Composition (atomic percent)

Ni	Ti	V	M_S	A(90)
49.50	43.50	7.00	-107	-88
50.00	44.00	6.00	-96	-84
49.00	43.00	8.00	-83	-61
50.00	45.00	5.00	-42	-33
49.00	45.00	6.00	-35	-12
50.50	48.00	1.50	-32	-6
48.50	44.50	7.00	-30	-13
50.00	46.00	4.00	-11	7
48.50	45.00	6.50	-10	15
49.00	45.50	5.50	-10	14
48.00	44.25	7.75	-7	8
48.50	45.50	6.00	-5	27
41.50	38.50	20.00	-2	86
46.50	43.50	10.00	-1	50
36.25	33.75	30.00	0	42
49.50	46.00	4.50	6	35
48.00	46.00	6.00	12	36
47.75	45.75	6.50	20	54
47.50	45.50	7.00	26	58
48.50	46.50	5.00	27	58
45.00	45.00	10.00	30	71
47.50	46.50	6.00	32	71
46.50	46.50	7.00	34	70

33C

#10 1/2

9438

GAU 3/16

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

James E. Jervis

Examiner: D. Keneally

Serial No.: 07/956,653

Group No. 3301

Filed: October 2, 1992

For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

Commissioner of Patents and Trademarks
Washington, D.C. 20231

STATUS INQUIRY

1. More than 3 months have passed since the filing of a response on 11/24/1993. No further communication has been received from the Patent and Trademark Office.

2. Kindly advise the undersigned of the present status of this application, by checking the appropriate box on the next page. A stamped return-addressed envelope is provided.

Respectfully submitted,

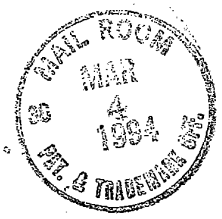
SHELDON & MAK

Date: 2/28/94

Jeffrey G. Sheldon
Reg. No. 27,953

225 South Lake Avenue
9th Floor
Pasadena, California 91101
(818) 796-4000

pc96\deborah\ptltrs\9000\9438.si



STATUS INQUIRY REPLY

APPLICATION SERIAL NO. 07/956,653 IS CURRENTLY

☐ ASSIGNED TO GROUP _____ AND AWAITS:

☐ ACTION BY THE EXAMINER

☐ APPLICANT'S RESPONSE TO THE OFFICE ACTION MAILED_____

☐ OTHER _____

pc96\deborah\ptltrs\9000\9438.si

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/[illegible]3	10/02/92	JERV J	[illegible]

KENEALY, D
EXAMINER

F3M1/0307

JEFFREY G. SHELDON
SHELDON & MAK
225 S. LAKE AVENUE - 9TH FLOOR
PASADENA, CA 91101

ART UNIT	PAPER NUMBER
	11

DATE MAILED: 03/07/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-57 are pending in the application.
   Of the above, claims 15,16,22,23, 37-40,43,54 are withdrawn from consideration.
2. ☑ Claims 1-10 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 11-14,17-21, 24-36, 41,42, 44-53,55-57 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☑ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev.9-89)

Applicant should note that preliminary amendment B filed 1/5/93 added a claim 54 (subsequently restricted). Applicant's additional claims 54-56 have been renumbered as claims 55-57. Applicant should refer to these claims as claims 55-57 in any later communications.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed. Applicant's declaration defining the A(90) temperature as the temperature at which 90% of the material has been transformed from martensite to austenite is not sufficient to now allow a claim for a specific value for the A(90) temperature being 0 degrees C. Nowhere in applicant's specification does he state the criticality of such a temperature for the A(90) temperature, nor does he ever state a preferred range in which the A(90) temperature should fall.

Claims 11-14,17 and 18 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim 25 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It cannot be discerned from the drawings or the specification how the SIM material inside a catheter can be deformed in a transverse dimension. If this claim is directed towards an IUD, it should have been restricted from this application. Examiner cannot find support for such a deformation of the catheter SIM invention.

Claims 11-14,17-21,24-27,31-36,41,42,44-53 and 55-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 4,665,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are directed towards a restraint in combination with an SIM medical device.

Claims 28-30 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 4665906 in view of Wilson. To have made the restraint out of SIM material and the catheter out of non-SIM material is well known in the art as shown by Wilson.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102

> of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 19,20,26-28,41,42,45,47,48,49,50, and 57 are rejected under 35 U.S.C. § 103 as being unpatentable over the Wayman article titled, "Some Applications of Shape Memory Alloys", of applicant's disclosure (referred to as Wayman). Wayman discloses an SIM alloy that can be used in orthodontic dental wires. The wire is placed in a restraint (bands placed on the user's teeth) and exhibits SIM behavior at body temperature inside the mouth of the patient. This SIM behavior cause the wire to act more like a spring and retain pressure or tension on the treated teeth. When the wire is taken out of the mouth it is assumed that the wire will return to its austenitic state and straighten out of the stress induced martensite state. The Wayman disclosure of the orthodontic device does not specifically disclose the use of SIM material for the wire, but the disclosure does describe the use of SIM as natural property of SMA's in general. It is not believed to have been outside of the scope of the skilled artisan to have used a wire with an Af temperature at about body temperature such that this

"super-elasticity" region can be taken advantage of in an orthodontic device as described later in the Wayman article.

Claims 21,29 rejected under 35 U.S.C. § 103 as being unpatentable over Wayman in view of Wilson. Wayman discloses the use of SIM alloys that exhibit SIM behavior at body temperature. Wilson teaches the use of SMA's in a catheter. It would have been obvious to have used the Wayman alloy in a catheter because if one had desired to have a catheter that could be bent and instantly retain its original unbent shape when the stress induced martensite transforms back to austenite, one could have looked to Wayman to see that such a material was available.

RESPONSE TO APPLICANT'S REMARKS

Applicant's remarks have been considered but are deemed moot in light of the new rejections set forth. This action has not been made final since the new rejection was not necessitated by applicant's amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Kenealy whose telephone number is (703) 308-2680.

DJK
David J. Kenealy
March 7, 1994

ROBERT A. WAUGH
S.P.E.
ART UNIT 331

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
95453			

EXAMINER	
ART UNIT	PAPER NUMBER
	12

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

(1) Mr. Sheldon (3) _____

(2) Exr. Keneally (4) _____

Date of interview 6/30/94

Type: ☐ Telephonic ☑ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☑ No. If yes, brief description: _____

Agreement ☑ was reached with respect to some or all of the claims in question. ☐ was not reached.

Claims discussed: all

Identification of prior art discussed: Wayman and Wilson -DJK

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Examiner agrees that the inclusion of a limitation requiring the restraining means to engage and stress the memory alloy element at a temperature below body temperature will define over the Wayman article as applied in the 3/7/94 rejection.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.) 112 rejecti was

Unless the paragraphs below have been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1–7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☑ It is not necessary for applicant to provide a separate record of the substance of the interview. discussed and case law was left with the examiner. (except Vos-Cath design case

☐ Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action.

David G Keneally
Examiner's Signature

PTOL-413 (REV. 1-84)

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110 - 115 group
198 - 103
296 - 102 GW 331
9438 9/25

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Group Art Unit: 3301**
JAMES E. JERVIS	**Examiner: KENEALY, D.**
Serial No.: 07/956,653	
Filed: October 2, 1992	**Pasadena, CA**
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	

330

#13 | ext 1

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

REQUEST FOR EXTENSION OF TIME IS GRANTED BY AUTHORITY OF THE PRIMARY EXAMINER FOR 1 mo.

Clerk, Group 330

H.C.P. ☐ ATTY Notified ☐

AMENDMENT

Sir:

In response to the Office Action of March 7, 1994, please amend the above-identified application as follows:

IN THE CLAIMS

Please amend Claim 16, 19, 23, 27, 28, 30, 32, 33, 42, and 57 as follows:

Claim 16, line 1, change "14" to --13--.

Claim 19, line 10, after "body" insert --in its deformed configuration--.

090 BA 07/12/94 07956653 1 102 296.00 CK
090 BA 07/12/94 07956653 1 103 198.00 CK
090 BA 07/12/94 07956653 1 115 110.00 CK

Claim 23, line 1, change "21" to --20--.

Sub F2 27. (Twice Amended) A medical device suitable for placement within or proximate to a mammalian body for treatment of the mammalian body, the device comprising:

(a) a memory alloy element formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying 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 memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element can be positioned within or in proximity to the mammalian body while the memory alloy element is in its deformed shape;

wherein the alloy is selected so that removal of the restraining means from the memory alloy element at a temperature greater than the As of the alloy when the device is placed within or proximate to the mammalian body, transforms at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape toward its unstressed shape, without any change in temperature of the restraining means or the memory alloy element being required for the transformation of the alloy.

28. (Twice Amended) A medical device for treatment of a mammalian body, the device comprising:

(a) a memory alloy element formed at least partly from a 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; and

(b) a hollow restraining member with the memory alloy element being within the restraining member, the restraining member engaging and stressing the memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element can be positioned within or in proximity to the mammalian body while the memory alloy element is in its deformed shape;

wherein the restraining member and the memory alloy element are movable relative to each other to transform at least a portion of the alloy from its stress-induced martensitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the memory alloy element.

Claim 30, line 1, change "27" to --29--.

Claim 32, lines 5 and 7, change "means" to --member--.

~~33.~~ (Twice Amended) A medical device for insertion into a ~~mammalian~~ human body, the device comprising (i) a restraining member and (ii) a hollow catheter formed at least party from a pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about human body temperature such that it has a stress-induced martensitic state and an austenitic state, the catheter having (i) an easily inserted 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;

the [restraint] restraining member engaging and stressing the catheter at a temperature greater than the As of the alloy so that the catheter is in its easily inserted shape so that the catheter can be inserted into the mammalian body;

wherein disengagement of the restraining member from the catheter at a temperature greater than the As of the alloy transforms at least a portion of the alloy from its stress-induced martensitic state to its austenitic state so that the catheter transforms from its easily inserted shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the catheter.

Claim 42, line 3, change "means" to --member--.

57. (Amended) A medical device suitable for placement within or proximate to a mammalian body for treatment of the mammalian body, the device comprising (i) a restraint, and (ii)

an element formed at least partly from a pseudoelastic shape-memory alloy,

the alloy displaying reversible stress-induced martensite by virtue of being above its A_s and above its M_s and below its M_d at about body temperature;

such that it has a stress-induced martensitic state and an austenitic state, the element having (i) a deformed shape when the alloy is in its stress-induced martensitic state and (ii) a different unstressed shape;

wherein the restraint is capable both (i) stressing the element for placement of the element in its deformed shape in or in proximity to the mammalian body, and (ii) of being at least partially removed from the element while the device is within or proximate to the [said] body at the [said] body temperature and the element is therefore at an operating temperature greater than the A_s and M_s and below the M_d of the alloy,

such removal of the restraint causing at least a portion of the alloy to transform from its stress-induced martensitic state to its austenitic state so that the element spontaneously transforms from its deformed shape toward its unstressed shape,

and such transformation can occur without a change in temperature of the restraint or of the element from the operating temperature.

Please add claims 58-65 to the application.

58. A medical device for treatment of a ~~mammalian~~ human body, the device comprising:

(a) a memory alloy element formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about human 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; and

(b) a hollow tubular restraining member with the memory alloy element being within the restraining member, the restraining member engaging and stressing the memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element is in its deformed shape;

wherein the memory alloy element is axially slidable within the tube, and wherein the memory alloy element can be extruded completely out of the tube for deployment in the mammalian body to transform at least a portion of the alloy from its stress-induced martensitic state towards its austenitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the memory alloy element.

59. A medical device which comprises:

(a) a tubular element for use within a ~~mammalian~~ human body or in such proximity to a ~~mammalian~~ human body that the device is substantially at body temperature, the tubular element comprising a shape memory alloy which displays stress-induced martensite behavior at body temperature; and

(b) a restraint within the tubular element holding and deforming the tubular shape memory alloy element in a deformed configuration to allow it to be positioned within or in proximity to a ~~mammalian~~ human body, the deformation occurring through the formation of stress-induced martensite;

wherein the tubular element is sufficiently deformed that removal of the restraint from the tubular shape memory alloy element, without change in temperature of the device, releases at least a portion of the tubular element from its deformed configuration.

60. A medical device for treatment of a mammalian body, the device comprising (i) a restraining member and (ii) a hollow memory alloy element formed at least partly from a 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;

the restraining member being within the hollow memory alloy element and engaging and stressing the memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element can be positioned within or in proximity to the mammalian body while the memory alloy element can be positioned within or in proximity to the mammalian body while the memory alloy element is in its deformed shape;

wherein the restraining member and the memory alloy element are movable relative to each other to transform at least a portion of the alloy from its stress-induced martensitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the memory alloy element.

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~~61~~. The device of Claim ~~60~~ 36 wherein the memory alloy element is a tube and the restraining member is axially slidable within the tube, and wherein the tube is sufficiently long that relative axial movement between the tube and the restraining member extends at least a portion of the tube beyond the restraining member and thereby transforms the tube toward its austenitic shape.

Sub F5

62. A medical device for insertion into a mammalian body, the device comprising ~~(i)~~ a restraining member and (ii) a hollow catheter formed at least partly from a 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 catheter having (i) an easily inserted 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;

the restraining member engaging and stressing the catheter at a temperature greater than the As of the alloy so that the catheter is in its easily inserted shape so that the catheter can be inserted into the mammalian body; and

wherein disengagement of the restraining member from the catheter at a temperature greater than the As of the alloy transforms at least a portion of the alloy from its stress-induced martensitic state to its austenitic state so that the catheter transforms from its easily inserted shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the catheter.

~~63.~~ 39 The invention of Claim ~~58~~ 34, ~~60~~ 36, or ~~61~~ 37 wherein the transformation of the alloy occurs without any change in the state of the restraining member.

~~64.~~ 40 The device of Claim ~~62~~ 38 wherein the device is adapted so that (i) the restraining member can be completely disengaged and separated from the catheter, and (ii) re-engaging the restraining member with the catheter after separation results

in the catheter transforming toward its easily inserted shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

REMARKS

Claims 11-64 are pending in this application, Claims 1-10 have been canceled, and Claims 15, 16, 22, 23, 25 (after this amendment), 37-40, 43, and 54 have been withdrawn from consideration. All of the claims originally submitted and examined were rejected. Claims 58-64 are added by this amendment. Re-examination, reconsideration, and allowance are respectfully requested.

Entry of the amendments to the claims originally submitted is respectfully requested. Claims 16, 23, and 30 have been amended to correct their dependency; Claims 19, 27, 28, 33, and 57 have been amended to make it clear that the because of the restraint, the shape memory alloy element can be positioned within or in proximity to a mammalian body while it is in its deformed configuration. Claims 32 and 42 have been amended to use the correct antecedent term, namely, "restraining member."

New claim 58 is claim 30 rewritten in independent form, rewritten as if it depended from Claim 29 (which it should have in the first place).

Claim 59 is Claim 24 rewritten in independent form.

Claims 60-64 correspond to claims 31, 32, 33, 42, and 51, respectively, where the independent claims include the limitation that the memory alloy element can be positioned within or in proximity to the mammalian body while it is in its deformed shape as a result of the restraining member.

REJECTION UNDER 35 U.S.C. 112

Claims 11-14, 17, 18, 25 were rejected under 35 U.S.C. § 112. With regard to the rejection under 35 U.S.C. § 112, of Claim 20, applicant agrees that Claim 25 should be withdrawn from consideration. The rejection of the remaining claims is respectfully traversed.

Claims 11-14, 17, and 18 were rejected under the first paragraph of 35 U.S.C. § 112 on the basis that the specification, as originally filed, does not provide support for the invention as it is claimed. In particular, the Office Action contends that the definition in the specification of the A(90) temperature and including a specific value of 0° C is not supported by the specification as originally filed. This rejection is respectfully traversed.

Both the Federal Circuit and the CCPA have held that including in the claims an inherent limitation of a composition described in the patent application is permissible. See Kennecott Corp. v. Kyocera International, Inc., 5 USPQ 2d 1194, 835 F.2d 419 (Fed. Cir. 1987); In Re Nathan, 140 USPQ 601, 321

F.2d 1005 (CCPA 1964). In the Kennecott decision, the Federal Circuit held that it is permissible to add to the claims the limitation that a ceramic body has a predominantly "equitaxed microstructure", even though the original application did not disclose such a structure, because the structure was inherent in the original disclosure. The Court stated:

> "The disclosure in a subsequent patent application of an inherent property of a product does not deprive that product of the benefit of an earlier filing date. Nor does the inclusion of a description of that property in later-filed claims change this reasonable result."

5 USPQ 2d at 1198.

Similarly, in Nathan, the CCPA held that it is permissible to include in the claims the limitation that a particular compound had an alpha orientation, even though that was not in the original disclosure, because it was "merely a statement of an inherent property of the steroids as disclosed in appellants' original disclosure."

If it is the examiner's position that applicant was required to indicate in the disclosure that 0°C is a preferred temperature for the A(90) temperature of the alloys, that contention is respectfully traversed. The requirement of 35 U.S.C. § 112, first paragraph, is: "The specification shall contain a written description of the invention . . . ". There is nothing in section 112 that requires the applicant to specify

that a particular limitation is preferred or critical; 112 only requests that the invention as claimed be described. See for example, In Re Eickmeyer, 202 USPQ 65 (CCPA 1979), where the CCPA held that a specification supported adding to the claims the limitation, "at least about 56° C". In that case, the patent office contended that the description requirement of 35 U.S.C. § 112 was not satisfied because applicant had not disclosed that 56° C was a minimum or critical lower limit for operation of the process. The CCPA reversed that rejection noting that the appellant was entitled to claim a range of temperatures below 56°C and above 56°C, stating:

> We are not persuaded that there is any requirement for the appellant to demonstrate the *criticality* of a lower limit to meet the description requirement. (Emphasis original.)

202 USPQ at 663.

The examiner's attention is also directed to the Federal Circuit decision in Vas-Cath, Inc. v. Mahurkaas, 35 F.2d 1555 (Fed. Cir. 1991), where the Federal Circuit held that a design patent application provided a sufficient basis under 35 U.S.C. § 112 for a utility patent. Certainly, if a design application, which contains substantially nothing but drawings, can support a utility patent application, applicant's disclosure herein supports the claims presented.

For these reasons, removal of the rejection under 35 U.S.C. § 112 is respectfully requested.

DOUBLE PATENTING REJECTION

Certain claims were rejected under the judicially created doctrine of obviousness-type double patenting. Applicant, without prejudice, to expedite prosecution, is willing to file a terminal disclaimer on resolution of the remaining issues present in this application.

ALLOWABLE CLAIMS

Upon filing of the terminal disclaimer, it is believed that Claims 24, 30-56, 35, 36, 42 (31, 33), 44 (35), 45 (31), 46, 48 (31, 33), 50 (48 (31, 33)), 51, 52, and 53 are allowable. Moreover, all of the new claims, are likewise allowable. In particular, Claims 58 and 59 are claims that are believed to be allowable based on the prior office action, rewritten in independent form. Claim 60-64 are narrower versions of claims containing allowable subject matter.

REJECTION UNDER 35 U.S.C. SECTION 103

Claims 19, 20, 26-28, 41, 42, 45, 47-50, and 57 were rejected under 35 U.S.C. 103. The rejection was based upon the Wayman article alone. In addition, Claims 21 and 29 were rejected as unpatentable over Wayman in view of Wilson. These rejections are respectfully traversed as applied to these claims as you presented.

It is believed that the claims as originally submitted are allowable over Wayman alone or Wayman in combination with Wilson. However, to further distinguish the claimed subject

matter over these two references, certain of the claims have been amended. In particular, all of the claims rejected under 35 U.S.C. § 103 now state that the restraining member stresses the SIM memory allow element so that the memory allow element can be positioned within or in proximity to the mammalian body while it is in a deformed shape, something not suggested by these references.

In particular, it is contended in the office action that Wayman suggests or teaches the use of dental wires using SIM (Stress-Induced Martensite) alloys. However, Wayman's device is clearly of the kind which is inserted into the body in an unstressed state, and is subsequently stressed within the body and fixed in the stressed state, so as to apply corrective pressure to a misaligned tooth.

The Wayman pressure-applying device does not require or suggest the presence of a restraint, which is essential to the claimed invention, for holding the SIM device in the deformed state during insertion into the body. There is no need in Wayman for a restraint to be applied to the dental wire before it is positioned in the body, since it is unstressed during insertion. Indeed, it is difficult to imagine how a pre-insertion restraint could be used with the dental wires, given their elongated form.

The claims presented specifically require that the restraint stresses the SIM memory alloy element so that it can be "positioned within or in proximity to the mammalian body while the memory alloy element is in its deformed shape." (See, for example, Claim 27.) The claimed device is constructed so that,

after the deformed device held in the restraint has been positioned within the body, the restraint can be removed to allow the SIM element to recover to its unstressed shape.

The claimed devices with the insertion restraint are highly advantageous in surgical techniques whereas the unstressed shape, to which the SIM element reverts on removal of the restraint within the body, is important for the therapeutic effect. This ability to release the unstressed shape after placing the SIM element where it is needed for treatment is the antithesis of deforming and stressing the element within the body, which would be essential to the use of an SIM dental wire.

Thus, the claimed "shape-forming" device claims should be regarded as a different class of medical devices from the "pressure-applying" Wayman device. The problems encountered in surgical use of the shape-forming devices generally are quite different from those of the pressure-applying devices, and it must be recognized that each special surgical procedure has its own unique set of problems.

Part of the claimed invention is the recognition of the problem in prior art devices that rely on temperature change. Note that Claim 27, for example, specifically states that the change in shape of the SIM member can occur "without any change in temperature of the restraining means or the memory alloy element".

Wilson does nothing to remedy the deficiencies of Wayman. Wilson, in fact, teaches away from the invention, in that Wilson requires a change in temperature of the catheter for

it to be effective. This is completely contrary to what is claimed by applicant. In effect, Wayman teaches away from the use of SIM material in combination with a restraint.

Further, there is no suggestion in the references to place an SIM element inside a restraint as specified in Claims 20, 21, 28, 29, and claims dependent therefrom. The most Wayman teaches is an SIM element engaged with a device on a tooth, and Wilson does not teach the use of any restraint. In the Wilson device, the catheter 10 does not restrain the rod 16 in any configuration. Rather, the shape of the rod is dependent only upon temperature. Thus, neither reference suggests the use of an external restraint for maintaining an SIM element in a deformed configuration.

CONCLUSION

Thus, for these additional reasons, it is respectfully submitted that these claims are allowable.

SHELDON & MAK, INC.

Date: June 24, 1994

By: _____
Jeffrey G. Sheldon
Reg. No. 27,953

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225 South Lake Avenue
Suite 900
Pasadena, California 91101
(818) 796-4000 (213) 681-9000

AMENDMENT COVER SHEET

DOCKET NO. 9438

IN RE APPLICATION OF: JAMES E. JERVIS
SERIAL NO.: 07/956,653 FILED: October 2, 1992
FOR: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is a paper in the above-identified application. Any necessary extension of time period set for this paper is hereby requested.

☐ No additional fee is required.

☑ The fee has been calculated as shown below:

☑ EXTENSION FEE

	RATE Non-Small Entity	RATE Small Entity	FEE
FIRST MONTH AFTER TIME PERIOD SET	110.00	55.00	$110.00
SECOND MONTH AFTER TIME PERIOD SET	360.00	180.00	$
THIRD MONTH AFTER TIME PERIOD SET	840.00	420.00	$
FOURTH MONTH AFTER TIME PERIOD SET	1,320.00	660.00	$

☑ TOTAL EXTENSION FEE $ 110.00

☑ FEE FOR EXTRA CLAIMS added by Amendment in this response:

	Column 1 Number of Claims after Amendment	Column 2 Number Previously Paid for	Column 3 Number of Extra Claims	RATE Non-Small Entity	RATE Small Entity	FEE
TOTAL CLAIMS	55	MINUS 46	* = 9	x 22	x 11	$198.00
INDEPENDENT	12	MINUS 8	* = 4	x 74	x 37	$296.00
First presentation of multiple dependent claim				+ 230	+ 115	$

TOTAL FEE FOR EXTRA CLAIMS $ 494.00

* If the entry in Column 1 is less than the entry of Column 2, write "0" in Column 3.
** If the number of Total Claims previously paid for is less than 20, write "20" in this space.
*** If the number of Independent Claims previously paid for is less than 3, write "3" in this space.

☑ Enclosed is the fee of $604.00 by Check No. 5012

☐ Please charge Deposit Account No. 19-2090 in the amount of $ _____

☑ The Commissioner is hereby authorized to charge payment of any additional fees, in particular the following fees, associated with this communication, or credit any overpayment to Deposit Account No. 19-2090:

Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
Any patent application processing fees under 37 C.F.R. § 1.17

SHELDON & MAK

Date: June 24, 1994

By: _____
Jeffrey G. Sheldon
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RECEIVED
PATENT
9438
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GROUP: 330

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Group Art Unit: 3301
JAMES E. JERVIS	Examiner: KENEALY, D.
Serial No.: 07/956,653	
Filed: October 2, 1992	
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	Pasadena, CA

SUPPLEMENTAL AMENDMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

In response to the Office action of March 7, 1994, and as a supplement to the Amendment of June 24, 1994, please amend the above-identified application as follows:

IN THE CLAIMS

Please amend claims 19, 27, 28, 57, 60, and 62 as follows:

19. (Thrice Amended) A medical device which comprises:

(a) an element for use within a mammalian body or in such proximity to a mammalian body that the device is substantially at body temperature, the element comprising a shape memory alloy which displays a stress-induced martensite behavior at body temperature; and

(b) a restraint holding the shape memory alloy element in a deformed configuration at a temperature less than the body temperature of the mammal [to allow it to be positioned] for positioning the shape memory alloy element within or in proximity to a mammalian body in its deformed configuration, the deformation occurring through the formation of stress-induced martensite;

wherein the element is sufficiently deformed that removal of the restraint from the shape memory allow element, without change in temperature of the device, releases at least a portion of the element from its deformed configuration.

~~27.~~ 9 (Thrice Amended) A medical device suitable for placement within or proximate to a mammalian body for treatment of the mammalian body, the device comprising:

(a) a memory alloy element formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying

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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 memory alloy element at a temperature less than the body temperature of ~~the mammal~~ a human and greater than the As of the alloy [so that] for positioning the memory alloy element [can be positioned] within or in proximity to the mammalian body while the memory alloy element is in its deformed shape;

wherein the alloy is selected so that removal of the restraining means from the memory alloy element at a temperature greater than the As of the alloy when the device is placed within or proximate to the ~~mammalian~~ human body, transforms at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape toward its unstressed shape, without any change in temperature of the restraining means or the memory alloy element being required for the transformation of the alloy.

~~28~~ 10. (Thrice Amended) A medical device for treatment of a mammalian body, the device comprising:

(a) a memory alloy element formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying

reversible stress-induced martensite at about human 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; and

(b) a hollow restraining member with the memory alloy element being within the restraining member, the restraining member engaging and stressing the memory alloy element at a temperature less than the body temperature of the ~~mammal~~ human and greater than the As of the alloy [so that] for positioning the memory alloy element [can be positioned] within or in proximity to the mammalian body while the memory alloy element is in its deformed shape;

wherein the restraining member and the memory alloy element are movable relative to each other to transform at least a portion of the alloy from its stress-induced martensitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the memory alloy element.

33. ~~57.~~ (Twice Amended) A medical device suitable for placement within or proximate to a mammalian body for treatment

of the mammalian body, the device comprising (i) a restraint, and (ii) an element formed at least partly from a pseudoelastic shape-memory alloy,

the alloy displaying reversible stress-induced martensite by virtue of being above its A_s and above its M_s and below its M_d at about body temperature;

such that it has a stress-induced martensitic state and an austenitic state, the element having (i) a deformed shape when the alloy is in its stress-induced martensitic state and (ii) a different unstressed shape;

wherein the restraint is [capable both] (i) stressing the element <u>at a temperature less than the body temperature of the mammal</u> for placement of the element in its deformed shape in or in proximity to the mammalian body and (ii) <u>is capable</u> of being at least partially removed from the element while the device is within or proximate to the body at the body temperature and the element is therefore at an operating temperature greater than the A_s and M_s and below the M_d of the alloy,

such removal of the restraint causing at least a portion of the alloy to transform from its stress-induced martensitic state to its austenitic state so that the element spontaneously transforms from its deformed shape toward its unstressed shape,

and such transformation can occur without a change in temperature of the restraint or of the element from the operating temperature.

~~60.~~ 36 (Amended) A medical device for treatment of a ~~mammalian~~ human body, the device comprising (i) a restraining member and (ii) a hollow memory alloy element formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about human 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;

the restraining member being within the hollow memory alloy element and engaging and stressing the memory alloy element at a temperature less than the body temperature of the human ~~mammal~~ and greater than the As of the alloy [so that] for positioning the memory alloy element [can be positioned] within or in proximity to the ~~mammalian~~ human body [while the memory alloy element can be positioned within or in proximity to the mammalian body] while the memory alloy element is in its deformed shape;

wherein the restraining member and the memory alloy element are movable relative to each other to transform at least a portion of the alloy from its stressed-induced martensitic

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state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member of the memory alloy element.

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~~62.~~ (Amended) A medical device for insertion into a human ~~mammalian~~ body, the device comprising (i) a restraining member and (ii) a hollow catheter formed at least partly from a pseudoelastic shape-memory allow, the alloy displaying reversible stress-induced martensite at about human body temperature such that it has a stress-induced martensitic state and an austenitic state, the catheter having (i) an easily inserted 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;

the restraining member engaging and stressing the catheter at a temperature less than the body temperature of the ~~mammal~~ human and greater than the As of the alloy so that the catheter is in its easily inserted shape [so that the] for inserting the catheter [can be inserted] into the ~~mammalian~~ human body; and

wherein disengagement of the restraining member from the catheter at a temperature greater than the As of the alloy transforms at least a portion of the alloy from it stress-induced

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martensitic state to its austenitic state so that the catheter transforms from its easily inserted shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the catheter.

REMARKS

Applicant wishes to thank the Examiner for the courtesy shown to Applicant's attorney, the undersigned, during the interview on June 30, 1994.

As indicated during the interview, and as stated on the Examiner's Interview Summary Record:

> "Examiner agrees that the inclusion of the limitation requiring the restraining means to engage and stress the memory alloy element at a temperature below body temperature will define over the Wayman article . . . ."

In accordance with that statement, the independent claims pending in this application that were subject to rejection under 35 U.S.C. § 103 (namely claims 19,27, 28, and 57) have been

so amended. In addition, other claims, namely claims 60 and 62, which were not so rejected, have been amended.

As indicated in the interview, for the purposes of a response, Applicant has assumed that Wayman teaches an SIM dental wire. However, as appreciated by the Examiner in the interview, Wayman's SIM dental wire is not stressed until it is in the mouth, and thus Wayman does not teach or suggest a restraining means "engaging and stressing the memory alloy element at a temperature less than the body temperature of the mammal."

Therefore, for this reason and in addition the reasons presented in the prior amendment, allowance of all of the claims is respectfully requested.

Applicant wishes to remind the Examiner of two comments made by Applicant's attorney during the interview. In particular, it was noted that at page 12, line 3, the word is "equiaxed" and not "equitaxed". It was also noted that at page 15 of the amendment, the paragraph bridging pages 15 and 16, in the first sentence, the claims being referred to were the claims rejected under 35 U.S.C. § 103. Not all of the claims presented include the limitations specified in that sentence, but only the

claims that were being argued with regard to the rejection under § 103.

Another typographical error has been noted. At page 11, line 9, the reference is to claim 25 and not claim 20.

Respectfully submitted,

SHELDON & MAK

Dated: July 28, 1994

By: _____
JEFFREY G. SHELDON
Regis. No. 27,953

AMENDMENT COVER SHEET

DOCKET NO. 9438

IN RE APPLICATION OF: **JAMES E. JERVIS**

SERIAL NO.: **07/956,653** FILED: **OCTOBER 2, 1992**

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

RECE
JUL 29 94
GROUP: 330

HONORABLE COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

334
Kenealy

Sir:

Transmitted herewith is a paper in the above-identified application. Any necessary extension of time period set for this paper is hereby requested.

[X] No additional fee is required.

[ ] The fee has been calculated as shown below:

[ ] EXTENSION FEE

	RATE Non-Small Entity	RATE Small Entity	FEE
FIRST MONTH AFTER TIME PERIOD SET	110.00	55.00	$
SECOND MONTH AFTER TIME PERIOD SET	360.00	180.00	$360.00
THIRD MONTH AFTER TIME PERIOD SET	840.00	420.00	$
FOURTH MONTH AFTER TIME PERIOD SET	1,320.00	660.00	$

[X] No extension fee is necessary because the original amendment was filed with the extension fee already paid.

[ ] FEE FOR EXTRA CLAIMS added by Amendment in this response:

	Column 1 Number of Claims after Amendment	Column 2 Number Previously Paid for	Column 3 Number of Extra Claims	RATE Non-Small Entity	RATE Small Entity	FEE
TOTAL CLAIMS		MINUS **	* =	x 22	x 11	$
INDEPENDENT		MINUS ***	* =	x 74	x 37	$
First presentation of multiple dependent claim				+ 230	+ 115	$

TOTAL FEE FOR EXTRA CLAIMS $ _____

* If the entry in Column 1 is less than the entry of Column 2, write "0" in Column 3.
** If the number of Total Claims previously paid for is less than 20, write "20" in this space.
*** If the number of Independent Claims previously paid for is less than 3, write "3" in this space.

[ ] Enclosed is the fee of $_____ by Check No. _____

[ ] Please charge Deposit Account No. 19-2090 in the amount of $ _____

[X] The Commissioner is hereby authorized to charge payment of any additional fees, in particular the following fees, associated with this communication, or credit any overpayment to Deposit Account No. 19-2090:

Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
Any patent application processing fees under 37 C.F.R. § 1.17

SHELDON & MAK

Date: 7/28/94

By: _____
Jeffrey G. Sheldon, Reg. No. 27,953

SHELDON & MAK
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PASADENA, CALIFORNIA 91101
(818) 796-4000 - Direct Line: (818) 356-1201

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/956,653	10/02/92	JERVIS	J 9438

EXAMINER
KENEALY, D

ART UNIT	PAPER NUMBER
3301	15

DATE MAILED: 10/31/94

F3M1/1031

JEFFREY G. SHELDON
SHELDON & MAK
225 S. LAKE AVENUE - 9TH FLOOR
PASADENA, CA 91101

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 7/29/94 ☑ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1-64 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☑ Claims 1-10, have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 11-64 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☑ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed. Applicant's declaration defining the A(90) temperature as the temperature at which 90% of the material has been transformed from martensite to austenite is not sufficient to now allow a claim for a specific value for the A(90) temperature being 0 degrees C. Nowhere in applicant's specification does he state the criticality of such a temperature for the A(90) temperature, nor does he ever state a preferred range in which the A(90) temperature should fall.

Claims 11-14,17 and 18 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim 25 is withdrawn since it is drawn to a non-elected species of invention.

Claims 11-14,17-21,24-27,31-36,41,42,44-53,55-57,59 and 60-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S.

Patent No. 4,665,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are directed towards a restraint in combination with an SIM medical device.

Claims 28-30,58 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 4665906 in view of Wilson. To have made the restraint out of SIM material and the catheter out of non-SIM material is well known in the art as shown by Wilson.

Claims 19,20,21,26-29,41,42,45,47,48,49,50,57 and 63 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's amended language requires the element to be restrained in a deformed configuration at a temperature **less than** body temperature. The claim also states that this deformation occurs through the formation of stress-induced martensite at that temperature less than body temperature. However, the device is earlier claimed as exhibiting stress-induced martensite behavior **at** body temperature.

RESPONSE TO APPLICANT'S REMARKS

Applicant's amended claim language is not believed to place the case in condition for allowance. Applicant is invited to discuss the claim language with the examiner to determine possible amendment to the claims to overcome the indefiniteness rejection.

With regard to the rejection under 35 USC 112 1st paragraph, it should be noted that if applicant believes that the A(90) temperature being greater than 0 degrees C is an inherent quality of any SIM material, then the only true limitation that claim 11 has is that the material exhibits stress induced martensite at body temperature. Examiner does not consider the value of A(90) temperature being 0 degrees C to be inherent. Thus this limitations is considered to be a new limitation presently set forth in the claims with no basis in the original specification.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Kenealy whose telephone number is (703) 308-2680.

DJK

David J. Kenealy
October 31, 1994

Robert W. Weig

AMENDMENT COVER SHEET

370-116 GP 330

DOCKET NO. 9438/MP0884-US7

IN RE APPLICATION OF: James A. Jervis

SERIAL NO.: 07/956,653 FILED: #16 BW 3/30

FOR: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is a paper in the above-identified application. Any necessary extension of time period set for this paper is hereby requested.

☐ No additional fee is required. [Mail to **Box Non Fee Amendment**]

☒ The fee has been calculated as shown below:

☒ EXTENSION FEE

	RATE Non-Small Entity	RATE Small-Entity	FEE
FIRST MONTH AFTER TIME PERIOD SET	110.00	55.00	$
SECOND MONTH AFTER TIME PERIOD SET	370.00	185.00	$370.00
THIRD MONTH AFTER TIME PERIOD SET	870.00	435.00	$
FOURTH MONTH AFTER TIME PERIOD SET	1,360.00	680.00	$

☒ TOTAL EXTENSION FEE $370.00.

☐ FEE FOR EXTRA CLAIMS added by Amendment in this response:

	Column 1 Number of Claims after Amendment	Column 2 Number Previously Paid for	Column 3 Number of Extra Claims	RATE Non-Small Entity	RATE Small Entity	FEE
TOTAL CLAIMS		MINUS **	* =	x 22	x 11	$
INDEPENDENT		MINUS ***	* =	x 76	x 38	$
First presentation of multiple dependent claim				+ 240	+ 120	$

TOTAL FEE FOR EXTRA CLAIMS $ _____

REQUEST FOR EXTENSION OF TIME AUTHORITY OF THE PAPER 2 mos.

* If the entry in Column 1 is Less than the entry in Column 2, write "0" in Column 3.
** If the number of Total Claims previously paid for is Less than 20, write "20" in this space.
*** If the number of Independent Claims previously paid for is Less than 3, write "3" in this space.

☒ Enclosed is the fee of $370.00 by Check No. H.C.P. ☐

Clerk, Group 330

ATTY Notified ☐

☐ Please charge Deposit Account No. 19-2090 in the amount of $ _____.

☒ The Commissioner is hereby authorized to charge payment of any additional fees, in particular the following fees, associated with this communication, or credit any overpayment to Deposit Account No. 19-2090:

Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims.
Any patent application processing fees under 37 C.F.R. § 1.17.

Date: 3/8/95 By: _____
Jeffrey G. Sheldon, Reg. No. 27,953

CERTIFICATE OF MAILING: I hereby certify that the above-identified correspondence, which is attached, is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on March 9, 1995.

Date Signed: 3-9-95 By: _____
Signature

SHELDON & MAK
225 South Lake Avenue, 9th Floor
Pasadena, California 91101
(818) 796-4000 (213) 681-8000

Marilyn C. Paik
Type or Print Name

100 MG 03/27/95 07956653

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Mar. 8, 1995

#17
8w3/30

9438\MP0884-US7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	)	Group Art Unit: 3301
JAMES E. JERVIS	)	Examiner: KENEALY, D
Serial No. 07/956,653	)	
Filed: October 2, 1992	)	
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	)	Pasadena, California

DECLARATION

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U. S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D. C. 20231 ON

March 9, 1995
3-9-95
(DATE SIGNED)

I, Dr. John D. Harrison, declare:

BACKGROUND

1. As established in my attached resume, I am an expert metallurgist, with special knowledge of alloys exhibiting martensite/austenite transformation characteristics.

2. In particular, I received a B.S. and M.S. in Metallurgy from Pennsylvania State University and an Sc.D. in Metallurgy in 1958 from the Massachusetts Institute of Technology.

3. My professional experience includes almost 30 years as a metallurgist associated with Raychem Corporation where, among other projects, I worked on the research and development which lead to commercial shape memory alloy products, including those based upon titanium/nickel alloys.

4. I left Raychem in 1981 to start my own consulting business. In my consulting business I have continued my work in titanium/nickel alloys, as exhibited by the list of publications provided in my curriculum vitae. For example, since 1989 I have had two publications dealing with shape memory effects and titanium/nickel alloys. Also, I was co-editor on a chapter on "Metals" in *Electronic Materials and Processes Handbook*.

5. In my position as a consultant, one of the companies I consult for is Raychem, from whom I also receive a pension as a result of my retirement. I am charging Raychem Corporation for the time expended in preparing this declaration at my normal billing rates.

6. In addition to the publications listed in my attached resume, I am also the inventor or co-inventor of the following U.S. patents, which relate to shape memory alloys:

Patent No.	Title
3,753,700	HEAT RECOVERABLE ALLOY
4,035,007	HEAT RECOVERABLE METALLIC COUPLING
4,198,081	HEAT RECOVERABLE METALLIC COUPLING
4,337,090	HEAT RECOVERABLE NICKEL/TITANIUM ALLOY WITH IMPROVED STABILITY AND MACHINABILITY
4,565,589	NICKEL/TITANIUM/COPPER SHAPE MEMORY ALLOY

There are also foreign patents corresponding to at least some of these U.S. patents.

MATERIALS REVIEWED

7. In preparation for this declaration, I reviewed the above-identified patent application, the Office Action of October 31, 1994, for this application, and U.S. Patent No. 4,505,767 to Quin ("Quin"), which is incorporated by reference into the above-identified patent application.

CONCLUSIONS

8. I wish in this declaration to correct some misconceptions that appear in the Office Action of October 31, 1994.

9. A(90) temperature is an inherent property of any alloy that can transform from the martensitic phase to the austenitic phase. It represents the temperature of such an alloy, annealed under standard conditions, where the transformation from the martensitic phase to the austenitic phase is 90% complete. Just like water has a freezing point of 0°C at standard pressure, each alloy that exhibits SIM behavior inherently has a fixed A(90) temperature, which is a function of its specific composition, when annealed under standard conditions.

10. The A(90) of an alloy is dependent upon its composition. At least one and possibly more of the alloys described in the Quin example and prepared using standard annealing conditions, i.e., those described in the example of the Quin patent, has an A(90) temperature "of not more than 0°C", a limitation that appears in claim 11. Stating it in another way,

at least one, but definitely not all, of the alloys in the hexagonal area in Fig. 2 of the Quin patent inherently has an A(90) of not more than 0°C, when annealed under standard conditions.

11. Accordingly, claim 11 has at least two important limitations on the shape memory alloy that is used to form the medical device of claim 11, namely the alloy has to display SIM behavior at body temperature, and has to have an A(90) of not more than 0°C. These properties clearly are not satisfied by all shape memory alloys.

12. As the table added to the application (and which appears in issued U.S. Patent No. 5,067,957) clearly shows alloys within the scope of the Quin patent have A(90) that ranges from at least -88°C to 86°C.

13. A person of ordinary skill in the art, by reading the above-identified patent application, will recognize that the preferred shape memory alloy for use in at least some medical devices according to the present invention has an A(90) of not more than 0°C. This is because the application makes it clear the invention requires "an alloy element which displays stress-induced martensite at said body temperature for the shape memory alloy element." (page 5, lines 29-31). It is evident that an alloy with an A(90) of not more than 0°C will assure good SIM effect in the body temperature range. A(90) above 0°C would give a mix of SIM and SME or all SME in the body temperature range. An A(90) far below 0°C would give permanent deformation in the body temperature range.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application and any patent or patents resulting therefrom.

Respectfully submitted,

Date: 25 February 1995

By: John D. Harrison
John D. Harrison

CURRICULUM VITAE

JOHN D. HARRISON, SC.D.
Watsonville, California 95076-5333

PROFESSIONAL EXPERIENCE

October 1981 to Present

JACK HARRISON, INC. (formerly John D. Harrison, Metallurgist)

December 1966 to October 1981

RAYCHEM CORPORATION, Menlo Park, California

First metallurgist at the corporation; primary activity was the research and development which led to shape memory alloy products; most intimately involved with TiNi alloys, extensively involved with copper-base memory alloys; participated in initial laboratory development, first production, product introduction to customers, trouble-shooting field problems; alloy development, thermomechanical processing, melting techniques from gas-fired crucibles through induction, electron beam and plasma; strategy for proprietary protection and patents; corporate-wide metals selection, corrosion studies, failure analysis.

September 1959 to November 1966

WESTINGHOUSE RESEARCH LABORATORIES, Churchill Borough, Pennsylvania

Research into solidification phenomena; special topics included interface morphology of ice during freezing from saline solutions, embrittlement of chromium-copper castings and seeded growth of selenium single crystals under high pressure.

August 1958 to August 1959

FRITZ-HABER-INSTITUT DER MAX-PLANK-GESELLSCHAFT, Berlin, German

Post-doctoral study of internal oxidation in alloys.

EDUCATION

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Sc.D., Metallurgy, 1958
Thesis Advisor: Professor Carl Wagner

PENNSYLVANIA STATE UNIVERSITY

M.S., Metallurgy & Ensign, USNR 1953
B.S., Metallurgy 1952

MILITARY EXPERIENCE

July 1953 to July 1955

U.S. Navy, Ensign, then Lt. j.g.
USS LST 32
Home port: Naples, Italy

September 1949 to June 1953

NROTC Midshipman

LIST OF PUBLICATIONS

K.N. Melton & J.D. Harrison, "Corrosion of TiNi," *Proceeding of Shape Memory & Superelasticity Technologies Conference*, Asilomar, March 6-10, 1994, in publication.

J.D. Harrison & D.E. Harrison, co-editors, Chap. 5, "Metals," *Electronic Materials & Processes Handbook*, second edition, editors: C.A. Harper and R.M. Sampson (McGraw-Hill, New York, 1993), p 5.1-5.69.

J.D. Harrison, "Measurable Changes Concomitant with the Shape Memory Effect Transformation," *Engineering Aspects of Shape Memory Alloys*, editors T.W. Duerig, K.N. Melton, D. Stoeckel & C.M. Wayman, (Butterworth, Boston, 1990) p. 106-111.

C.M. Wayman & J.D. Harrison, "The Origins of the Shape Memory Effect," *JOM* 41 no. 9 26 (September 1989).

J.D. Harrison & D.E. Hodgson, "Use of TiNi in Mechanical and Electrical Connectors," *Shape Memory Effects in Alloys*, edited by A.J. Perkins (Plenum Press. New York, 1975), p. 517-523.

J.D. Harrison & D.E. Harrison, "Etch Pit Studies on Single Crystals of Hexagonal Selenium Grown from the Melt at High Pressures," *The Physics of Selenium and Tellurium*, edited by W.C. Cooper, (Pergamon Press, New York, 1969), p 115-134.

J.D. Harrison, "Seeded Growth of Selenium Crystals under High Pressure," *Journal of Applied Physics* 39 no. 8 3672 (July 1968).

J.D. Harrison, "Measurement of Brine Droplet Migration in Ice," *Journal of Applied Physics* 36 3811 (December 1965).

J.D. Harrison, "Solute Transpiration Pores in Ice," *Journal of Applied Physics* 36 326 (January 1965).

J.D. Harrison & W.A. Tiller, "Ice Interface Morphology and Texture Developed During Freezing," *Journal of Applied Physics* 34 3349 (November 1963).

J.D. Harrison & W.A. Tiller, "Controlled Freezing of Water," *Ice and Snow Properties, Processes and Applications*, edited by W.D. Kingery (Technology Press, Cambridge, Massachusetts, 1963) p 215.

J.D. Harrison & W.A. Tiller, "The Controlled Solidification of Aqueous Solutions," *Desalination Research Conference Proceedings, NAS-NRC* Publication 942 312 (1963).

J.D. Harrison & W.A. Tiller, "Optimum Conditions for Zone Refining," *Trans. AIME* 221 649 (June 1961).

J.D. Harrison & C. Wagner, "The Attack of Solid Alloys by Liquid Metals and Salt Melts," *Acta Met.* 7 722 (November 1959).

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U. S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D. C. 20231 ON

March 9, 1995

3-9-95 Mark Paul

(DATE SIGNED)

fee JP

qw 3.30.95

9438\MP0884-US7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Group Art Unit: 3301
JAMES E. JERVIS	Examiner: KENEALY, D
Serial No. 07/956,653	
Filed: October 2, 1992	Office Action Mailed: 10/31/94
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	Pasadena, California

#18 / G4

GW 6/29/95

AMENDMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

This is submitted in response to the final rejection of October 31, 1994. It is believed this response places this application in condition for allowance, and such allowance is respectfully requested.

OK to enter

IN THE CLAIMS

Cancel claim 54.

REMARKS

Claims 11-53 and 55-64 are in this application with claim 25 being withdrawn as being directed to a non-elected species of the invention. All the claims presented were rejected under 35 U.S.C. § 112 and/or for double-patenting. Reexamination, reconsideration, and allowance are respectfully requested.

DOUBLE-PATENTING REJECTION

All the claims under consideration have been rejected for double-patenting. Applicant respectfully disagrees with the Examiner that a terminal disclaimer is appropriate with regard to at least some of the claims subject to the double-patenting rejection. However, to expedite issuance of this application, a terminal disclaimer is submitted herewith.

SPECIES CLAIMS

Claims 15, 16, 22, 23, 25, 37-40, and 43 were withdrawn from consideration as being directed to a non-elected species. However, for the reasons detailed below and in view of the terminal disclaimer, the generic claims are allowable in this application, and thus the species claims should also be allowed.

REJECTION OF CLAIM 25

Claim 25 complies with 35 U.S.C. § 112. As the Examiner noted, at least the IUD version of the invention supports claim 25. Applicant recognizes that claim 25 is not under consideration. However, since a generic claim is allowable, claim 25 should be allowed.

REJECTION UNDER 35 U.S.C. § 112

REGARDING TEMPERATURE LIMITATIONS

Claims 19-21, 26-29, 41, 42, 45, 47-50, 57, and 63 were rejected under 35 U.S.C. § 112, second paragraph for being indefinite. In particular, the Examiner was not clear as to how

the element can be restrained in a deformed configuration at a temperature **less than body temperature**, while the claim also requires that the element display stress-induced martensite behavior **at body temperature.**

The undersigned placed a telephone call to the Examiner regarding this rejection in December, 1994, and it is believed that in view of the telephone conversation and the remarks made by the undersigned, the rejection will be withdrawn.

In particular, the two limitations referred to by the Examiner are two limitations on the claimed device, which are complimentary, and not inconsistent. The first limitation requires that the element which is used within a mammalian body be a shape memory alloy (SMA) which displays stress-induced martensite behavior at body temperature. In particular, this limitation requires that the element be made out of a particular alloy that has specific properties, namely SIM behavior at body temperature. This is a physical parameter of the element; analogous to Applicant specifying that the shape memory alloy has a melting temperature at body temperature.

The second limitation referred to requires that the restraining portion of the claimed medical device holds the shape memory alloy element in a deformed configuration at a temperature less than the body temperature of the mammal. In particular, the claimed combination of the SMA element and the restraint must at

some time be at a temperature less than body temperature, a limitation which helps distinguish over prior art dental arch wires. Using the same analogy above as with regard to the melting temperature of a shape memory alloy, this is akin to requiring that the medical device be provided at a temperature less than the melting point of the shape memory alloy.

Accordingly, the two limitations are not inconsistent, but rather are complimentary. The shape memory alloy must display SIM behavior at body temperature, but in addition the SMA element must be restrained by the restraint at some point in time at a temperature lower than body temperature.

It is believed that in view of this explanation, this rejection under 35 U.S.C. § 112 should be withdrawn.

REJECTION RELATING TO A(90) TEMPERATURE

Claims 11-14, 17 and 18 were rejected under 35 U.S.C. § 112, and similarly the specification was objected to under 35 U.S.C. § 112 with regard to the reference to A(90) temperature.

It is believed that the rejection is based on the following grounds:

1. Reference to A(90) is not in the application as originally submitted, i.e., is new matter; and

2. The specification as originally submitted did not state the criticality of the A(90) temperature and the preferred range.

This rejection is respectfully traversed for the following reasons.

First, the addition of the A(90) temperature in the specification is not new matter. This is in inherent property of the alloys described in the Quin patent, which is incorporated by reference into the present application. Provided herewith is a declaration by an expert in the field, Dr. John D. Harrison, where he concludes, based upon facts, that:

> "A(90) temperature is an inherent property of any alloy that can transform from the martensitic phase to the austenitic phase."

The Examiner's attention is directed to the declaration and the factual basis in the declaration for that conclusion.

Since we are dealing with an inherent property of the material, it is not new matter to add A(90) values to the specification and the claims. Both the Federal Circuit and the C.C.P.A. have held that an inherent property of a product that is not disclosed in the original specification can be recited in later filed claims without losing the benefit of the earlier

filing date. Kennecott Corp. v. Kyocera Int'l, Inc., 5 U.S.P.Q.2d 1194, 1197, 835 F.2d 419 (Fed. Cir. 1987); In re Nathan, 140 U.S.P.Q. 601, 321 F.2d 1005 (C.C.P.A. 1964). In Kennecott, the Federal Circuit held that it is permissible to add claims directed to a ceramic body having a predominantly "equitaxed microstructure," even though the originally filed specification directed to a process for producing the ceramic did not disclose that the ceramic body had such structure. The Court allowed the later filed claims because the "equitaxed microstructure" was an inherent property of the ceramic material fabricated in the original patent. The Court stated:

> "The disclosure in a subsequent filed patent application of an inherent property of a product does not deprive that product of the benefit of an earlier filing date. Nor does the inclusion of a description of that property in later filed claims change this reasonable result."

Id. at 1198.

Similarly, in Nathan, the C.C.P.A. held that is permissible to include in later added claims, a limitation that a particular compound had an "alpha orientation," even though that was not in the original disclosure because the alpha orientation was "an inherent characteristic" of the claimed subject matter. The Nathan Court explained that "a subsequent clarification of,

or a change in, an original disclosure does not necessarily make that original disclosure fatally defective." 140 U.S.P.Q. at 603.

Another C.C.P.A. case supporting this established rule of law is In re Reynolds, 170 U.S.P.Q. 94, 443 F.2d 384 (C.C.P.A. 1971). In Reynolds, the claimed product had an inherent function that was not expressly described in the specification. The issue was whether words describing this function could be added to the Specification by Amendment, or whether such description was "new matter." The Court held that the express description of the inherent property was not "new matter" and could be added to the Specification, without losing the original filing date. Id. at 98.

Accordingly, in view of this case law, and in view of Dr. Harrison's explanation that at least one and possibly more of the alloys described in the Quin example (which was incorporated by reference in this application) has an A(90) temperature "of not more than 0°C," it is clear that if the Examiner is suggesting the specification and claims create issues of new matter, this suggestion is incorrect.

It should also be noted that the Examiner's comment that an A(90) greater than 0°C is an inherent property of "any SIM material" is incorrect. All SIM materials do not have such an A(90). Dr. Harrison notes that "at least one, but definitely

not all, of the alloys in the hexagonal area in Fig. 2 of the Quin patent inherently has an A(90) of not more than 0°C, when annealed under standard conditions" (paragraph 10).

With regard to the suggestion that Applicant needed to recognize the criticality of the limitation, this suggestion is respectfully traversed. It is believed the law does not support the contention. For example, in Kennecott and Nathan, cited above, the claims were amended to include a limitation that was not in the application as originally filed, but was inherent in the application as filed. Similarly here, Applicant is entitled to include in his claims a claim limitation which is inherent in the specification as filed.

A leading case on this issue is In re Voss, 194 U.S.P.Q. 267, 271-3 (CCPA 1977). In that case the CCPA held that:

> It is only required, for example, that the specification describe the invention sufficiently for those of ordinary skill in the art to recognize that the Applicant invented the subject matter he now claims. The PTO has the initial burden of presenting evidence or reasons why those skilled in the art would not recognize in the specification

> a description of the invention defined by the present claims. (citations omitted)

Applying this principle, the Court held that the Patent Office improperly rejected claims under 35 U.S.C. § 112 even though the expression "at least 50 percent" crystal content did not appear in the parent application. The Court noted that the application at issue incorporated by reference a discussion of glass-ceramic materials from another patent application, and even though that portion incorporated by reference did not include "at least 50 percent," the Court concluded that the "at least 50 percent" limitation "merely quantifies the percent of crystallinity one of ordinary skill in the art at that time would have attributed to the term 'glass-ceramic material'" (emphasis original).

Likewise, here, we have the necessary information incorporated by reference. Moreover, Dr. Harrison, in his accompanying declaration, concludes:

> A person of ordinary skill in the art, by reading the above-identified patent application, will recognize that the preferred shape memory alloy for use in at least some medical devices according to the present invention has an A(90) of not more than 0°C.

Thus, based on Voss, the claims submitted are supported by the specification and should be allowed.

The Examiner's attention is also directed to the decision of the Patent and Trademark Office Board of Appeals in Ex Parte Cure, 215 U.S.P.Q. 567 (1982), which likewise is factually similar to the present application. In Cure, the claims at issued included a limitation "said shield being constructed of a metal which melts at 2800°F," but there was no disclosure in the application of that limitation. The only disclosure was that the shield could be made with low carbon steel. The Board concluded that based on the disclosure of low carbon steel, one having ordinary skill in the art would have understood that "other metals having a melting point less than 2800°F are suitable for use as shield materials in Appellant's invention." The Examiner should note that claims in Cure were not limited just to low carbon steel having such a melting point, but any metal.

Likewise here, as stated by Dr. Harrison, "one of ordinary skill in the art from the disclosure will recognize that the preferred shape memory alloy for use in at least in some medical devices claimed in the present invention has an A(90) of not more than 0°C." Accordingly, the rejection under 35 U.S.C. § 112 should be withdrawn in view of Cure.

CONDITIONAL NOTICE OF APPEAL

Accompanying this amendment is a conditional notice of appeal which should be entered in case the amendment does not place this application in condition for allowance.

CONCLUSION

In view of the foregoing remarks, allowance of all the claims is respectfully requested.

Respectfully submitted,

SHELDON & MAK

3/9/95
Date

By: Jeffrey G. Sheldon
Reg. No. 27,953

225 South Lake Avenue, 9th Floor
Pasadena, California 91101
(818) 796-4000

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U. S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D. C. 20231 ON

March 9, 1995

3-9-95
(DATE SIGNED)

GW 3/30/95 appeal notice #18

9438\MP0884-US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	)	**Group Art Unit: 3301**
JAMES E. JERVIS	)	**Examiner: KENEALY, D**
Serial No. 07/956,653	)	
Filed: October 2, 1992	)	**Office Action Mailed: 10/31/94**
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	)	**Pasadena, California**

CONDITIONAL NOTICE OF APPEAL

I HEREBY CERTIFY THAT THIS CORRESPONDENC IS BEING DEPOSITED WITH THE U. S. POSTA SERVICE AS FIRST CLASS MAIL IN AN ENVELOF ADDRESSED TO: COMMISSIONER OF PATENTS AN TRADEMARKS, WASHINGTON, D. C. 20231 C

March 9, 1995

3-9-95 Mark Sheldon
(DATE SIGNED)

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

Applicant conditionally appeals from the final rejection of October 31, 1994, rejecting claims 1-64.

This appeal should be entered only if the accompanying amendment does not place this application in condition for allowance.

Please charge the requisite $280 (Large Entity) fee to our Deposit Account No. 19-2090 if this Notice of Appeal is entered.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 19-2090.

Respectfully submitted,

3/9/95
Date

By: Jeffrey G. Sheldon
Reg. No.: 27,953

SHELDON & MAK
225 South Lake Avenue, 9th Floor
Pasadena, California 91101
(818) 796-4000

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GP 3301
V. Douglas
4-6-95

9438\MP0884-US7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	**Group Art Unit: 3301**
JAMES E. JERVIS	**Examiner: KENEALY, D**
Serial No. 07/956,653	
Filed: October 2, 1992	**Office Action Mailed: 10/31/94**
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	**Pasadena, California**

TERMINAL DISCLAIMER

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

I, Herbert G. Burkard, residing at 256 Prior Lane, Atherton, California 84027, represent that I am Corporate Counsel and Assistant Secretary of Raychem Corporation, a corporation having its principal place of business at 300 Constitution Drive, Menlo Park, California 94025, and that Raychem Corporation is the assignee of the entire right, title and interest to Application Serial No. 07/956,653, filed October 2, 1992, for a method for inserting medical devices incorporating SIM alloy elements.

I, on behalf of Raychem Corporation, hereby disclaim the terminal part of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173 as shortened by any terminal disclaimer filed prior to U.S. Patent No. 4,665,906, issued May 19, 1987, and hereby agree that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title

090 BA 03/27/95 07956653
1 1 148 110.00 CK

to said patent be the same as the legal title to the above referenced patent, this agreement to run with any patent granted on the above-identified application and to be binding upon the grantee, its successors or assigns.

In making the above disclaimer, petitioner does not disclaim the terminal part of any patent granted on the present application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of the above-listed application in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is otherwise terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer filed prior to the grant of the patent.

The undersigned has reviewed all the evidentiary documents accompanying or referred to in the instant Terminal Disclaimer and it is certified to the best of the undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by find or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

The fee of $110 required by 37 C.F.R. § 1.20(d) is submitted herewith.

Respectfully submitted,

RAYCHEM CORPORATION

24 March 95
Date

By: Herbert G. Burkard
Herbert G. Burkard
Assistant Secretary

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U. S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D. C. 20231 ON

March 9, 1995

3-9-95
(DATE SIGNED)

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/956,653	10/02/92	JERVIS J	9438

F3M1/0426

JEFFREY G. SHELDON
SHELDON & MAK
225 S. LAKE AVENUE - 9TH FLOOR
PASADENA, CA 91101

KENEALY, EXAMINER	
ART UNIT	PAPER NUMBER
3301	21

DATE MAILED: 04/26/95

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☑ THE PERIOD FOR RESPONSE:

a) ☑ is extended to run 2 mos. or continues to run _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☑ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☑ Applicant's response to the final rejection, filed 3/13/95 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☑ Upon the filing an appeal, the proposed amendment ☑ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: 51-53, 55,56, 58-60 *
   Claims objected to: 24, 30-37, 43, 44, 46
   Claims rejected: 11-14, 17, 18, 19, 20, 21, 26-29, 41, 42, 45, 47, 48, 49, 50, 57, 63

   However,

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☑ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because see attachment

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☑ Other

* attachment

ROBERT A. HAFER
S.P.E.
ART UNIT 331

PTOL-303 (REV. 5-89)

Attachment To Advisory Action

With regard to the rejection relating to the A(90) temperature, examiner agrees that an A(90) temperature is inherent to SIM materials. Like the ceramic that inherently has an "equitaxed microstructure", SIM materials inherently have an A(90) temperature. However, a specific value for the A(90) temperature is not an inherent quality of all SIM materials. In fact, the specific value for the A(90) temperature is exactly what applicant bases patentability on. Therefore it is difficult to see how applicant can argue that the specific value is inherent without also conceding that the claim is obvious. Examiner concludes that the O degree value for the A(90) temperature is new matter that is unsupported in applicant's original specification and validly rejected under 35 USC § 112 1st paragraph.

Examiner is hesitant to allow claim 19 despite applicant's arguments and explanations. The claim that the device be at "body temperature" is still indefinite because different mammals have different body temperatures. Does the material exhibit SIM behavior at **and** below body temperature?

Finally, examiner also requests drawings to accompany the case since applicant's claim 19 requires structural entities to restrict a wire.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Exr. Kenealy whose telephone number is (703) 308-2680.

David Kenealy
4/24/95

ROBERT A. HAFER
S.P.E.
ART UNIT 331

9438\MP0884-US7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	) Group Art Unit: 3301
JAMES E. JERVIS	) Examiner: KENEALY, D
Serial No. 07/956,653	)
Filed: October 2, 1992	)
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	) Pasadena, California

#22
6/26/95

FAX COPY RECEIVED
JUN 7 1995
GROUP 3300

REQUEST FOR EXTENSION OF TIME TO FILE APPEAL BRIEF

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Applicant requests an extension of time of one month to file an appeal brief in the above-identified application. A Notice of Appeal had been previously filed on March 9, 1995.

The Examiner is authorized to charge the requisite fee of $110 to our Deposit Account No. 19-2090.

	Small Entity	"Large" Entity
First Month After Time Period Set	$ 55.00	$ 110.00
Second Month After Time Period Set	185.00	370.00
Third Month After Time Period Set	435.00	870.00
Fourth Month After Time Period Set	680.00	1,360.00

If any additional extension of time is required, such extension is hereby requested. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-2090.

DK to enter -DK

6/7/95

Respectfully submitted,

SHELDON & MAK

By: _____
Jeffrey G. Sheldon, Reg. No. 27,953

225 South Lake Street, Suite 900
Pasadena, California 91101
(818) 796-4000 (213) 681-9000

P 30136 06/22/95 07956653 19-2090 030 115 110.00CH

AMENDMENT COVER SHEET

G3301

DOCKET NO. 9438/MP0884-US7

IN RE APPLICATION OF: [illegible]ES E. JERVIS

SERIAL NO.: 07/956,653 FILED: October 2, 1992

FOR: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

HONORABLE COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is a paper in the above-identified application. Any necessary extension of time period set for this paper is hereby requested.

[ ] No additional fee is required.

[ ] The fee has been calculated as shown below:

[X] EXTENSION FEE

	RATE Non-Small Entity	RATE Small Entity	FEE
FIRST MONTH AFTER TIME PERIOD SET	110.00	55.00	$110
SECOND MONTH AFTER TIME PERIOD SET	360.00	180.00	$
THIRD MONTH AFTER TIME PERIOD SET	840.00	420.00	$
FOURTH MONTH AFTER TIME PERIOD SET	1,320.00	660.00	$

[X] TOTAL EXTENSION FEE 110.00

[ ] FEE FOR EXTRA CLAIMS added by Amendment in this response:

	Column 1 Number of Claims after Amendment	Column 2 Number Previously Paid for	Column 3 Number of Extra Claims	RATE Non-Small Entity	RATE Small Entity	FEE
TOTAL CLAIMS		MINUS **	* =	x 20	x 10	$
INDEPENDENT		MINUS ***	* =	x 72	x 36	$
First presentation of multiple dependent claim				+ 220	+ 110	$

TOTAL FEE FOR EXTRA CLAIMS $

* If the entry in Column 1 is less than the entry of Column 2, write "0" in Column 3.
** If the number of Total Claims previously paid for is less than 20, write "20" in this space.
*** If the number of Independent Claims previously paid for is less than 3, write "3" in this space.

[ ] Enclosed is the fee of $_____ by Check No. _____

[X] Please charge Deposit Account No. 19-2090 in the amount of $110.00.

[X] The Commissioner is hereby authorized to charge payment of any additional fees, in particular the following fees, associated with this communication, or credit any overpayment to Deposit Account No. 19-2090:

Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
Any patent application processing fees under 37 C.F.R. § 1.17

SHELDON & MAK

Date: 6/7/95 By: Jeffrey G. Sheldon

Jeffrey G. Sheldon, Reg. No.: 27,953

CERTIFICATION OF FACSIMILE TRANSMISSION: I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Date Transmitted: June 7, 1995

Date Signed: June 7, 1995

By: Marilyn C. Falk

250 TL
25086

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U.S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231 ON

June 7, 1995

6/7/95 Marilyn Falk

(DATE SIGNED)

SHELDON & MAK
225 SOUTH LAKE AVENUE, SUITE 800
PASADENA, CALIFORNIA 91101
(818) 796-4000 - Direct Line: (818) 356-1201

9438\MP0684-US7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Group Art Unit: 3301
JAMES E. JERVIS	Examiner: KENEALY, D
Serial No. 07/956,653	VIA FACSIMILE (703) 305-3590
Filed: October 2, 1992	
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	Pasadena, California

AMENDMENT

CERTIFICATION OF FACSIMILE TRANSMISSION
I hereby certify that this paper is being facsimile transmitted to the Patent Office and Trademark Office on the date shown below.
Marilyn C. Pair
Type or print name of person signing certification
Marilyn Pair 6/7/95
Signature Date

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

In response to the Advisory Action of April 26, 1995, please amend the above-identified application as follows:

IN THE CLAIMS

Cancel claims 11-18, without prejudice. Applicant may present these claims in a continuation application.

Please amend claim 19 as follows:

~~19.~~ (Fourth Amendment) A medical device which comprises:

(a) an element for use within a [mammalian] human body or in such proximity to a [mammalian] human body that the device

is substantially at human body temperature, the element comprising a shape memory alloy which displays a stress-induced martensite behavior at body temperature; and

(b) a restraint holding the shape memory alloy element in a deformed configuration at a temperature less than the body temperature of the [mammal] human for positioning the shape memory alloy element within or in proximity to [a mammalian] the human body in its deformed configuration, the deformation occurring through the formation of stress-induced martensite; wherein the shape memory alloy element is sufficiently deformed that when the shape memory alloy element is at human body temperature removal of the restraint from the shape memory [allow] alloy element, without change in temperature of the device, releases at least a portion of the shape memory alloy element from its deformed configuration.

H/ cancel

REMARKS

Applicant wishes to thank the Examiner for the courtesy shown to Applicant's attorney, the undersigned, during a telephone interview on May 16, 1995.

During the telephone interview, the amendments to claim 19 were discussed. The Examiner indicated that the amendments made herein to claim 19 would obviate the rejections under 35 U.S.C. § 112.

55

With regard to the claims that contain the "A(90)" limitation, Applicant respectfully disagrees with the position of the Patent Office. Nevertheless, to expedite issuance of this application, the claims containing "A(90)" are cancelled by this amendment, thereby obviating the rejection as to those claims.

In the Advisory Action, the Examiner requested drawings to accompany the case. During the telephone interview, the undersigned advised the Examiner of the filing of Figs. 3 and 4, which are believed to meet the drawing requirements of 37 C.F.R.

Applicant wishes to advise the Examiner that claim 19 is not restricted to a wire. This comment is being made because the Examiner refers to a wire in the Office Action. Claim 19 only refers to a "shape memory alloy element" and a "restraint". Although one or more of these elements may be a wire, the claim does not so require.

In view of the amendments to the application and the above remarks, it is believed that this application is in condition for allowance. Such allowance is respectfully requested. Since Applicant's appeal brief was due on May 9, 1995, it is unclear to Applicant whether an extension of time is required for submitting this amendment. In an abundance of caution, such an extension is hereby requested, and an

authorization to charge our Deposit Account 19-2090 for the extension fee is included. If for some reason the extension is not necessary, it is requested that the deposit account not be charged.

Applicant wishes to advise the Examiner that Applicant may file a continuation application that includes the "A(90)" claims, as well as a claim comparable to claim 19 that is not limited to humans. Applicant respectfully disagrees with the rejections for new matter and under § 112. However, to expedite issuance of this patent, Applicant has agreed to amend the application as indicated above.

Respectfully submitted,

SHELDON & MAK

6/7/95
Date

By: _____
Jeffrey G. Sheldon
Reg. No. 27,953

225 South Lake Avenue, 9th Floor
Pasadena, California 91101
(818) 796-4000

a 56653

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	24

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

(1) Exr. Kenealy (3) _____

(2) Mr. Sheldon (4) _____

Date of interview 6/26/95

Type: ☑ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☑ No. If yes, brief description: _____

Agreement ☑ was reached with respect to some or all of the claims in question. ☐ was not reached.

Claims discussed: all

Identification of prior art discussed: all

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: The attached Examiner's Amdt will place case into condition for allowance

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

Unless the paragraphs below have been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1–7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview.

☐ Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action.

Examiner's Signature

PTOL-413 (REV. 1-84)

ORIGINAL FOR INSERTION IN RIGHT HAND FLAP OF FILE WRAPPER

GW629

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/956,653	10/02/92	JERVIS	

KENEALY, D
EXAMINER

F3M1/0706

JEFFREY G. SHELDON
SHELDON & MAK
225 S. LAKE AVENUE - 9TH FLOOR
PASADENA, CA 91101

ART UNIT	PAPER NUMBER
331	28

07/10/95

DATE MAILED:

NOTICE OF ALLOWABILITY

PART I.

1. ☑ This communication is responsive to paper #22 Amdt AF
2. ☑ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☑ The allowed claims are 19-36, 41, 44-53, 55-64.
4. ☐ The drawings filed on _____ are acceptable.
5. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [_] been received. [_] not been received. [_] been filed in parent application Serial No. _____, filed on _____.
6. ☑ Note the attached Examiner's Amendment.
7. ☑ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☐ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☐ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☑ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
   a. ☑ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. _____. CORRECTION IS REQUIRED.
   b. ☐ The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
   c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
   d. ☑ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- ☑ Examiner's Amendment
- ☑ Examiner Interview Summary Record, PTOL-413
- _ Reasons for Allowance
- _ Notice of References Cited, PTO-892
- _ Information Disclosure Citation, PTO-1449
- _ Notice of Informal Application, PTO-152
- _ Notice re Patent Drawings, PTO-948
- _ Listing of Bonded Draftsmen
- _ Other

ROBERT A. HAFER
S.P.E.
ART UNIT 331

PTOL-37 (REV. 4-89) *

USCOMM-DC 89-3789

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. Sheldon on 6/26/95.

The following changes have been made to the claims:

Claim 27: At line 3 of subparagraph b), the phrase "the mammal" has been deleted and replaced with the phrase "a human".

At line 10 of subparagraph b), the term "mammalian" has been deleted and replaced with the term "human".

Claim 28: At line 3 of subparagraph **a**), the term "human" has been inserted in between the term "about" and the term "body".

At line 5 of subparagraph b), the term "mammal" has been deleted and replaced with the term "human".

Claim 33: At line 2 the term "mammalian" has been deleted and replaced with the term "human".

At line 5 the term "human" has been inserted in between the term "about" and the term "body".

Claim 35: At line 1 the term "mammalian" has been deleted and replaced with the term "human".

At line 5 the term "human" has been inserted in between the term "about" and the term "body".

Claims 37-40 and 43: Have been cancelled.

Claim 54: Has been cancelled.

Claim 58: At line 1 the term "mammalian" has been deleted and replaced with the term "human".

At line 5 the term "human" has been inserted in between the term "about" and the term "body".

Claim 59: At line 1 of subparagraph a), the term "mammalian" has been deleted and replaced with the term "human".

At line 2 of subparagraph a), the term "mammalian" has been deleted and replaced with the term "human".

At line 4 of subparagraph a), the term "human" has been inserted in between the term "~~about~~ at" and the term "body".

- DVR 9/13/95 per conversation of Steve Roeder

At line 4 of subparagraph **b**), the term "mammalian" has been deleted and replaced with the term "human".

Claim 60: At line 2 the term "mammalian" has been deleted and replaced with the term "human".

At line 5 the term "human" has been inserted in between the term "about" and the term "body".

At line 12 the term "mammal" has been deleted and replaced with the term "human".

At line 15 the term "mammalian" has been deleted and replaced with the term "human".

Claim 62: At line 2 the term "mammalian" has been deleted and replaced with the term "human".

At line 5 the term "human" has been inserted in between the term "about" and the term "body".

At line 12 the ~~term~~ "mammal" has been deleted and replaced with the term "human".

At line 14 the term "mammalian" has been deleted and replaced with the term "human".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Kenealy whose telephone number is (703) 308-2680.

DJK
David J. Kenealy
June 28, 1995

ROBERT A. HAFER
S.P.E.
ART UNIT 331

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: Box ISSUE FEE
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

F3M1/0706

JEFFREY G. SHELDON
SHELDON & MAK
225 S. LAKE AVENUE - 9TH FLOOR
PASADENA, CA 91101

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

☐ Note attached communication from the Examiner
☐ This notice is issued in view of applicant's communication filed _____

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/956,653	10/02/92	040	KENEALY, P	3301 07/06,

First Named Applicant: JERVIS, JAMES E.

TITLE OF INVENTION: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3	9429	606-079,000	N17	UTILITY	NO	$1210.00	10/06,

THE APPLICATION IDENTIFIES ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY Status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:
A. Pay FEE DUE shown above, or
B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

PTOL-85B (REV. 4-94) (0651-0033)

MAIL ROOM AUG 17 1995

PART C—CHARGE TO DEPOSIT ACCOU

7218 442.B
38 SW

3. CORRESPONDENCE ADDRESS

F3M1/0706

JEFFREY G. SHELDON
SHELDON & MAK
225 S. LAKE AVENUE - 9TH FLOOR
PASADENA, CA 91101

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/956,653	10/02/92	040	KENEALY, P. 3301	07/06/

First Named Applicant: JERVIS, JAMES E.

TITLE OF INVENTION: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

ATTY'S DOCKET NO.	CLASS/SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 9433	606-078.000	N17	UTILITY	NO	$1210.00	10/06/

DO NOT USE THIS SPACE

080 VH 08/28/95 07956653 1 142 1,210.00 CK
080 VH 08/28/95 07956653 1 561 30.00 CK

2a. The following fees are enclosed: check #5968 for $1,240.
☒ Issue Fee ☒ Advance Order - # of Copies 10

2b. The following fees should be charged to:
DEPOSIT ACCOUNT NUMBER 19-2090
☐ Issue Fee ☐ Advance Order - # of Copies
☒ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Authorized Signature) 27,953 8/16/95

NOTE: The Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

TRANSMIT THIS FORM WITH PART B WHEN AUTHORIZING USE OF A DEPOSIT ACCOUNT

PTOL-85C (REV. 4-94) (0651-0033)

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
	26

DATE MAILED:

SUPPLEMENTAL
NOTICE OF ALLOWABILITY

PART I.

1. ☐ This communication is responsive to _____.
2. ☑ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☑ The allowed claims are 19-36, 41, 44-53, 55-64.
4. ☐ The drawings filed on _____ are acceptable.
5. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [_] been received. [_] not been received. [_] been filed in parent application Serial No. _____, filed on _____.
6. ☑ Note the attached Examiner's Amendment.
7. ☑ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☐ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☑ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449. *

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☑ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
   a. ☑ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. _____. CORRECTION IS REQUIRED.
   b. ☐ The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
   c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
   d. ☑ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- _ Examiner's Amendment
- _ Examiner Interview Summary Record, PTOL-413
- _ Reasons for Allowance
- _ Notice of References Cited, PTO-892
- _ Information Disclosure Citation, PTO-1449
- _ Notice of Informal Application, PTO-152
- _ Notice re Patent Drawings, PTO-948
- _ Listing of Bonded Draftsmen
- _ Other

* any reference citations that had no date marked have been crossed out and have not been considered.

ROBERT A. HAFER
S.P.E.
ART UNIT 331

PTOL-37 (REV. 4-89) *

USCOMM-DC 89-3789

1 OH B

9438

#26 OH

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	)	Group No.: 27,953
	)	
James E. Jervis	)	Examiner: Kenealy, D.
	)	
Serial No.: 07/956,653	)	
	)	
Filed: October 2, 1992	)	Batch No. N17

For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

TRANSMITTAL OF FORMAL DRAWINGS

Patent and Trademark Office
Washington, D.C. 20231

Attention: Official Draftsman

Dear Sir:

Please find (2) sheets of formal drawing(s) for this application. Each sheet of drawing indicates the serial number and Group Art Unit on the reverse side of the drawing.

Respectfully submitted,

SHELDON & MAK, INC.

Date: 8/14/95 By _____
Jeffrey G. Sheldon
Reg. No. 27,953

SHELDON & MAK
225 South Lake Avenue
9th Floor
Pasadena, California 91101
(818) 796-4000

CERTIFICATE OF MAILING: I hereby certify that this paper is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to:

Box ISSUE FEE
Commissioner of Patents and Trademarks, Washington, D.C. 20231

Date signed: 8/14/95 By _____
John Willis

93/john/ptltrs/9000/9438fd.trn

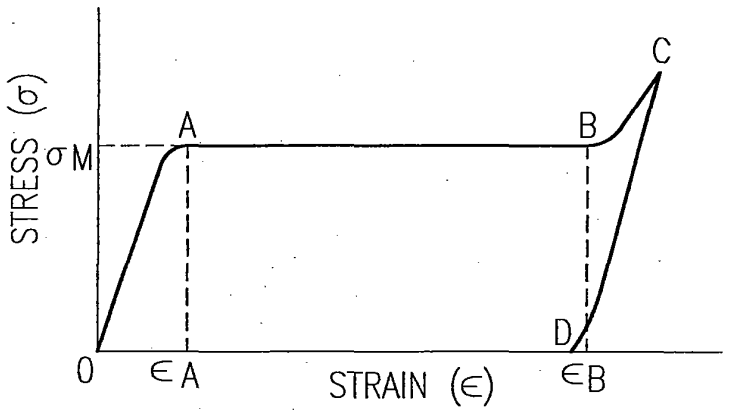


FIG. 1

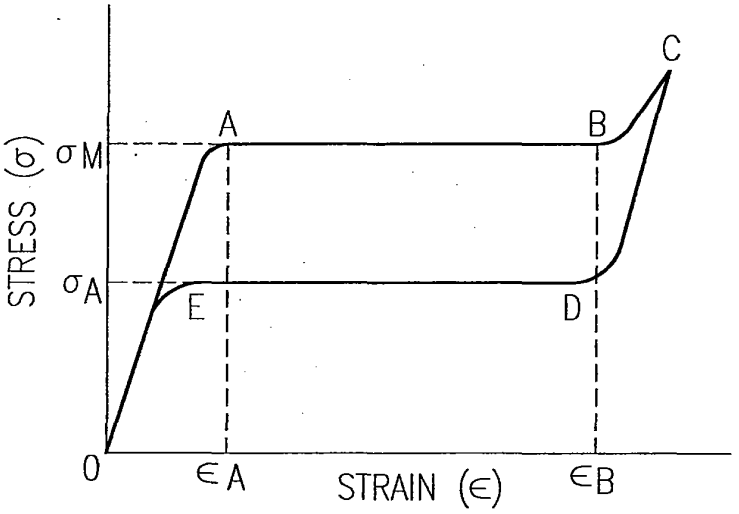


FIG. 2

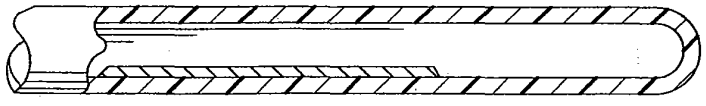
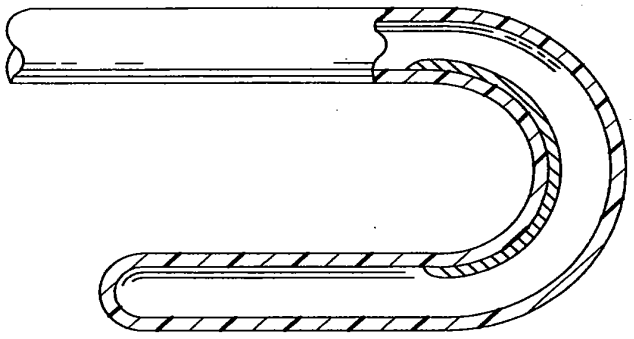


FIG. 3

07/956,653
Grp. Art 3301
SEM #9438
1 of 2

FIG. 4



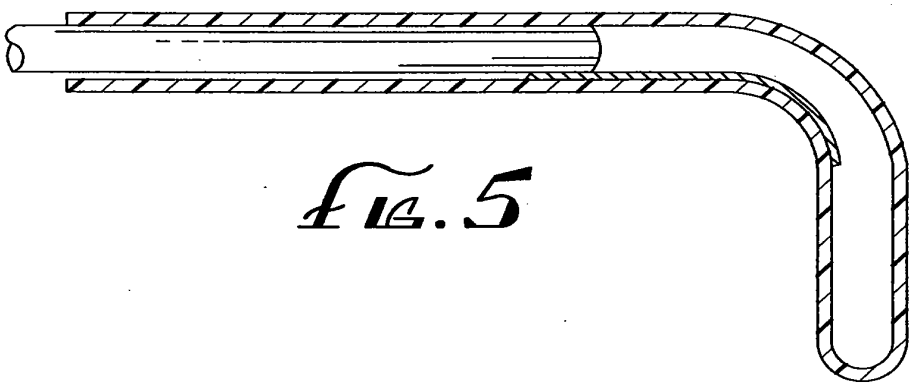


FIG. 5

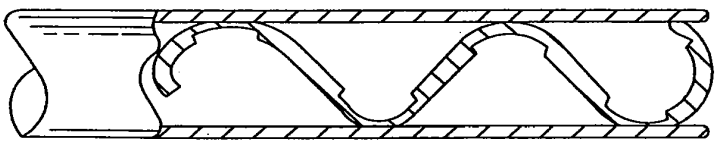


FIG. 6

08/956,653
Grp. Art #3301
S&M #9438
2 of 2

121° 142-B
30 56

PART B—ISSUE FEE TRANSMITTAL

#27

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance orders and notification of maintenance fees will be mailed to addressee entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block 3 below; or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. **See reverse for Certificate of Mailing.**

1. CORRESPONDENCE ADDRESS	2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)
MAIL ROOM AUG 17 1995 PAT. & TRADEMARK OFFICE F3M1/0706 JEFFREY G. SHELDON SHELDON & MAK 225 S. LAKE AVENUE - 9TH FLOOR PASADENA, CA 91101	INVENTOR'S NAME Street Address City, State and ZIP Code CO-INVENTOR'S NAME Street Address City, State and ZIP Code ☐ Check if additional changes are on reverse side

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/956,658	10/02/92	040	KENEALY, D 3301	07/06/95

First Named Applicant: JERVIS, JAMES E.

TITLE OF INVENTION: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3	9438	606-078.000	N17	UTILITY	NO	$1210.00	10/06/95

3. Correspondence address change (Complete only if there is a change)

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR, alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.
1 Jeffrey G. Sheldon
2 SHELDON & MAK, INC.
3

DO NOT USE THIS SPACE

080 VM 08/28/95 07956657 1 142 1,210.00 CK
080 VM 08/28/95 07956653 1 561 30.00 CK

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)

(1) NAME OF ASSIGNEE: Raychem Corporation
(2) ADDRESS: (CITY & STATE OR COUNTRY) Menlo Park, California

A. ☐ This application is NOT assigned.
☐ Assignment previously submitted to the Patent and Trademark Office.
☐ Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.
PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed: check #5968 for $1,240.
☒ Issue Fee ☒ Advance Order - # of Copies 10
6b. The following fees should be charged to:
DEPOSIT ACCOUNT NUMBER 19-2090
(ENCLOSE PART C)
☐ Issue Fee ☐ Advance Order - # of Copies
☐ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Authorized Signature) Jeffrey G. Sheldon 27,953 (Date) 7/28/95

NOTE: The Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

TRANSMIT THIS FORM WITH FEE-CERTIFICATE OF MAILING OF REVERSE

PTOL-85B (REV. 4-94) (0651-0033)

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Box ISSUE FEE
Commissioner of Patents and Trademarks
Washington, D.C. 20231

on August 14, 1995
(Date)

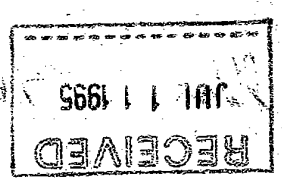
John Willis
(Name of person making deposit)

John Willis
(Signature)

8/14/95
(Date)

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

Burden Hour Statement: This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Office of Information Systems, Patent and Trademark Office, Washington, D.C. 20231, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, (Project 0651-0033), Washington, D.C. 20503. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents and Trademarks, Box Issue Fee, Washington, DC 20231.



PTO UTILITY GRANT
Paper Number 28

The United States of America

The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person or persons having title to this patent the right to exclude others from making, using or selling the invention throughout the United States of America for the term of seventeen years from the date of this patent, subject to the payment of maintenance fees as provided by law.

Bruce Lehman

Commissioner of Patents and Trademarks

Marjorie V. Turner

Attest

PTO-1584

Raychem

MP884-US7

#29

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	)	Group Art Unit: 3301
JAMES E. JERVIS	)	Examiner: Kenealy, D.
Serial No. 07/956,653	)	Raychem Corporation 300 Constitution Drive
Filed: Otober 2, 1992	)	Menlo Park, CA 94025
For: MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS	)	February 1, 1996

POWER TO INSPECT AND MAKE COPIES

Honorable Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This communication gives Shonda Reed-Baten and Jennifer Harris of Barbara Harris & Associates the right to inspect and make copies of our patent application, titled Medical Devices Incorporating Sim Alloy Elements, U.S. Serial No. 07/956,653, filed October 2, 1992.

If you have any questions or concerns, please feel free to call the undersigned at (415) 361-3338.

Respectfully submitted,

Herbert G. Burkard
Registration No. 24,500
Tel. No. (415) 361-3338

PROCESSED BY
FEB 2 2 1996
FIU

PATENT APPLICATION FEE DETERMINATION RECORD

Effective October 1, 1992

Application or Docket Number: 456653

CLAIMS AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
DO NOT	REFUND MONEY						
BASIC FEE				$355.00	OR		$710.00
TOTAL CLAIMS	1 minus 20 =	*	x$11=		OR	x$22=	
INDEPENDENT CLAIMS	1 minus 3 =	*	x 37=		OR	x 74=	
MULTIPLE DEPENDENT CLAIM PRESENT			+115=		OR	+230=	
			TOTAL		OR	TOTAL	710

* If the difference in column 1 is less then zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
Total	*	Minus	**	=	x$11=		OR	x$22=	
Independent	*	Minus	***	=	x 37=		OR	x 74=	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					+ 115=		OR	+230=	
					TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
Total	* 44	Minus	** 43	= 1	x$11=		OR	x$22=	22
Independent	* 9	Minus	*** 8	= 1	x 37=		OR	x 74=	74
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					+ 115=		OR	+ 230=	—
					TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	96

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
Total	* 40	Minus	** 44	30	x$11=		OR	x$22=	
Independent	* 10	Minus	*** 9	= 1	x 37=		OR	x 74=	74
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					+115=		OR	+230=	—
					TOTAL ADDIT. FEE		OR	TOTA ADDIT. F	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in colum

FORM PTO-875 (Rev 10-92) — Patent and Trademark Office; U.S. DEPARTME

54 — 49 — 7 — 139
14 — 10 — 4 x 14 = 56

PTO FORM 948
(REV. 7-92)

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

GROUP	ATTACHMENT TO PAPER NUMBER
	APPLICATION NUMBER 956653

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

THE PTO DRAFTSMEN REVIEW ALL ORIGINALLY FILED DRAWINGS REGARDLESS OF WHETHER THEY WERE DESIGNATED AS INFORMAL OR FORMAL. ADDITIONALLY, THE PATENT EXAMINER WILL ALSO REVIEW THE DRAWINGS FOR COMPLIANCE WITH THE REGULATIONS.

The drawings filed 10/2/92

A. ☐ are approved by the draftsperson.

B. ☒ are objected to by the draftsperson under 37 CFR 1.84 for the reason(s) checked below. The examiner will require submission of new, corrected drawings at the appropriate time. Corrected drawings must be submitted according to the instructions listed on the back of this Notice.

1. Paper and ink. 37 CFR 1.84(a)
   ☐ Sheet(s)_____ Poor.

2. Size of Sheet and Margins. 37 CFR 1.84(b)
   Acceptable Paper Sizes and Margins

Margin	Paper Size: 8 1/2 by 14 inches	8 1/2 by 13 inches	DIN size A4 21 by 29.7 cm.
Top	2 inches	1 inch	2.5 cm.
Left	1/4 inch	1/4 inch	2.5 cm.
Right	1/4 inch	1/4 inch	1.5 cm.
Bottom	1/4 inch	1/4 inch	1.0 cm.

   ☐ Proper Size Paper Required. All Sheets Must be Same Size.
   Sheet(s) _____
   ☒ Proper Margins Required.
   Sheet(s) 1
   ☒ TOP ☐ RIGHT
   ☐ LEFT ☐ BOTTOM

3. Character of Lines. 37 CFR 1.84(c)
   ☒ Lines Pale or Rough and Blurred.
   Fig(s) 1,2
   ☐ Solid Black Shading Not Allowed.
   Fig(s) _____

4. ☐ Photographs Not Approved.
   _____
   ☐ Comments;

5. Hatching and Shading. 37 CFR 1.84(d)
   ☐ Shade Lines are Required.
   Fig(s) _____
   ☐ Criss-Cross Hatching Not Allowed.
   Fig(s) _____
   ☐ Double Line Hatching Not Allowed.
   Fig(s) _____
   ☐ Parts in Section Must be Hatched.
   Fig(s) _____

6. Reference Characters. 37 CFR 1.84(f)
   ☒ Reference Characters Poor or Incorrectly Sized.
   Fig(s) 1,2
   ☐ Reference Characters Placed Incorrectly.
   Fig(s) _____

7. Views. 37 CFR 1.84(i) & (j)
   ☐ Figures Must be Numbered Properly.
   ☐ Figures Must Not be Connected.
   Fig(s) _____

8. ☒ Identification of Drawings. 37 CFR 1.84(l)
   ~~Extraneous Matter~~ or Copy Machine Marks Not Allowed. Fig(s) 1,2

9. ☐ Changes Not Completed from Prior PTO-948 dated _____

Telephone inquires concerning this review should be directed to the Chief Draftsperson at telephone number (703) 305-8404.

Reviewing Draftsperson

10/29/92
Date

Note: Any objection to the drawings made by the examiner will be communicated separately in an office action.

PTO Copy

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. **Correction of Informalities—37 CFR 1.85**

   File new drawing with the changes incorporated therein. The art unit number, serial number and number of drawing sheets should be written on the drawing in accordance with 37 CFR 1.84(l). Applicant may delay filing of the new drawings until receipt "Notice of Allowability" (PTOL-37). If delayed, the new drawings **MUST** be Filed within the **THREE MONTH** shortened statutory period set for response in the"Notice of Allowability" (PTOL-37). Extensions of time may be obtained under the provisions of 37 CFR 1.136. The drawing should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

   Timing of Corrections

   Applicant is required to submit **acceptable** corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTOL-37). Within the three month period, two weeks should be allowed for review by the Office of the correction.if a correction is determined to be unacceptable by the Office, applicant must arrange to have acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time and paying the extension fee. Therefore, applicant should file corrected drawings as soon as possible.

   Failure to take corrective action within set (or extended) period will result in **ABANDONMENT** of the Application.

2. **Corrections other than Informalities Noted by the Draftsperson on the PTO-948**

   All changes to the drawings, other than informalities noted by the Draftsperson, **Must** be made in the same manner as above except that, normally, a red ink sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

PTO 1130 (REV 11/91) U.S. DEPARTMENT OF COMMERCE– PATENT & TRADEMARK OFFICE

PACE DATA ENTRY CODING SHEET

08/956653

1ST EXAMINER R. Ricks — DATE 10/22/97

2ND EXAMINER — DATE

APPLICATION NUMBER	TYPE APPL	FILING DATE MONTH	DAY	YEAR	SPECIAL HANDLING	GROUP ART UNIT	CLASS	SHEETS OF DRAWING
	1	10	02	92	2	3301	606	01

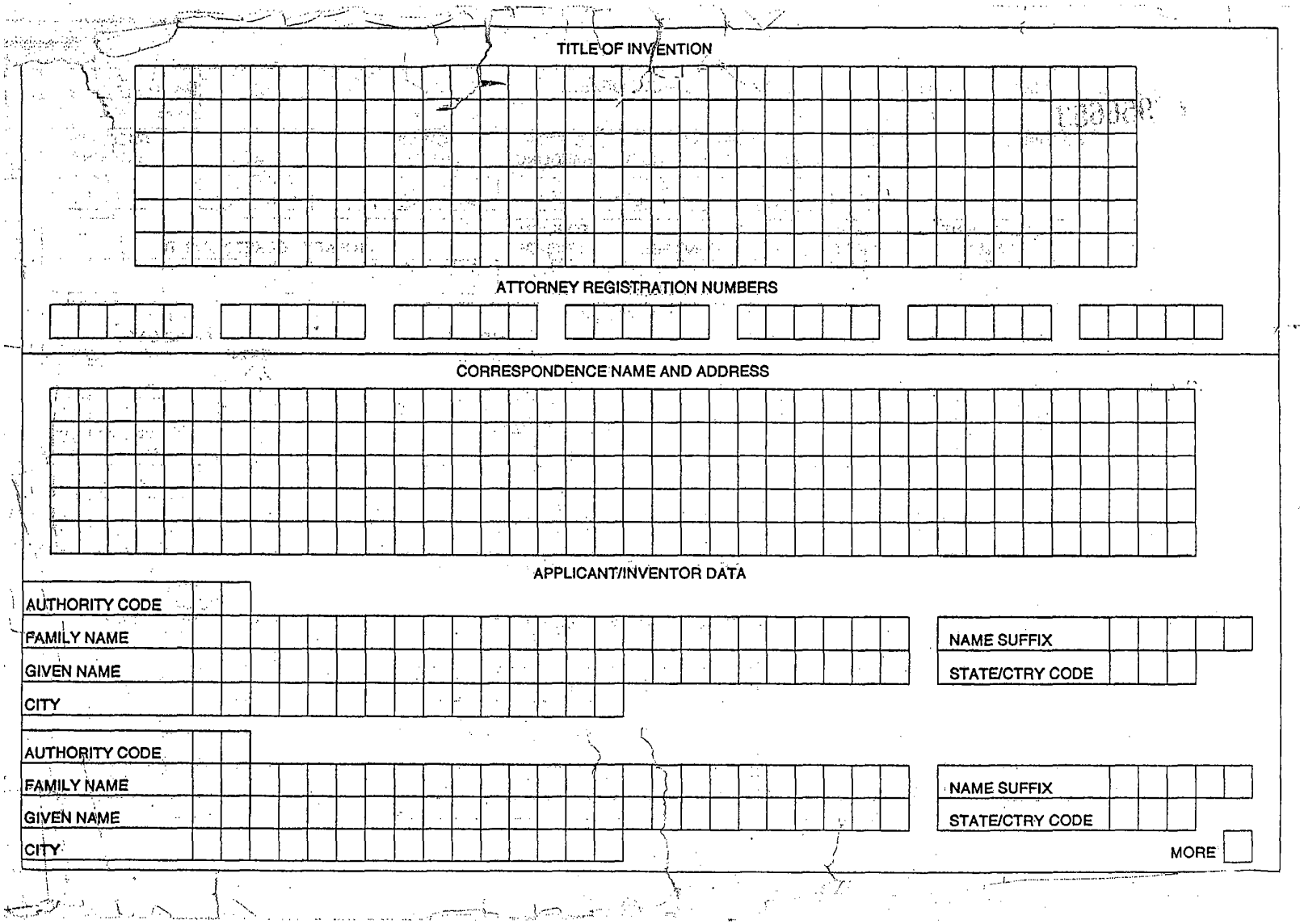
TOTAL CLAIMS	INDEPENDENT CLAIMS	SMALL ENTITY?	FILING FEE	FOREIGN LICENSE	ATTORNEY DOCKET NUMBER
01	01	0	2190	Y	9738

CONTINUITY DATA

CONTINUITY CODE	STATUS CODE	PARENT APPPLICATION SERIAL NUMBER	PARENT PATENT NUMBER	PARENT FILING DATE MONTH	DAY	YEAR
01	2	07/682,243		04	09	91
11	1	07/525,201	5067957	09	27	88
12	3	07/177,817		03	30	88
12	3	07/470,824		05	08	87
12	1	06/576,103	4665906	05	21	86
12	3	07/654,852		10	1483	

PCT/FOREIGN APPLICATION DATA

FOREIGN PRIORITY CLAIMED	COUNTRY CODE	PCT/FOREIGN APPLICATION SERIAL NUMBER	FOREIGN FILING DATE MONTH	DAY	YEAR



US005597378A

United States Patent [19]

Jervis

[11] Patent Number: 5,597,378

[45] Date of Patent: *Jan. 28, 1997

[54] **MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS**

[75] Inventor: **James E. Jervis**, Atherton, Calif.

[73] Assignee: **Raychem Corporation**, Menlo Park, Calif.

[*] Notice: The portion of the term of this patent subsequent to May 19, 2004, has been disclaimed.

[21] Appl. No.: **956,653**

[22] Filed: **Oct. 2, 1992**

Related U.S. Application Data

[62] Division of Ser. No. 682,243, Apr. 9, 1991, Pat. No. 5,190,546, which is a division of Ser. No. 252,019, Sep. 27, 1988, Pat. No. 5,067,957, which is a continuation of Ser. No. 177,817, Mar. 30, 1988, abandoned, which is a continuation of Ser. No. 47,824, May 8, 1987, abandoned, which is a continuation of Ser. No. 865,703, May 21, 1986, Pat. No. 4,665,906, which is a continuation of Ser. No. 541,852, Oct. 14, 1983, abandoned.

[51] **Int. Cl.**[6] **A61B 17/58**

[52] **U.S. Cl.** **606/78**; 606/76; 604/281

[58] **Field of Search** 606/78, 76, 77; 623/11; 604/281, 280, 282, 283

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,348,548	10/1967	Chardack	128/418
3,416,531	12/1968	Edwards	128/348
3,419,012	12/1968	Williams	125/350
3,500,820	3/1970	Almen	128/303
3,516,412	6/1970	Ackerman	128/418
3,539,033	11/1970	Tafeen	128/221
3,558,369	1/1971	Wang et al.	148/11.5
3,605,725	9/1971	Bentov	128/2.05 R
3,620,212	11/1971	Fannon, Jr.	128/130
3,729,008	4/1973	Berkovits	128/418
3,740,839	6/1973	Otte et al.	29/628
3,757,768	9/1973	Kline	128/2 M
3,786,806	1/1974	Johnson et al.	128/92 YN
3,789,841	2/1974	Antoshkiw	128/2.05
3,857,391	12/1974	Lerner	128/127
3,868,956	3/1975	Alfidi et al.	606/78
3,889,666	6/1975	Lerner	128/127
3,890,977	6/1975	Wilson	604/281

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

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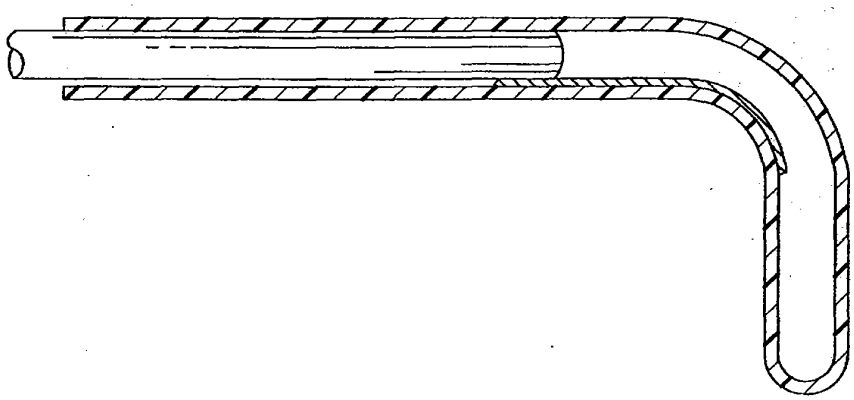
[57] **ABSTRACT**

Medical devices which are currently proposed to use elements made form shape memory alloys may be improved by the use of stress-induced martensite alloy elements instead. The use of stress-induced martensite decreases the temperature sensitivity of the devices, thereby making them easier to install and/or remove.

40 Claims, 2 Drawing Sheets



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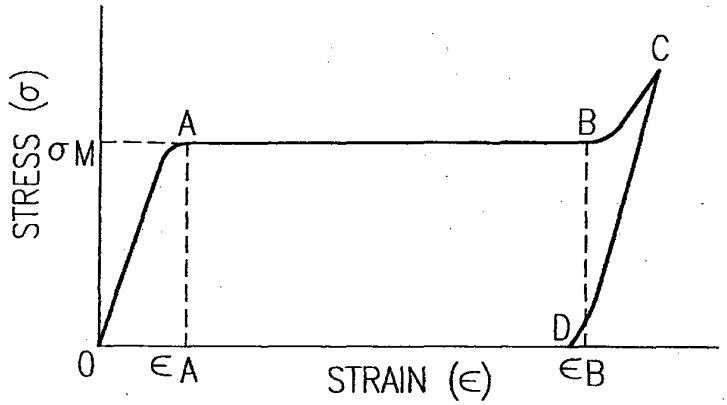


FIG. 1

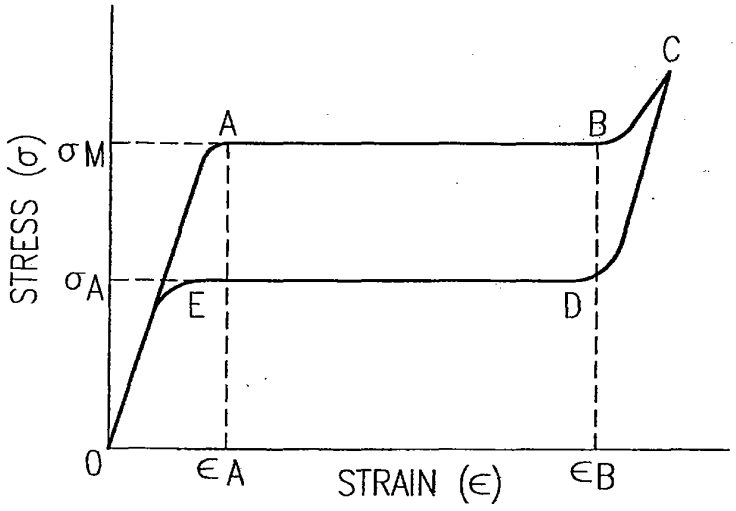


FIG. 2

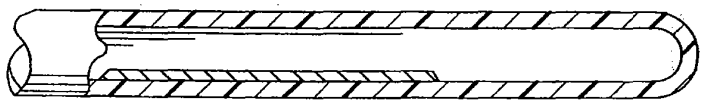
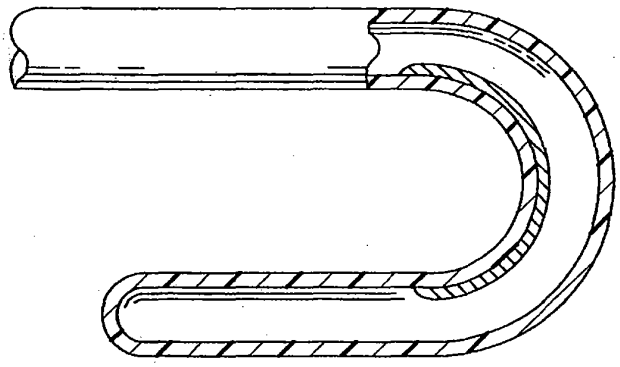


FIG. 3

FIG. 4



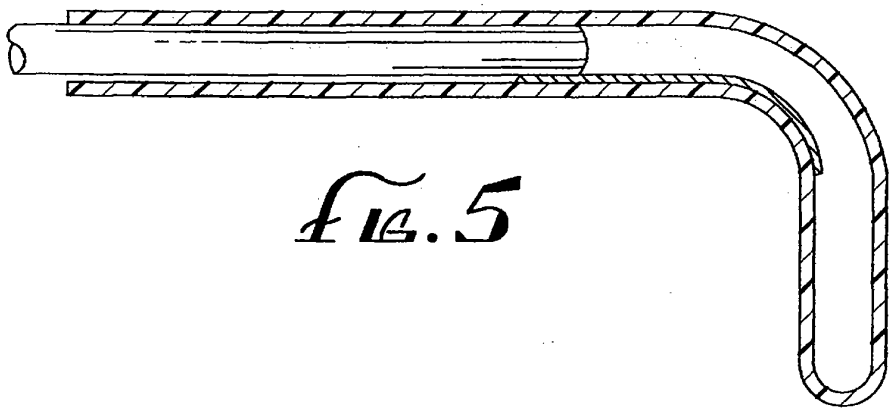


FIG. 5

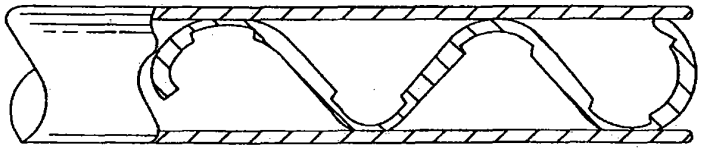


FIG. 6

MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of application Ser. No. 682,243 filed on Apr. 9, 1991, now U.S. Pat. No. 5,190,546, which is a divisional of Ser. No. 252,019 filed on Sep. 27, 1988, now U.S. Pat. No. 5,067,957, which is a continuation of Application Ser. No. 177,817 filed Mar. 30, 1988, now abandoned; which is a continuation of Application Ser. No. 047,824 filed May 8, 1987, now abandoned; which is a continuation of Application Ser. No. 865,703 filed May 21, 1986, now U.S. Pat. No. 4,665,906; which is a continuation of Application Ser. No. 541,852 filed Oct. 14, 1983, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to medical devices incorporating shape memory alloys, and to improvements therein.

2. Introduction to the Invention

Materials, both organic and metallic, capable of possessing shape memory are well known. An article made of such materials can be deformed from an original, heat-stable configuration to a second, heat-unstable configuration. The article is said to have shape memory for the reason that, upon the application of heat alone, it can be caused to revert, or to attempt to revert, form its heat-unstable configuration to its original, heat-stable configuration, i.e. it "remembers" its original shape.

Among metallic alloys, the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state with a change in temperature. This transformation is sometimes referred to as a thermoelastic martensitic transformation. An article made from such an alloy, for example a hollow sleeve, is easily deformed from its original configuration to a new configuration when cooled below the temperature at which the alloy is transformed from the austenitic state to the martensitic state. The temperature at which this transformation begins is usually referred to as M_s and the temperature at which it finishes M_f. When an article thus deformed is warmed to the temperature at which the alloy starts to revert back to austenite, referred to as A_s (A_f being the temperature at which the reversion is complete) the deformed object will begin to return to its original configuration.

Many shape memory alloys (SMAs) are known to display stress-induced martensite (SIM). When an SMA sample exhibiting stress-induced martensite is stressed at a temperature above M_s (so that the austenitic state is initially stable), but below M_d (the maximum temperature at which martensite formation can occur even under stress) it first deforms elastically and then, at a critical stress, begins to transform by the formation of stress-induced martensite. Depending on whether the temperature is above or below A_s, the behavior when the deforming stress is released differs. If the temperature is below A_s, the stress-induced martensite is stable; but if the temperature is above A_s, the martensite is unstable and transforms back to austenite, with the sample returning (or attempting to return) to its original shape. The effect is seen in almost all alloys which exhibit a thermoelastic martensitic transformation, along with the shape memory

effect. However, the extent of the temperature range over which SIM is seen and the stress and strain ranges for the effect vary greatly with the alloy.

In copending and commonly assigned U.S. patent application to Quin, now U.S. Pat. No. 4,503,767 the disclosure of which is incorporated herein by reference, a nickel/titanium/vanadium alloy having SIM over a wide temperature range is disclosed.

Shape memory alloys have found use in recent years in, for example, pipe couplings (such as are described in U.S. Pat. Nos. 4,035,007 and 4,198,081 to Harrison and Jervis), electrical connectors (such as are described in U.S. Pat. No. 3,740,839 to Otte & Fischer), switches (such as are described in U.S. Pat. No. 4,205,293), actuators, etc.

Various proposals have also been made to employ shape memory alloys in the medical field. For example, U.S. Pat. No. 3,620,212 to Fannon et al. proposes the use of an SMA intrauterine contraceptive device, U.S. Pat. No. 3,786,806 to Johnson et al. proposes the use of an SMA bone plate, U.S. Pat. No. 3,890,977 to Wilson proposes the use of an SMA element to bend a catheter or cannula, etc.

These medical SMA devices rely on the property of shape memory to achieve their desired effects. That is to say, they rely on the fact that when an SMA element is cooled to its martensitic state and is subsequently deformed, it will retain its new shape; but when it is warmed to its austenitic state, the original shape will be recovered.

However, the use of the shape memory effect in medical applications is attended with two principal disadvantages. First, it is difficult to control the transformation temperatures of shape memory alloys with accuracy as they are usually extremely composition-sensitive, although various techniques have been proposed (including the blending by powder metallurgy of already-made alloys of differing transformation temperatures: see U.S. Pat. No. 4,310,354 to Fountain et al.). Second, in many shape memory alloys there is a large hysteresis as the alloy is transformed between austenitic and martensitic states, so that reversing of the state of an SMA element may require a temperature excursion of several tens of degrees Celsius. The combination of these factors with the limitation that (a) it is inconvenient to have to engage in any temperature manipulation, and (b) human tissue cannot be heated or cooled beyond certain relatively narrow limits (approximately 0°–60° C. for short periods) without suffering temporary or permanent damage is expected to limit the use that can be made of SMA medical devices. It would thus be desirable to develop a way in which the advantageous property of shape memory alloys, i.e. their ability to return to an original shape after relatively substantial deformation, could be used in medical devices without requiring the delicacy of alloying control and/or the temperature control of placement or removal needed by present shape memory alloy devices.

DESCRIPTION OF THE INVENTION

Summary of the Invention

I have discovered that if, in a medical device containing a shape memory alloy element which uses the shape memory property of that alloy, an element which shows the property of stress-induced martensite is used instead, an improved device results.

Accordingly, this invention provides a medical device intended for use within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature, which device comprises a shape

memory alloy element, the improvement in which comprises the substitution of an alloy element which displays stress-induced martensite at said body temperature for the shape memory alloy element.

BRIEF DESCRIPTION OF THE DRAWING

FIGS. 1 and 2 illustrate the stress-strain behavior of an alloy which exhibits constant stress versus strain behavior due to stress-induced martensite.

FIG. 3 is a side elevation view of a partial section of a catheter of the present invention in a stressed configuration.

FIG. 4 is a side elevation view of the catheter of FIG. 3 in an unstressed configuration.

FIG. 5 is a tracheal catheter, which is curved in its unstressed configuration, partially straightened by a straight pin restraint.

FIG. 6 shows an IUD formed at least partly from a pseudoelastic shape-memory alloy being restrained in a deformed shape by a restraining tube.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention will be discussed first by introducing the concept of stress-induced martensite and the effect achievable by its use, and then by examples showing how SIM alloy elements can be substituted for conventional SMA elements in medical devices to achieve the beneficial effect of the invention.

The Figures illustrate the phenomenon of stress-induced induced martensite by means of stress-strain curves. In both FIG. 1 and FIG. 2, the alloy is at a temperature between M_s and M_d so that it is initially austenitic; and it will be assumed for the purposes of this discussion that M_s is equal to M_f, and A_s equal to A_f. FIG. 1 shows the case when the temperature is below A_s, so that any martensite formed by the applied stress is stable; while FIG. 2 shows the case where the temperature is above A_s, so that austenite is the only stable phase at zero stress.

In FIG. 1, when a stress is applied to the alloy, it deforms elastically along the line OA. At a critical applied stress, σ_M, the austenitic alloy begins to transform to (stress-induced) martensite. This transformation takes place at essentially constant stress until the alloy becomes fully martensitic at point B. From that point on, as further stress is applied, the martensite yields first elastically and then plastically (only elastic deformation is shown at point C). When the stress is released, the martensite recovers elastically to point D, at which there is zero residual stress, but a non-zero residual strain. Because the alloy is below A_s, the deformation is not recoverable until heating above A_s results in a reversion to austenite. At that point, if the sample is unrestrained, the original shape will be essentially completely recovered: if not, it will be recovered to the extent permitted by the restraint. However, if the material is then allowed to re-cool to the original temperature at which it was deformed (or a temperature where SIM behavior of this type is seen), the stress produced in the sample will be constant regardless of the strain provided that the strain lies within the "plateau" region of the stress-strain curve. That is, for a stress between ϵ_B and E_A, the strain will be σ_M. This means that a known, constant force (calculable from σ_M) can be applied over a wide (up to 5% or more for certain Ni/Ti alloys) strain range. Thus, though this resembles the conventional shape memory effect, because the alloy shows SIM and is below A_s a constant force can be achieved.

In FIG. 2, when a stress is applied to the alloy, it deforms elastically along line DA, then by SIM along line AB, and by deformation of the martensite to point C, just as in FIG. 1. However, the stress-strain behavior on unloading is significantly different, since the alloy is above A_s and the stable phase is therefore austenite. As the stress is removed, the alloy recovers elastically from C to D: then, at a critical stress, σ_A, the alloy reverts to austenite without requiring a change in temperature. Thus reversion occurs at essentially constant stress. Finally if the stress is removed from the reverted austenite, it recovers elastically along line EO. The recoverable deformation associated with the formation and reversion of stress-induced martensite has been referred to as pseudoelasticity. While σ_M may be comparatively high, e.g. 50 ksi, σ_A is usually substantially lower, e.g. less than 10 ksi; thereby creating a constant-force spring with an effective working range of about 5% (ϵ_B–ϵ_A). The shape change available in the SMA is thus mechanically, rather than thermally, actuated and controlled, permitting a greater control over a device incorporating it.

Suitable alloy for this invention i.e. those displaying stress-induced martensite at temperatures near mammalian body temperature (35°–40° C.), may be selected from known SMAs by those of ordinary skill in the art having regard to this disclosure by testing for the existence of the SIM effect at the desired temperature. A particularly preferred alloy is the nickel/titanium/vanadium alloy of U.S. patent application No. now U.S. Pat. No. 4,505,767 referred to previously.

The following table sets forth transformation temperature data for alloys disclosed in U.S. Pat. No. 4,505,767:

TABLE

Composition (atomic percent)				
Ni	Ti	V	M_S	A(90)
49.50	43.50	7.00	−107	−88
50.00	44.00	6.00	−96	−84
49.00	43.00	8.00	−83	−61
50.00	45.00	5.00	−42	−33
49.00	45.00	6.00	−35	−12
50.50	48.00	1.50	−32	−6
48.50	44.50	7.00	−30	−13
50.00	46.00	4.00	−11	7
48.50	45.00	6.50	−10	15
49.00	45.50	5.50	−10	14
48.00	44.25	7.75	−7	8
48.50	45.50	6.00	−5	27
41.50	38.50	20.00	−2	86
46.50	43.50	10.00	−1	50
36.25	33.75	30.00	0	42
49.50	46.00	4.50	6	35
48.00	46.00	6.00	12	36
47.75	45.75	6.50	20	54
47.50	45.50	7.00	26	58
48.50	46.50	5.00	27	58
45.00	45.00	10.00	30	71
47.50	46.50	6.00	32	71
46.50	46.50	7.00	34	70

The invention will now be discussed in detail by some Examples of the use of an SIM alloy.

EXAMPLE I

Heart Valves

Akins, in U.S. Pat. No. 4,233,690, the disclosure of which is incorporated herein by reference, describes the use of a

shape memory alloy ring to hold a sewing cuff to the body of an artificial heart valve. The ring is made in the austenitic phase, cooled to the martensitic phase, deformed, placed around the valve body, and heated or allowed to warm to cause reversion to the austenitic phase and recovery of the ring into engagement with the valve body.

However, this technique has not found commercial acceptance. Present medical technique requires that the valve body be capable of being rotated relative to the cuff, thereby enabling the surgeon to set the rotational orientation of the valve after it has been sewn into place. This is desirable because the techniques used make it difficult to visualize or accomplish optimal orientation during initial placement.

In order to accomplish the desired torque control to permit the desired rotation and yet ensure a firm hold of the cuff on the valve body, precise control of the pressure exerted on the valve body by the ring is needed. This is difficult because there are substantial manufacturing tolerances in the valve body which may be made, for example, of pyrolytic graphite or ceramics, etc. Because the austenite stress-strain curve is extremely steep, it is not considered practical to use the simple shape memory technique proposed by Akins. Indeed, Akins does not even address the issue of rotation of the cuff with respect to the valve body.

However, if an SIM alloy is used instead of conventional shape memory, the process may be considerably simplified.

First, if the alloy has a stress-strain curve like that of FIG. 1, the alloy ring may be made just as for Akins. The ring is then expanded from its initial austenitic state by the formation of SIM. When the ring is placed about the valve body, it needs only to be heated above A_f and allowed to cool to its original temperature for the ring to engage the valve body with a constant force, even if the valve body has a deviation from the specified size. The torque may thus be controlled to the desired level despite manufacturing tolerances.

Second, if the alloy has a stress-strain curve like that of FIG. 2, the ring may be expanded, placed over the valve body, and the stress released all at the same temperature. Because the austenitic phase is stable, the stress-induced martensite spontaneously reverts to austenite until recovery is restrained by the ring engaging the valve body. Because the reversion to austenite takes place at constant stress, a constant force (and hence constant torque) may be obtained regardless of manufacturing tolerances. Close temperature control is not required, either; and the fact that the patient in a heart valve replacement operation is conventionally cooled as much as 15° C. or so below normal body temperature does not affect the operation of the ring.

To control the torque at a sufficiently low level, it may be desirable for the alloy ring to be other than a solid ring, such as, for example, a continuous helical spring, a flat zigzag spring, etc. Such variations permit the achievement of a greater range of movement with constant force and a reduction in the force exerted by the ring on the value body, since the ring recovers in a bending mode rather than in tension.

EXAMPLE II

Catheters and Cannulas

Wilson, in U.S. Pat. No. 3,890,977, the disclosure of which is incorporated herein by reference, discloses a catheter or cannula (both being included hereinafter in the word "catheter") made of, or containing, an SMA element to cause all or a portion of the catheter to deploy in a useful form once introduced into a living body.

However, again this device has not been commercialized. Possible defects of the device which have prevented commercialization include (i) the inability to slowly emplace the catheter in a desired position when the transition temperature of the alloy is below body temperature (since the SMA element will attempt to revert to its original shape as it reaches body temperature), thus limiting the ability of the physician to place the device carefully and precisely; or alternatively, if the transition temperature of the alloy is above body temperature, the requirement that the device be heated to a temperature above body temperature to cause recovery and that the device be placed so as not to change shape again when it re-cools (since the body temperature is below the transition temperature); (ii) the inability to remove the device easily: and (iii) the need for controlled temperature storage to prevent premature reversion to austenite of the SMA, with consequent shape change.

The issue of removal of a catheter is especially significant, and not addressed by Wilson. Consider, for example, a tracheal puncture catheter. This should be straight for easy insertion into the trachea through a puncture into the front of the neck, but should curve after insertion so that the flow of air or oxygen through the catheter passes axially down the trachea rather than impinging on the surface of the trachea and damaging it. If a shape memory catheter is used as contemplated by Wilson, it would presumably become austenitic and bend after insertion (see FIGS. *1a* and *1b*, and corresponding text, of Wilson). But removal would require either cooling to below the transition temperature (which could easily mean cooling to so low a temperature that the tracheal tissue is damaged), removal in the bent shape (presumably damaging tissue), or forcing the austenitic SMA to straighten to permit direct removal (unlikely to be satisfactory since the austenitic alloys e.g. of Ni/Ti may have yield strengths of 100 ksi or more, and force sufficient to cause plastic deformation would be required).

If an SMI element is used instead, however, removal can be accomplished almost as easily as insertion. If the catheter is made in a bent shape (as in Wilson), it can be straightened by insertion of a straight pin down the catheter axis, the catheter deforming by the formation of stress-induced martensite. Insertion of the catheter into the trachea is accomplished while the catheter is straight, at whatever rate is desired (permitting easy and accurate placement), and the pin is gradually withdrawn to permit the catheter to take up its desired shape as the martensite reverts to austenite. [It is assumed here that the stress-strain curve of the alloy at the temperature of use is of the form of FIG. 2, so spontaneous reversion occurs on removal of the stress induced by the pin]. When removal is desired, it may be achieve simply by the gradual insertion of the pin, straightening the catheter and permitting easy withdrawal. Insertion of the catheter into the body and pin removal may, of course, take place simultaneously if desired, as may pin reinsertion and removal of the catheter from the body.

EXAMPLE III

IUDS

Fannon et al., in U.S. Pat. No. 3,620,212, the disclosure of which is incorporated herein by reference, discloses an intrauterine contraceptive device (an IUD) proposed to be formed of a shape memory alloy. The device is suggested to be deformed in the martensitic phase (the transition temperature being below the temperature of the uterus), and the deformed device insulated with, e.g., wax and inserted.

Removal is contemplated only by using two SMA elements in opposition, the higher temperature one being martensitic at body temperature but strong enough so that, if heated, it will overcome the lower temperature element and deform the IUD back to a removable shape. The heating contemplated is electrical. The storage problem discussed in Example II also exists here, so that the device must be stored below its transition temperature.

By the use of an SIM element, however, these disadvantages may be overcome. Again, assume that the alloy is SIM psuedoelastic, i.e. that it has the stress-strain curve of FIG. 2. Then an IUD may be formed into the desired shape in the austenitic state, and deformed by compression into a tubular placement device (the deformation being such that the strain levels lie within the "plateau" of the stress-strain curve). The IUD has a longitudinal dimension and a transverse dimension. When the placement device is inserted into the uterus, the IUD may be deployed by extrusion of the IUD from the placement device. Deployment is then controlled but immediate, so that the physician may satisfy himself with placement. Removal is the reversal of placement: the placement device is inserted into the uterus, the IUD deformed by withdrawal into the placement device, and the placement device withdrawn. Temperature control is not required.

EXAMPLE IV

Bone Plates

Johnson et al., in U.S. Pat. No. 3,786,806, the disclosure of which is incorporated herein by reference, propose the use of Ni/Ti SMA bone plates in fracture fixation. The plate is deformed in its martensitic state, screwed to the two ends of the bone it is desired to compress together, and warmed (or allowed to warm) to the austenitic state, when the plate contracts, compressing the bone ends together. The Johnson et al. bone plate is of generally oblong configuration, overlaps a bone fracture and is secured by two screws to one portion of the bone and by two other screws to the other portion of the bone.

Because of the high elastic moduli of the austenitic shape memory alloys, it will be difficult to control the amount of force which may be applied by a bone plate of the type proposed by Johnson et al., and precision placement of the bone ends and elongation of the plate will be required.

If, however, an SIM pseudoelastic bone plate is used, it will be easily possible to elongate the plate and fasten it to the bone ends without requiring high precision. Because of the comparatively large (e.g. 5%) strain range at essentially constant stress, the force which will be put on the bone ends to compress them will be readily adjustable (by the size of the plate, for example) and will be insensitive to precise placement of the bone ends and/or elongation of the plate. Also, the recovery of the plate, since it is controlled by mechanical restraint, may be as gradual as desired, achieving excellent force and time control, and permitting the surgeon to make adjustments as desired.

EXAMPLE V

Marrow Nails

Baumgart et al., in U.S. Pat. No. 4,170,990, the disclosure of which is incorporated herein by reference, discloses the use of the two-way shape memory effect (where an SMA element exhibits a first shape in the austenitic state and a second in the martensitic state, and spontaneously changes between the two shapes with a change in temperature) in, inter alia, implants such as marrow nails (see FIGS. 1*a* through 1*e*, and corresponding text, of Baumgart et al.) Marrow nails according to Baumgart et al. comprise a tube of memory alloy which has been split along its longitudinal axis and which may have a circular, elliptical, clover-leaf on other rotation preventing cross section, which may also be variable along the axis of the nail. A prepared marrow nail having a reduced diameter is loosely inserted into a slightly, or not at all, pre-drilled marrow channel of a bone which has been broken or fractured. By means of a heating probe the marrow nail is heated and thus expands. This achieves a relative fixing of the two bone ends along the marrow channel axis. Compression of the fracture is effected by the available muscle tension. If it should be necessary, the marrow nail may also be additionally prestretched along its longitudinal axis so that it is additionally compressed in the longitudinal direction when heated. In this case it is necessary, however, to anchor the nail at both of its ends which anchoring can be effected, for example, by sprockets or teeth on the outer surface of the nail.

The method proposed, however, requires the use of a wide temperature range in order to cause the phase change which is the origin of the two-way shape memory effect (5° C. to 60° C. for the water used to cool or heat the nail). In addition, it requires the manufacture of two-way shape memory elements, which is generally more complex than the manufacture of conventional shape memory elements; and precise control of the transition temperature is required.

However, if an SIM pseudoelastic alloy element is employed, these disadvantages may be overcome. If internal tangs, which may be gripped by an inserted tool, are provided within a marrow nail of the type shown in FIG. 1*a* of Baumgart et al., then the nail may be radially compressed by the application of stress by such a tool. When the nail is released by the tool, it will expand to fill the bone channel with a constant force (not readily available by Baumgart et al.); and it may be withdrawn by the reverse procedure.

EXAMPLE VI

Dental Arch Wire

Andreasen, in U.S. Pat. No. 4,037,324, the disclosure of which is incorporated herein by reference, proposes the use of dental arch wires made of Ni/Ti alloys instead of conventional 18-8 stainless steel wires. The wires are stated to be of lower elastic modulus and higher elastic limit than stainless steel, which is stated to be advantageous. Heat recovery of an SMA wire is also suggested as a technique for orthodonture.

The technique of using the conventional shape memory effect is not believed to have found clinical application, possibly because such a technique would require rapid placement of the wire in its martensitic state to avoid premature recovery, and would result in rapid recovery with extremely high forces, which would be painful for the patient.

The use of a wire which displays lower elastic modulus and higher elastic limit than stainless steel has found some application, however. Otsuka et al. in Metals Forum, v. 4, pp. 142–52 (1981) have suggested that this behavior may be the result of elasticity enhanced by cold working and martensite-to-martensite psuedoelasticity in an alloy which has a transition temperature below body temperature. The alloy, then, is martensitic rather than austenitic in its undeformed state.

While the use of an enhanced elasticity wire may offer some advantages over the more usual stainless steel wire, it

remains the situation that the amount of motion in the teeth that may be produced by an arch wire without further adjustment is largely limited by the pain tolerance of the patient (since the force applied by the arch wire is proportional to the deformation of the wire). However, is an SIM pseudoelastic wire is used, it can exert a relatively constant force (chosen by the dentist to be sufficient to cause tooth movement but not painful) over a strain range of up to 5%. The load may be applied mechanically, and is thus more readily established, and no precise temperature control of the alloy is needed as would be required for the shape memory effect.

EXAMPLE VII

Coil Stents and Filters

The use of tubular coiled wire stent grafts has been discussed in the medical literature since 1969. Although the coils helped maintain patency of the vessels in which they were placed, they were difficult of insertion unless narrow enough to significantly narrow the lumen of the vessel. Recently it has been proposed, see Radiology, v. 147, pp. 259–60 and pp. 261–3 (1983), the disclosures of which are incorporated herein by reference, to use SMA wire to form these tubular coils. The wire, which has a transformation temperature below body temperature, is introduced through a catheter after being straightened in its martensitic state. When the wire is heated, the coil re-forms.

Because of the difficulty of controlling the transformation temperature accurately, it has proved necessary to cool the straightened wire during insertion and/or to heat the wire to form the coil after insertion. These procedures add to the complexity of the operation.

If an SIM pseudoelastic wire is used to form the coil, which is then isothermally deformed by loading into a catheter, then the need for temperature control is avoided. The wire remains straight when in the catheter, but re-forms the coil spontaneously when it is extruded from the catheter. Accurate placement is thus readily obtainable, since there is no urgency as might be required with a conventional shape memory effect element.

It has similarly been proposed to use SMA wire to form a filter for emplacement by catheter in the vena cava to trap blood clots. The filter is formed in the austenitic state, the wire straightened in the martensitic state and inserted, and the filter re-forms on warming. Just as for the coil stents discussed above, the use of an SIM pseudo-elastic wire would greatly simplify manufacture and insertion of such a vena cava filter, permitting accurate placement with no need for urgency or temperature manipulation.

EXAMPLE VIII

Bone Staples, Clips, etc.

Bone staples are frequently used to hold fragments of fractured bone together when the fracture is fixed, and may be used in some cased as a replacement for bone plates in the same situation. Sometimes the staples are inserted into drilled holes, sometimes merely driven into the bone directly.

It would be desirable to have a bone staple which provided a controlled force between the tines which would tend to hold the staple in place. Shape memory alloys have been proposed for this application, but again the problem of accurate placement while operating quickly enough to prevent the shape change associated with the martensite-to-austenite transition and/or the need for temperature control complicate their use.

If an SIM alloy is used, these disadvantages may be readily overcome. If the alloy is below A_s, it may be emplaced in the martensitic state. Brief heating will then be required to cause it to become austenitic, but on re-cooling to body temperature, a constant force can be achieved. If the alloy is above A_s, the staple can be held deformed by a moderate force, then released after insertion to also provide an accurately-known force. In either event, removal is easier than if the alloy is purely austenitic, as discussed above for Examples II and V, for example.

Similarly, SIM alloy (especially alloy which is pseudoelastic, above A_s at its utilization temperature) may be used to manufacture vascular clips, etc. The alloy element here acts as a constant force spring over a wide strain range (greater than conventional elastic metals), resulting in ease of use.

From the foregoing, it is clear that, in a situation where narrow temperature differences are available or preferable, as often is the case in medical applications, mechanically constrained shape change is a much more useful solution than heat actuated shape change. It offers a degree of control heat actuation does not, it offers easier alloy composition control, it eases mating part tolerance requirements, and it offers simple mechanical reversal at minimal stress levels, all without heating, cooling or insulation complications.

It will be obvious to those skilled in the art, having regard to this disclosure, that other variations on this invention beyond those specifically exemplified here, and other medical devices making use of stress-induced martensite, may be made. Such variations are, however, to be considered as coming within the scope of this invention as limited solely by the following claims.

I claim:

1. A medical device which comprises:

(a) an element for use within a human body or in such proximity to a human body that the device is substantially at human body temperature, the element comprising a shape memory alloy which displays a stress-induced martensite behavior at body temperature; and

(b) a restraint holding the shape memory alloy element in a deformed configuration at a temperature less than the body temperature of the human for positioning the shape memory alloy element within or in proximity to the human body in its deformed configuration, the deformation occurring through the formation of stress-induced martensite;

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

2. A device as claimed in claim 1, in which the restraint is hollow, and the shape memory alloy element is positioned at least partially within the restraint.

3. A device as claimed in claim 2, in which the restraint is a catheter.

4. A device as claimed in claim 2, in which the shape memory alloy element is an intrauterine contraceptive device.

5. A device as claimed in claim 2, in which the shape memory alloy element is a filter for a blood vessel.

6. A device as claimed in claim 1, in which the shape memory alloy element is tubular, and the restraint is positioned within the shape memory alloy element to deform it.

7. A device as claimed in claim 2, in which the shape memory alloy element has a transverse dimension and a longitudinal dimension, and wherein the shape memory alloy element is deformed by its transverse dimension being reduced, and wherein the restraint prevents transverse expansion of the element.

8. The device of claim 1, 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 memory alloy element from its deformed configuration without change in state of the restraint.

9. A medical device suitable for placement within or proximate to a mammalian body for treatment of the mammalian body, the device comprising:

(a) a memory alloy element formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying 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 memory alloy element at a temperature less than the body temperature of a human and greater than the As of the alloy for positioning the memory alloy element within or in proximity to the mammalian body while the memory alloy element is in its deformed shape;

wherein the alloy is selected so that removal of the restraining means from the memory alloy element at a temperature greater than the As of the alloy when the device is placed within or proximate to the human body, transforms at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape toward its unstressed shape, without any change in temperature of the restraining means or the memory alloy element being required for the transformation of the alloy.

10. A medical device for treatment of a mammalian body, the device comprising:

(a) a memory alloy element formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about human 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; and

(b) a hollow restraining member with the memory alloy element being within the restraining member, the restraining member engaging and stressing the memory alloy element at a temperature less than the body temperature of the human and greater than the As of the alloy for positioning the memory alloy element within or in proximity to the mammalian body while the memory alloy element is in its deformed shape;

wherein the restraining member and the memory alloy element are movable relative to each other to transform at least a portion of the alloy from its stress-induced martensitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the memory alloy element.

11. The medical device of claim 10 wherein the restraining member is a tube and the memory alloy element is axially slidable within the tube, and wherein the memory alloy element is sufficiently long that relative axial movement between the tube and the memory alloy element extends at least a portion of the memory alloy element beyond the tube and thereby transforms the memory alloy element toward its austenitic state.

12. The device of claim 11 wherein the memory alloy element can be extruded completely out of the tube for deployment in the mammalian body.

13. A medical device for treatment of a mammalian body, the device comprising (i) a restraining member and (ii) a hollow memory alloy element formed at least partly from a 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;

the restraining member being within the hollow memory alloy element and engaging and stressing the memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element is in its deformed shape;

wherein the restraining member and the memory alloy element are movable relative to each other to transform at least a portion of the alloy from its stress-induced martensitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the alloy is selected that the transformation can occur without any change in temperature of the restraining member or the memory alloy element.

14. The device of claim 13 wherein the memory alloy element is a tube and the restraining member is axially slidable within the tube, and wherein the tube is sufficiently long that relative axial movement between the tube and the restraining members extends at least a portion of the tube beyond the restraining means and thereby transforms the tube toward its austenitic shape.

15. A medical device for insertion into a human body, the device comprising (i) a restraining member and (ii) a hollow catheter formed at least party from a pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about human body temperature such that it has a stress-induced martensitic state and an austenitic state, the catheter having (i) an easily inserted 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;

the restraining member engaging and stressing the catheter at a temperature greater than the As of the alloy so that the catheter is in its easily inserted shape so that the catheter can be inserted into the mammalian body;

wherein disengagement of the restraining member from the catheter at a temperature greater than the As of the alloy transforms at least a portion of the alloy from its stress-induced martensitic state to its austenitic state so that the catheter transforms from its easily inserted shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the catheter.

16. The medical device of claim 15 wherein the catheter is a cannula.

17. A medical device for insertion into a human body, the device comprising (i) a straight pin and (ii) a catheter formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at

about human body temperature such that it has a stress-induced martensitic state and an austenitic state, the catheter having (i) a straight shape when the alloy is in its stress-induced martensitic state and (ii) a curved unstressed shape when the alloy is in its austenitic state;

the straight pin engaging and stressing the inside of the catheter at a temperature greater than the As of the alloy so that the catheter is in its straight shape;

wherein withdrawal of the pin from the catheter at a temperature greater than the As of the alloy transforms at least a portion of the alloy from its stress-induced martensitic state to its austenitic state so that the catheter transforms from its straight shape to its curved shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the pin or the catheter.

18. The medical device of claim **17** wherein the catheter is a tracheal insertion catheter.

19. The invention of claim **9** wherein the transformation of the alloy occurs without any change in the state of the restraining means.

20. The invention of claim **10, 13** or **15** wherein the transformation of the alloy occurs without any change in the state of the restraining member.

21. The invention of claim **17** wherein the transformation of the alloy occurs without any change in the state of the pin.

22. The invention of claim **9, 10** or **13** wherein the memory alloy element exerts constant stress during its transformation.

23. The invention of claim **15** or **17** wherein the catheter exerts constant stress during its transformation.

24. The medical device of claim **9** wherein the removal of the restraining means from the memory alloy element causes at least a portion of the alloy to transform to its austenitic state.

25. The medical device of claim **10, 13, 15** wherein relative movement of the restraining member and the memory alloy element causes at least a portion of the alloy to transform to its austenitic state.

26. The device of claim **24** wherein the alloy is selected so that engaging the restraining means with the memory alloy element after removal results in the memory alloy element transforming toward its deformed shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

27. The device of claim **25** wherein (i) the restraining member can be completely disengaged and separated from the memory alloy element, and (ii) the alloy is selected so that engaging the restraining member with the memory alloy element after separation results in the memory alloy element transforming towards its deformed shape by reversion to its stress-induced martensitic state.

28. The device of claim **15** wherein (i) the restraining member can be completely disengaged and separated from the catheter, and (ii) the alloy is selected so that reengaging the restraining member with the catheter after separation results in the catheter transforming toward its easily inserted shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

29. The device of claim **17** wherein (i) the pin can be completely disengaged and separated from the catheter, and (ii) the alloy is selected so that reengaging the restraining means with the memory alloy element after separation results in the catheter transforming toward its deformed shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

30. The device of claim **36** wherein (i) the placement device can be completely disengaged and separated from the catheter, and (ii) the alloy is selected so that reengaging the placement device with the catheter after separation results in the catheter transforming toward its deformed shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

31. The medical device of claim **15** wherein the restraint externally engages the catheter.

32. The medical device of claim **15** wherein the restraint internally engages the catheter.

33. A medical device suitable for placement within or proximate to a mammalian body for treatment of the mammalian body, the device comprising (i) a restraint, and (ii) an element formed at least partly from a pseudoelastic shape-memory alloy,

the alloy displaying reversible stress-induced martensite by virtue of being above its A_s and above its M_s and below its M_d at about body temperature;

such that it has a stress-induced martensitic state and an austenitic state, the element having (i) a deformed shape when the alloy is in its stress-induced martensitic state and (ii) a different unstressed shape;

wherein the restraint is (i) stressing the element at a temperature less than the body temperature of the mammal for placement of the element in its deformed shape in or in proximity to the mammalian body and (ii) is capable of being at least partially removed from the element while the device is within or proximate to the body at the body temperature and the element is therefore at an operating temperature greater than the A_s and M_s and below the M_d of the alloy,

such removal of the restraint causing at least a portion of the alloy to transform from its stress-induced martensitic state to its austenitic state so that the element spontaneously transforms from its deformed shape toward its unstressed shape,

and such transformation can occur without a change in temperature of the restraint or of the element from the operating temperature.

34. A medical device for treatment of a human body, the device comprising:

(a) a memory alloy element formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about human 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; and

(b) a hollow tubular restraining member with the memory alloy element being within the restraining member, the restraining member engaging and stressing the memory alloy element at a temperature greater than the As of the alloy so that the memory alloy element is in its deformed shape;

wherein the memory alloy element is axially slidable within the tube, and wherein the memory alloy element can be extruded completely out of the tube for deployment in the mammalian body to transform at least a portion of the alloy from its stress-induced martensitic state towards its austenitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the memory alloy element.

35. A medical device which comprises:

(a) a tubular element for use within a human body or in such proximity to a human body that the device is substantially at human body temperature, the tubular element comprising a shape memory alloy which displays stress-induced martensite behavior at body temperature; and

(b) a restraint within the tubular element holding and deforming the tubular shape memory alloy element in a deformed configuration to allow it to be positioned within or in proximity to a human body, the deformation occurring through the formation of stress-induced martensite;

wherein the tubular element is sufficiently deformed that removal of the restraint from the tubular shape memory alloy element, without change in temperature of the device, releases at least a portion of the tubular element from its deformed configuration.

36. A medical device for treatment of a human body, the device comprising (i) a restraining member and (ii) a hollow memory alloy element formed at least partly from a pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about human 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;

the restraining member being within the hollow memory alloy element and engaging and stressing the memory alloy element at a temperature less than the body temperature of the human and greater than the As of the alloy for positioning the memory alloy element within or in proximity to the human body while the memory alloy element is in its deformed shape;

wherein the restraining member and the memory alloy element are movable relative to each other to transform at least a portion of the alloy from its stressed-induced martensitic state at a temperature greater than the As of the alloy so that the memory alloy element transforms from its deformed shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member of the memory alloy element.

37. The device of claim 36 wherein the memory alloy element is a tube and the restraining member is axially slidable within the tube, and wherein the tube is sufficiently long that relative axial movement between the tube and the restraining member extends at least a portion of the tube beyond the restraining member and thereby transforms the tube toward its austenitic shape.

38. A medical device for insertion into a human body, the device comprising (i) a restraining member and (ii) a hollow catheter formed at least partly from a pseudoelastic shape-memory allow, the alloy displaying reversible stress-induced martensite at about human body temperature such that it has a stress-induced martensitic state and an austenitic state, the catheter having (i) an easily inserted 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;

the restraining member engaging and stressing the catheter at a temperature less than the body temperature of the human and greater than the As of the alloy so that the catheter is in its easily inserted shape for inserting the catheter into the human body; and

wherein disengagement of the restraining member from the catheter at a temperature greater than the As of the alloy transforms at least a portion of the alloy from it stress-induced martenistic state to its austenitic state so that the catheter transforms from its easily inserted shape toward its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraining member or the catheter.

39. The invention of claim 34, 36 or 37 wherein the transformation of the alloy occurs without any change in the state of the restraining member.

40. The device of claim 38 wherein the device is adapted so that (i) the restraining member can be completely disengaged and separated from the catheter, and (ii) re-engaging the restraining member with the catheter after separation results in the catheter transforming toward its easily inserted shape by reversion of at least a portion of the alloy from its austenitic state to its stress-induced martensitic state.

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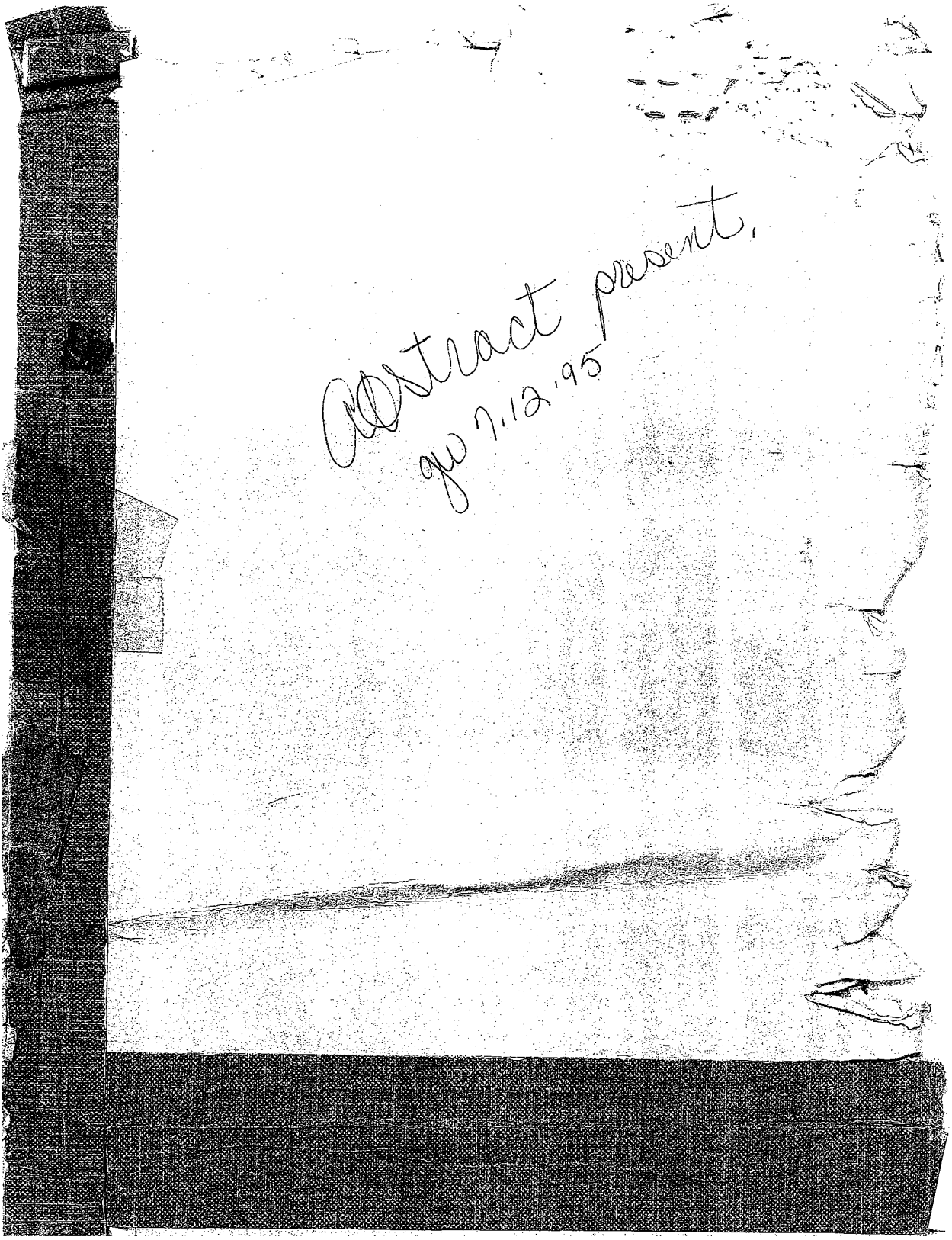
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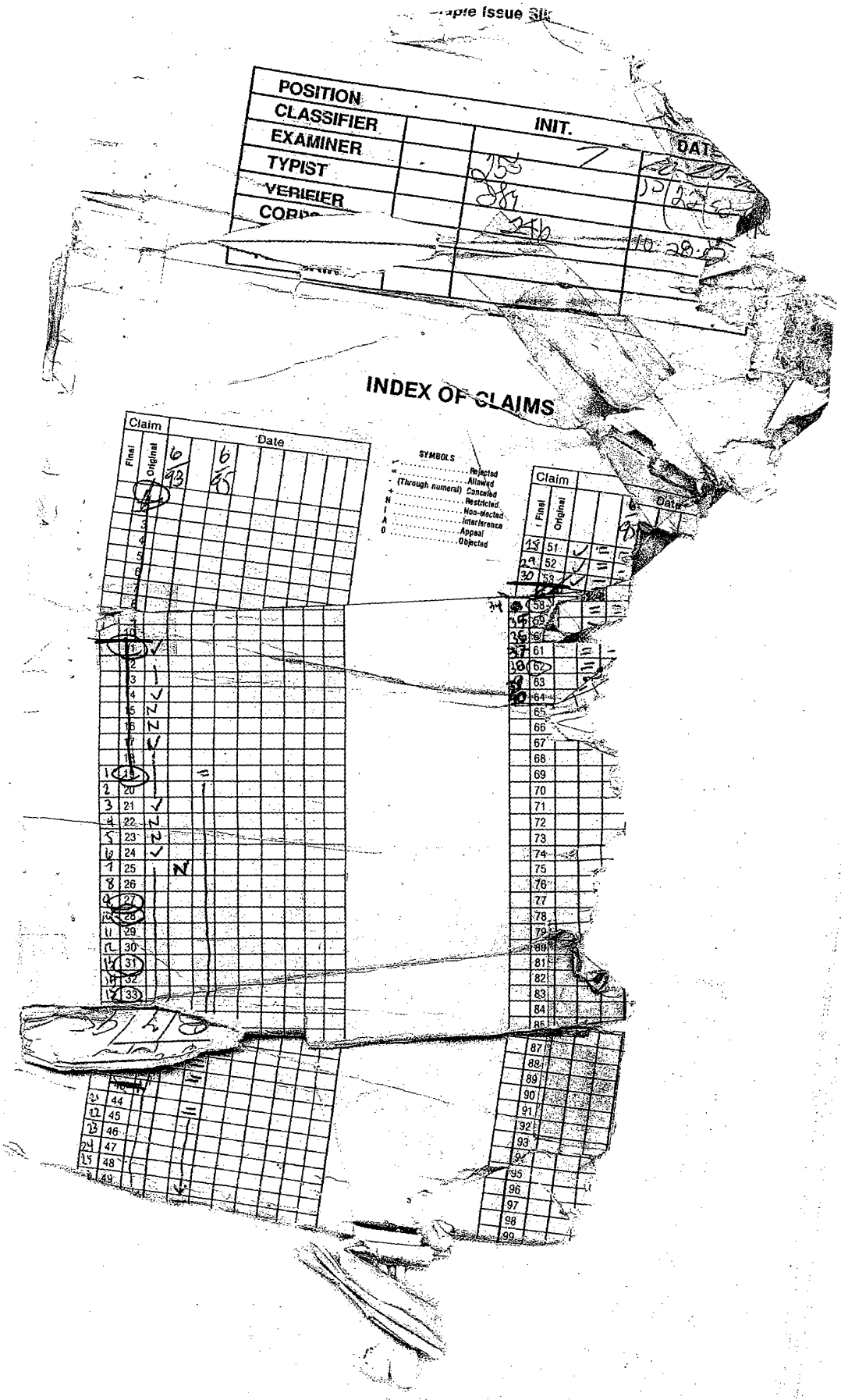
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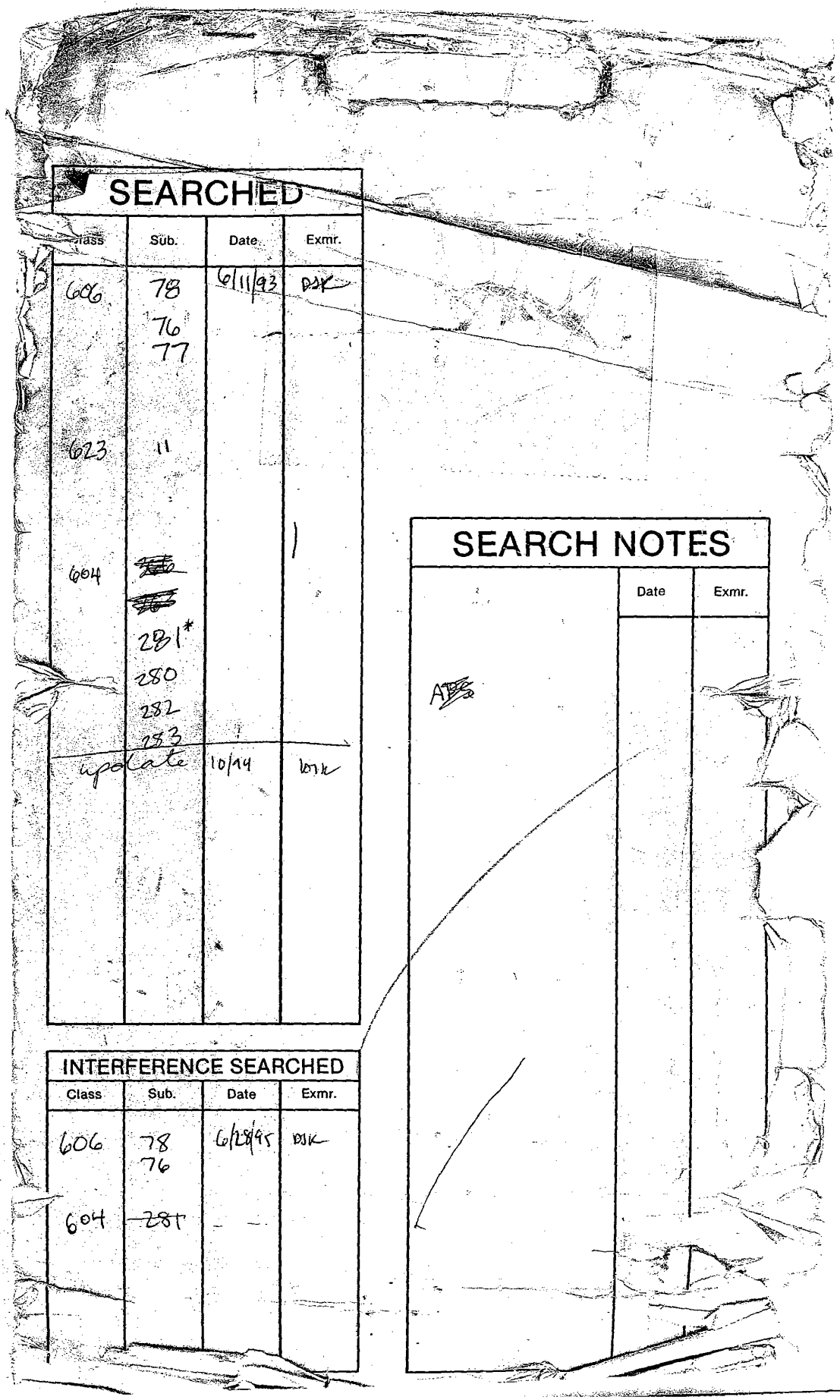

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	282		
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update		10/14	DSK

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
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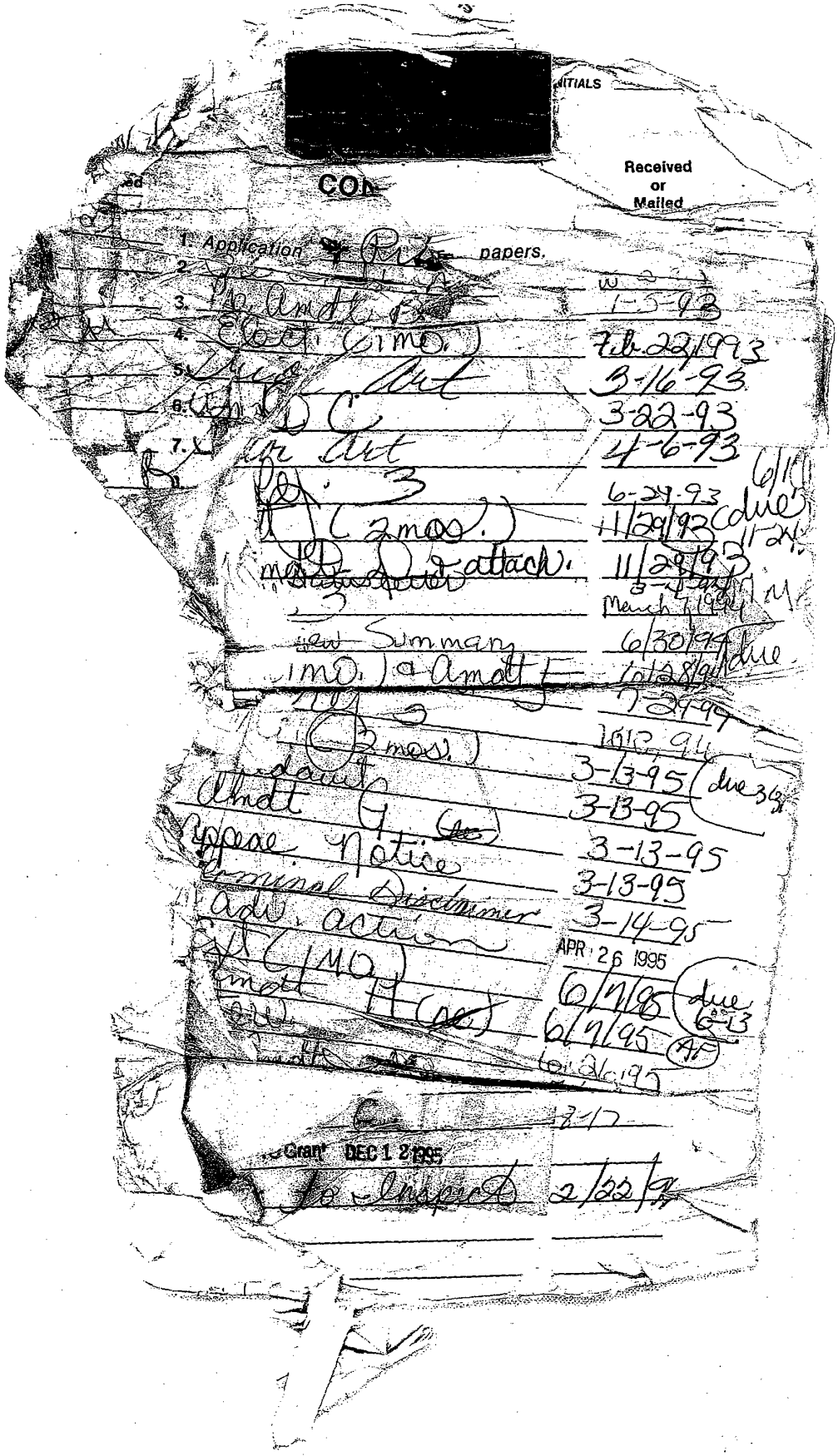
SEARCH NOTES

	Date	Exmr.
~~ABS~~		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COD
Received or Mailed
1. Application papers.
2.
3. to Amdt. E
4. Elect. (1 mo.)
5.
6.
7.
Amdt
(2 mos.)
attach.
Summary
(1 mo.) a Amdt E
(2 mos.)
Amdt
Appeal Notice
Original Disclaimer
Adv. action
(40)
Amdt
Grant
to Inspect
1-5-93
Feb 22 1993
3-16-93
3-22-93
4-6-93
6-24-93
11/29/93 due
11/29/93
March 1994
6/30/94 due
6/28/94 due
7-29-94
3-13-95 due 3-3
3-13-95
3-13-95
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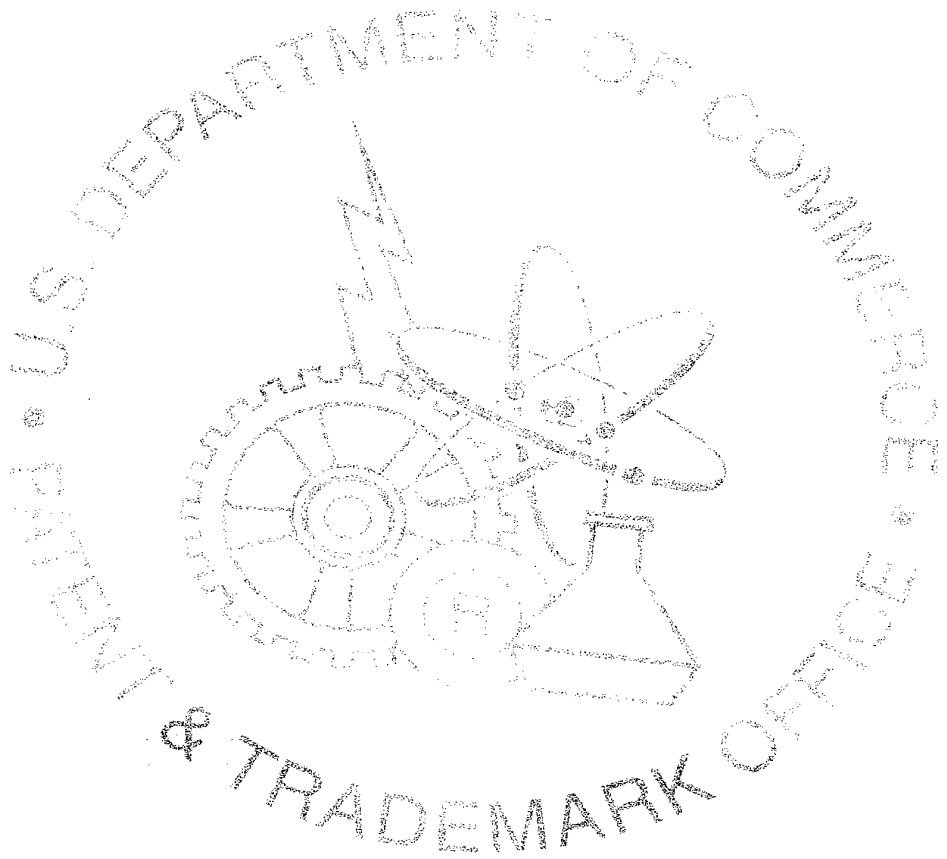
3-14-95
APR 26 1995
6/7/95 due 6-13
6/7/95
6/21/95
DEC 1 2 1995
2/22/96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PATENT & TRADEMARK OFFICE