read in the Patel application, this heat-treatment is repeated on the same Nitinol wire, ribbon, sheet or tubing. The application does not state the number of times it is repeated but it is referred to as not complete in one step. This process of heat-treatment and cold working will produce "long fatigue life Nitinol which is the title of this application. Now that the Nitinol wire, ribbon, sheet or tubing has been heat-treated for stress relief (underlining added) (referred to in [0013] as "interspersed anneal cycles for stress relief"), it needs to be cold worked to reestablish its superelasticity which is reinforced in paragraph [0013] as shown below:

> "[0013] the present invention high fatigue life Nitinol is preferably processed from an ingot of the composition specified above. The ingot is cold reduced or cold worked and annealed repeatedly (underlining added) to preferably a wire, ribbon, sheet, or tubing form. The Nitinol is then cold worked through wire drawing, tube drawing, rolling, or like processes with interspersed anneal cycles for stress relief. As mentioned earlier, the final, after full anneal, cold working step (underlining added) is preferably limited to less than approximately 30% reduction in cross sectional area to achieve the desired long fatigue life."

8. Patel explains in paragraph [0030], ". . the ingot undergoes a sequence of cold working and anneal cycles to reduce the ingot into preferably a wire, ribbon, tubing or sheet of a desired cross-sectional area through the processing steps explained above." This is confirmed in a paper, "Effect of heat treatment on the superelasticity and hardness of NiTi" by Mortagy, O and Farag, M available as an online publication found at the following site:

http://www.academia.edu/820015/Effect_of_Heat_Treatment_on_the_Superelasticity_and_Hardness_of_NiTi

The conclusions drawn by the authors are that superelasticity of annealed cold-worked NiTi was influenced by arranged dislocations and precipitation. This was accomplished

through heat-treatment and final cold-worked NiTi. Another conclusion was that superelasticity of annealed cold-worked NiTi increased as micro and nanohardness increased. This will account for the long fatigue life Nitinol which Patel was attempting to make with the Patel application.

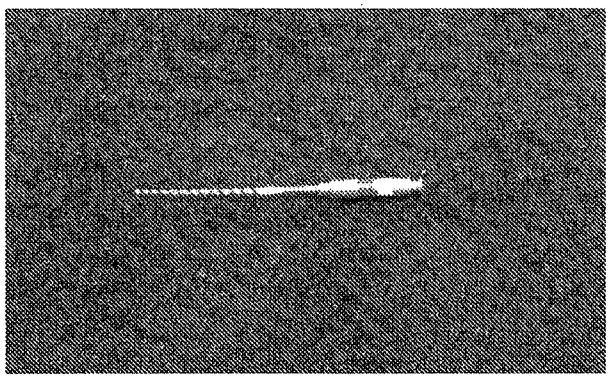
9. Lastly with Patel the final step (underlining added) for this invention was cold working the Nitinol wire, ribbon, tubing or sheet to assure the Nitinol was in a superelastic state (underlining added). The fact that the Nitinol wire, ribbon, sheet, or tubing is superelastic means it remains in an austenitic state.

10. 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 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 above-identified application or any patent issuing thereon.

Dated: February 13, 2013

Dr. Neill H. Luebke

Applicant's Exhibit 1
Standard Nickel Titanium Endodontic File

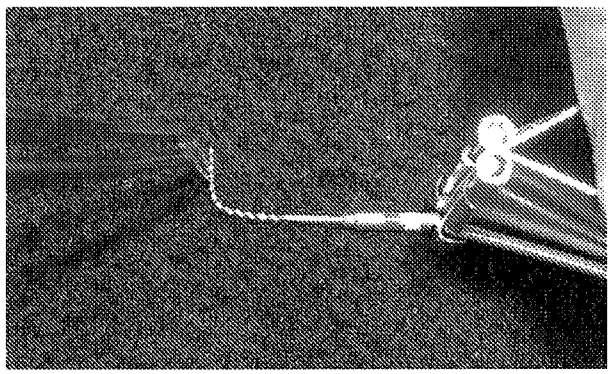


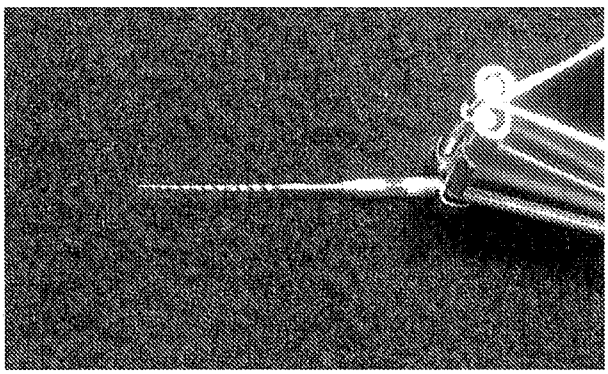
File Size 25 with 04 taper

Natural straight orientation before pressure is applied

File Size 25 with 04 taper

with pressure applied

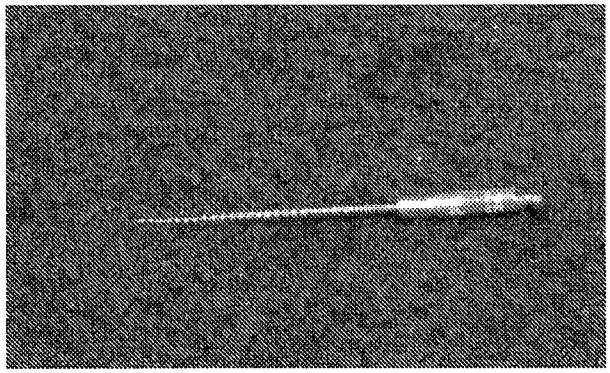




File Size 25 with 04 taper

with pressure released, file returns to natural straight orientation

Applicant's Exhibit 2
Luebke Heat-Treated Endodontic File
Size 25 with 04 taper



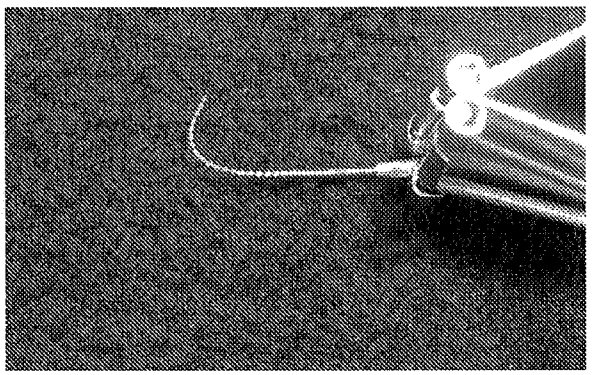
File Size 25 with 04 taper

Natural straight state before pressure is applied

File Size 25 with 04 taper

Curved state after bending pressure applied and after pressure released.

It does not return to original state



Electronic Acknowledgement Receipt	
EFS ID:	14964945
Application Number:	13336579
International Application Number:	
Confirmation Number:	4379
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton LUEBKE
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	115207.00007
Receipt Date:	14-FEB-2013
Filing Date:	23-DEC-2011
Time Stamp:	18:01:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		response-final-2-14-13.pdf	90371 b38f09cb7f7629b1f5f42ee3b861af4a8abf669d	yes	8

	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment After Final		1	1	
	Claims		2	4	
	Applicant Arguments/Remarks Made in an Amendment		5	8	
Warnings:					
Information:					
2	Affidavit-submitted prior to Mar 15, 2013	Luebke_Inventor_Declaration_2-14-2013.PDF	1337681 9ba05aab80545a8f32943b4f99d81e597d520155	no	7
Warnings:					
Information:					
		Total Files Size (in bytes):	1428052		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/336,579	Filing Date 12/23/2011	☐ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 02/14/2013	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 13	Minus	** 20	= 0	X $31 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $125 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* 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 column 1.

Legal Instrument Examiner:
/NINA RATANAVONG/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/336,579	12/23/2011	Neill Hamilton LUEBKE	115207.00007	4379

26710 7590 03/07/2013

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER	
NELSON, MATTHEW M	
ART UNIT	**PAPER NUMBER**
3776	

NOTIFICATION DATE	DELIVERY MODE
03/07/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Advisory Action **Before the Filing of an Appeal Brief**	**Application No.** *13/336,579*	**Applicant(s)** LUEBKE, NEILL HAMILTON
	Examiner MATTHEW NELSON	**Art Unit** 3776

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 February 2013 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance;

(2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.

Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because

a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);

b) ☐ They raise the issue of new matter (see NOTE below);

c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): (a) ☒ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

STATUS OF CLAIMS

14. The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: .

Claim(s) objected to: .

Claim(s) rejected: 1-14.

Claim(s) withdrawn from consideration: .

/TODD E. MANAHAN/ Supervisory Patent Examiner, Art Unit 3776	/Matthew M Nelson/ Examiner, Art Unit 3776

Continuation of 3. NOTE: The amendment merely brings a limitation of the dependent claims into the independent claim and therefore does not further reduce or simplify the issues for appeal.

Continuation of 11. does NOT place the application in condition for allowance because: The affidavit is acknowledged. However, the test comparison (no heat treatment) is not representative of the prior art of Patel which states heat treatment in [0041]-[0042].
Applicant argues that incorporating "nickel-titanium alloy" into the independent claim overcomes the 112 enablement rejection, however this is not sufficient and the 112 rejection would remain that not all nickel-titanium alloys subjected to this heat treatment would result in that degree of deformation (as evidenced by Applicant stating that cold working after the heat treatment would remove the alloy from the martensitic state). The dependent claims do not provide further steps that would always result in this degree of permanent deformation (such as prohibiting a cold working step to place the alloy back in austenitic for instance).
Applicant argues that the material created by the method of Patel is superelastic, however Patel shows in [0041] and [0042] the exact same method steps of the current claims and therefore the resulting structure would need to be the same unless the claim is not fully enabled.
Applicant argues that Patel would not be able to achieve the permanent deformation limitation since the final step is a cold work bringing it back to austenitic phase, however the claim is not specific as to when the device has this deformation amongst the method steps. Patel is in a martensitic phase after the heat treatment and would therefore meet this permanent deformation at that point in time.
Applicant argues that the orthodontic wire of [0004] would not have the permanent deformation, however, as stated above, it would have this deformation after one of its heat treating steps.
In summary, the independent claim remains unenabled because not all nickel-titanium alloys subjected to the specified heat treatment at some point in the manufacturing results in the permanent deformation stated (i.e. if a cold work step was performed after the heat treatment). Additionally, the claim remains unspecific as to when the flexion test is conducted.

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	13336579	Filing Date	2011-12-23	Docket Number (if applicable)	115207.00007	Art Unit	3776
First Named Inventor	Neill Hamilton Luebke			Examiner Name	Matthew M. Nelson		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☒ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 170055

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2013-06-19
Name	Richard T. Roche	Registration Number	38599

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Docket Number: 115207.00007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	13/336,579
Filing Date:	December 23, 2011
Title:	Dental And Medical Instruments Comprising Titanium
Art Unit:	3776
Examiner:	Matthew M. Nelson

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

1. I am the named inventor for the above-identified patent application.

2. As detailed in my Inventor's Declaration dated February 15, 2010 and submitted in U.S. Patent Application No.11/628,933 (from which the above-identified patent application claims priority), as a control standard, I obtained an instrument in accordance with ISO Standard 3630-1 made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium and including an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. The control (non-heat treated) instrument had a natural straight orientation before pressure was applied. See the top photo in attached Applicant's Exhibit 1. Pressure was applied to the control instrument with cotton pliers until the

control instrument had a bend of approximately 90 degrees. See the middle photo in Applicant's Exhibit 1. After the bending pressure was released, the control instrument returned to the original natural straight orientation. See the bottom photo in Applicant's Exhibit 1.

3. Another instrument in accordance with ISO Standard 3630-1 made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium and including an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank was heat-treated in a furnace at 500°C for 75 minutes. The heat-treated instrument had a natural straight orientation before pressure was applied. See the top photo in attached Applicant's Exhibit 2. Pressure was applied to the heat-treated instrument with cotton pliers until the heat-treated instrument had a bend of approximately 90 degrees. After the bending pressure was released, the heat-treated instrument did not return to its original natural straight orientation. See the bottom photo in Applicant's Exhibit 2.

4. It is believed that the control instrument detailed in Item 2 above exhibited superelastic behavior as described in U.S. Patent Application Publication No. 2005/0090844 to Patel *et al.* ("Patel") that was cited in the Office Action mailed on December 19, 2012.

5. In contrast, the heat-treated instrument detailed in Item 3 above underwent permanent deformation as in the claimed invention of my above-identified patent application.

6. It is noted that pending claim 1 of my above-identified patent application recites permanent deformation and not just deformation. The Office Action cites the mention of orthodontic wires in Patel as an example for deformation but the orthodontic wires in Patel are austenitic NiTi which means they will be superelastic and will deform under stress but will return to their original shape which is the precise mechanism that allows teeth to be orthodontically moved. This explains why an orthodontic wire may be deformed to fit the dental arch and still be superelastic (austenitic NiTi). Permanent deformation refers to martensitic NiTi and will remain permanently deformed (underlining added) which is recited in claim 1 in this application. Items 2-5 above and the attached photographs of Exhibits 1 & 2 demonstrate the differences between superelasticity and permanent deformation.

7. Further, Patel is attempting to make a high fatigue life Nitinol wire, ribbon, sheet, or tubing to be made into a device implanted in the body which has a long period of service. To accomplish this end, in paragraph [0011] Patel heat-treats the Nitinol wire, ribbon, sheet or tubing between 450°C and 500°C with no time stated. In paragraph [0012] Patel states, "In accordance with the present invention, the high fatigue metal wire (underlining added) in a heat-treated condition has a fatigue life greater than approximately 22,760 mean cycles to failure . . .". As one continues to

read in the Patel application, this heat-treatment is repeated on the same Nitinol wire, ribbon, sheet or tubing. The application does not state the number of times it is repeated but it is referred to as not (underlining added) complete in one step. This process of heat-treatment and cold working will produce "long fatigue life Nitinol" which is the title of Patel's application. Now that the Nitinol wire, ribbon, sheet or tubing has been heat-treated for stress relief (underlining added) (referred to in [0013] as "interspersed anneal cycles for stress relief"), it needs to be cold worked to reestablish its superelasticity which is reinforced in paragraph [0013] as shown below:

> "[0013] The present invention high fatigue life Nitinol is preferably processed from an ingot of the composition specified above. The ingot is cold reduced or cold worked and annealed repeatedly (underlining added) to preferably a wire, ribbon, sheet, or tubing form. The Nitinol is then cold worked through wire drawing, tube drawing, rolling, or like processes with interspersed anneal cycles for stress relief. As mentioned earlier, the final, after full anneal, cold working step (underlining added) is preferably limited to less than approximately 30% reduction in cross sectional area to achieve the desired long fatigue life."

8. Patel explains in paragraph [0030], ". . the ingot undergoes a sequence of cold working and anneal cycles to reduce the ingot into preferably a wire, ribbon, tubing or sheet of a desired cross-sectional area through the processing steps explained above." This is confirmed in a paper, "Effect of heat treatment on the superelasticity and hardness of NiTi" by Mortagy, O and Farag, M available as an online publication found at the following site:

http://www.academia.edu/820015/Effect_of_Heat_Treatment_on_the_Superelasticity_and_Hardness_of_NiTi

The conclusions drawn by the authors are that superelasticity of annealed cold-worked NiTi was influenced by arranged dislocations and precipitation. This was accomplished

through heat-treatment and final cold-worked NiTi. These same findings and techniques can be found in many other refereed manuscripts and is known to one skilled in the art of processing NiTi. The list of references can be cited upon request. Another conclusion was that superelasticity of annealed cold-worked NiTi increased as micro and nanohardness increased. This will account for the long fatigue life Nitinol which Patel was attempting to make with the Patel application.

9. With Patel the final step (underlining added) for this invention was cold working the Nitinol wire, ribbon, tubing or sheet to assure the Nitinol was in a superelastic state (underlining added). The fact that the Nitinol wire, ribbon, sheet, or tubing is superelastic means it remains in an austenitic state.

10. Amended independent claim 1 of my above-identified patent application now recites that "the heat treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1". Part 1 of ISO 3630 defines general requirements and test methods for endodontic instruments. The endodontic instruments are tested with a torque measuring device at a temperature range of 23 ± 2 °C.

11. The specification used to test orthodontic wires is *ANSI/ADA Specification 32: Orthodontic wires*, which is a direct copy of *ISO 15841:2006 Dentistry -- Wires for use in orthodontics* without the Tables of documentation. Nickel-titanium alloy orthodontic wire in *ANSI/ADA Specification 32: Orthodontic wires* is considered Type 2

orthodontic wire and hence would be tested at 37 ± 1 °C. For a nickel-titanium alloy orthodontic wire as mentioned in Patel, the *ANSI/ADA Specification 32: Orthodontic wires,* "Test format is to be three-point, symmetric bending in the plane of the thickness of a wire", and the bending test is "conducted at oral temperature (37 ± 1) °C".

12. The Office Action of December 19, 2012 states that "Patel discusses orthodontic wires in [0004] which would have a predetermined deformation over 10 degrees, forming to the dental arch, to elicit desired tooth movements and this test on this embodiment of Patel would result in greater than 10 degrees)".

13. It is acknowledged that Patel mentions orthodontic wires at paragraph [0004]. However, I respectfully disagree with the statement that the Patel orthodontic wires "would have a predetermined deformation over 10 degrees ... and this test on this embodiment of Patel would result in greater than 10 degrees".

14. As noted above, Type 2 orthodontic wires are tested at oral temperature (37 ± 1) °C using a three-point, symmetric bending test. Simply put, orthodontic wires are not tested using ISO Standard 3630-1. More generally, Type 2 orthodontic wires are not tested using the bending test to measure torque in mN•m (or gm•cm) as in ISO Standard 3630-1, i.e., rather, *ANSI/ADA Specification 32: Orthodontic wires* describes a three-point, symmetric bending test that measures ". . . deflection measurements in millimeters . . . to be taken during unloading".

15. Thus, I believe that the Patent Office will not be able to provide factual support for the statement that the Patel orthodontic wires "would have a predetermined deformation over 10 degrees ... and this test on this embodiment of Patel would result in greater than 10 degrees". In this regard, (i) orthodontic wires are bend tested for deflection, i.e., Type 2 orthodontic wires are tested for bending in three point bending and reported in millimeters versus endodontic instruments are tested in bending in a torque measuring device and reported in mN•m (or gm•cm); and (ii) Type 2 (nickel titanium) orthodontic wires are tested at 37 ± 1 °C versus endodontic instruments are tested at 23 ± 2 °C thereby making any comparison of test results of little value.

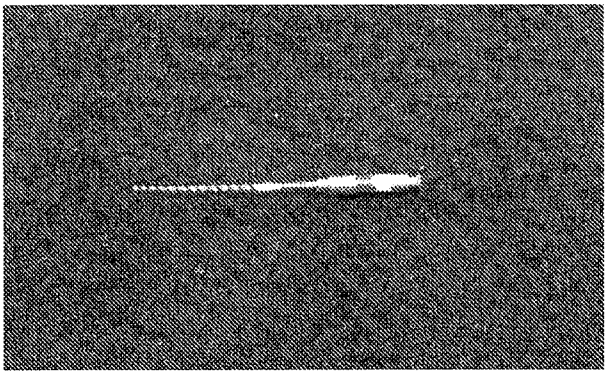
16. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like made are punishable by fine or imprisonment, 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 above-identified application or any patent issuing thereon.

Dated: June 18, 2013

Neill H. Luebke

Dr. Neill H. Luebke

Applicant's Exhibit 1
Standard Nickel Titanium Endodontic File

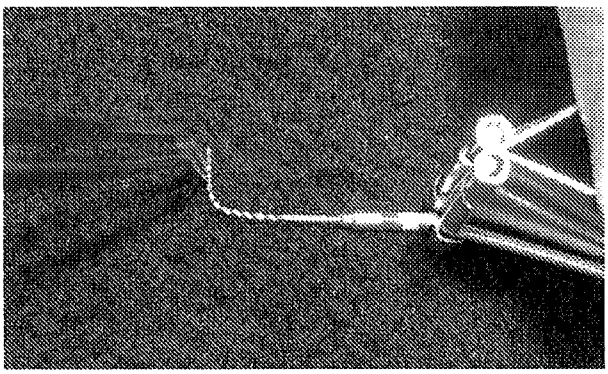


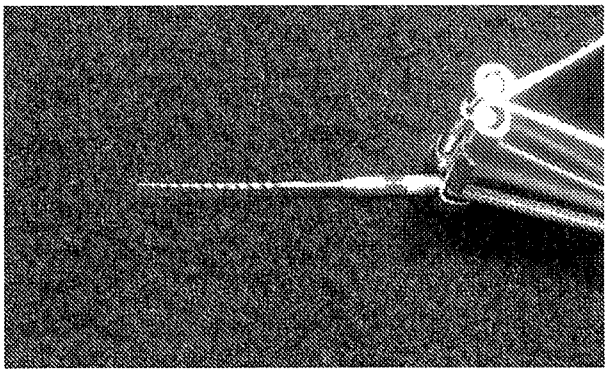
File Size 25 with 04 taper

Natural straight orientation before pressure is applied

File Size 25 with 04 taper

with pressure applied

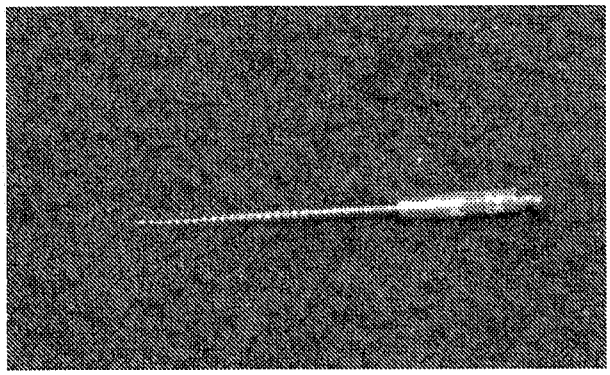




File Size 25 with 04 taper

with pressure released, file returns to natural straight orientation

Applicant's Exhibit 2
Luebke Heat-Treated Endodontic File
Size 25 with 04 taper



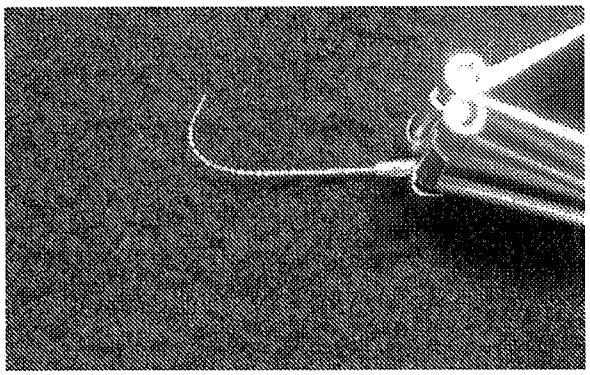
File Size 25 with 04 taper

Natural straight state before pressure is applied

File Size 25 with 04 taper

Curved state after bending pressure applied and after pressure released.

It does not return to original state



Electronic Patent Application Fee Transmittal

Application Number:	13336579
Filing Date:	23-Dec-2011
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton LUEBKE
Filer:	Richard T. Roche
Attorney Docket Number:	115207.00007

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with $0 paid	2253	1	700	700

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for Continued Examination	2801	1	600	600
		Total in USD ($)		**1300**

Electronic Acknowledgement Receipt	
EFS ID:	16080760
Application Number:	13336579
International Application Number:	
Confirmation Number:	4379
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton LUEBKE
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	115207.00007
Receipt Date:	19-JUN-2013
Filing Date:	23-DEC-2011
Time Stamp:	12:01:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1300
RAM confirmation Number	10271
Deposit Account	170055
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		response-6-19-13.pdf	91186 0893778dca5cf8eb7ba819ecb5c224fe3b56f323	yes	8
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment After Final		1	1	
	Claims		2	4	
	Applicant Arguments/Remarks Made in an Amendment		5	8	
Warnings:					
Information:					
2	Extension of Time	Extension.PDF	141229 6a57caea5e3a6b861c3c27b54361d2cad775af5b	no	1
Warnings:					
Information:					
3	Request for Continued Examination (RCE)	RCE.PDF	1323505 3dc61b724c9f7ce4337c1e9f1f6cb9bde82c4503	no	2
Warnings:					
Information:					
4	Affidavit-traversing rejectns or objectns rule 132	InventorDeclaration_6-19-2013.PDF	1468798 76eb58a957c7d9a32b58b351f3c1b0ee8c9d6dea	no	9
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	31865 9e8f7af5f6974a679319af937ad219c1a9e4c482	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3056583		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: 115207.00007

I hereby certify that this correspondence is being electronically transmitted to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date: June 19, 2013

/Richard T. Roche/
Richard T. Roche, Reg. No. 38,599

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	13/336,579
Filing Date:	December 23, 2011
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	4379
Art Unit:	3776
Examiner:	Matthew M. Nelson

RESPONSE TO FINAL OFFICE ACTION

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Final Office Action mailed on December 19, 2012.

Please amend the above-identified patent application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Amendments To The Claims

1. (Currently Amended) A method for manufacturing or modifying a dental instrument or device, the method comprising:

(a) providing a dental instrument or device including an elongated shank comprising a titanium alloy, and

(b) heat-treating the entire instrument or device at a temperature from 400°C up to but not equal to the melting point of the titanium alloy,

wherein the heat-treated instrument or device has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1, and

wherein the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.

2. (Previously Presented) The method of claim 1 wherein:

step (b) further comprises heat-treating the entire instrument or device in an atmosphere consisting essentially of a gas unreactive with the instrument or device.

3. (Previously Presented) The method of claim 2 wherein:

the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon.

4. (Original) The method of claim 1 wherein:

the temperature is from 475°C to 525°C.

5. (Original) The method of claim 1 wherein:

the instrument or device is heat-treated for 1 to 2 hours.

6. (Cancelled)

7. (Cancelled)

8. (Currently Amended) The method of claim 2 wherein:

~~the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium,~~

the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon,

the temperature is from 475°C to 525°C, and

the instrument or device is heat-treated for 1 to 2 hours.

9. (Previously Presented) The method of claim 2 wherein:

the instrument or device consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium,

the gas is argon,

the temperature is 500°C, and

the instrument or device is heat-treated for 1 to 2 hours.

10. (Original) The method of claim 1 wherein:

the instrument or device is heat-treated in step (b) at a single temperature.

11. (Cancelled)

12. (Original) The method of claim 10 wherein:

the single temperature is from 400°C to 525°C.

13. (Original) The method of claim 10 wherein:

the single temperature is from 475°C to 525°C.

14. (Original) The method of claim 1 wherein:

the instrument or device is an endodontic instrument or device.

15. (Cancelled)

REMARKS

Claim Amendments

Independent claim 1 has been amended to include the limitations of original claim 7. Independent claim 1 has also been amended to recite that the heat treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 as described at the first sentence of Example 4 of the application.

Claims 6 and 7 and 11 have been cancelled.

Claim 8 has been amended to remove the limitations now present in claim 1.

Claim Rejection - 35 USC § 112

Claims 1-14 were rejected under 35 U.S.C. 112, first paragraph due to a perceived enablement issue. Specifically, the Office Action states that "not all titanium alloys subjected to this treatment [of claim 1] would result in that degree of deformation [of claim 1]". Claim 1 has been amended to recite that the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium. This was an example alloy (54-57 weight percent nickel and 43-46 weight percent titanium) used in Example 4 of the application that provided the resulting deformation recited in claim 1. Therefore, it is believed that the amendment to claim 1 overcomes the 35 U.S.C. 112 rejection.

Claim Rejection - 35 USC § 103

Claims 1-10 and 12-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2005/0090844 to Patel *et al.* ("Patel") in view of U.S. Patent Application Publication No. 2004/0129352 to Shiota

("Shiota"). Claim 11 was rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of U.S. Patent No. 5,380,200 to Heath *et al.* ("Heath").

Independent claim 1 has been amended to recite that the dental instrument or device has been treated in the method such that the heat-treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1. Patel does not teach a method that provides this property.

Attached for Office consideration is an Inventor's Declaration under 37 C.F.R. § 1.132. Patel is directed to a superelastic Nitinol wire, ribbon, sheet or tubing to fabricate a biomedical device. See, paragraphs [0022], [0024], and [0046], and claim 1, line 3, and claim 23, lines 1 and 5 of Patel. The Inventor's Declaration points out that this means that the Patel wire material will return to its original shape after deformation and that the Patel wire material would not undergo permanent deformation as recited in amended independent claim 1. The Inventor's Declaration further notes that one skilled in the art when reviewing Patel would understand that the Patel superelastic material (Nitinol) would not undergo an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion as recited in amended independent claim 1.

To the extent that Patel mentions orthodontic wire, the Inventor's Declaration explains that orthodontic wires are not bend tested for torque, i.e., Type 2 orthodontic wires are tested in three point bending for millimeters at 37 ± 1 °C. In contrast, endodontic instruments (as recited in independent claim 1) are tested with a torque measuring device at 23 ± 2 °C thereby making any comparison of test results of little value. Thus, one skilled in the art would not test orthodontic wires in accordance with

ISO Standard 3630-1 as recited in amended independent claim 1. In this regard, it is well settled that "a prima facie case of obviousness can be rebutted if the applicant ... can show 'that the art in any material respect taught away' from the claimed invention." *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997) *citing In re Malagari*, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974).

Thus, Patel does not teach a method that produces an endodontic instrument having a heat-treated shank that has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 as recited in amended independent claim 1.

Shiota was cited as teaching a non-reactive gas. Therefore, Shiota does not make up for the deficiencies in Patel.

Heath was cited as teaching the torque testing of dental devices. However, as explained above, one skilled in the art would not test the orthodontic wires mentioned in Patel in accordance with ISO Standard 3630-1 as recited in amended independent claim 1.

It is well settled that in order to establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Taken together, Patel and Shiota and Heath fail to teach or suggest a method that produces a dental instrument or device having a heat-treated shank that has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 as recited in amended independent claim 1.

Accordingly, it is submitted that independent claim 1 (and claims 2-5 and 8-10 and 12-14 that depend thereon) are patentable over Patel, Shiota and Heath.

Conclusion

Claims 1-5 and 8-10 and 12-14 are believed to be in condition for allowance. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

The RCE and extension fees are submitted herewith. If any other fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,
Neill H. Luebke

Dated: June 19, 2013

By: /Richard T. Roche/
Richard T. Roche
Registration No. 38,599
Quarles and Brady LLP
411 East Wisconsin Ave.
Milwaukee, WI 53202
(414) 277-5805

PTO/AIA/22 (03-13)
Approved for use through 3/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 115207.00007

Application Number: 13/336,579

Filed: December 23, 2011

For: Dental and Medical Instruments Comprising Titanium

Art Unit: 3776

Examiner: Matthew M. Nelson

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$200	$100	$50	$
☐ Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☑ Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$ 700
☐ Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐ Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☑ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 170055.

☐ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 38,599.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Richard T. Roche/ — Signature

June 19, 2013 — Date

Richard T. Roche — Typed or printed name

414-277-5805 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

21624230

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/336,579	Filing Date 12/23/2011	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 = *		X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	06/19/2013	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 11	Minus	** 20	= 0	X $40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* 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 column 1.

LIE
/TONI HAKIM/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/336,579	12/23/2011	Neill Hamilton LUEBKE	115207.00007	4379

26710 7590 07/08/2013

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER	
NELSON, MATTHEW M	
ART UNIT	PAPER NUMBER
3776	

NOTIFICATION DATE	DELIVERY MODE
07/08/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No. 13/336,579	Applicant(s) LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3776	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2013*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is 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.

Disposition of Claims

5)☒ Claim(s) *1-5,8-10 and 12-14* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5,8-10 and 12-14* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some * c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

4) ☐ Other: _____.

DETAILED ACTION

Amendment filed on 6/19/2013 is acknowledged.

Claim Rejections - 35 USC § 103

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

> (a) 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.

- Claims 1-5, 8-10, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (US 2005/0090844) in view of Shiota (US 2004/0129352).

- Patel shows a method for manufacturing or modifying a dental or medical instrument or device, the method comprising providing a dental or medical device comprising a titanium alloy (10), the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium ([0029]), and heat-treating the entire instrument or device at a temperature from 400 degrees Celsius up to but not equal to the melting point of the titanium alloy ([0041]-[0042]), wherein the heat-treated instrument or device has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 (this step is not positively recited as part of the method and therefore Patel's device after heat treatment only needs to be structurally capable of bending in this manner, which it would be since the exact same heat treatment and material requirements are disclosed by Patel as in the present invention before any cold working.

It is also noted that this test would be entirely dependent on what degree the instrument was permanently deformed to before the test; for instance, Patel discusses orthodontic wires in [0004] which would have a predetermined deformation over 10 degrees, forming to the dental arch, to elicit desired tooth movements and this test on this embodiment of Patel would result in greater than 10 degrees). With respect to claim 4, the temperature is from 475 to 525 degrees Celsius ([0042]). With respect to claim 5, the instrument or device is heat-treated for 1 to 2 hours ([0041]). Claims 8-9 are rejected similarly to the above and below. With respect to claims 10, 12-13, heat-treated at a single temperature ([0042]). With respect to claims 14-15, the listed device examples could be used medically or endodontically ([0005] for instance). However, Patel fails to show the heat-treatment is conducted in an atmosphere consisting essentially of a gas unreactive with the instrument or device, such as helium, neon, argon, krypton, xenon, and radon.

- Shiota teaches heat-treatment of a medical Ni-Ti alloy wherein the heat-treatment is conducted in an atmosphere consisting essentially of a gas unreactive with the instrument or device, such as helium, neon, argon, krypton, xenon, and radon ([0043]). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Patel's method by including the atmosphere of Shiota in order to utilize known heat-treatment methods in the art and prevent oxidation of the material for instance.

Response to Amendment

- The affidavit under 37 CFR 1.132 filed 6/19/2013 is insufficient to overcome the rejection of claims 1-5, 8-10, 12-14 based upon Patel in view of Shiota as set forth in the last Office action because: The affidavit does not provide a comparison that is representative of Patel's method as rejected. Patel tested for bending after the heat treatment described in the claims would be the same as that of Applicant's, since both are directed to the same nickel titanium alloy undergoing the same heat treatment. That Patel is later cold-worked is not of issue in regards to the present claims.
- That Patel has "no time stated", please see [0041].
- The affidavit also discusses the tests that would be done on the respective devices, however no bending test is positively recited in the claims, so the devices just need to be capable of performing in the same manner if they were subjected to those bending tests.

Response to Arguments

- Applicant's arguments filed 6/19/2013 have been fully considered but they are not persuasive.
- Applicant argues that the amendments regarding the bending test are not taught by Patel, however this bending test has not been positively recited as part of the method. That the wire of Patel would not typically be tested in this manner is moot, since the test is not actually claimed. Patel's device only needs to be capable of bending in this manner, which it would be expected to do so since the same heat

treatment steps are conducted on the same alloy. That Patel's device is superelastic AFTER cold working is not of issue since the bending test appears to be conducted on the heat treated device as presently claimed. It is also noted that Patel is directed generally to devices and the orthodontic wire is just one specific example. The invention is not limited to the specific embodiments in which further detail is provided.

- Applicant argues that Heath's test would not be applied to Patel's device. Heath had been provided to show the use of the specific bending test when applied to a specific device. Patel generally is not specific to just the orthodontic wire, and in appropriate cases the test of Heath would be applicable to a test of Patel. However, the rejection including Heath has been removed due to the bending test not being claimed as a step of the method.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW NELSON whose telephone number is (571)270-5898. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm EDT.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Todd Manahan, at (571) 272-4713***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robyn Doan/
Primary Examiner, Art Unit 3776

/MMN/

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13336579	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/28/2012	12/05/2012	06/29/2013						
	1	✓	✓	✓						
	2	✓	✓	✓						
	3	✓	✓	✓						
	4	✓	✓	✓						
	5	✓	✓	✓						
	6	✓	✓	-						
	7	✓	✓	-						
	8	✓	✓	✓						
	9	✓	✓	✓						
	10	✓	✓	✓						
	11	✓	✓	-						
	12	✓	✓	✓						
	13	✓	✓	✓						
	14	✓	✓	✓						
	15	✓	-	-						

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2882	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/06/29 09:53
S2	6	"6431863".pn. "6422865".pn. "6428634".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 07:56
S5	1068	Ni adj Ti AND anneal$2 AND time	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S6	544	Ni adj Ti AND anneal$2 AND time AND hour	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S7	16	Ni adj Ti AND anneal$2 AND time AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:54
S8	876	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:54
S9	53	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:55
S10	183	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 15:12
S11	29	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND	US-PGPUB; USPAT;	OR	ON	2008/04/29 15:16

		(anneal$3 OR heat NEAR5 treated)	USOCR; FPRS; EPO; JPO; DERWENT			
S12	891	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S13	67	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S14	16	Ni adj Ti AND anneal$2 AND time AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S15	30	S12 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:58
S19	11	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((flexib$5) SAME ("400" "425" "450" "475" "500" "525")) AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 14:47
S20	34	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((temperature) SAME ("400" "425" "450" "475" "500" "525")) AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 14:48
S21	62	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((temperature) SAME (degree)) AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 15:17
S22	903	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/24 12:26
S23	71	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/24 12:26
S24	1092	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT;	OR	ON	2009/08/03 13:13

			USOCR; FPRS; EPO; JPO; DERWENT			
S25	78	S24 AND (heat WITH treat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S26	917	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S27	32	S26 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S28	917	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S29	192	S28 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S30	1099	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:33
S31	18	S30 AND microstructure	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:34
S32	200	S30 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:35
S33	2	("7175655").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/18 13:12
S34	1112	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT;	OR	ON	2010/03/22 09:45

			USOCR; FPRS; EPO; JPO; DERWENT			
S35	1	(ISO WITH 3630-1) AND S34	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:45
S36	8	(ISO WITH "3630") AND S34	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:46
S37	989	("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel WITH Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/07 11:31
S38	258	("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel WITH Titanium)) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/07 11:32
S39	83	("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel WITH Titanium)) AND endodontic AND deformation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/07 11:33
S40	1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:02
S41	226	S40 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:02
S42	52	S41 AND ((shape NEAR1 memory) (permanent NEAR1 deformation))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:34
S43	2	"5843244".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:56
S44	1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT;	OR	ON	2010/10/19 18:06

			USOCR; FPRS; EPO; JPO; DERWENT			
S45	226	S44 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S46	1	S45 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S47	11	S45 AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:07
S48	10	(US-20040121283-$).did. or (US-6431863-$ or US-6428634-$ or US-6375458-$ or US-4490112-$ or US-5775902-$ or US-5080584-$ or US-6206695-$ or US-7137815-$ or US-5653590-$).did. or (US-6422865-B-$).did.	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S49	0	S48 AND gas	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S50	2	S48 AND atmosphere	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S51	982	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:32
S52	8	S51 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) AND (gas atmosphere)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:32
S53	10068	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (gas atmosphere)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:35
S54	1335	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:36
S55	6	(endodontic) AND ((Ni NEAR1 Ti) OR	US-PGPUB;	OR	ON	2011/05/12

		(Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			09:36
S56	2	(endodontic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S57	2	(endodontic "433".clas.) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S58	16	(endodontic "433".clas.) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S59	51	(endodontic "433".clas.) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:40
S61	1346	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:46
S64	126	((Ni ADJ Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) SAME (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:52
S65	10	((Ni ADJ Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) SAME (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:56
S66	8234	(anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S67	8	"433".clas. AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S68	2	Nitinol AND (anneal$3 OR heat	US-PGPUB;	OR	ON	2011/05/12

		NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			10:01
S69	130	(titanium ADJ alloy) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:02
S70	37	(titanium ADJ alloy) SAME (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:02
S71	2	"6783438".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:33
S72	99	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:27
S73	54	29/896.11	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:27
S74	985	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:27
S75	41	(S72 S73 S74) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:28
S76	1411	148/402,421,426.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:17
S77	822	S76 AND titanium	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:18
S78	621	S76 AND titanium AND heat	US-PGPUB;	OR	ON	2011/09/07

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT			13:18
S79	254	S76 AND titanium AND heat AND atmosphere	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:18
S80	159	S76 AND titanium AND heat AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S81	126	S76 AND titanium AND (heat WITH treat$4) AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S82	121	S76 AND titanium AND (heat ADJ treat$4) AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S83	3	S76 AND titanium AND (heat ADJ treat$4) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:20
S84	3	148/402.ccls. AND (heat ADJ treat$4) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
S85	191	148/402.ccls. AND (heat ADJ treat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
S86	0	148/402.ccls. AND (heat ADJ treat$4) SAME shank	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
S87	19	148/402.ccls. AND (heat ADJ treat$4) SAME (atmosphere argon helium neon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:25
S89	336	148/669.ccls. AND titanium	US-PGPUB;	OR	ON	2011/09/07

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT			15:03
S90	48	148/669.ccls. AND titanium AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 15:04
S92	20245	((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:36
S93	11539	((shape ADJ memory) superelastic) AND (medical dental) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:36
S94	7768	((shape ADJ memory) superelastic) AND (medical dental) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium)) AND temperature	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:37
S95	5395	((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:37
S96	282	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:06
S97	184	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:07
S98	71	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) AND (inert gas) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:25
S99	18	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) SAME (inert gas) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:26
S100	13	"148".clas. AND ((shape ADJ	US-PGPUB;	OR	ON	2012/08/28

		memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) SAME (inert gas) SAME temperature AND @ad<="20040608"	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			13:32
S101	51	(medical dental) AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) SAME (inert gas) SAME temperature AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:33
S102	3	"12977625"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:40
S103	2	"5380200".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/05 08:39
S104	2819	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/12/05 09:41

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S88	0	(29/896.1,896.11).CCLS.	UPAD	OR	OFF	2011/09/07 14:33
S91	0	(148/669).CCLS.	UPAD	OR	OFF	2011/09/07 15:04

6/29/2013 9:54:01 AM
C:\Users\mnelson3\Documents\EAST\Workspaces\13336579 Dental and medical instruments comprising titanium.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13336579	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
433	102, 224	8/28/2012	MN
29	896.1, 896.11	8/28/2012	MN
148	402, 421, 426, 669	8/28/2012	MN
29, 148, 433	Updated	12/5/2012	MN
29, 148, 433	Updated	6/29/2013	MN

SEARCH NOTES		
Search Notes	Date	Examiner
See EAST search history	8/28/2012	MN
Reviewed parent	8/28/2012	MN
Updated EAST search	12/5/2012	MN
Search help in 148 from George Wyszomierski and Jessee Roe	12/5/2012	MN
Updated EAST search	6/29/2013	MN

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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Applicant Initiated Interview Request Form

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JUL 25 2013

Application No.: 13/336,579 First Named Applicant: Neill H. Luebke
Examiner: Matthew M. Nelson Art Unit: 3776 Status of Application: Non-Final Rejection

Tentative Participants:
(1) Examiner Nelson (2) Neill H. Luebke, Inventor
(3) Richard T. Roche (38599) (4) _____

Proposed Date of Interview: July 26, 2013 **Proposed Time:** 1 PM (AM/PM)

Type of Interview Requested:
(1) [✓] Telephonic (2) [ ] Personal (3) [ ] Video Conference

Exhibit To Be Shown or Demonstrated: [ ] YES [✓] NO
If yes, provide brief description: _____

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) 103 Rej.	1	US 2005/0090844 (Patel)	[ ]	[ ]	[ ]
(2)			[ ]	[ ]	[ ]
(3)			[ ]	[ ]	[ ]
(4)			[ ]	[ ]	[ ]

[✓] Continuation Sheet Attached [ ] Proposed Amendment or Arguments Attached
Brief Description of Arguments to be Presented: _____

An interview was conducted on the above-identified application on _____

NOTE: This form should be completed and filed by applicant in advance of the interview (see MPEP § 713.01). If this form is signed by a registered practitioner not of record, the Office will accept this as an indication that he or she is authorized to conduct an interview on behalf of the principal (37 CFR 1.32(a)(3)) pursuant to 37 CFR 1.34. This is not a power of attorney to any above named practitioner. See the Instruction Sheet for this form, which is incorporated by reference. By signing this form, applicant or practitioner is certifying that he or she has read the Instruction Sheet. After the interview is conducted, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible. This application will not be delayed from issue because of applicant's failure to submit a written record of this interview.

/Richard T. Roche/
Applicant/Applicant's Representative Signature

Examiner/SPE Signature

Richard T. Roche
Typed/Printed Name of Applicant or Representative

38599
Registration Number, if applicable

(1) U.S. Patent Application Publication No. 2005/0090844 to Patel *et al.* ("Patel") has been cited against the claims. Page 4 of the Office Action of July 8, 2013 states: "The affidavit under 37 CFR 1.132 filed 6/19/2013 is insufficient to overcome the rejection of claims 1-5, 8-10, 12-14 based upon Patel in view of Shiota as set forth in the last Office action because: The affidavit does not provide a comparison that is representative of Patel's method as rejected. Patel tested for bending after the heat treatment described in the claims would be the same as that of Applicant's, since both are directed to the same nickel titanium alloy undergoing the same heat treatment." Applicant respectfully disagrees with the conclusion that Patel tested for bending after the heat treatment described in the claims would be the same as that of Applicant's.

(2) Applicant understands that the U.S. Patent Office possesses the authority to require the Applicant to prove that the subject matter shown to be in the prior art does not possess a characteristic relied on in a patent claim to establish patentability. See, *In re Swinehart*, 439 F.2d 210, 212-213 (CCPA 1971). However, Applicant has provided evidence and can provide further evidence that the subject matter of Patel does not possess the flexion test properties recited in claim 1.

(3) Patel is manufacturing a wire, ribbon, sheet, tubing, or the like for a medical device. The manufacture of medical devices is explained in the following excerpt from "Study of Mechanical, Fatigue and Corrosion Properties of the Superelastic NiTi Alloy" by D. Vojtěch in Metal 2011:

> "Stents are often manufactured from nitinol wires and, during processing of these wires, nitinol experiences various heat treatment and forming procedures to achieve shape, mechanical properties and transformation behavior suitable for the final application. Final steps in production of superelastic nitinol wires are often cold drawing to a desired diameter followed by straight annealing. Straight annealing consists of heating a preloaded (20-100 MPa) cold drawn wire at an appropriate temperature (450-700°C). It ensures an optimum straight shape and desired functional properties of a wire. A very important step in a following fabrication of stents from the straight annealed superelastic wire is the shape setting. It involves a short (several minutes) heat treatment of the wire which is wound in a desired pattern on a mandrel. The shape setting treatment is generally carried out at moderate temperatures (around 500°C) and its purpose is to induce relaxation of a material for achievement of a desired stable shape of an implant. Moderate temperatures and short times are used to prevent the permanent deformation of implants and to maintain their superelastic behavior."

Thus, the medical devices, or its components, as in Patel are manufactured by a process including: cold drawing followed by straight annealing followed by shape setting. In a typical shape setting treatment, "[m]oderate temperatures and short times are used to prevent the permanent deformation of implants and to maintain their superelastic behavior" (underlining added - see Vojtěch above).

(4) Patel distinguishes between annealing and shape setting heat treatments. For example, paragraph [0027] states "[a] full anneal implies that the alloy has been completely stress relieved, typically at about 750°C for 5 to 10 minutes", and paragraphs [0041] and [0042] describe shape setting heat treatments. Regardless of these distinctions, the Vojtěch article above refutes the Office Action conclusion that Patel's wire after the heat treatment would have the same properties as the claimed invention (same material/manufacture steps). The Vojtěch article above points out that the shape setting heat treatment of straight annealed superelastic wire maintains the superelastic behavior. Thus, Patel's annealed wire would be superelastic, and Patel's shape set wire would be superelastic.

(5) The Inventor's Declaration filed 6/19/2013 compared and distinguished a superelastic wire and the invention of claim 1. Throughout Patel, the term "superelastic" is used to describe the Patel device (see, e.g., Abstract and paragraphs [0022], [0032], [0046], and claim 1).

(6) Thus, the Applicant has provided evidence that the Patel device is superelastic and that the subject matter of claim 1 does not have this property of Patel.

U.S. Patent Application No. 13/336,579

Synopsis of Following Pages of Research and Analysis for Examiner Nelson

A. Patel Clause [0013] describes full anneal followed by a final step of cold working, [0024] cold working at each step. Therefore his process is a series of cold work and anneal followed by a final cold working. Seven supporting references showing use of cold working described by Patel in [0024] as "typical". Clause [0035] The greatest difference between the standard wire versus the present invention wire is the amount of final cold work, where the amount of the final cold work step in the present invention wire is much lower. The expression "final cold work" as defined earlier is intended to mean the last cold work step bringing the part into its final dimensions, after a full anneal (underline added and continued below), (pages 4-6)

Clause [0035] The greatest difference between the standard wire versus the present invention wire is the amount of final cold work, where the amount of the final cold work step in the present invention wire is much lower. The expression "final cold work" as defined earlier is intended to mean the last cold work step bringing the part into its final dimensions, after a full anneal, and before the shape setting step where the shape memory is imparted into the alloy. (underline added) Further references to shape setting are in [0040, 0041, 0043]
One skilled in the art knows that shape setting occurs in a *fixture* whether it is straight or has a specific configuration. This is cited again in Claim 17. The use of a fixture is different from the Luebke application. See further explanation and five references to shape setting. (pages 6-8

References to Martensite-Austenite and Af Temperatures

An extensive discussion of critical differences between martensite and austenite phases in behavior and the significance of Af temperatures between Patel and Luebke appears on pages 8-12.

Clauses referring to Af temperatures are [0003], [0006], [0011], [0025],[0026], [0028] [0042] . Clause [0042] The cold-drawn nitinol wire embodiment is preferably heat treated between 450-500° C and preferably has a final Af temperature between 26° C and 36° C (underline added) as measured by the DSC technique. (pages 8-12)

Patel is fabricating a component to be placed into the human body which has a temperature of 37°C. Since these components are for a cardiac harness device, Patel wants them to be Austenitic and to have an Af (Austenitic finish temperature) below 37°C. Further, Patel does NOT indicate a specific temperature or a time for his treatment. The Af (Austenitic finish temperature) for the instrument or device for the Luebke application is at 39°C which is unsuitable for the purpose of Patel's application. In addition, the temperature of the body is NOT sufficient to transform the Luebke application instrument or device to Austenite. The endodontic files produced by the Luebke application will be Martensitic during its application.

B. Documentation of process for Patent Application 13336549. Two references to research on the martensitic phase of NiTi.

U.S. Patent Application No. 13/336,579

Examiner Nelson comments for oral presentation on Friday, July 26, 2013. Presented below are the following sections of this document:

A. Process that Patel employs in his Patent Application with supporting documentation, and

B. Documentation of the process for the Patent Application 13336549.

A. Process that Patel employs:

I would like to focus on the "heart" of the Patel Publication No. US 2005/0090844 Al which is clause [0013]. In reading this clause, one sees the sole aspect that constitutes the essence of this patent application, which is the 30% (or less) cold working step. I want to reference in the literature from those skilled in the art, how nitinol is processed to be made into wire, ribbon, sheet, or tubing form using the anneal and cold working process outlined in [0013].

[0013] The present invention high fatigue life nitinol is preferably processed from an ingot of the composition specified above. The ingot is cold reduced or **cold worked** and annealed (Note 1) repeatedly to preferably a wire, ribbon, sheet, or tubing form. The nitinol is then cold worked through wire drawing, tube drawing, rolling, or like processes with interspersed **anneal** cycles for stress relief. As mentioned earlier, the final, after **full anneal (Note 2)** the cold working step is preferably limited to less, than approximately 30% reduction in cross-sectional area to achieve the desired long fatigue life. In contrast, conventional processing of nitinol typically involves cold work at 35% or more.

(Note 1) From [0024] "Typically, the nitinol receives **cold working** in the range of 40 to 50% at each step, and is also **annealed** at about 600 to 800° C for stress release after each cold work step"

Patel's use of the term "typically" and the process described in [0024] is known to those skilled in the art of cold work and annealing. The following citations are from those skilled in the art that cold work and anneal NiTi.

Manufacturing and processing of NiTi implants: A review by M.H. Elahinia et al. in *Progress in Materials Science 57 (2012) 911–46.*

"As-cast microstructure and surface properties of NiTi products are not acceptable for medical applications and further processing is required. These post-processes can include hot working, cold working, machining, surface treatments, joining, and heat treatments."

Effect of Annealing on Strain-Temperature Response under Constant Tensile Stress in Cold-Worked NiTi Thin Wire by X Yan and J Van Humbeeck in Smart Materials Research, Volume 2011, Article ID 160927, 6 pages

"The transformation is sensitive to factors such as material composition, deformation processing, and heat treatments. Therefore, a mix of cold work followed by a specific annealing process has been comprehensively considered to optimize the physical and mechanical properties of a NiTi product and achieve shape memory and/or superelasticity."

Fatigue Performance of Nitinol Round Wire with Varying Cold Work Reductions by J Schaffer and D Plumley in Journal of Materials Engineering and Performance Volume 18(5–6) August 2009, 563-8.

"There are many processing parameters which can influence the mechanical, thermal, and bioreactive properties of nitinol wire and its suitability for particular applications. Variables may include: ingot composition; inclusion particle size and shape distribution; cold work history; annealing temperature, stress, atmosphere and resultant microstructural cell size; surface conditioning including oxide thickness, acidic oxide removal or mechanical polishing; shape-setting temperature and others."

Influence of Short-period Heat Treatment on Mechanical Properties of NiTi Wires by J Čapek and J Kubasek in Comat 2012

"Nitinol is commonly fabricated by vacuum induction melting (VIM), vacuum arc remelting (VAR), or by their combination. After fabrication, ingots are usually hot and cold worked (forging, rolling, or wire drawing) and these semi-finished products are then treated into the final shape. The fabrication process usually continues with heat treatment and sometimes with a surface treatment."

EFFECT OF ANNEALING PARAMETERS ON THE SHAPE MEMORY PROPERTIES OF NITI THIN FILMS, http://www.mrl.columbia.edu/Gen_ICALEO08.pdf

"Annealing, in metallurgy and materials science, is a heat treatment that alters a material to increase its ductility and to make it more workable. It involves heating material to above its critical temperature, maintaining a suitable temperature, and then cooling. Annealing can induce ductility, soften material, relieve internal stresses, refine the structure by making it homogeneous, and improve cold working properties."

The Effects of Cold Work and Heat Treatment on the Properties of Nitinol Wire by M. Drexel et al in Medical Device Materials IV: Proceedings from the Materials & Processes for Medical Devices Conference 2007

"Heat treatments that provide the thermal energy required for precipitation can also activate the processes of annealing, during which the rearrangement of defects and the decrease in defect density reduce the stored strain energy within Nitinol. These processes affect both the thermal and mechanical properties. The driving force for annealing is greater in more heavily cold-worked metals due to their higher amount of stored internal energy. Therefore, the response of a specific material to heat treatment is dependent on time, temperature, processing history, and amount of prior cold work."

Effect of Ni-Content on Mechanical and Transformation Behavior of NiTi Shape Memory Alloys for Orthodontics Applications by A. Phukaoluan et al in The First TSME International Conference on Mechanical Engineering, 20-22 October, 2010

"The properties of NiTi can be modified to a great extent by judicious choice of composition, cold work and heat treatment. The results obtained can be use to determine optimum alloy composition of NiTi alloy to be used as orthodontic wires. "

(Note 2) From [0027] "A **full anneal** implies that the alloy has been completely stress relieved, typically at about 750° C. for 5 to 10 minutes"

Technical Bulletin from Johnson Matthey Medical Components

"The DSC yields excellent, repeatable results on fully annealed samples (annealed at temperatures above 700 deg. C for sufficient time to achieve a full anneal, generally about 10 to 15 minutes for small samples)."
In the Patel application anneal (or heat treatment) are sometimes used synonymously except when Patel explains the full anneal and when Patel explains the percentage of cold work necessary to obtain a fatigue resistant wire for extended life.
The only other heat temperatures that are relevant are the shape setting temperature(s) [Patel refers to heat treatment as well]. These are found in the following citations.
ABSTRACT A high fatigue/life superelastic nickel-titanium (nitinol) wire, ribbon, sheet, tubing, or the like is disclosed. The nitinol has a 54.5 to 57.0 weight percent nickel with a balance of titanium composition and has less than 30 percent cold working final step after a full anneal and before **shape setting heat treatment**. Through a rotational beam fatigue test, fatigue life improvement of 37 percent has been observed.

[0028] As is known in the art, **heat treatment** and cold work can change the transition temperature of the alloy. For a metric that reflects the processing received by the alloy, the "final Af temperature" is used. The final Af temperature is determined by using the DSC test on the alloy after it has been **shape set** to its remembered shape.

[0035] The greatest difference between the standard wire versus the present invention wire is the amount of final cold work, where the amount of the final cold work step in the present invention wire is much lower. The expression "final cold work" as defined earlier is intended to mean the last cold work step bringing the part into its final dimensions, after a full anneal, and before the **shape setting** step where the shape memory is imparted into the alloy. (incomplete citation)
[0040] The tested specimens in the described rotary beam fatigue test were not polished after the **shape setting heat treatment**. Therefore, they exhibited a blue oxide surface.

[0041] The present invention nitinol wire, ribbon, tubing or sheet stock can be **shape set** to the desired shape through processes known in the art. This is usually accomplished by manipulating the nitinol wire, ribbon, tubing, or sheet into a **fixture** (Note 3) duplicating the remembered shape. The nitinol wire, ribbon, tubing or sheet is heated to well above the alloy's martensite deformation temperature (Md). For a wire, ribbon, tubing, or sheet, the **shape set temperature** is

typically in the range of 250-600° C.; the heating occurs for an average of a few minutes up to an hour, with longer times for lower temperatures and vice versa.

(Note 3) This is highlighted because one skilled in the art knows that shape setting occurs in a *fixture* whether it is straight or has a specific configuration. This is cited again in Claim 17 below. The use of a fixture is different from the Luebke application. See further explanation further down this document.

[0043] The blue oxide surface formed from the **shape setting heat treatment** can optionally be removed by electropolishing. This further improves fatigue resistance. Moreover, the final Af temperature of the formed wire can optimally be adjusted by the **shape setting heat treatment** without deviation from the scope of the present invention.

Claim17. The process of claim 15, wherein after the final cold working step the process includes mounting the wire, ribbon, sheet or tubing on a **fixture (see (Note 3) explanation above)** and **shape setting** the wire, ribbon, sheet or tubing at approximately 250-600° C. for 1 to 60 minutes.

Effect of Annealing on Strain-Temperature Response under Constant Tensile Stress in Cold-Worked NiTi Thin Wire by X Yan and J Van Humbeeck in Smart Materials Research, Volume 2011

"Among many shape memory alloys (SMAs), NiTi has been widely used in many technological and engineering applications due to its excellent shape memory effect, superelasticity, high damping capacity, and others. Its remarkable properties result from a reversible martensitic phase transformation between austenite and martensite phases, which can be either stress induced or temperature driven. The transformation is sensitive to factors such as material composition, deformation processing, and heat treatments. Therefore, a mix of cold work followed by a specific annealing process has been comprehensively considered to optimize the physical and mechanical properties of a NiTi product and achieve shape memory and/or superelasticity."

INFLUENCE OF SHORT-PERIOD HEAT TREATMENT ON MECHANICAL PROPERTIES OF NITI WIRES by J ČAPEK and J KUBÁSEK in COMAT 2012

"After fabrication, ingots are usually hot and cold worked (forging, rolling, or wire drawing) and these semi-finished products are then treated into the final shape. The fabrication process usually continues with heat treatment and sometimes with a surface treatment.... The final heat treatment is usually performed at temperatures between 300 and 600°C in the case of nickel-rich alloys containing up to 51 at % of nickel, which are used for production of stents. At temperatures up to approximately 500°C formation of Ni14Ti11 and Ni4Ti3 is preferred."

While these indicate temperatures and time, the purpose of these heat treatments is to shape the final component for the device Patel is fabricating. I now want to present the fact that Patel is fabricating a component to be placed into the human body which has a temperature of 37°C. Since these components are for a cardiac harness device, Patel wants

them to be Austenitic and to have an Af (Austenitic finish temperature) below 37°C. One will see later that the Af (Austenitic finish temperature) for the instrument or device for the Luebke application is at 39°C which is unsuitable for the purpose of Patel's application. Perhaps the best way to elucidate this is for references to Martensite and the relationship to Austenite and finally the Af Finish Temperatures references.

Martensite-Austenite References

[0002] There has been great interest in shape memory and superelastic alloys such as nickel-titanium. This family of alloys, also known as nitinol (i.e., Nickel-Titanium Naval Ordinance Laboratory) is typically made from a nearly equal composition of nickel and titanium. Key to exploiting the performance of nitinol alloys is the phase transformation in the crystalline structure that transitions between an **austenitic** phase and a **martensitic** phase. The **austenitic** phase is commonly referred to as the high temperature phase, and the **martensitic** phase is commonly referred to as the low temperature phase. The back and forth phase changes is the mechanism for achieving superelasticity and the shape memory effect.

[0003] As the name implies, shape memory means that the alloy can be twisted into a particular shape in the **martensitic** phase, and when heated to the **austenitic** phase, the metal returns to its remembered shape. In contrast, superelasticity refers to the ultra high elastic behavior of the alloy under stress. Typical reversible strains of up to 8 percent elongation can be achieved in a superelastic nitinol wire as compared to 0.5 percent reversible strain in a steel wire, for example. This superelasticity appears in the austenitic phase when stress is applied to the alloy and the alloy changes from the **austenitic** phase to the **martensitic** phase. This particular **martensitic** phase is more precisely described as stress-induced **martensite** (SIM), which is unstable at temperatures above Af (the austenitic finish) temperature. As such, if the applied stress is removed, the stress-induced **martensite** reverts back to the **austenitic** phase. It is understood that this phase change is what enables the characteristic recoverable strains achievable in superelastic nitinol.

The superelastic nitinol (austenitic) has the shape memory as well which allows the wire component of the cardiac harness to function in the body.

[0025] As explained earlier, the transformation temperature of the nitinol separates the **austenitic** phase from the **martensitic** phase. Typically, the transition temperature is measured by the austenite finish (Af) temperature, which indicates the completion of the phase transformation from **martensite** to **austenite** during heating.

This can include the temperature of the body which is sufficient to transform from martensite to austenite for the Patel application. However, the temperature of the body is NOT sufficient to transform the Luebke application instrument or device to austenite.

The alloy transformation temperatures are determined by, among other factors, the ratio of nickel and titanium in the alloy. To be sure, the transformation temperatures are extremely sensitive to very small changes in the Ni-Ti composition. As a result, the presence of impurities or trace

elements aside from nickel and titanium might unexpectedly change the transformation temperature of the alloy.

[0026] The Af temperature is commonly used as a metric in defining the characteristic of a nitinol device since it defines when the nitinol is completely in the austenitic phase. The Af temperature is usually measured by a technique called Differential Scanning Calorimetry (DSC) or by a "bend and free recovery" technique. The DSC technique detects the heat released and absorbed during the **martensitic** (exothermic) and **austenitic** (endothermic) transformations, respectively, and thus produces data indicating Af temperature. The bend and free recovery technique requires cooling the nitinol sample to a low temperature so that it is in the **martensitic** phase, bending the sample to a prescribed strain (typically 2% to 3%), and observing the temperature at which the sample returns to its original shape in the **austenitic** phase when heated, thus indicating the Af temperature.

[0041] The present invention nitinol wire, ribbon, tubing or sheet stock can be shape set to the desired shape through processes known in the art. This is usually accomplished by manipulating the nitinol wire, ribbon, tubing, or sheet into a fixture duplicating the remembered shape. The nitinol wire, ribbon, tubing or sheet is heated to well above the alloy's **martensite** deformation temperature (Md). For a wire, ribbon, tubing, or sheet, the shape set temperature is typically in the range of 250-600° C; the heating occurs for an average of a few minutes up to an hour, with longer times for lower temperatures and vice versa.

[0046] More important is the systole and diastole contraction and relaxation of the heart which apply repeated cyclical pressure on the cardiac harness 10. Due to this cyclic stress, the cardiac harness should exhibit a relatively high fatigue life after implantation in the patient. Therefore, the wires forming the cardiac harness 10 are made from superelastic nitinol in accordance with the present invention embodiments and are in the austenitic phase at body temperature when no load is applied and the alloy is stress-free. When placed over the heart as shown in FIG. 6, the contact pressure between the harness 10 and heart 12 may create stress-induced **martensite** (SIM) in the material. Depending on the stress-strain "flag" curve of the superelastic nitinol alloy, the actual stress encountered by the nitinol wire may fall on a stress plateau or may be sufficiently low to fall in the linear stress-strain range. In any event, the present invention high fatigue life wire minimizes the possibility under such conditions of a fracture or fatigue failure in the harness. More details regarding the cardiac harness 10 may be found in, for example, U.S. Pat. No. 6,595,912 to Lau et al, whose entire contents are hereby incorporated by reference.

Annealing Temperature Effect on Superelastic and Cyclic Response of NiTi SMA by Li Lan et al., 2009, Advanced Materials Research, 79-82

"The SMA starts to transform into the low temperature martensite, when cooling down to the martensite start temperature (Ms). The transformation is complete after the temperature is cooled down past the Ms, down to the martensite finish temperature (Mf). When in this phase, the alloy can be easily manipulated in a very large strain range. In between the Ms and Mf, the alloy would exist in both the martensitic and austenitic phases. In contrast, when heating the alloy past the austenite start temperature (As) up to the

austenite finish temperature (Af), the alloy starts transformation into the stronger higher temperature austenite phase and completes transformation."

Af Finish Temperatures References
[0003] . . . This particular martensitic phase is more precisely described as stress-induced martensite (SIM), which is unstable at temperatures above Af (the austenitic finish) temperature. As such, if the applied stress is removed, the stress-induced martensite reverts back to the austenitic phase. It is understood that this phase change is what enables the characteristic recoverable strains achievable in superelastic nitinol.

[0006] U.S. Pat. No. 5,843,244 to Pelton discloses cold working and annealing a nitinol alloy to lower the Af temperature. United States Publication No. US 2003/0120181A1, published Jun. 26, 2003, is directed to work-hardened pseudoelastic guide wires.

[0011] Further, the cold-drawn nitinol wire, ribbon, sheet or tubing is preferably heat treated between 450-500° C and preferably has a final Af temperature between 26° C and 36° C as measured by Differential Scanning Calorimetry (DSC).

(I will fully explain these clauses below after the others have been presented.)

[0026] The Af temperature is commonly used as a metric in defining the characteristic of a nitinol device since it defines when the nitinol is completely in the austenitic phase. The Af temperature is usually measured by a technique called Differential Scanning Calorimetry (DSC) or by a "bend and free recovery" technique. The DSC technique detects the heat released and absorbed during the martensitic (exothermic) and austenitic (endothermic) transformations, respectively, and thus produces data indicating Af temperature. The bend and free recovery technique requires cooling the nitinol sample to a low temperature so that it is in the martensitic phase, bending the sample to a prescribed strain (typically 2% to 3%), and observing the temperature at which the sample returns to its original shape in the austenitic phase when heated, thus indicating the Af temperature.

[0028] As is known in the art, heat treatment and cold work can change the transition temperature of the alloy. For a metric that reflects the processing received by the alloy, the "final Af temperature" is used. The final Af temperature is determined by using the DSC test on the alloy after it has been shape set to its remembered shape.

[0033] Once the foregoing conditions are met, one embodiment of the present invention nitinol wire with a 0.013 inch diameter exhibited a 37% increase in fatigue resistance over a conventional nitinol wire in a rotary beam fatigue test. In this test, the heat treated wire specimen with an Af temperature of 32±3° C. is gripped at the opposite ends where one end is motor driven and where both gripped ends are parallel and coplanar. The entire specimen is held within a vertical plane with the motor-driven end rotating to create alternating compressive and tensile strain in the specimen. The alternating strain ranged from about -0.75% to +0.75%. The specimen was also immersed in a water bath at 37° C. to approximate human body temperature. Being above the Af temperature of the wire, the ambient temperature also places the superelastic nitinol specimen in the austenitic phase. The motor-driven end rotated the specimen

at a rate of 3,600 cycles per minute. In this test, the standard nitinol wire with a cold work of 40%± 5% failed at an average of about 16,560 cycles; one embodiment of the present invention nitinol wire failed at about 22,760 cycles, which is an improvement of 37% in fatigue life.

[0042] The cold-drawn nitinol wire embodiment is preferably heat treated between 450-500° C. and preferably has a final Af temperature between 26° C. and 36° C. as measured by the DSC technique.

See explanation of the Af temperature below the next two clauses and citations. Now, the two references that approximate 500°C is shown with explanation.

[0011] Further, the cold-drawn nitinol wire, ribbon, sheet or tubing is preferably heat treated between 450-500° C and preferably has a final Af temperature between 26° C and 36° C as measured by Differential Scanning Calorimetry (DSC).

[0042] The cold-drawn nitinol wire embodiment is preferably heat treated between 450-500° C and preferably has a final Af temperature between 26° C and 36° C as measured by the DSC technique.

One skilled in the art would utilize these temperatures to make an Austenitic wire, ribbon, sheet or tubing as shown by the following references:

Technical Bulletin from Johnson Matthey Medical Components
"The use of a Nitinol shape memory or superelastic element for a particular application generally requires the setting of a custom shape in a piece of Nitinol. The process required to set the shape is similar whether beginning with Nitinol in the form of wire, ribbon, strip, sheet, tubing, or bar. Shape setting (or *training*) is accomplished by constraining the Nitinol element on a mandrel or fixture of the desired shape and applying an appropriate heat treatment. The heat treatment methods used to set shapes in both shape memory and superelastic forms of Nitinol are similar. The heat treatment parameters chosen to set both the shape and the properties of the part are critical, and usually need to be determined experimentally for each desired part's requirements. In general, temperatures as low as 400 °C and times as short as 1-2 minutes can set the shape, but generally one uses a temperature closer to 500°C and times over 5 minutes. Rapid cooling of some form is preferred via a water quench or rapid air cool (if both the parts and the fixture are small)."

Technical Bulletin from memry, a SAES Group company
"Shape setting a nitinol component: The material needs to be rigidly fixtured and constrained in the desired shape and heat treated. Typically for superelastic material, a heat treatment in the 500°C range is adequate. The length of heat treatment varies with the equipment used for the heat treatment and the thermal mass of the shaping fixture. In a molten salt bath for example, the heat treatment time is generally between 2 and 5 minutes, whereas in an air convection furnace the heat treatment time can be as long as 45 minutes or more for larger tools."

Heat Treatment of Nitinol Alloys (Part 1) by Daniel H. Herring in Heat Treat Industry News, March 18, 2010

"Shape setting refers to the process used to form Nitinol. Whether the Nitinol is superelastic or shape memory, in the cold work or straightened condition, it is often necessary to form the material into a new "memory" shape. This is done by firmly constraining the material into its new shape in a fixture or on a mandrel and then performing a heat treatment. The heating method can be an air or vacuum furnace, salt bath, sand bath, heated die or other heating method. The temperature should be in the range of 500-550°C (930-1020°F) with higher temperatures resulting in lower tensile strengths."

"Aging can be done to raise the Af temperature of superelastic Nitinol components. Aging is done by heat treating to about 475°C (890°F) for extended periods. Aging and shape setting can be done simultaneously by firmly constraining the material to its new shape in a fixture and heating to around 475°C (890°F) for up to an hour."

Effect of Heat Treatment on the Superelasticity and Hardness of NiTi by O Mortagy and M Farag,
http://www.academia.edu/820015/Effect_of_Heat_Treatment_on_the_Superelasticity_and_Hardness_of_NiTi

"At 500°C Ti11 Ni14 precipitates had grown in size but were still coherent and the material also showed shape memory behavior. No precipitates were observed at 600°C, and, as a result the alloy did not exhibit the shape memory property."

Study of Mechanical, Fatigue and Corrosion Properties of the Superelastic NiTi Alloy by D VOJTĚCH in Metal 2011

"Stents are often manufactured from nitinol wires and, during processing of these wires, nitinol experiences various heat treatment and forming procedures to achieve shape, mechanical properties and transformation behavior suitable for the final application. Final steps in production of superelastic nitinol wires are often cold drawing to a desired diameter followed by straight annealing. Straight annealing consists of heating a preloaded (20-100 MPa) cold drawn wire at an appropriate temperature (450-700°C). It ensures an optimum straight shape and desired functional properties of a wire. A very important step in a following fabrication of stents from the straight annealed superelastic wire is the shape setting. It involves a short (several minutes) heat treatment of the wire which is wound in a desired pattern on a mandrel. The shape setting treatment is generally carried out at moderate temperatures (around 500°C) and its purpose is to induce relaxation of a material for achievement of a desired stable shape of an implant. Moderate temperatures and short times are used to prevent the permanent deformation of implants and to maintain their superelastic behavior."

Influence of Heat Treatment of Shape Memory NiTi Alloy on its Mechanical Properties by D VOJTĚCH in Metal 2010

"NiTi alloys (nitinol) show the shape memory effect, superelastic behavior, high strength, good corrosion resistance and biocompatibility. These characteristics make them of interest for medical applications, such as dental medicine or manufacture of stents, i.e. tubular implants serving to restore blood vessels. In manufacture of stents, nitinol experience various heat treating procedures which may significantly, and sometimes negatively, affect its mechanical properties. For this reason, this work is aimed in determination of mechanical properties of nitinol short-time heat treated at around 500°C. The temperature of 500°C was selected, because in manufacture of stents, shape setting is a step generally performed at about 500°C."

Influence of thermomechanical processing on the superelastic properties of a Ni-rich Nitinol shape memory alloy, D. Favier et al in Materials Science and Engineering A 429 (2006) 130–6

"A single heat treatment at temperatures near 775 K [500°C] is usually applied in the production of the pre-expanded stents whereas the fabrication of pre-cut stents requires a succession of post-cutting expansion and heat treatment. The single heat treatment for the pre-expanded stents is a simple ageing process, whereas that of the pre-cut stents, on the other hand, is more complicated." "These stents are deployed in application in superelastic state, so to enable instantaneous self-restoration of the designed shape after each pulse contraction. "
Finally, the two references that indicate the Af temperature of Patel's components.
[0011] Further, the cold-drawn nitinol wire, ribbon, sheet or tubing is preferably heat treated between 450-500° C and preferably has a final Af temperature between 26° C and 36° C as measured by Differential Scanning Calorimetry (DSC).

[0042] The cold-drawn nitinol wire embodiment is preferably heat treated between 450-500° C and preferably has a final Af temperature between 26° C and 36° C as measured by the DSC technique.

As one can see, the Af temperature is below body temperature and hence the wire component described by Patel will work in the human body. It is therefore Austenitic in its application. Further, Patel does NOT indicate a specific temperature or a time for his treatment. As the reference below shows, the endodontic files produced by the Luebke application will be Martensitic during its application. The next section will further explain the process of creating a Martensitic instrument or device and that temperature is critical and time also plays a role in the establishment of the Af temperature for the application of the instrument or device.

Mechanical and Thermal Properties of Heat-Treated NiTi Endodontic Files by N.H. Luebke*, D.W. Berzins at 2013 IADR Annual Session, Seattle WS

"As-received Twisted Files® ([TF], 25/06; SybronEndo) and another group that were heat-treated at 500°C for 75 minutes (US Patent 8,083,873) (n=10/group) were tested for

bending, torque, and rotational angular deflection according to ISO 3630-1. Additional files of both groups (n=5/group) were analyzed with DSC to determine their thermal properties by scanning from -100°C↔100°C at 10°C/min. DSC thermograms were qualitatively compared and the austenite finish temperature (Af) and martensite-to-austenite heating enthalpy determined. The mechanical and thermal properties were statistically compared by a t-test (a = 0.05)."

Table 2. Thermal properties of Twisted Files before and after heat-treatment (*=statistically significant (P<0.01)).

	Af (°C)
As-received	18.9±1.6*
Heat-treated	39.3±5.6*

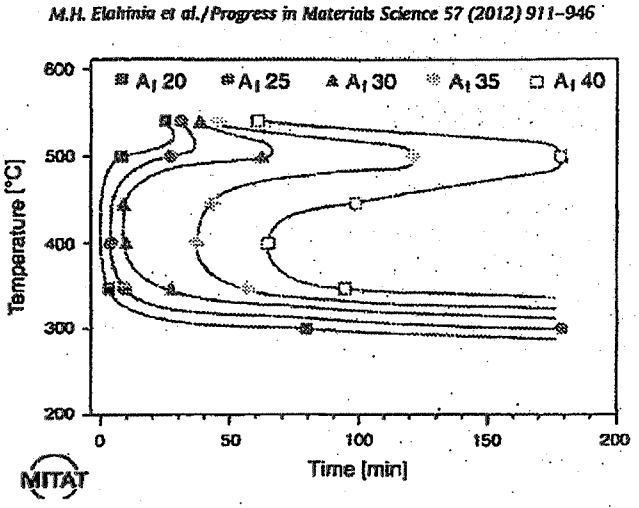
B. Documentation of the process for the Patent Application 13336549

These are the only references found concerning the Martensitic phase of NiTi in the research for this presentation. They are presented below.

Annealing Temperature Effect on Superelastic and Cyclic Response of NiTi SMA by Li Lan et al., 2009, Advanced Materials Research, 79-82
"The SMA starts to transform into the low temperature martensite, when cooling down to the martensite start temperature (Ms). The transformation is complete after the temperature is cooled down past the Ms, down to the martensite finish temperature (Mf). When in this phase, the alloy can be easily manipulated in a very large strain range. "

Manufacturing and processing of NiTi implants: A review by M Elahinia et al in Progress in Materials Science, 57: 911-46, June 2012

"Fig. 4 depicts the effect of aging temperature and time on the phase transformation of Ti–50.8% Ni wire with an initial Af temperature of 11° C. To achieve the balance between driving force and diffusion rate required for phase transformation, for all curves with different Af temperatures, the maximum precipitation rate occurs at about 400° C, which is the best temperature for aging. On the other hand, the higher Af temperature, the wider the area of the temperature hysteresis between austenite and martensite phases. Based on this fact, it is possible to obtain totally martensite microstructure in samples with high Af temperatures easier and in lower cooling rates. Nevertheless, above 500° C, higher diffusion rate takes place and therefore the time required for transformation to be finished decreases. There are abundant amounts of processing data available in the industry to process the SMA material. However, they are often kept proprietary and not released in the public domain. More so than other materials, its manufacturing processes significantly affect properties of NiTi. "



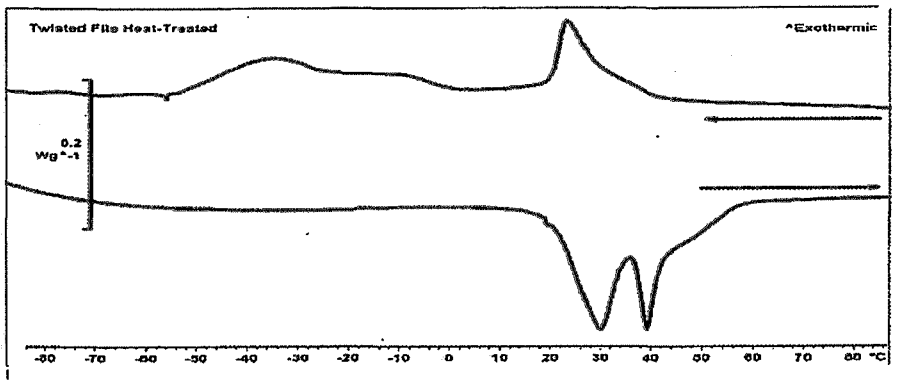
As seen by the graph above, obtaining an Af temperature of 39°C is accomplished with 500°C temperature and approximately two hours of heating. This is what this application accomplishes.

Effect of aging on martensitic transformation behavior of Ti48.8Ni50.8V0.4 alloy by Y Tong et al in J Mater Sci (2011) 46:6432-6

"When the samples were aged at 500 °C for no longer than 2 h, both the forward and reverse DSC curves are characterized by two-stage transformation."

U.S. Patent Application No. 13/336,579

Mechanical and Thermal Properties of Heat-Treated NiTi Endodontic Files by N.H. Luebke*, D.W. Berzins at 2013 IADR Annual Session, Seattle WS



This is a "typical" DSC thermograph of NiTi endodontic files treated according to US Patent 8,083,873 (Luebke) which corresponds to the above reference of two stage transformation.

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414/277-5591

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Milwaukee and Madison, Wisconsin
Phoenix and Tucson, Arizona
Chicago, Illinois
Naples and Tampa, Florida
Washington, D.C.

FAX TRANSMITTAL COVER SHEET

To: 5712738300
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Phone number: 414-277-5708
Senders direct fax:

Number of Pages (including cover sheet): 18
Date & Time Faxed: 7/25/2013 10:28:53 AM

Message:
Attn: Examiner Matthew Nelson
Re: Applicant Initiated Interview Request Form
Docket No. 115207.00007

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/336,579	12/23/2011	Neill Hamilton LUEBKE	115207.00007	4379

26710 7590 08/01/2013

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER	
NELSON, MATTHEW M	
ART UNIT	**PAPER NUMBER**
3776	

NOTIFICATION DATE	DELIVERY MODE
08/01/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	13/336,579	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	MATTHEW NELSON	3776	

All participants (applicant, applicant's representative, PTO personnel):

(1) *MATTHEW NELSON*.

(2) *Richard Roche*.

(3) *Neill Luebke*.

(4) *Fran Luebke*.

Date of Interview: *26 July 2013*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1*.

Identification of prior art discussed: *Patel*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Discussed the differences between the present invention and the prior art, specifically that the prior art conducts the heat treatment described on a nickel-titanium alloy for annealing and shape setting purposes to arrive at a superelastic device, whereas the present invention is conducting the heat treatment on a superelastic device (rather than as part of the forming a superelastic device) resulting in non-superelastic properties that allow for some degree of permanent deformation. Suggested incorporating language into the claims to this effect in order to differentiate from the prior art of record. Further search and consideration will be required.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/Matthew M Nelson/ Examiner, Art Unit 3776	/Robyn Doan/ Primary Examiner

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Docket No.: 115207.00007

I hereby certify that this correspondence is being electronically transmitted to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date: August 6, 2013

/Richard T. Roche/
Richard T. Roche, Reg. No. 38,599

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	13/336,579
Filing Date:	December 23, 2011
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	4379
Art Unit:	3776
Examiner:	Matthew M. Nelson

RESPONSE TO NON-FINAL OFFICE ACTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Non-Final Office Action mailed on July 8, 2013.

Please amend the above-identified patent application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Amendments To The Claims

1. (Currently Amended) A method for manufacturing or modifying a dental instrument or device, the method comprising:

(a) providing a dental instrument or device including an elongated shank comprising a superelastic nickel titanium alloy, and

(b) heat-treating the entire instrument or device at a temperature from 400°C up to but not equal to the melting point of the titanium alloy,

wherein the heat-treated instrument or device has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1~~, and~~

~~wherein the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium~~.

2. (Previously Presented) The method of claim 1 wherein:

step (b) further comprises heat-treating the entire instrument or device in an atmosphere consisting essentially of a gas unreactive with the instrument or device.

3. (Previously Presented) The method of claim 2 wherein:

the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon.

4. (Original) The method of claim 1 wherein:

the temperature is from 475°C to 525°C.

5. (Original) The method of claim 1 wherein:

the instrument or device is heat-treated for 1 to 2 hours.

6. (Cancelled)

7. (Cancelled)

8. (Previously Presented) The method of claim 2 wherein:

the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon,

the temperature is from 475°C to 525°C, and

the instrument or device is heat-treated for 1 to 2 hours.

9. (Previously Presented) The method of claim 2 wherein:

the instrument or device consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium,

the gas is argon,

the temperature is 500°C, and

the instrument or device is heat-treated for 1 to 2 hours.

10. (Original) The method of claim 1 wherein:

the instrument or device is heat-treated in step (b) at a single temperature.

11. (Cancelled)

12. (Original) The method of claim 10 wherein:

the single temperature is from 400°C to 525°C.

13. (Original) The method of claim 10 wherein:

the single temperature is from 475°C to 525°C.

14. (Original) The method of claim 1 wherein:

the instrument or device is an endodontic instrument or device.

15. (Cancelled)

16. (New) The method of claim 1 wherein:

the superelastic nickel titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.

REMARKS

Examiner Interview

Applicant and Applicant's Representative wish to express appreciation to Examiner Nelson for the courtesy of a telephone interview on July 26, 2013. In the Interview Summary dated August 1, 2013, the Substance of the Interview was summarized in part as follows:

> "Discussed the differences between the present invention and the prior art, specifically that the prior art conducts the heat treatment described on a nickel-titanium alloy for annealing and shape setting purposes to arrive at a superelastic device, whereas the present invention is conducting the heat treatment on a superelastic device (rather than as part of the forming a superelastic device) resulting in non-superelastic properties that allow for some degree of permanent deformation. Suggested incorporating language into the claims to this effect in order to differentiate from the prior art of record."

The Applicant has noted the helpful recommendation in the Interview Summary regarding "incorporating language into the claims to this effect in order to differentiate from the prior art of record", and is proceeding accordingly in this amendment.

Claim Amendments

Independent claim 1 has been amended to recite providing a dental instrument or device including an elongated shank comprising a superelastic nickel titanium alloy as described at page 7, lines 1-5 of the specification.

The phrase "wherein the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium" in previous claim 1 has been moved to new claim 16 (which also has a basis at page 7, lines 1-5 of the specification).

Claim Rejection - 35 USC § 103

Claims 1-5, 8-10 and 12-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2005/0090844 to Patel *et al.* ("Patel") in view of U.S. Patent Application Publication No. 2004/0129352 to Shiota ("Shiota").

As detailed in the Interview Summary dated August 1, 2013, Patel conducts the heat treatment described on a nickel-titanium alloy for annealing and shape setting purposes to arrive at a superelastic device, whereas the present invention is conducting the heat treatment on a superelastic device (rather than as part of the forming a superelastic device) resulting in non-superelastic properties that allow for permanent deformation. Amended independent claim 1 recites these differences between Patel and the claimed invention. Specifically, amended independent claim 1: (i) recites in step (a), providing a dental instrument or device including an elongated shank comprising a superelastic nickel titanium alloy; (ii) recites in step (b), heat-treating the instrument or device including the elongated shank comprising the superelastic nickel titanium alloy; and (iii) recites the permanent deformation noted in the Interview Summary dated August 1, 2013.

The technical literature confirms that medical devices, such as those in Patel, are manufactured by a process including: cold drawing followed by straight annealing followed by shape setting that yields a superelastic device. The manufacture of medical devices is explained at the first paragraph of the Introduction in attached Exhibit A (Vojtěch *et al.*, "Study of Mechanical, Fatigue and Corrosion Properties of the Superelastic NiTi Alloy", Metal 2011) as follows:

> "Stents are often manufactured from nitinol wires and, during processing of these wires, nitinol experiences various heat treatment and forming procedures to achieve shape, mechanical properties and transformation behavior suitable for the final application. Final steps in production of superelastic nitinol wires are often cold drawing to a desired diameter followed by straight annealing. Straight annealing consists of heating a preloaded (20-100 MPa) cold drawn wire at an appropriate temperature (450-700°C). It ensures an optimum straight shape and desired functional properties of a wire. A very important step in a following fabrication of stents from the straight annealed superelastic wire is the shape setting. It involves a short (several minutes) heat treatment of the wire which is wound in a desired pattern on a mandrel. The shape setting treatment is generally carried out at moderate temperatures (around 500°C) and its purpose is to induce relaxation of a material for achievement of a desired stable shape of an implant. Moderate temperatures and short times are used to prevent the permanent deformation of implants and to maintain their superelastic behavior."

As explained above in the excerpt from Exhibit A, in a typical shape setting treatment, "[m]oderate temperatures and short times are used to prevent the permanent deformation of implants and to maintain their superelastic behavior" (underlining added). Accordingly, after the shape setting treatment of Patel, one has a superelastic device.

Thus, the reasoning in the Interview Summary dated August 1, 2013 that "Patel conducts the heat treatment described on a nickel-titanium alloy for annealing and shape setting purposes to arrive at a superelastic device" is confirmed in the technical literature. In addition, amended independent claim 1 now makes it clear that the present invention is conducting the heat treatment on a superelastic device rather than as part of the forming a superelastic device as noted in the Interview Summary dated August 1, 2013.

With respect to U.S. 2004/0129352 to Shiota, the Shiota publication was cited as teaching a non-reactive gas. Therefore, Shiota does not make up for the deficiencies in Patel detailed above.

Summarizing, Patel and Shiota do not teach a method that heat treats a dental instrument or device including an elongated shank comprising a superelastic nickel titanium alloy to produce a dental instrument or device that has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 as recited in amended independent claim 1. It is well settled that in order to establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Accordingly, it is submitted that independent claim 1 (and claims 2-5 and 8-10, 12 and 16 that depend thereon) are patentable over Patel and Shiota.

Conclusion

Claims 1-5 and 8-10, 12-14 and 16 are believed to be in condition for allowance. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application. No fees are believed to be due. If any fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: August 6, 2013

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18. - 20. 5. 2011, Brno, Czech Republic, EU

STUDY OF MECHANICAL, FATIGUE AND CORROSION PROPERTIES OF THE SUPERELASTIC NI-TI ALLOY

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Abstract

Ni-Ti alloys (Nitinol) show superelastic behavior, shape memory, excellent corrosion resistance, good biocompatibility and strength. For these reasons, they are widely used in medicine for stents, i.e., tubular implants serving to restore damaged blood vessels, oesophagus etc. Increasing demands for the mechanical and chemical performance of implants have motivated detailed studies focused on the influence of processing parameters on resulting properties. This study is devoted to the effect of heat and chemical treatments on properties of a NiTi wire used for medical stents. The wire was heat-treated at 450-600°C and direct relationships between processing, mechanical, fatigue and corrosion characteristics were found and discussed.

Keywords: Ni-Ti alloy, Nitinol, shape memory, superelasticity, heat treatment

1. INTRODUCTION

Nitinol, i.e. nearly equi-atomic Ni-Ti alloy, became of interest in production of various medical devices, such as stents, due to shape memory behavior, superelasticity, biocompatibility, corrosion resistance and good mechanical properties. Stents are often manufactured from nitinol wires and, during processing of these wires, nitinol experiences various heat treatment and forming procedures to achieve shape, mechanical properties and transformation behavior suitable for the final application. Final steps in production of superelastic nitinol wires are often cold drawing to a desired diameter followed by straight annealing. Straight annealing consists of heating a pre-loaded (20-100 MPa) cold drawn wire at an appropriate temperature (450-700°C). It ensures an optimum straight shape and desired functional properties of a wire. A very important step in a following fabrication of stents from the straight annealed superelastic wire is the shape setting. It involves a short (several minutes) heat treatment of the wire which is wound in a desired pattern on a mandrel. The shape setting treatment is generally carried out at moderate temperatures (around 500°C) and its purpose is to induce relaxation of a material for achievement of a desired stable shape of an implant. Moderate temperatures and short times are used to prevent the permanent deformation of implants and to maintain their superelastic behavior.

In general, nitinol shape memory alloys exhibit three phases, the high-temperature B2 austenite phase (structure of CsCl), low-temperature B19´ martensite phase (monoclinic structure) and intermediate-temperature R-phase (rhombohedral structure) [1-3]. Transformations of these phases are of a great importance, because they determine the superelastic and shape memory characteristics of nitinol, as well as its mechanical and functional properties and performance. These transformations can proceed by various ways, B2↔B19´, B2↔R, R↔B19´, depending on thermal and mechanical history of alloys. The direct transformation of austenite B2 to martensite B19´upon cooling generally occurs when an alloy is in a solution annealed state, i.e. annealed at a high temperature and water quenched. Upon subsequent ageing, the solid solution decomposes to form Ti_3Ni_4 precipitates. All stages of precipitation strongly influence both phase transformations and mechanical characteristics of a material, mainly yield strength and tensile strength.

Strength may be increased by an elastic lattice stress introduced by coherent and semi-coherent Ti_3Ni_4 precipitates.

In addition to mechanical properties, processing of nitinol also affects its surface chemistry and, subsequently, corrosion resistance. Although nitinol is generally regarded as being highly corrosion resistant, similarly to stainless steels or titanium, corrosion may be a serious problem in some cases. Corrosion of a nitinol implant in a patient may have two aspects: 1. Due to corrosion, nickel releases into a surrounding body fluids. Unfortunately, nickel is a toxic element that may cause allergic reactions of an organism. 2. In an extreme case, corrosion processes may cause pitting and a reduction of an implant cross-section. This may lead to a serious damage of a stent and its fracture into dangerous sharp fragments. There are several reports in which stent damage and failure due to corrosion are described [4].

Corrosion resistance of nitinol is mainly influenced by its surface chemistry and state. When even a weak oxidizing environment, such as water, air or humidity, is in contact with nitinol, a few nm thick native passive layer dominated by titanium dioxide forms on the nitinol surface. However, there may be defects in this passive layer acting as sites for pitting and accelerated corrosion. Therefore, any treatment leading to an improvement of the passive layer quality would reduce corrosion rate of nitinol. In addition, any heat-treatment induces surface oxidation which modifies the surface oxide layer and its protective effect. Taking into account thermodynamics of the Ni-Ti-O system, it is beneficial that titanium oxidizes preferentially in wide intervals of oxygen partial pressure and temperature. Therefore, thermodynamics says that, when oxidizing a nitinol, a protective TiO_2-enriched and Ni-depleted oxide layer forms on the surface. Simultaneously, inward diffusion of nickel results in a Ni-enriched and Ti-depleted region beneath the external oxide [5, 6].

To our best knowledge, relatively little information is available on changes of mechanical properties and corrosion resistance of nitinol due to a short-term heat treatment at moderate temperatures in air. For this reason, our study is concerned with the short-time annealing of a nitinol wire commonly employed in stent fabrication at 450-600°C. Influence of these heat treatments on mechanical, fatigue and corrosion properties is the main objective of our study.

2. EXPERIMENT

A nitinol wire having a thickness of 0.3 mm and a chemical composition of 50.9 % Ni was used in our experiment (hereafter, all concentrations are in at. % unless otherwise stated). The wire was produced by the standard procedure, including vacuum induction-melting, hot forging and repeated cold drawing with intermediate annealing. Final cold drawing reduced the wire diameter by 40 %, and this step was followed by the straight annealing of the wire. Surface finishing of the wire included chemical etching in an intensively stirred acid bath containing HF, HNO_3 and H_2O (1:4:5 by volume) at room temperature for 4 min, followed by ultrasonic washing in distilled water for 5 min. Hereafter, the wire prepared by the procedure above will be referred to as "as-prepared" for simplicity.

Short-time heat-treatments (HT) of the wire included annealing at 450-600°C for 10 min in air, followed by quenching in water at 20°C. The temperatures of 450-600°C were selected to simulate shape-setting procedures. It was expected that the heat treatments would induce surface oxidation and also changes of the internal structure and, therefore, the mechanical properties of the wire.

The internal structures and surfaces of treated wires were investigated by a transmission electron microscope (TEM), energy dispersion spectrometer (EDS) and by a scanning electron microscope (SEM) equipped with a high-speed electron backscatter diffraction (EBSD) camera. Elemental profiling in a thin sub-surface zone was performed by a glow discharge spectrometer (GDS) (GD Profiler 2).

Tensile tests were conducted on an Instron 3343 tensile machine at a strain rate of $8.3 \cdot 10^{-4}$ s^{-1} and at a temperature of 23°C. All samples showed an upper plateau on the stress-strain diagram, suggesting that the matrix of the alloy was dominated by austenite B2 phase at this temperature. During all tensile tests, tensile loading increased up to the fracture to determine the tensile strength.

Low-cycle fatigue behavior was studied in the bend-type loading mode. The wire was fixed to two arms of a cyclic bend-type loading machine. One arm was kept in a stable position, while the other periodically moved with simultaneous recording of the number of cycles. This cyclic motion enabled the wire to be periodically bent up to the fracture with a constant bending angle of 50°. The fatigue test was stopped automatically when wire fracture occurred. The cyclic loading frequency was 3 Hz, and the testing temperature was 23°C. Fatigue tests were performed ten times for each heat treatment regime.
Corrosion behavior was examined by immersion tests. The wires were immersed in a simulated physiological solution (9 g/l NaCl, pH=2 adjusted by the addition of HCl) for 168 hours at 23°C. Afterwards, the nickel and titanium released into the solution were determined by an inductively coupled plasma – mass spectrometer (ICP-MS).

3. RESULTS AND DISCUSSION

3.1 Structure and surface

The structures of the wire are presented in Fig. 1.

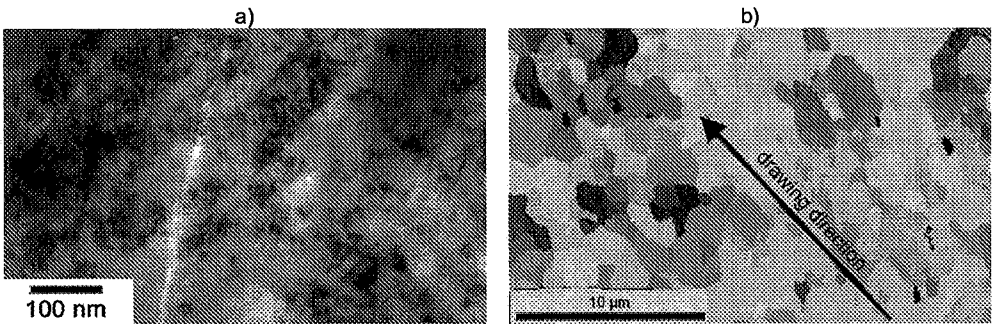

Fig. 1: Structures of the wire: a) as-prepared (TEM), b) heat-treated at 600°C/10 min (EBSD)

One can see that the structure of the as-prepared wire possesses typical features of the cold-worked and annealed state. Cold working induces the formation of a large concentration of lattice defects, mainly dislocations. Dislocations accumulate in clusters, which appear as dark areas in Fig. 1a. Dislocation clusters are mainly associated with the deformation texture, i.e., they mainly appear within B2 grains elongated in the drawing direction. These deformed grains are of about 50-100 nm in size. Regarding the mechanical properties, the large concentration of lattice defects and the extremely fine grains are strengthening factors contributing to the tensile strength of the as-prepared wire, as will be shown later.
It is expected that the heat treatments at 450-600°C will accelerate the recrystallization and grain growth. At 450-500°C/10 min, however, the structural changes are relatively small, the structures are similar to those in Fig. 1a, and, as a result, the strength also remains similar to that of the as-prepared wire (heat-treatment at 450°C) or slightly lower (heat-treatment at 500°C) (see below). After heat treatment at 600°C/10 min, the wire structure is significantly modified, as illustrated in Fig. 1b. This figure shows an EBSD map of the wire heat-treated at this temperature. One can observe that the deformation texture vanishes and that all grains have nearly equi-axed shapes. The grain size ranges between 500 nm and 5 µm. It will be illustrated later that the structural changes induced by this short-time heat-treatment strongly influence the tensile mechanical properties of the wire.
Both fatigue and the corrosion behavior are influenced by the surface structure and chemistry of a wire. SEM images of the surface of as-prepared wire and the wire heat-treated at 600°C/10 min are shown in Fig. 2.

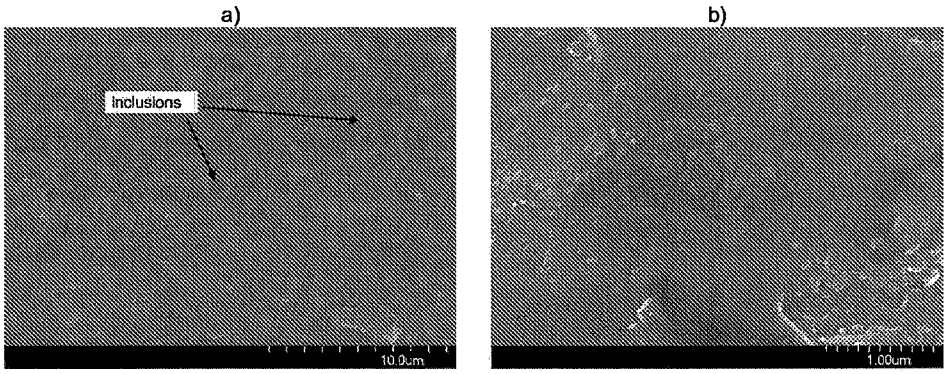

Fig. 2: Surface of the as-prepared wire (a) and the wire heat-treated at 600°C/10 min (b).

The as-prepared wire in Fig. 2a is characterized by a typical dimple-like morphology due to chemical etching. In some dimples there are non-metallic inclusions (marked by arrows). Chemical etching produces a very thin (a few nm), compact and defect free oxide layer on the surface. It is evident from Fig. 2b that the heat treatment causes oxidation of the surface. The surface oxide has a grainy morphology, and the average grain size is about 100 nm. The oxides formed at such high temperatures are dominated by rutile (TiO_2), due to the preferential oxidation of Ti over Ni. It is also important that the surface of the heat-treated wire contains many defects, mainly micro-cracks. They may serve as sites for fatigue crack initiation and, more likely, localized corrosion. Defects originate from the external mechanical or thermal loading of a material, from differences between the molar volumes of metals and oxides and from cooling from heat treatment temperatures.

3.2 Mechanical and fatigue properties

Stress-strain curves for various states of the wire are presented in Fig. 3. All curves exhibit typical deformation stages of nitinol including elastic deformation of austenite, stress-induced martensitic transformation (plateau), elastic deformation of martensite, plastic deformation of martensite and fracture. The as-prepared wire has a tensile strength of 1650 MPa. This high strength level is attributable to two main strengthening contributions: 1. dislocation strengthening due to cold drawing and 2. Hall-Petch strengthening due to a very fine grain size (Fig. 1a). After heat treatment at 450°C/10 min, the stress-strain behavior and tensile strength (1660 MPa) remain almost identical to those of the as-prepared wire. This is in accordance with the structural investigation given before and with the fact that recrystallization is slow at 450°C. The heat-treatment at 500°C/10 min also leads to only a slight decrease in strength to 1505 MPa. At this temperature, recrystallization is still relatively slow. A considerable strength reduction to 998 MPa is observed after heat treatment at 600°C/10 min. Here, grains become relatively coarse (see Fig. 1b), and the dislocation strengthening effect vanishes. It is also observed in Fig. 3 that the stress-induced martensite shows a high plasticity. As a result, the maximum strain of the wire heat-treated at 600°C is above 50 %, i.e., more than three times larger than those corresponding to the other treatment regimes. The high plasticity is attributed to the large grain size and to the absence of dislocations from cold working.

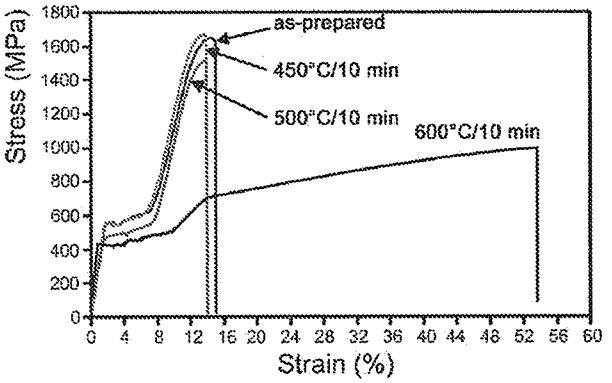

Fig. 3: Stress-strain curves of the wires treated by various regimes.

Fig. 4 summarizes the fatigue lives of the wires, i.e., the numbers of bending cycles to fracture. Each treatment regime is characterized by ten measurements, and all data are included in the figure to better observe important trends. The following findings can be deduced from this figure: 1. Heat treatments at 450-500°C/10 min have small effects on the fatigue life. 2. Heat treatments at higher temperatures improve fatigue life, in comparison to the as-prepared wire; the best fatigue performance is observed for the wire treated at the highest temperature. The large scatter of measured fatigue lives is associated with the heterogeneity of the wire surface. It is shown in Fig. 2 that there are surface imperfections on the wire, mainly inclusions. These inclusion act as sites at which fatigue cracks nucleate. However, the defects are not distributed uniformly. During bend-type cyclic loading, the maximum tensile stress is periodically induced on the external surface of the bend. Therefore, large surface defects present in this area lead to the early initiation of fatigue cracks and to a significant reduction of the fatigue life. If, however, defects in this area are small and rounded, the time needed for fatigue crack initiation is longer. It is known that surface defects are not the only factors influencing the fatigue behavior. The total fatigue lives are also influenced by the internal structure of the wire. As given before, the heat treatment at 600°C prolongs the fatigue life in comparison with the as-prepared wire. It can be assumed that the positive effect of heat treatment can be attributed to the structural changes occurring in the wire, especially the recrystallization and reduction of dislocation density (Figs. 1 and 3). In particular, the heat treatment at 600°C/10 min produces a very ductile stress-induced martensite (Fig. 3). A similar stress-induced martensite also forms at the tip of a growing fatigue crack due to a stress concentration, and its high ductility is associated with a good fatigue crack growth resistance. This is the reason why the highest heat treatment temperature results in the best fatigue performance. The heat treatment temperatures of 450 and 500°C only slightly modify the wire structure, and, therefore, their influences on the fatigue life are small (Fig. 4).

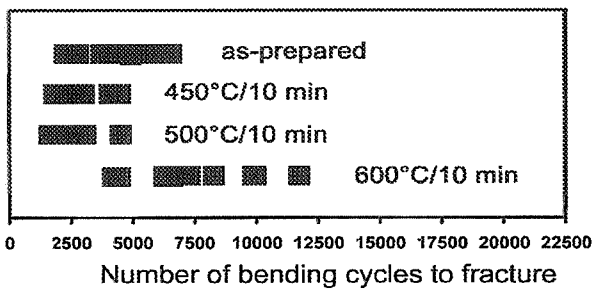

Fig. 4: The fatigue lives of the wires expressed as the numbers of bending cycles to fracture (each state is represented by ten measurements).

3.3 Corrosion resistance

Corrosion behavior was assessed by immersion tests and the results of these tests are summarized in Fig. 5 as functions of Ti and Ni release versus heat treatment temperature.

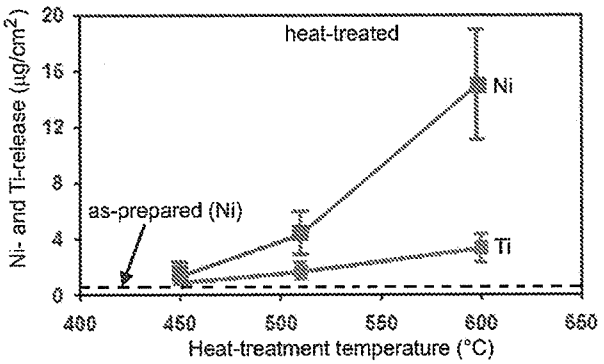

Fig.5: Ti and Ni release into the corrosive medium as a function of heat treatment temperature.

One can see that there is a clear relationship between the Ti and Ni amounts released into the corrosion media and the heat treatment temperature; the higher the temperature, the higher the element release. The best corrosion resistance is observed for the as-prepared wire whose surface was finished by chemical etching. From the biocompatibility point of view, nickel release is of primary importance. The difference in the total Ni release between the as-prepared wire and that treated at 600°C is more than 14 μg/cm^2. It was shown before (Fig. 2) that the increase of heat treatment temperature results in the growth of thickness of Ni-depleted surface titania. Therefore, one could postulate that the heat treatment at 600°C provides a good barrier against element release. However, the immersion tests presented in Fig. 5 reveal the totally opposite trend. This trend can be explained in terms of the internal defectiveness of the surface oxide layer. Figure 2b shows that there are many micro-cracks in the surface oxide formed by oxidation at 600°C. The origin of such defects was already explained before, and it is well known that their formation is supported by two factors, namely a large oxide thickness and an increase of the oxide grain size. Both these factors enhance the internal stress induced in the oxide, for example, that due to temperature variations. Once a micro-crack is created, it serves as a good path for nickel transport from the metallic substrate towards the corrosion medium. In contrast, the as-prepared wire is coated with a very thin and almost defect-free oxide (Fig. 2a) and, therefore, it exhibits the highest corrosion resistance (Fig. 5).

Consider now the results of immersion tests in the context of biocompatibility. If we have, for example, an esophageal stent with a length of 10 cm made of a nitinol wire of 0.3 mm in diameter, the total surface area of this stent can be estimated as 40 cm^2. The total Ni release of 15 μg/cm^2 achieved after one weak exposure of the wire treated at 600°C/10 min (Fig. 5) gives approximately 80 μg of Ni released from one stent per day. Of course, the real Ni release rate can be higher due to mechanical loading and other factors. However, by comparing the estimated 80-μg Ni/day with the estimated Ni dietary intake of 200-300 mg/day [7], it can be assumed that the nickel release from nitinol can only cause problems for allergic patients.

4. CONCLUSIONS

It is demonstrated in the present work that the functional properties of NiTi wire are modified considerably by 10-min heat treatments at moderate temperatures of 450-600°C. These modifications should be taken into account when the shape-setting treatment of stents is performed. Modifications of the tensile properties occurring mainly after treatment at 600°C can be attributed to recrystallization processes in the work-hardened wire. It is clear that lower heat treatment temperatures up to 500°C do not considerably affect the

tensile strength. The fatigue as well as the corrosion properties are influenced by the heat treatment of the wire. Fatigue life is found to improve with increasing heat treatment temperature. The reason for this is that the heat treatment induces structural changes beneficial for the formation of plastic stress-induced martensite at the crack tip, which increases the crack growth resistance. The effect of heat treatment on the corrosion resistance is negative due to the formation of thick and defect-containing oxide layers which worsen the protective effect.

ACKNOWLEDGEMENTS

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Electronic Acknowledgement Receipt

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International Application Number:	
Confirmation Number:	4379
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First Named Inventor/Applicant Name:	Neill Hamilton LUEBKE
Customer Number:	26710
Filer:	Richard T. Roche
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Application Type:	Utility under 35 USC 111(a)

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		response-8-6-13.pdf	11550913 f42626f034542d8d10e38f30a677f089ffde45f6	yes	15

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/336,579	Filing Date 12/23/2011	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 = *		X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 08/06/2013

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	(Column 3) ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 12	Minus	** 20	= 0	x $40 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	x $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	(Column 3) ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* 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 column 1.

LIE
/JACQUELINE COUPLIN/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26710 7590 09/03/2013

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER	
NELSON, MATTHEW M	
ART UNIT	PAPER NUMBER
3776	

DATE MAILED: 09/03/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/336,579	12/23/2011	Neill Hamilton LUEBKE	115207.00007	4379

TITLE OF INVENTION: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$890	$300	$0	$1190	12/03/2013

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) 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. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility 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.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26710 7590 09/03/2013
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. 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 or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/336,579	12/23/2011	Neill Hamilton LUEBKE	115207.00007	4379

TITLE OF INVENTION: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$890	$300	$0	$1190	12/03/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
NELSON, MATTHEW M	3776	433-102000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

☐ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

☐ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) 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 United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/336,579	12/23/2011	Neill Hamilton LUEBKE	115207.00007	4379

26710 7590 09/03/2013

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MILWAUKEE, WI 53202-4426

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3776	

DATE MAILED: 09/03/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 13/336,579	Applicant(s) LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3776	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All 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 (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *amendment filed on 8/6/2013*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-5,8-10,12-14 and 16*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20130820* .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Matthew M Nelson/
Examiner, Art Unit 3776

EXAMINER'S AMENDMENT

• 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 CFR 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 Richard Roche on 8/19/2013.

The application has been amended as follows:

Claim 1: Replace "(b) heat-treating" with "(b) after step (a), heat-treating".

Claim 1: Replace "melting point of the titanium alloy" with "melting point of the superelastic nickel titanium alloy".

• The following is an examiner's statement of reasons for allowance: A method of manufacturing or modifying a dental instrument/device where a dental instrument or device is provided having an elongated shank of superelastic nickel titanium alloy and then subsequently heat-treating the entire instrument or device at 400 C or above but not the melting temperature, resulting in a device with shape memory characteristics in that an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 was neither taught nor suggested by the prior art as a whole, either alone or in combination, and in combination with the elements set forth in the claims. The closest prior art does not

tend to heat treat entire instruments, nor does it more importantly perform these heat treatments on superelastic dental instruments or devices. Rather, the prior art is interested in heat-treating in order to arrive at a superelastic instrument. So what the present invention is essentially doing is taking a completed superelastic instrument (the prior art) and then conducting further heat-treatment in order to arrive at a shape memory alloy with the prescribed deformation characteristics. After discussion with class 148 regarding the properties of the alloys and heat-treatment, it was understood that while a titanium alloy will not always result in the above properties, a shape memory nickel-titanium alloy will result from the claimed method distinguished from the superelastic properties of the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW NELSON whose telephone number is (571)270-5898. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm EDT.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Todd Manahan, at (571) 272-4713.*** The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robyn Doan/
Primary Examiner, Art Unit 3776

/MMN/

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	13/336,579	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	MATTHEW NELSON	3776	

All participants (applicant, applicant's representative, PTO personnel):

(1) *MATTHEW NELSON*. (3)_____.

(2) *Richard Roche*. (4)_____.

Date of Interview: *19 August 2013*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1*.

Identification of prior art discussed: *none*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Discussed amendments to the claims in order to place the application in condition for allowance, such as specifying the order of steps and making clear the heat treatment was on the superelastic nickel titanium alloy.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/Matthew M Nelson/ Examiner, Art Unit 3776	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	3034	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/08/20 10:36
S2	6	"6431863".pn. "6422865".pn. "6428634".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 07:56
S5	1068	Ni adj Ti AND anneal$2 AND time	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S6	544	Ni adj Ti AND anneal$2 AND time AND hour	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S7	16	Ni adj Ti AND anneal$2 AND time AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:54
S8	876	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:54
S9	53	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:55
S10	183	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 15:12
S11	29	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND	US-PGPUB; USPAT;	OR	ON	2008/04/29 15:16

		(anneal$3 OR heat NEAR5 treated)	USOCR; FPRS; EPO; JPO; DERWENT			
S12	891	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S13	67	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S14	16	Ni adj Ti AND anneal$2 AND time AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S15	30	S12 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:58
S19	11	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((flexib$5) SAME ("400" "425" "450" "475" "500" "525")) AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 14:47
S20	34	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((temperature) SAME ("400" "425" "450" "475" "500" "525")) AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 14:48
S21	62	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((temperature) SAME (degree)) AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 15:17
S22	903	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/24 12:26
S23	71	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/24 12:26
S24	1092	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT;	OR	ON	2009/08/03 13:13

			USOCR; FPRS; EPO; JPO; DERWENT			
S25	78	S24 AND (heat WITH treat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S26	917	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S27	32	S26 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S28	917	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S29	192	S28 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S30	1099	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:33
S31	18	S30 AND microstructure	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:34
S32	200	S30 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:35
S33	2	("7175655").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/18 13:12
S34	1112	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT;	OR	ON	2010/03/22 09:45

			USOCR; FPRS; EPO; JPO; DERWENT			
S35	1	(ISO WITH 3630-1) AND S34	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:45
S36	8	(ISO WITH "3630") AND S34	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:46
S37	989	("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel WITH Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/07 11:31
S38	258	("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel WITH Titanium)) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/07 11:32
S39	83	("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel WITH Titanium)) AND endodontic AND deformation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/07 11:33
S40	1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:02
S41	226	S40 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:02
S42	52	S41 AND ((shape NEAR1 memory) (permanent NEAR1 deformation))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:34
S43	2	"5843244".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:56
S44	1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT;	OR	ON	2010/10/19 18:06

			USOCR; FPRS; EPO; JPO; DERWENT			
S45	226	S44 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S46	1	S45 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S47	11	S45 AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:07
S48	10	(US-20040121283-$).did. or (US-6431863-$ or US-6428634-$ or US-6375458-$ or US-4490112-$ or US-5775902-$ or US-5080584-$ or US-6206695-$ or US-7137815-$ or US-5653590-$).did. or (US-6422865-B-$).did.	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S49	0	S48 AND gas	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S50	2	S48 AND atmosphere	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S51	982	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:32
S52	8	S51 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) AND (gas atmosphere)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:32
S53	10068	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (gas atmosphere)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:35
S54	1335	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:36
S55	6	(endodontic) AND ((Ni NEAR1 Ti) OR	US-PGPUB;	OR	ON	2011/05/12

		(Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			09:36
S56	2	(endodontic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S57	2	(endodontic "433".clas.) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S58	16	(endodontic "433".clas.) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S59	51	(endodontic "433".clas.) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:40
S61	1346	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:46
S64	126	((Ni ADJ Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) SAME (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:52
S65	10	((Ni ADJ Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) SAME (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:56
S66	8234	(anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S67	8	"433".clas. AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S68	2	Nitinol AND (anneal$3 OR heat	US-PGPUB;	OR	ON	2011/05/12

		NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			10:01
S69	130	(titanium ADJ alloy) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:02
S70	37	(titanium ADJ alloy) SAME (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:02
S71	2	"6783438".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:33
S72	99	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:27
S73	54	29/896.11	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:27
S74	985	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:27
S75	41	(S72 S73 S74) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:28
S76	1411	148/402,421,426.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:17
S77	822	S76 AND titanium	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:18
S78	621	S76 AND titanium AND heat	US-PGPUB;	OR	ON	2011/09/07

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT			13:18
S79	254	S76 AND titanium AND heat AND atmosphere	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:18
S80	159	S76 AND titanium AND heat AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S81	126	S76 AND titanium AND (heat WITH treat$4) AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S82	121	S76 AND titanium AND (heat ADJ treat$4) AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S83	3	S76 AND titanium AND (heat ADJ treat$4) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:20
S84	3	148/402.ccls. AND (heat ADJ treat$4) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
S85	191	148/402.ccls. AND (heat ADJ treat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
S86	0	148/402.ccls. AND (heat ADJ treat$4) SAME shank	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
S87	19	148/402.ccls. AND (heat ADJ treat$4) SAME (atmosphere argon helium neon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:25
S89	336	148/669.ccls. AND titanium	US-PGPUB;	OR	ON	2011/09/07

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT			15:03
S90	48	148/669.ccls. AND titanium AND (anneal$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 15:04
S92	20245	((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:36
S93	11539	((shape ADJ memory) superelastic) AND (medical dental) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:36
S94	7768	((shape ADJ memory) superelastic) AND (medical dental) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium)) AND temperature	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:37
S95	5395	((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:37
S96	282	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:06
S97	184	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:07
S98	71	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) AND (inert gas) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:25
S99	18	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) SAME (inert gas) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:26
S100	13	"148".clas. AND ((shape ADJ	US-PGPUB;	OR	ON	2012/08/28

		memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) SAME (inert gas) SAME temperature AND @ad<="20040608"	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			13:32
S101	51	(medical dental) AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) SAME (inert gas) SAME temperature AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:33
S102	3	"12977625"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:40
S103	2	"5380200".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/05 08:39
S104	2819	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/12/05 09:41
S105	2882	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/06/29 09:53
S106	3033	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/08/19 08:13
S107	56	S106 AND ((shape ADJ memory) AND superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treat$4) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/08/19 08:13
S108	2	"8083873".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/08/19 08:15

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp

L1	1	(433/102).CCLS.	UPAD	OR	OFF	2013/08/20 10:36
S88	0	(29/896.1,896.11).CCLS.	UPAD	OR	OFF	2011/09/07 14:33
S91	0	(148/669).CCLS.	UPAD	OR	OFF	2011/09/07 15:04

8/ 20/ 2013 10:36:55 AM
C:\ Users\ mnelson3\ Documents\ EAST\ Workspaces\ 13336579 Dental and medical instruments comprising titanium.wsp

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13336579	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	MATTHEW NELSON	3776

CPC		
Symbol	**Type**	**Version**

CPC Combination Sets				
Symbol	**Type**	**Set**	**Ranking**	**Version**

/MATTHEW NELSON/ Examiner.Art Unit 3776	8/20/2013	**Total Claims Allowed:**
(Assistant Examiner)	(Date)	12
/ROBYN DOAN/ Primary Examiner.Art Unit 3776	08/21/2013	O.G. Print Claim(s) / O.G. Print Figure
(Primary Examiner)	(Date)	1 / 1a

U.S. Patent and Trademark Office

Part of Paper No. 20130820

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	13336579	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
433	102	A	6	1	C	5 / 02 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

/MATTHEW NELSON/ Examiner.Art Unit 3776	8/20/2013	Total Claims Allowed:	
(Assistant Examiner)	(Date)	12	
/ROBYN DOAN/ Primary Examiner.Art Unit 3776	08/21/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1a

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	Examiner	**Art Unit**
	MATTHEW NELSON	3776

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1														
2	2														
3	3														
4	8														
5	9														
6	4														
7	5														
8	10														
9	12														
10	13														
11	14														
12	16														

/MATTHEW NELSON/ Examiner.Art Unit 3776	8/20/2013	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	12	
/ROBYN DOAN/ Primary Examiner.Art Unit 3776	08/21/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1a

U.S. Patent and Trademark Office

Part of Paper No. 20130820

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13336579	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/28/2012	12/05/2012	06/29/2013	08/20/2013					
	1	✓	✓	✓	=					
	2	✓	✓	✓	=					
	3	✓	✓	✓	=					
	4	✓	✓	✓	=					
	5	✓	✓	✓	=					
	6	✓	✓	-	-					
	7	✓	✓	-	-					
	8	✓	✓	✓	=					
	9	✓	✓	✓	=					
	10	✓	✓	✓	=					
	11	✓	✓	-	-					
	12	✓	✓	✓	=					
	13	✓	✓	✓	=					
	14	✓	✓	✓	=					
	15	✓	-	-	-					
	16				=					

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13336579	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
433	102, 224	8/28/2012	MN
29	896.1, 896.11	8/28/2012	MN
148	402, 421, 426, 669	8/28/2012	MN
29, 148, 433	Updated	12/5/2012	MN
29, 148, 433	Updated	6/29/2013	MN
29, 148, 433	Updated	8/20/2013	MN

SEARCH NOTES		
Search Notes	Date	Examiner
See EAST search history	8/28/2012	MN
Reviewed parent	8/28/2012	MN
Updated EAST search	12/5/2012	MN
Search help in 148 from George Wyszomierski and Jessee Roe	12/5/2012	MN
Updated EAST search	6/29/2013	MN
Updated EAST search	8/20/2013	MN

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
433	102	8/20/2013	MN

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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BIB DATA SHEET

CONFIRMATION NO. 4379

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/336,579	12/23/2011 RULE	433	3776	115207.00007

APPLICANTS
Neill Hamilton LUEBKE, Brookfield, WI;

** **CONTINUING DATA** **********
This application is a CON of 12/977,625 12/23/2010 PAT 8083873
which is a DIV of 11/628,933 12/07/2006 PAT 8062033
which is a 371 of PCT/US05/19947 06/07/2005 /MMN/
which claims benefit of 60/578,091 06/08/2004

** **FOREIGN APPLICATIONS** ********** NONE /MMN/

** **IF REQUIRED, FOREIGN FILING LICENSE GRANTED** ** SMALL ENTITY ** /MMN/
02/01/2012

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /MATTHEW M NELSON/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		WI	7	15	1

ADDRESS

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426
UNITED STATES

TITLE

Dental and Medical Instruments Comprising Titanium

FILING FEE RECEIVED	FEES: Authority has been given in Paper	☐ All Fees
530	No._____ to charge/credit DEPOSIT ACCOUNT	☐ 1.16 Fees (Filing)
	No._____ for following:	☐ 1.17 Fees (Processing Ext. of time)
		☐ 1.18 Fees (Issue)
		☐ Other _____
		☐ Credit

BIB (Rev. 05/07).

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26710 7590 09/03/2013
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. 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 or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/336,579	12/23/2011	Neill Hamilton LUEBKE	115207.00007	4379

TITLE OF INVENTION: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$890	$300	$0	$1190	12/03/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
NELSON, MATTHEW M	3776	433-102000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Quarles & Brady LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Gold Standard Instruments, LLC
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Brookfield, WI

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 170055 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

☐ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

☒ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) 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 United States Patent and Trademark Office.

Authorized Signature /Richard T. Roche/ Date September 17, 2013

Typed or printed name Richard T. Roche Registration No. 38,599

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal

Application Number:	13336579
Filing Date:	23-Dec-2011
Title of Invention:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
First Named Inventor/Applicant Name:	Neill Hamilton LUEBKE
Filer:	Richard T. Roche
Attorney Docket Number:	115207.00007

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	1780	1780
Publ. Fee- Early, Voluntary, or Normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**2080**

Electronic Acknowledgement Receipt

EFS ID:	16878233
Application Number:	13336579
International Application Number:	
Confirmation Number:	4379
Title of Invention:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
First Named Inventor/Applicant Name:	Neill Hamilton LUEBKE
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	115207.00007
Receipt Date:	17-SEP-2013
Filing Date:	23-DEC-2011
Time Stamp:	16:40:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$2080
RAM confirmation Number	3905
Deposit Account	170055
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Issue Fee Payment (PTO-85B)	IssueFee.PDF	113199 83f66c424ec26acad81b21aaf0a249d0f612bb0f	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32059 2ebb37d58f289ff20566f7a121a1f17ca6617f27	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	145258		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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PTO/SB/08a (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet | | of |

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Neill H. Luebke
Art Unit	
Examiner Name	Matthew M. Nelson
Attorney Docket Number	

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6783438	~~10/28/2003~~	Aloise et al.	August 31, 2004
Change(s) applied to document, /D.D./ 9/18/2013		US-20040171333	09/02/2004	Aloise et al.	
		US-20060014480	01/13/2006	Aloise et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature	/Matthew Nelson/	Date Considered	08/28/2012

*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. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.N./

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/336,579	10/22/2013	8562341	115207.00007	4379

26710 7590 10/02/2013

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Neill Hamilton LUEBKE, Brookfield, WI;

PTO/SB/44 (09-07)
Approved for use through 08/31/2010. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,562,341

APPLICATION NO.: 13/336,579

ISSUE DATE : October 22, 2013

INVENTOR(S) : Neill H. Luebke

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3, line 27 " g•cm " should read -- gOcm--

Column 7, line 22 " g•cm " should read -- gOcm--

Column 10, line 43 " supereiastic" should read -- superelastic --

MAILING ADDRESS OF SENDER (Please do not use customer number below):

115207.00007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

US Patent No.:	8,562,341
Issued:	October 22, 2013
Applicants:	Neill H. Luebke
Serial No.:	13/336,579
Filed:	December 23, 2010
Docket:	115207.00007
Title:	Dental and Medical Instruments Comprising Titanium

Request for Certificate of Correction

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Accompanying this Request for a Certificate of Correction is a completed form PTO/SB/44, entitled Certificate of Correction. In reviewing the above-referenced patent, various printing errors were discovered in the specification. These corrections do not affect the integrity of the patent itself. No new matter has been entered in this application.

Issuance of a Certificate of Correction for this patent is, therefore, requested. It is believed the listed errors are not due to Applicant, and that no fee is due. If this is not correct, and a fee is required, please charge Deposit Account No. 17-0055 in the amount of the fee.

Respectfully submitted,

Neill H. Luebke

/Richard T. Roche/

Date: March 21, 2014

Richard T. Roche, Reg. No. 38,599
Quarles & Brady, LLP
411 East Wisconsin Avenue
Suite 2350
Milwaukee, WI 53202
Tel. (414) 277-5805

QB\115207.00007\25762874.1

Electronic Acknowledgement Receipt

EFS ID:	18544674
Application Number:	13336579
International Application Number:	
Confirmation Number:	4379
Title of Invention:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
First Named Inventor/Applicant Name:	Neill Hamilton LUEBKE
Customer Number:	26710
Filer:	Richard T. Roche/Sara Kerstein
Filer Authorized By:	Richard T. Roche
Attorney Docket Number:	115207.00007
Receipt Date:	21-MAR-2014
Filing Date:	23-DEC-2011
Time Stamp:	10:35:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	luebke_7_certcorrection.pdf	104023 63cd5400652fd8abf31ee1e5c4e57ea4c18f0028	no	1

Warnings:	
Information:	

2	Request for Certificate of Correction	luebke_7_transmittal.pdf	75651 019bb8f5e2a77996bebcef16472f9009a823145d	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	179674	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,562,341 B2
APPLICATION NO. : 13/336579
DATED : October 22, 2013
INVENTOR(S) : Neill H. Luebke

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

Column 3, line 27 "g•cm" should read -- g⊙cm --

Column 7, line 22 "g•cm" should read -- g⊙cm --

In the Claims

Column 10, line 43 "supereiastic" should read -- superelastic --

Signed and Sealed this
Twentieth Day of May, 2014

Michelle K. Lee

Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office