

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke
Filed: December 23, 2011
For: Dental and Medical Instruments Comprising Titanium

INFORMATION DISCLOSURE STATEMENT

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

Dear Sir:

Pursuant to 37 CFR 1.97-1.98, Applicants are submitting herewith a listing of documents on an Information Disclosure Statement.

The references cited on the attached Information Disclosure Statement have already been cited and submitted by the Applicants or Examiner in U.S. Patent Application No. 12/977,625 from which the present application claims priority. Therefore, Applicants are not submitting copies with this submission.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicants do not waive any rights to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicants respectfully request that the listed documents be considered by the Examiner, be made of record in the present application and that an initialed copy of the Information Disclosure Statement by Applicant be returned in accordance with MPEP § 609.

Respectfully submitted,

Date: December 23, 2011

/Richard T. Roche/
Richard T. Roche, Reg. No. 38,599
Attorney for Applicant
Quarles & Brady LLP
411 E. Wisconsin Ave.
Milwaukee, WI 53202
414-277-5805

QB\15413574.1

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

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-4,490,112 A	12-1984	Tanaka et al.	433/20
	B	US-5,080,584 A	01-1992	Karabin, Roger J.	433/20
	C	US-5,653,590 A	08-1997	Heath et al.	433/102
	D	US-5,775,902 A	07-1998	Matsutani et al.	433/102
	E	US-6,206,695 B1	03-2001	Wong et al.	433/102
	F	US-6,375,458 B1	04-2002	Moorlegghem et al.	433/2
	G	US-6,431,863 B1	08-2002	Sachdeva et al.	433/102
	H	US-6,428,634 B1	08-2002	Besselink et al.	148/421
	I	US-2002/0191878 A1	12-2002	Ueda et al.	384/492
	J	US-2004/0121283 A1	06-2004	Mason, Robert M.	433/102
	K	US-7,137,815 B2	11-2006	Matsutani et al.	433/102
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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	Q					
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	S					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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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

Table with columns: Examiner Initials*, Cite No., Document Number (Number-Kind Code), Publication Date (MM-DD-YYYY), Name of Patentee or Applicant of Cited Document, Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear. Includes entries for US-6783438, US-20040171333, and US-20060014480.

FOREIGN PATENT DOCUMENTS

Table with columns: Examiner Initials*, Cite No., Foreign Patent Document (Country Code, Number, Kind Code), Publication Date (MM-DD-YYYY), Name of Patentee or Applicant of Cited Document, Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear, T6.

Examiner Signature, Date Considered

*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.

This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, 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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number			
	Filing Date			
	First Named Inventor	Neill H. Luebke		
	Art Unit	3732		
	Examiner Name	Matthew M. Nelson		
	Attorney Docket Number			

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7175655	B1	2007-02-13	Molaci	

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U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵
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NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

Application Number	
Filing Date	
First Named Inventor	LUEBKE, Neill Hamilton
Art Unit	
Examiner Name	
Attorney Docket Number	

Sheet of

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-6,431,863	08-13-2002	Lal Sachdeva, et al.	
		US-6,422,865	07-23-2002	Fischer	
		US-6,428,634	08-06-2002	Besselink, et al.	
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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
		Country Code ³ Number ⁴ Kind Code ³ (if known)				

Examiner Signature	<input type="text"/>	Date Considered	<input type="text"/>
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This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO <h3 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h3> <p style="text-align: center;"><i>(Use as many sheets as necessary)</i></p>		<div style="text-align: right; margin-bottom: 5px;"> <i>Complete if known</i> </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td></td> </tr> <tr> <td>Filing Date</td> <td></td> </tr> <tr> <td>First Named Inventor</td> <td>LUEBKE, Neill Hamilton</td> </tr> <tr> <td>Art Unit</td> <td></td> </tr> <tr> <td>Examiner Name</td> <td></td> </tr> <tr> <td>Attorney Docket Number</td> <td></td> </tr> </table>		Application Number		Filing Date		First Named Inventor	LUEBKE, Neill Hamilton	Art Unit		Examiner Name		Attorney Docket Number	
Application Number															
Filing Date															
First Named Inventor	LUEBKE, Neill Hamilton														
Art Unit															
Examiner Name															
Attorney Docket Number															
Sheet	-	of													

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Copy of International Search Report corresponding to PCT/US2005/019947, under date of mailing of 10 November 2005.	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	115207.00007
First Inventor	Neill H. Luebke
Title	Dental and Medical Instruments Comprising Titanium
Express Mail Label No.	

<p style="text-align: center;">APPLICATION ELEMENTS</p> <p style="text-align: center;"><i>See MPEP chapter 600 concerning utility patent application contents.</i></p> <p>1. <input type="checkbox"/> Fee Transmittal Form (e.g., PTO/SB/17)</p> <p>2. <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.</p> <p>3. <input checked="" type="checkbox"/> Specification [Total Pages <u>18</u>] Both the claims and abstract must start on a new page (For information on the preferred arrangement, see MPEP 608.01(e))</p> <p>4. <input checked="" type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets <u>1</u>]</p> <p>5. Oath or Declaration [Total Sheets <u>2</u>] a. <input type="checkbox"/> Newly executed (original or copy) b. <input checked="" type="checkbox"/> A copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional with Box 18 completed) i. <input type="checkbox"/> DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).</p> <p>6. <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76</p> <p>7. <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix) <input type="checkbox"/> Landscape Table on CD</p> <p>8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. - c. are required) a. <input type="checkbox"/> Computer Readable Form (CRF) b. <input type="checkbox"/> Specification Sequence Listing on: i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or ii. <input type="checkbox"/> Paper c. <input type="checkbox"/> Statements verifying identity of above copies</p>	<p>ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450</p> <hr/> <p style="text-align: center;">ACCOMPANYING APPLICATION PARTS</p> <p>9. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) Name of Assignee _____</p> <p>10. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input type="checkbox"/> Power of Attorney (when there is an assignee)</p> <p>11. <input type="checkbox"/> English Translation Document (if applicable)</p> <p>12. <input checked="" type="checkbox"/> Information Disclosure Statement (PTO/SB/08 or PTO-1449) <input type="checkbox"/> Copies of citations attached</p> <p>13. <input type="checkbox"/> Preliminary Amendment</p> <p>14. <input type="checkbox"/> Return Receipt Postcard (MPEP 503) (Should be specifically itemized)</p> <p>15. <input type="checkbox"/> Certified Copy of Priority Document(s) (if foreign priority is claimed)</p> <p>16. <input type="checkbox"/> Nonpublication Request under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.</p> <p>17. <input type="checkbox"/> Other: _____</p>
<p>18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:</p> <p><input checked="" type="checkbox"/> Continuation <input type="checkbox"/> Divisional <input type="checkbox"/> Continuation-in-part (CIP) of prior application No.: <u>12/977,625</u></p> <p>Prior application information: Examiner <u>Matthew Nelson</u> Art Unit: <u>3776</u></p>	
19. CORRESPONDENCE ADDRESS	
<p><input checked="" type="checkbox"/> The address associated with Customer Number: <u>26710</u> OR <input type="checkbox"/> Correspondence address below</p>	
Name	
Address	
City	State
Country	Zip Code
Telephone	Email
Signature	Date
/Richard T. Roche/	December 23, 2011
Name (Print/Type)	Registration No. (Attorney/Agent)
Richard T. Roche	38,599

This collection of information is required by 37 CFR 1.53(b). 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Electronic Patent Application Fee Transmittal

Application Number:				
Filing Date:				
Title of Invention:	Dental and Medical Instruments Comprising Titanium			
First Named Inventor/Applicant Name:	Neill H Luebke			
Filer:	Richard T. Roche			
Attorney Docket Number:				
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	95	95
Utility Search Fee	2111	1	310	310
Utility Examination Fee	2311	1	125	125
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				530

Electronic Acknowledgement Receipt

EFS ID:	11702410
Application Number:	13336579
International Application Number:	
Confirmation Number:	4379
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill H Luebke
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	
Receipt Date:	23-DEC-2011
Filing Date:	
Time Stamp:	15:12:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$530
RAM confirmation Number	2037
Deposit Account	170055
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Oath or Declaration filed	Luebke_00007_Decl.pdf	107668 a4f0f6609fdad0b6b78dd58edeefc3330e340b2	no	2
Warnings:					
Information:					
2		Luebke_00007_Spec.pdf	105890 6ae19a45a80e43c1477316481b4cc25aa03d713c	yes	18
Multipart Description/PDF files in .zip description					
Document Description		Start	End		
Specification		1	14		
Claims		15	17		
Abstract		18	18		
Warnings:					
Information:					
3	Drawings-only black and white line drawings	Luebke_00007_Drawings.pdf	131351 0304268e926b2c50d38157a5c298958f53ca1172	no	7
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	Luebke_00007_IDS.pdf	1325379 68fa3a1f6d8f7c3541c59b05e8d4472f5daae33b	no	6
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
5	Transmittal Letter	Transmittal.pdf	201304 bc3a71fde717e94975b7a376a0d4de94bbf055d7	no	1
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	32393 6d825c95b0d2b1696b4b37a90ff1fac5bfed4d77	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1903985		

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.

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)	Attorney Docket Number	115207.00002
	First Named Inventor	LUEBKE, Neill Hamilton
	<i>COMPLETE IF KNOWN</i>	
	Application Number	
	Filing Date	
	Art Unit	
<input checked="" type="checkbox"/> Declaration Submitted With Initial Filing OR <input type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)		Examiner Name

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

(Title of the Invention)

the specification of which

is attached hereto

OR

was filed on (MM/DD/YYYY) 07 Jun 05 (07.06.05) as United States Application Number or PCT International Application Number PCT/US05/019947 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

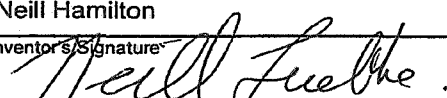
This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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DECLARATION — Utility or Design Patent Application

Direct all correspondence to: <input checked="" type="checkbox"/> The address associated with Customer Number:		26710	OR <input type="checkbox"/> Correspondence address below	
Name ROCHE, Richard T., QUARLES & BRADY LLP				
Address 411 E. Wisconsin Avenue				
City Milwaukee		State WI		ZIP 53202
Country US		Telephone 414-277-5805		Fax 414-271-3552
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.				
NAME OF SOLE OR FIRST INVENTOR:			<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any]) Neill Hamilton			Family Name or Surname LUEBKE	
Inventor's Signature 			Date 9-29-06	
Residence: City Brookfield		State WI		Country US
Mailing Address 18010 Continental Drive				
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Country US		Citizenship US		
NAME OF SECOND INVENTOR:			<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])			Family Name or Surname	
Inventor's Signature			Date	
Residence: City		State		Country
Mailing Address				
City		State		Zip
Country				
<input type="checkbox"/> Additional inventors or a legal representative are being named on the supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.				

Dental and Medical Instruments Comprising Titanium

CROSS-REFERENCES TO RELATED APPLICATIONS

5 [0001] This application is a continuation of U.S. Patent Application No. 12/977,625 filed December 23, 2010, which is a divisional application of U.S. Patent Application No. 11/628,933, now U.S. Patent No. 8,062,033, filed December 7, 2006 which is a 371 of PCT/US05/19947 filed June 7, 2005 which claims priority from United States Patent Application No. 60/578,091 filed June 8, 2004.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable.

BACKGROUND OF THE INVENTION

10 1. Field of the Invention

[0003] The invention relates to instruments used in medicine and dentistry. More particularly, the invention relates to medical and dental instruments such as drills, burs and files, and to endodontic instruments such as drills, burs and files used by dentists.

15 2. Description of the Related Art

[0004] Endodontics or root canal therapy is the branch of dentistry that deals with diseases of the dental pulp and associated tissues. One aspect of endodontics comprises the treatment of infected root canals by removal of diseased pulp tissues and subsequent filling.

20 [0005] Figure 1 shows a representation of a tooth to provide background. Root canal therapy is generally indicated for teeth having sound external structures but having diseased, dead or dying pulp tissues. Such teeth will generally possess intact enamel 10 and dentin 12, and will be satisfactorily engaged with the bony tissue 20, by among other things, healthy periodontal ligaments 18. In such teeth, the pulp
25 tissue 14, and excised portions of the root 16, should be replaced by a biocompatible substitute. Figure 1 also shows the apical foramen 22 through which blood and nerves pass to support the pulp tissues.

5 [0006] One method for the preparation of a root canal for filling is represented by Figures 2a-2e. A tooth having a basically sound outer structure 24 but diseased pulp 26, is cut with conventional or coated dental drill 28 creating a coronal access opening 30. A broach is used for gross removal of pulp material 26 from the root canal through the coronal access opening 30. The void 32 formed is enlarged as in Figure 2d with file 34, to result in a fully excavated cavity 36. Debris is removed from this cavity by flushing and the cavity cleansed to remove all diseased tissue. The excavated canal is then ready for filling.

10 [0007] During this procedure, small endodontic instruments (e.g., file 34) are utilized to clean and enlarge the long narrow tapered root canals. While most files perform entirely satisfactorily when cleaning and enlarging a straight root canal, problems have been encountered when using certain files to clean and enlarge a curved root canal. As will be understood by those skilled in the art, a very large portion of the root canals encountered by a practicing dentist and/or endodontist are
15 of the curved variety, and thus this problem is a significant one for the profession.

[0008] When performing an operation on a curved root canal with a smaller diameter file, the file can easily be inserted into the curved canal and will easily bend to fit the curved shape of the canal due to the flexibility of the small diameter file. In Figure 1a, there is shown the file 34 of Figure 2d in a bent position. The file 34 has a shank 42 mounted at its proximate end 47 to a handle 43. The shank 42 may include calibrated depth markings 45 and further includes a distal end 48. The shank 42 includes two continuous helical flutes 51 as shown in Figure 1b that extend along its lower portion. The flutes 51 define a cutting edge. A helical land 53 is positioned between axially adjacent flutes as shown in Figure 1b.

25 [0009] While file 34 can easily bend to fit the curved shape of a canal due to the flexibility of the small diameter shank 42, with increasingly larger sizes of files, the file becomes significantly less flexible and becomes more and more difficult to insert through the curved portion of the canal. In some cases, the relatively inflexible file will cut only on the inside of the curve and will not cut on the outside of the curvature
30 of the root canal. Thus, the problems, which occur during the therapy of a root canal,

are often the result of the basic stiffness of the files, particularly with the respect to the instruments of larger diameter.

[0010] Various solutions have been proposed to limit the problems encountered when cleaning and enlarging a curved root canal with a file. For example, U.S.

5 Patent No. 4,443,193 describes a shaped endodontic instrument that is said to solve this problem. U.S. Patent No. 5,380,200 describes an endodontic instrument having an inner core and an outer shell wherein one of the cores or shell is a nickel-titanium alloy and the other core or shell is selected from stainless steel, titanium alpha alloy, titanium beta alloy, and titanium alpha beta alloy. (For background on beta-titanium,

10 see U.S. Patent Nos. 4,197,643; 4,892,479; 4,952,236; 5,156,807; 5,232,361;

5,264,055; 5,358,586; 5,947,723; 6,132,209; and 6,258,182.) U.S. Patent No.

5,464,362 describes an endodontic instrument of a titanium alloy that is machined under certain specific operating parameters to produce an instrument having high

flexibility, high resistance to torsion breakage, and sharp cutting edges. U.S. Patent

15 No. 6,315,558 proposes the use of superelastic alloys such as nickel-titanium that can withstand several times more strain than conventional materials without

becoming plastically deformed. This property is termed shape memory, which allows

the superelastic alloy to revert back to a straight configuration even after clinical use, testing or fracture (separation).

20 **[0011]** In spite of the aforementioned advances, there remains a need for medical and dental instruments, and particularly endodontic instruments, such as drills, burs and files, that have high flexibility, have high resistance to torsion breakage, maintain shape upon fracture, can withstand increased strain, and can hold sharp cutting edges.

25 **SUMMARY OF THE INVENTION**

[0012] The present invention overcomes the problems encountered when cleaning and enlarging a curved root canal. In one aspect, the invention provides an endodontic instrument for use in performing root canal therapy on a tooth. The instrument includes an elongate shank having a cutting edge extending from a distal

30 end of the shank along an axial length of the shank. The shank comprises a titanium

alloy, and the shank is prepared by heat-treating the shank at a temperature above 25°C in an atmosphere consisting essentially of a gas unreactive with the shank.

The shank has high flexibility, high resistance to torsion breakage, maintains shape upon fracture, can withstand increased strain, and can hold sharp cutting edges.

5 Thus, it solves the problems encountered when cleaning and enlarging a curved root canal.

[0013] In another aspect, the invention provides an endodontic instrument for use in performing root canal therapy on a tooth. The instrument has an elongate shank having a cutting edge extending from a distal end of the shank along an axial length
10 of the shank. The shank consists essentially of a titanium alloy selected from alpha-titanium alloys, beta-titanium alloys, and alpha-beta-titanium alloys. The shank avoids the use of complex two material systems that are expensive to produce and are prone to delamination of the materials. This version of the invention also solves the problems encountered when cleaning and enlarging a curved root canal.

15 **[0014]** These and other features, aspects, and advantages of the present invention will become better understood upon consideration of the following detailed description, drawings, and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Figure 1 is a cross-sectional view of a tooth.

20 **[0016]** Figure 1a is a side elevational view of an endodontic instrument.

[0017] Figure 1b is a partial detailed view of the shank of the endodontic instrument shown in Figure 1a.

[0018] Figures 2a-2e represent a prior art procedure for preparing a tooth for endodontic restoration.

25 **[0019]** Figure 3 is a graph showing the results of a study of torsion (M_t) reported in g·cm performed in accordance with "ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification No. 28, Endodontic files and reamers" for untreated (Control) files, heat-treated files (TT), and titanium nitride coated files (Ti-N).

5 [0020] Figure 4 is a graph showing the results of a study of torsion (A_t) reported in degrees of deflection performed in accordance with "ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification No. 28, Endodontic files and reamers" for untreated (Control) files, heat-treated files (TT), and titanium nitride coated files (Ti-N).

10 [0021] Figure 5 is a graph showing the results of a study of maximum torque at 45° of flexion (M_f) reported in g \cdot cm performed in accordance with "ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification No. 28, Endodontic files and reamers" for untreated (Control) files, heat-treated files (TT), and titanium nitride coated files (Ti-N).

15 [0022] Figure 6 is a graph showing the results of a study of angle of permanent deformation after the flexion test (ADP) reported in degrees of deflection performed in accordance with "ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification No. 28, Endodontic files and reamers" for untreated (Control) files, heat-treated files (TT), and titanium nitride coated files (Ti-N).

20 [0023] Figure 7 is a graph showing the results of a study of fatigue reported in cycles (revolutions) to failure for untreated (Control) files, heat-treated files (TT), and titanium nitride coated files (Ti-N). This study was performed in accordance with the ISO Standard 3630-2 Dental root-canal instruments - Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers".

DETAILED DESCRIPTION OF THE INVENTION

25 [0024] One embodiment of the invention provides an improved endodontic instrument for use in performing root canal therapy on a tooth. This embodiment of the invention is an endodontic instrument as shown in Figure 1a that includes an elongate shank 42 mounted at its proximate end 47 to a handle 43. The shank 42 may be about 30 millimeters long. The proximate end 47 may have a diameter of about 0.5 to about 1.6 millimeters. The shank 42 may include calibrated depth markings 45 and further includes a distal end 48. The shank 42 includes two
30 continuous helical flutes 51 as shown in Figure 1b that extend along its lower portion.

The flutes 51 define a cutting edge. A helical land 53 is positioned between axially adjacent flutes as shown in Figure 1b.

[0025] The shank 42 comprises a titanium alloy, and is prepared by heat-treating the shank at a temperature above 25°C in an atmosphere consisting essentially of a gas unreactive with the shank. Preferably, the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and most preferably, the temperature is from 475°C to 525°C. Preferably, the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon. Most preferably, the gas is argon. In one example embodiment, the shank is heat-treated for approximately 1 to 2 hours. In another example embodiment, the shank is heat-treated at 500°C for 75 minutes. However, other temperatures are suitable as they are dependent on the time period selected for heat exposure.

[0026] The titanium alloy may be selected from alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys, and nickel-titanium alloys. Non-limiting examples of alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys for use in this embodiment of the invention are: Ti-5Al-2.5Sn alpha alloy; Ti-5Al-2.5Sn-ELI (low O₂) alpha alloy; Ti-3Al-2.5V alpha alloy; Ti-5Al-5Zr-5Sn alpha alloy; Ti-6Al-2Cb-1Ta-0.8Mo alpha alloy; Ti-5Al-5Sn-2Zr-2Mo-0.25Si near alpha alloy; Ti-6Al-2Nb-1Ta-1Mo near alpha alloy; Ti-8Al-1Mo-1V near alpha alloy; Ti-6Al-2Sn-4Zr-2Mo near alpha alloy; Ti-6Al-2Sn-1.5Zr-1Mo-0.35Bi-0.1Si near alpha alloy; Ti-2.25Al-11Sn-5Zr-1Mo-0.2Si near alpha alloy; Ti-3Al-2.5V alpha-beta alloy; Ti-10V-2Fe-3Al alpha-beta alloy; Ti-5Al-2Sn-2Zr-4Mo-4Cr alpha-beta alloy; Ti-6Al-2Sn-4Zr-6Mo alpha-beta alloy; Ti-4Al-4Mn alpha-beta alloy; Ti-6Al-2Sn-2Zr-2Mo-2Cr-0.25Si alpha-beta alloy; Ti-4Al-3Mo-1V alpha-beta alloy; Ti-6Al-2Sn-4Zr-6Mo alpha-beta alloy; Ti-11Sn-5Zr-2Al-1Mo alpha-beta alloy; Ti-6Al-4V alpha-beta alloy; Ti-6Al-4V-ELI (low O₂) alpha-beta alloy; Ti-6Al-6V-2Sn-0.75Cu alpha-beta alloy; Ti-7Al-4Mo alpha-beta alloy; Ti-6Al-2Sn-4Zr-2Mo alpha-beta alloy; Ti-5Al-1.5Fe-1.5Cr-1.5Mo alpha-beta alloy; Ti-8Mn alpha-beta alloy; Ti-8Mo-8V-2Fe-3Al beta alloy; Ti-11.5Mo-6Zr-4.5Sn beta alloy; Ti-3Al-8V-6Cr-4Mo-4Zr beta alloy; and Ti-3Al-13V-11Cr beta alloy (the numbers being percent by weight). An example, nickel-titanium alloy includes 54-57 weight

percent nickel and 43-46 weight percent titanium. Preferably, the titanium alloy used for the shank includes 54-57 weight percent nickel and 43-46 weight percent titanium and is commercially available as Nitinol 55. Thus, most preferably, the shank consists essentially of 54-57 weight percent nickel and 43-46 weight percent titanium thereby avoiding the inclusion of elements that affect the superelastic properties of the alloy.

[0027] Another embodiment of the invention provides an improved endodontic instrument for use in performing root canal therapy on a tooth. This embodiment of the invention is an endodontic instrument as shown in Figure 1a that includes an elongate shank 42 mounted at its proximate end 47 to a handle 43. The shank 42 may be about 30 millimeters long. The proximate end 47 may have a diameter of about 0.5 to about 1.6 millimeters. The shank 42 may include calibrated depth markings 45 and further includes a distal end 48. The shank 42 includes two continuous helical flutes 51 as shown in Figure 1b, which extend along its lower portion. The flutes 51 define a cutting edge. A helical land 53 is positioned between axially adjacent flutes as shown in Figure 1b. The endodontic instrument is fabricated solely from an alpha-titanium alloy, a beta-titanium alloy, or an alpha-beta-titanium alloy to avoid the problems associated with multiple alloy systems.

[0028] Non-limiting examples of alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys for use in this embodiment of the invention are: Ti-5Al-2.5Sn alpha alloy; Ti-5Al-2.5Sn-ELI (low O₂) alpha alloy; Ti-3Al-2.5V alpha alloy; Ti-5Al-5Zr-5Sn alpha alloy; Ti-6Al-2Cb-1Ta-0.8Mo alpha alloy; Ti-5Al-5Sn-2Zr-2Mo-0.25Si near alpha alloy; Ti-6Al-2Nb-1Ta-1Mo near alpha alloy; Ti-8Al-1Mo-1V near alpha alloy; Ti-6Al-2Sn-4Zr-2Mo near alpha alloy; Ti-6Al-2Sn-1.5Zr-1Mo-0.35Bi-0.1Si near alpha alloy; Ti-2.25-Al-11Sn-5Zr-1Mo-0.2Si near alpha alloy; Ti-3Al-2.5V alpha-beta alloy; Ti-10V-2Fe-3Al alpha-beta alloy; Ti-5Al-2Sn-2Zr-4Mo-4Cr alpha-beta alloy; Ti-6Al-2Sn-4Zr-6Mo alpha-beta alloy; Ti-4Al - 4Mn alpha-beta alloy; Ti-6Al-2Sn-2Zr-2Mo-2Cr-0.25Si alpha-beta alloy; Ti-4Al-3Mo-1V alpha-beta alloy; Ti-6Al-2Sn-4Zr-6Mo alpha-beta alloy; Ti-11Sn-5Zr-2Al-1Mo alpha-beta alloy; Ti-6Al-4V alpha-beta alloy; Ti-6Al-4V-ELI (low O₂) alpha-beta alloy; Ti-6Al-6V-2Sn-0.75Cu alpha-beta alloy; Ti-

7Al-4Mo alpha-beta alloy; Ti-6Al-2Sn-4Zr-2Mo alpha-beta alloy; Ti-5Al-1.5Fe-1.5Cr-1.5Mo alpha-beta alloy; Ti-8Mn alpha-beta alloy; Ti-8Mo-8V-2Fe-3Al beta alloy; Ti-11.5Mo-6Zr-4.5Sn beta alloy; Ti-3Al-8V-6Cr-4Mo-4Zr beta alloy; and Ti-3Al-13V-11Cr beta alloy (the numbers being percent by weight). These alloys of titanium include phase stabilizing amounts of a metal selected from molybdenum, tin, bismuth, tantalum, vanadium, zirconium, niobium, chromium, cobalt, nickel, manganese, iron, aluminum and lanthanum. An endodontic instrument according to this embodiment of the invention has improved sharpness, cutting ability, and instrument longevity compared to instruments fabricated from untreated nickel-titanium. Alpha-titanium, beta-titanium and alpha-beta-titanium are superior because they are harder and hence will hold an edge better and still maintain near the flexibility of nickel-titanium to negotiate curved canals. These alpha-titanium, beta-titanium and alpha-beta-titanium instruments may include medical, dental and endodontic instruments (both hand and engine driven), cutting burs (drills), and enlarging instruments including hand, mechanical and rotary.

[0029] Present medical and dental practice entails cutting of hard tissues such as bone or teeth with instruments manufactured of carbide steel, stainless steel and nickel-titanium. Present endodontic practice entails the preparation, cleaning, and shaping of root canals in teeth utilizing carbide steel, stainless steel and nickel-titanium instruments for hand, mechanical and rotary applications. This version of the invention would use an alpha-titanium alloy, a beta-titanium alloy, or an alpha-beta-titanium alloy to fabricate these instruments. It may be coated (as described below) or uncoated. Today a growing number of physicians and dentists (endodontists) are utilizing engine driven drills and files with various names and applications. This aspect of the present invention pertains to the fabrication of these cutting instruments such as drills and files solely from an alpha-titanium alloy, a beta-titanium alloy, or an alpha-beta-titanium alloy to produce a sharper cutting edge that should provide for better cutting or a smooth finished surface. This includes instrumentation that will facilitate the cleaning and sealing of the root canal system. In addition, a coating or heat-treatment may relieve stress in the instrument to allow it to withstand more

torque, rotate through a larger angle of deflection, change the handling properties, or visually exhibit a near failure of the instrument. This aspect of the invention relates to all drills, burs, files, and instruments used in medicine and dentistry.

5 [0030] In another aspect, the present invention provides for coating and optionally thereafter heat-treating dental and medical instruments including the coatings to maintain and/or improve their sharpness, cutting ability, and/or instrument longevity. Such an instrument may be manufactured from nickel-titanium, an alpha-titanium alloy, a beta-titanium alloy, or an alpha-beta-titanium alloy, stainless steel, carbide steel, as well as other materials. These instruments may be electropolished before
10 or after coating or heat-treating. These instruments will include medical, dental and endodontic instruments (both hand and engine driven), cutting burs (drills), and enlarging instruments including hand, mechanical and rotary.

[0031] The coating processes may include but not limited to the following processes: composite electroless plating (see, e.g., U.S. Patent Nos. 4,820,547;
15 4,997,686; 5,145,517; 5,300,330; 5,863,616; and 6,306,466); chemical vapor deposition (see, e.g., U.S. Patent No. 4,814,294); microwave deposition (see, e.g., U.S. Patent No. 4,859,493); laser ablation process (see, e.g., U.S. Patent No. 5,299,937); ion beam assisted deposition (see, e.g., U.S. Patent No. 5,725,573); physical vapor deposition (see, e.g., U.S. Patent Nos. 4,670,024, 4,776,863,
20 4,984,940, and 5,545,490); electropolishing; coatings including titanium nitride and titanium aluminum nitride commercially available under the trademark Firex™; coatings such as titanium nitride (TiN), titanium carbonitride (TiCN), titanium aluminum nitride (TiAlN), aluminum titanium nitride (AlTiN); or multiple coatings or combinations of coatings.

25 [0032] As detailed above, present medical and dental practice entails cutting of hard tissues such as bone or teeth with instruments manufactured of carbide steel, stainless steel and nickel-titanium. Present endodontic practice entails the preparation, cleaning, and shaping of root canals in teeth utilizing carbide steel, stainless steel and nickel-titanium. These can be manufactured as hand, mechanical
30 and rotary instruments. Today a growing number of physicians and dentists

(endodontists) are utilizing engine driven drills and files with various names and applications. This aspect of the present invention pertains to the application of coatings and optionally heat-treatment to cutting instruments such as drills and files to produce a sharper cutting edge and a higher resistance to heat degradation that should provide for better cutting, a smooth surface and/or different metallurgical properties than the material from which it was manufactured. This includes instrumentation that will facilitate the cleaning and sealing of the root canal system. In addition, a heat-treatment separately applied or as utilized in the coating process may relieve stress in the instrument which should allow for more instrument longevity by the ability to withstand more torque, rotate through a larger angle of deflection, change the handling properties, remove shape memory or visually exhibit a near failure of the instrument. This aspect of the invention relates to all drills, burs, files, and instruments used in medicine and dentistry.

[0033] One example process of this aspect of the present invention for such instruments is a titanium nitride coating. This coating process is done with physical vapor deposition with an inherent heat-treatment. Another process is a multilayer process utilizing a titanium nitride coating and then a titanium aluminum nitride coating. This last coating process is commercially available under the trademark FIREX™.

[0034] Another example process of this aspect of the present invention for such instruments is a metal or metal alloy coating incorporating particulate matter. One process to produce such a coating to an instrument includes contacting the surface of the instrument with a stable electroless metallizing bath comprising a metal salt, an electroless reducing agent, a complexing agent, an electroless plating stabilizer, a quantity of particulate matter which is essentially insoluble or sparingly soluble in the metallizing bath, and a particulate matter stabilizer, and maintaining the particulate matter in suspension in the metallizing bath during the metallizing of the instrument for a time sufficient to produce a metallic coating with the particulate matter dispersed.

Examples

5 [0035] The following Examples have been presented in order to further illustrate the invention and are not intended to limit the invention in any way.

Example 1

10 [0036] Thirty ISO size SX files, thirty ISO size S1 files, thirty ISO size S2 files, thirty ISO size F1 files, thirty ISO size F2 files and thirty ISO size F3 files were used in a study of torsion (M_t) reported in g·cm performed in accordance with “ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification No. 28, Endodontic files and reamers”. The results are shown in Figure 3. The files were made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and included an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. Ten of each ISO size were untreated (Control) files. Ten of 15 each ISO size were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes and then slowly cooled. These are labeled “TT” in Figure 3. Ten of each ISO size were coated with titanium nitride using physical vapor deposition with an inherent heat-treatment. These are labeled “Ti-N” in Figure 3. M_t was determined for 20 each of the thirty files, and the mean and standard deviation for each group (Control, TT, Ti-N) of ten files were calculated. The ten files that were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes showed the best result with the highest M_t .

Example 2

25 [0037] Thirty ISO size SX files, thirty ISO size S1 files, thirty ISO size S2 files, thirty ISO size F1 files, thirty ISO size F2 files and thirty ISO size F3 files were used in a study of torsion (A_t) reported in degrees of deflection performed in accordance with “ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification No. 28, Endodontic files and reamers”. 30 The results are shown in Figure 4. The files were made from a titanium alloy

comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and included an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. Ten of each ISO size were untreated (Control) files. Ten of each ISO size were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes and then slowly cooled. These are labeled “TT” in Figure 4. Ten of each ISO size were coated with titanium nitride using physical vapor deposition with an inherent heat-treatment. These are labeled “Ti-N” in Figure 4. A_t was determined for each of the thirty files, and the mean and standard deviation for each group (Control, TT, Ti-N) of ten files were calculated. The ten files that were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes showed the best results with the highest A_t .

Example 3

[0038] Thirty ISO size SX files, thirty ISO size S1 files, thirty ISO size S2 files, thirty ISO size F1 files, thirty ISO size F2 files and thirty ISO size F3 files were used in a study of maximum torque at 45° of flexion (Mf) reported in g·cm performed in accordance with “ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification No. 28, Endodontic files and reamers”. The shank is held in a torque meter, flexed at an angle of 45°, and then torque is measured. The results are shown in Figure 5. The files were made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and included an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. Ten of each ISO size were untreated (Control) files. Ten of each ISO size were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes and then slowly cooled. These are labeled “TT” in Figure 5. Ten of each ISO size were coated with titanium nitride using physical vapor deposition with an inherent heat-treatment. These are labeled “Ti-N” in Figure 5. Mf was determined for each of the thirty files, and the mean and standard deviation for each group (Control, TT, Ti-N) of ten files were calculated. It can be seen that the heat-treated files can withstand increased strain, and have higher high flexibility, have higher resistance to torsion breakage than untreated

(control) files.

Example 4

[0039] Thirty ISO size SX files, thirty ISO size S1 files, thirty ISO size S2 files,
5 thirty ISO size F1 files, thirty ISO size F2 files and thirty ISO size F3 files were used
in a study of angle of permanent deformation after the flexion test (ADP) reported in
degrees of deflection performed in accordance with "ISO Standard 3630-1 Dentistry -
Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification
10 No. 28, Endodontic files and reamers". The results are shown in Figure 6. The files
were made from a titanium alloy comprising 54-57 weight percent nickel and 43-46
weight percent titanium, and included an elongate shank having a cutting edge
extending from a distal end of the shank along an axial length of the shank. Ten of
each ISO size were untreated (Control) files. Ten of each ISO size were heat-treated
15 in a furnace in an argon atmosphere at 500°C for 75 minutes and then slowly cooled.
These are labeled "TT" in Figure 6. Ten of each ISO size were coated with titanium
nitride using physical vapor deposition with an inherent heat-treatment. These are
labeled "Ti-N" in Figure 6. ADP was determined for each of the thirty files, and the
mean and standard deviation for each group (Control, TT, Ti-N) of ten files were
20 calculated. The ten files that were heat-treated in a furnace in an argon atmosphere
at 500°C for 75 minutes showed the highest ADP. Thus, the heat-treated files
maintain the acquired (test deformed) shape rather than the shape memory exhibited
in the untreated control (nickel-titanium instruments).

Example 5

[0040] Six groups of thirty ISO size SX, S1, S2, F1, F2 and F3 files were used in a
25 study of the fatigue reported in cycles (revolutions) to failure performed in accordance
with the ISO Standard 3630-2 Dental root-canal instruments - Part 2: Enlargers and
ANSI/ADA Specification No. 95, for Root canal enlargers". The results are shown in
Figure 7. The files were made from a titanium alloy comprising 54-57 weight percent
nickel and 43-46 weight percent titanium, and included an elongate shank having a
30 cutting edge extending from a distal end of the shank along an axial length of the

shank. Ten files of each ISO size were untreated (Control) files. Ten files of each ISO size were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes and then slowly cooled. These are labeled “TT” in Figure 7. Ten files of each ISO size were coated with titanium nitride using physical vapor deposition with an inherent heat-treatment. These are labeled “Ti-N” in Figure 7. Fatigue cycles were determined for each of the files, and the mean and standard deviation for each group (Control, TT, Ti-N) of the six file sizes were calculated. In five of the six file sizes, the files that were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes showed the highest fatigue cycles (revolutions) to failure.

[0041] The Examples show that heat-treated files (TT) exhibit higher resistance to torsion breakage, can withstand increased strain, have higher flexibility, have increased fatigue life and maintain any acquired shape upon fracture better when compared to untreated (Control) files. Thus, the invention provides medical and dental instruments, and particularly endodontic instruments, such as drills, burs and files, that have high resistance to torsion breakage, maintain shape upon fracture, can withstand increased strain, and can hold sharp cutting edges such that the instruments overcome the problems encountered when cleaning and enlarging a curved root canal.

[0042] Although the present invention has been described in considerable detail with reference to certain embodiments, one skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which have been presented for purposes of illustration and not of limitation. For example, while the present invention finds particular utility in the field of endodontic instruments, the invention is also useful in other medical and dental instruments used in creating or enlarging an opening. Therefore, the scope of the appended claims should not be limited to the description of the embodiments contained herein.

CLAIMS

What is claimed is:

1. A method for manufacturing or modifying a dental or medical instrument or device, the method comprising:

(a) providing a dental or medical instrument or device 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 in an atmosphere consisting essentially of a gas unreactive with the instrument or device.

2. The method of claim 1 wherein:

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

3. The method of claim 1 wherein:

step (a) comprises providing a dental or medical instrument or device comprising a titanium alloy.

4. The method of claim 1 wherein:

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

5. The method of claim 1 wherein:

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

6. The method of claim 1 wherein:

the titanium alloy is selected from alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys, and nickel-titanium alloys.

7. The method of claim 1 wherein:
the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.

8. The method of claim 1 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. The method of claim 1 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. The method of claim 1 wherein:
the instrument or device is heat-treated in step (b) at a single temperature.

11. The method of claim 1 wherein:
the entire instrument or device is heat-treated in step (b) at a single temperature.

12. The method of claim 10 wherein:
the single temperature is from 400°C to 525°C.

13. The method of claim 10 wherein:
the single temperature is from 475°C to 525°C.

14. The method of claim 1 wherein:
the instrument or device is an endodontic instrument or device.

15. The method of claim 1 wherein:
the instrument or device is a medical instrument or device.

ABSTRACT OF THE DISCLOSURE

Endodontic instruments for use in performing root canal therapy on a tooth are disclosed. In one form, the instruments include an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. The shank comprises a titanium alloy, and the shank is prepared by heat-treating the shank at a temperature above 25°C in an atmosphere consisting essentially of a gas unreactive with the shank. In another form, the endodontic instruments have an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. The shank consists essentially of a titanium alloy selected from alpha-titanium alloys, beta-titanium alloys, and alpha-beta-titanium alloys. The instruments solve the problems encountered when cleaning and enlarging a curved root canal.

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15412864

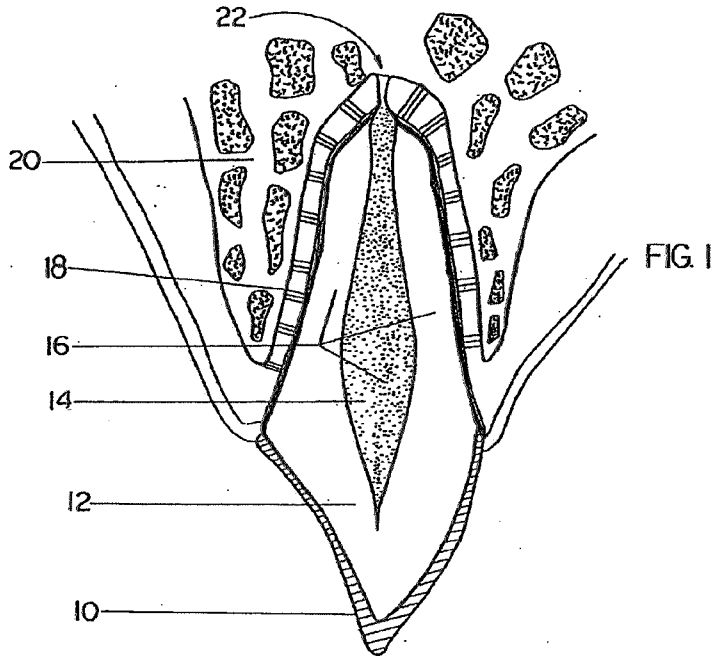
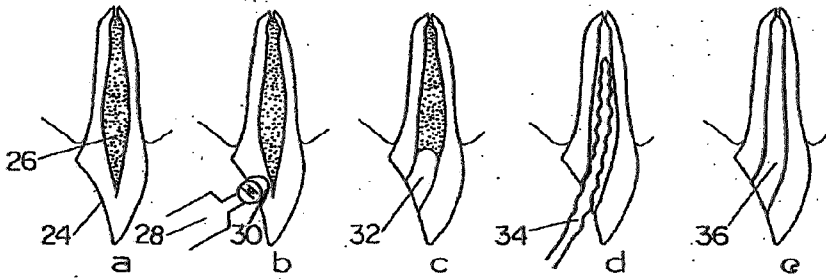


FIG. 2



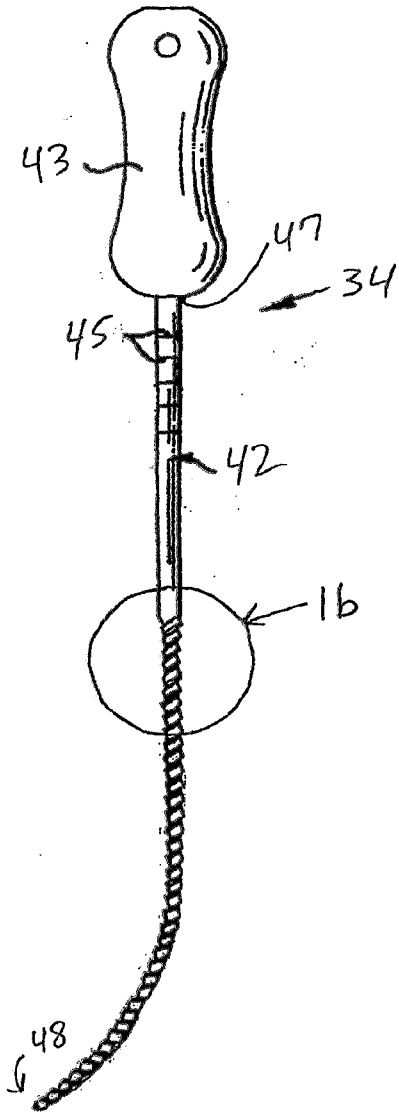


Fig. 1a

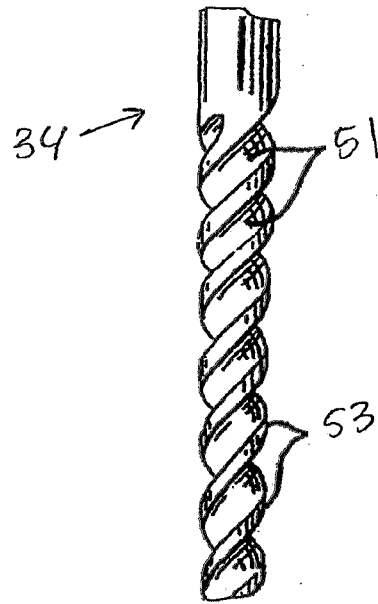
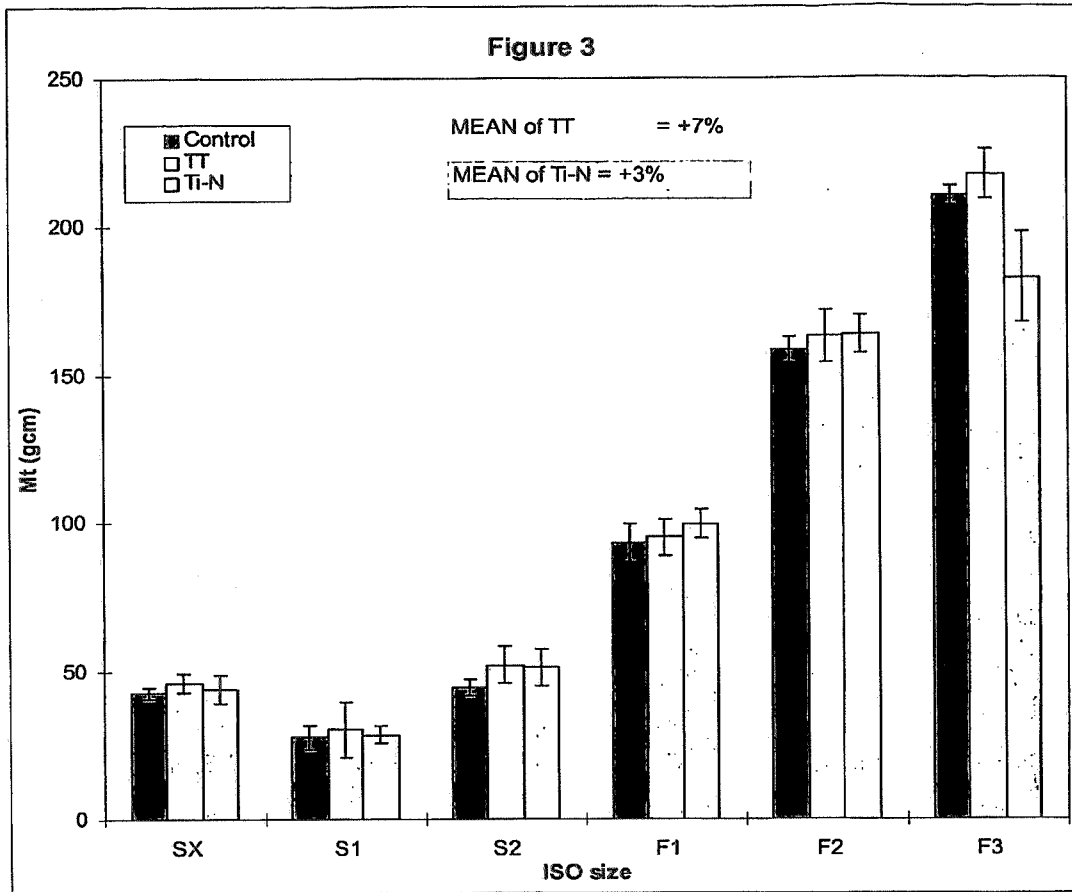
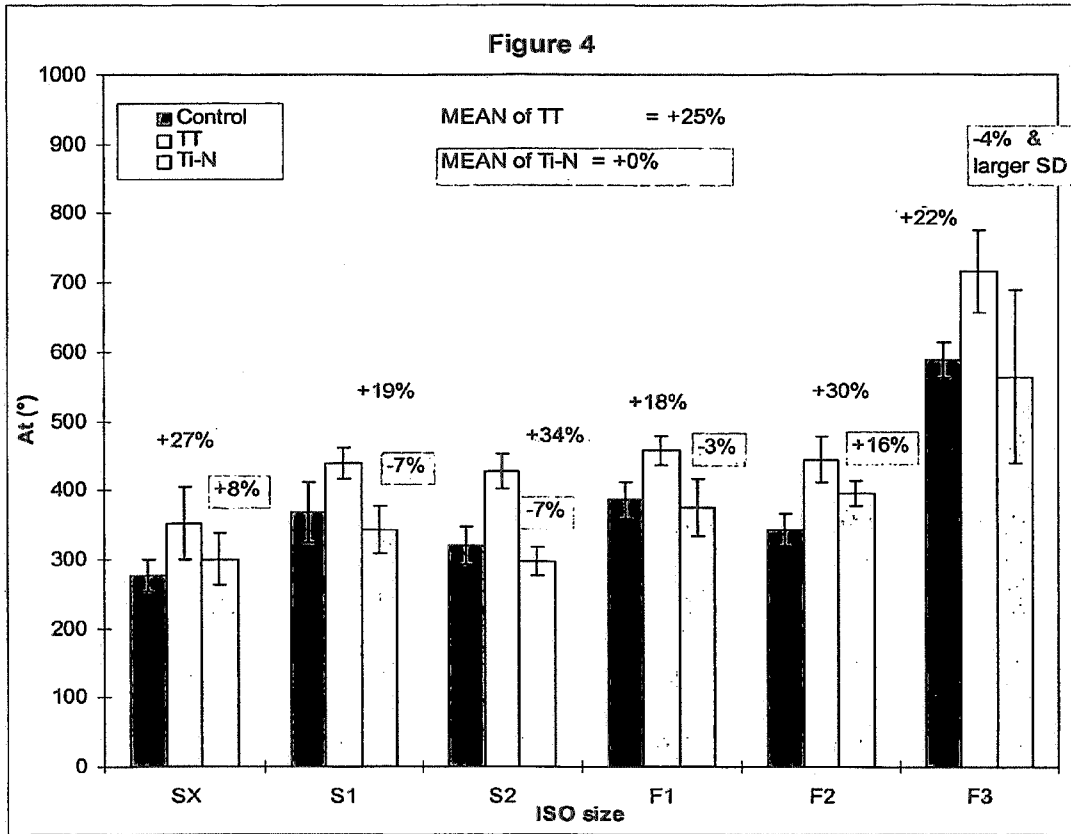
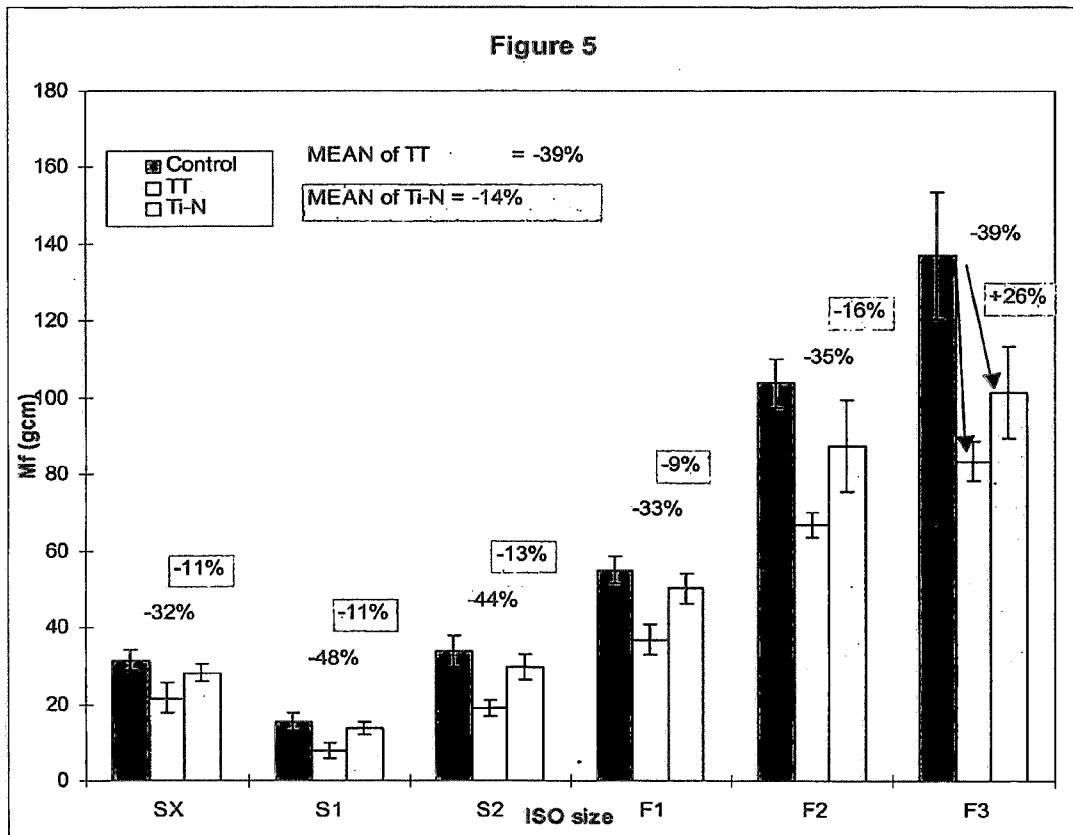
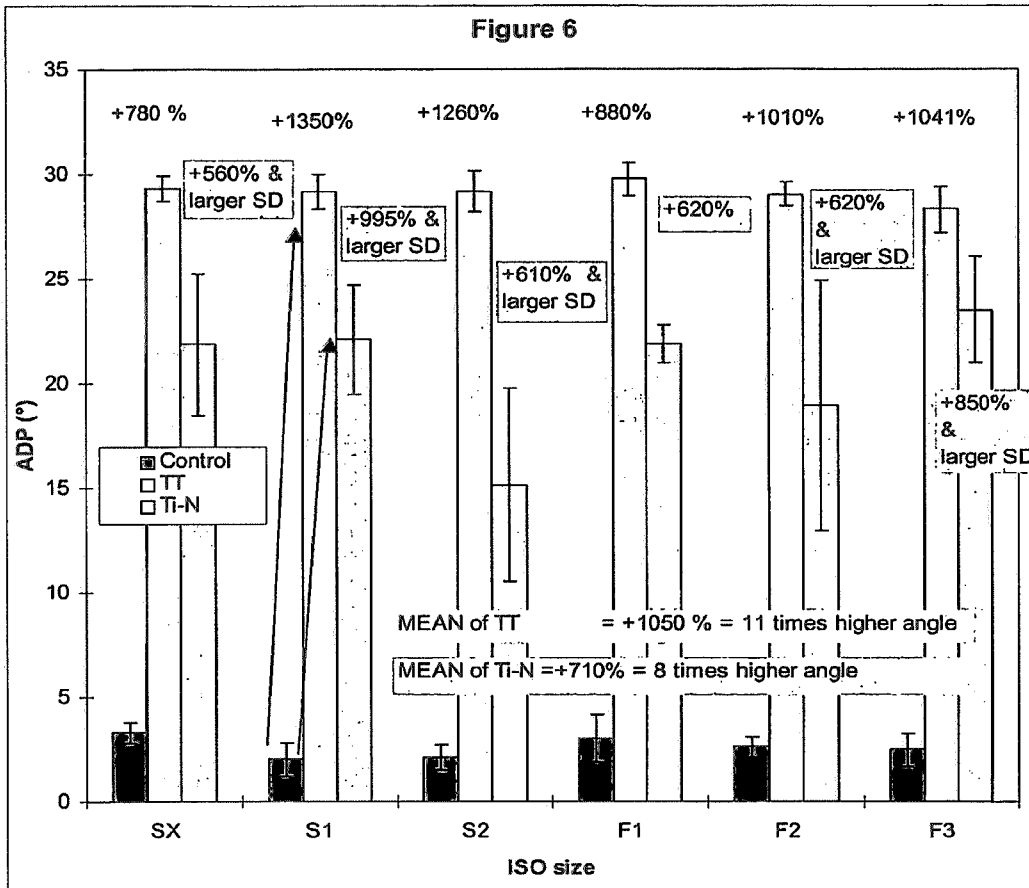


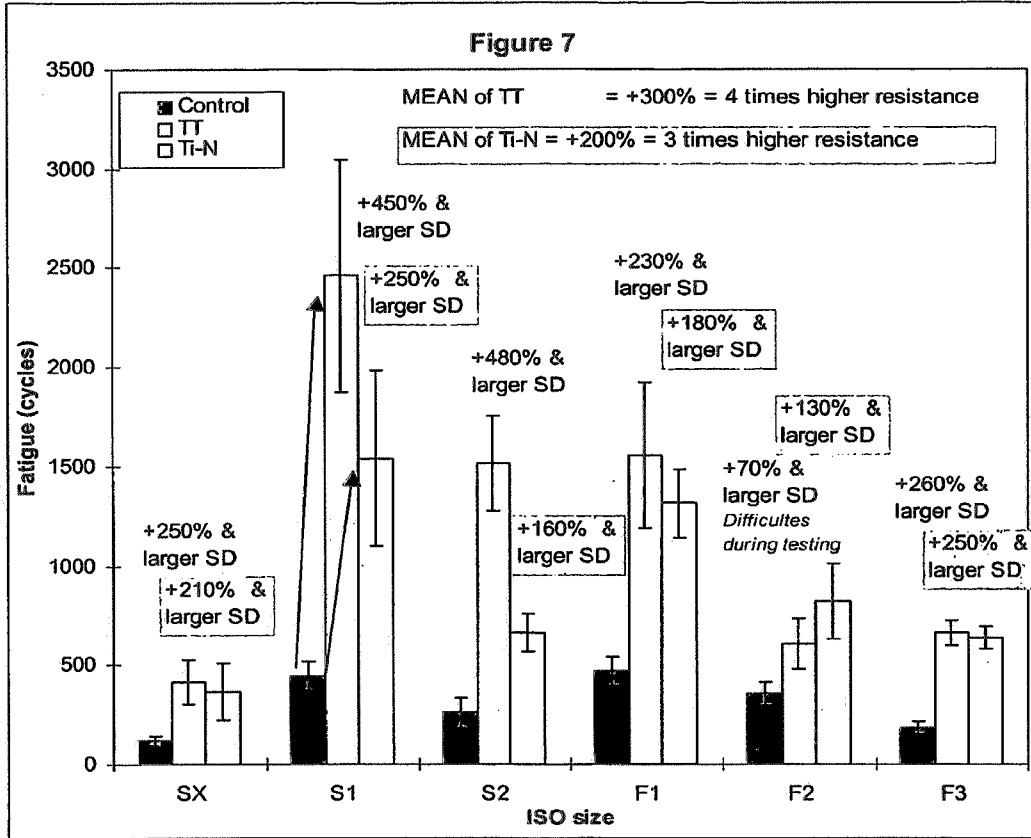
Fig. 1b











PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number
13/336,579

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A
TOTAL CLAIMS (37 CFR 1.16(i))	15 minus 20 = *	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 = *	
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))		

SMALL ENTITY	
RATE(\$)	FEE(\$)
N/A	95
N/A	310
N/A	125
x 30 =	0.00
x 125 =	0.00
	0.00
TOTAL	530

OTHER THAN SMALL ENTITY	
RATE(\$)	FEE(\$)
N/A	
N/A	
N/A	
TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED - PART II

AMENDMENT A	(Column 1)	(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total (37 CFR 1.16(i))	Minus **	=
	Independent (37 CFR 1.16(h))	Minus ***	=
Application Size Fee (37 CFR 1.16(s))			
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			

SMALL ENTITY	
RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

OTHER THAN SMALL ENTITY	
RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

AMENDMENT B	(Column 1)	(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total (37 CFR 1.16(i))	Minus **	=
	Independent (37 CFR 1.16(h))	Minus ***	=
Application Size Fee (37 CFR 1.16(s))			
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			

SMALL ENTITY	
RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

OTHER THAN SMALL ENTITY	
RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
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 found in the appropriate box in column 1.



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Table with 7 columns: APPLICATION NUMBER, FILING or 371(c) DATE, GRP ART UNIT, FIL FEE REC'D, ATTY.DOCKET.NO, TOT CLAIMS, IND CLAIMS. Row 1: 13/336,579, 12/23/2011, 3732, 530, 115207.00007, 15, 1

CONFIRMATION NO. 4379

FILING RECEIPT



26710
QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

Date Mailed: 02/06/2012

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections

Applicant(s)

Neill Hamilton LUEBKE, Brookfield, WI;

Power of Attorney: None

Domestic Priority data as claimed by applicant

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
which claims benefit of 60/578,091 06/08/2004

Foreign Applications (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see http://www.uspto.gov for more information.)

If Required, Foreign Filing License Granted: 02/01/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US 13/336,579

Projected Publication Date: 05/17/2012

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Dental and Medical Instruments Comprising Titanium

Preliminary Class

433

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/336,579	12/23/2011	Neill Hamilton LUEBKE	115207.00007

CONFIRMATION NO. 4379

26710
QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

PUBLICATION NOTICE



Title: Dental and Medical Instruments Comprising Titanium

Publication No. US-2012-0118445-A1

Publication Date: 05/17/2012

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

**PETITION TO MAKE SPECIAL BASED ON AGE FOR ADVANCEMENT OF EXAMINATION
UNDER 37 CFR 1.102(c)(1)**

Application Information

Application Number	13336579	Confirmation Number	4379	Filing Date	2011-12-23
Attorney Docket Number (optional)	115207.00007	Art Unit	3732	Examiner	
First Named Inventor	Neill H. Luebke				
Title of Invention	Dental and Medical Instruments Comprising Titanium				

Attention: Office of Petitions

An application may be made special for advancement of examination upon filing of a petition showing that the applicant is 65 years of age, or more. No fee is required with such a petition. See 37 CFR 1.102(c)(1) and MPEP 708.02 (IV).

APPLICANT HEREBY PETITIONS TO MAKE SPECIAL FOR ADVANCEMENT OF EXAMINATION IN THIS APPLICATION UNDER 37 CFR 1.102(c)(1) and MPEP 708.02 (IV) ON THE BASIS OF THE APPLICANT'S AGE.

A grantable petition requires one of the following items:

- (1) Statement by one named inventor in the application that he/she is 65 years of age, or more; or
- (2) Certification by a registered attorney/agent having evidence such as a birth certificate, passport, driver's license, etc. showing one named inventor in the application is 65 years of age, or more.

Name of Inventor who is 65 years of age, or older

Given Name	Middle Name	Family Name	Suffix
Neill	Hamilton	Luebke	

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the format of the signature.

Select (1) or (2) :

- (1) I am an inventor in this application and I am 65 years of age, or more.
- (2) I am an attorney or agent registered to practice before the Patent and Trademark Office, and I certify that I am in possession of evidence, and will retain such in the application file record, showing that the inventor listed above is 65 years of age, or more.

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2012-07-16
Name	Richard T. Roche	Registration Number	38599

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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 the Freedom of Information Act requires disclosure of these records.
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 inspections 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.



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In re Application of
Neill Hamilton LUEBKE

:
:

Application No. 13336579

:DECISION ON PETITION TO MAKE SPECIAL
:UNDER 37 CFR 1.102(c)(1)

Filed: December 23, 2011

:

Attorney Docket No. 115207.00007

This is a decision on the electronic petition under 37 CFR 1.102 (c)(1), filed 16-JUL-2012 to make the above-identified application special based on applicant's age as set forth in MPEP § 708.02, Section IV.

The petition is **GRANTED**.

A grantable petition to make an application special under 37 CFR 1.102(c)(1), MPEP § 708.02, Section IV: Applicant's Age must include a statement by applicant or a registered practitioner having evidence that applicant is at least 65 years of age. No fee is required.

Accordingly, the above-identified application has been accorded "special" status and will be taken up for action by the examiner upon the completion of all pre-examination processing.

Telephone inquiries concerning this electronic decision should be directed to the Electronic Business Center at 866-217-9197.

All other inquiries concerning either the examination or status of the application should be directed to the Technology Center.

Electronic Acknowledgement Receipt

EFS ID:	13256519
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:	16-JUL-2012
Filing Date:	23-DEC-2011
Time Stamp:	11:46:22
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	Petition automatically granted by EFS	Petition-Age.PDF	752340 <small>e26008ad74212344132ee07e9469df4c30e2b699</small>	no	2

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Information:

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.



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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes contact info for Quarles & Brady LLP and examiner details for Matthew M. Nelson.

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	

-- 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 23 December 2011.
- 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) 1-15 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) 1-15 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on 23 December 2011 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).
- 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
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) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/23/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

- The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- Claims 1-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-16 of U.S. Patent No. 8,083,873. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims of the application and claims of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus, the invention is in effect a "species" of the "generic" invention. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the invention is anticipated by the patent, it is not patentably distinct from the patent.

Claim Rejections - 35 USC § 112

- Claims 3 and 11 are rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. Claim 3 recites the same limitation provided in claim 1. Also, claim 11 recites the same limitations as claim 10 (including claim 1). Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

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 negated by the manner in which the invention was made.

- Claims 1-15 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) 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]). 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]). With respect to claim 6, the titanium alloy is selected from nickel-titanium alloys ([0029]). With respect to claim 7, the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium ([0029]). Claims 8-9 are rejected similarly to the above and below. With respect to claims 10-13, 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

Art Unit: 3776

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.

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.

/MMN/

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

Notice of References Cited	Application/Control No. 13/336,579	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3776	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,490,112 A	12-1984	Tanaka et al.	433/20
*	B	US-5,080,584 A	01-1992	Karabin, Roger J.	433/20
*	C	US-5,653,590 A	08-1997	Heath et al.	433/102
*	D	US-5,775,902 A	07-1998	Matsutani et al.	433/102
*	E	US-6,206,695 B1	03-2001	Wong et al.	433/102
*	F	US-6,375,458 B1	04-2002	Moorleghem et al.	433/2
*	G	US-6,431,863 B1	08-2002	Sachdeva et al.	433/102
*	H	US-6,428,634 B1	08-2002	Besselink et al.	148/421
*	I	US-2002/0191878 A1	12-2002	Ueda et al.	384/492
*	J	US-2004/0121283 A1	06-2004	Mason, Robert M.	433/102
*	K	US-2004/0129352 A1	07-2004	Shiota, Hiroyuki	148/527
*	L	US-2004/0193246 A1	09-2004	Ferrera, David A.	623/001.15
*	M	US-2005/0090844 A1	04-2005	Patel et al.	606/151

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 13/336,579	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3776	Page 2 of 2

U.S. PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-7,137,815 B2	11-2006	Matsutani et al.	433/102
	B US-			
	C US-			
	D US-			
	E US-			
	F US-			
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BIB DATA SHEET

CONFIRMATION NO. 4379

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
13/336,579	12/23/2011	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 8,083,873 which is a DIV of 11/628,933 12/07/2006 PAT 8,062,033 which is a 371 of PCT/US05/19947 06/07/2005 which claims benefit of 60/578,091 06/08/2004						
** FOREIGN APPLICATIONS *****						
** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** ** SMALL ENTITY ** 02/01/2012						
Foreign Priority claimed 35 USC 119(a-d) conditions met Verified and Acknowledged	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No /MATTHEW M NELSON/ Examiner's Signature	<input type="checkbox"/> Met after Allowance Initials	STATE OR COUNTRY WI	SHEETS DRAWINGS 7	TOTAL CLAIMS 15	INDEPENDENT CLAIMS 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 530	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit			

Receipt date: 12/23/2011

13336579 - GAU: 3776

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

U.S. PATENT DOCUMENTS

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	A	US-4,490,112 A	12-1984	Tanaka et al.	433/20
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	C	US-5,653,590 A	08-1997	Heath et al.	433/102
	D	US-5,775,902 A	07-1998	Matsutani et al.	433/102
	E	US-6,206,695 B1	03-2001	Wong et al.	433/102
	F	US-6,375,458 B1	04-2002	Moorlegghem et al.	433/2
	G	US-6,431,863 B1	08-2002	Sachdeva et al.	433/102
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	I	US-2002/0191878 A1	12-2002	Ueda et al.	384/492
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	L	US-			
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Receipt date: 12/23/2011

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PTO/SB/08a (04-07)
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 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Complete if Known			
	Application Number			
	Filing Date			
	First Named Inventor	Neill H. Luebke		
	Art Unit			
	Examiner Name	Matthew M. Nelson		
Sheet		of	Attorney Docket Number	

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (# 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	10/23/2003	Aloise et al.	
		US-20040171333	09/02/2004	Aloise et al.	
		US-20060014480	01/13/2006	Aloise et al.	
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Examiner Initials*	Cite No. ¹	Foreign Patent Document		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
		Country Code ³	Number ⁴ Kind Code ⁵ (# known)				

Examiner Signature	/Matthew Nelson/	Date Considered	08/28/2012
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13336579 - GAI: 3776

Doc code: IDS

Information Disclosure Statement (IDS) Filed

Approved for use through 03/31/2009. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number			
	Filing Date			
	First Named Inventor	Neill H. Luebke		
	Art Unit	3732		
	Examiner Name	Matthew M. Nelson		
	Attorney Docket Number			

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	7175655	B1	2007-02-13	Molaci	

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		Application Number	
		Filing Date	
		First Named Inventor	LUEBKE, Neill Hamilton
		Art Unit	
		Examiner Name	--
Sheet	of	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-6,431,863	08-13-2002	Lal Sachdeva, et al.	
		US-6,422,865	07-23-2002	Fischer	
		US-6,428,634	08-06-2002	Besselink, et al.	
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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
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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Complete if Known Application Number _____ Filing Date _____ First Named Inventor LUEBKE, Neill Hamilton Art Unit _____ Examiner Name _____ Attorney Docket Number _____
Sheet _____ of _____	

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Copy of International Search Report corresponding to PCT/US2005/019947, under date of mailing of 10 November 2005.	

Examiner Signature	/Matthew Nelson/	Date Considered	08/28/2012
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	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
L4	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
L5	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
L6	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
L7	13	"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) SAME temperature AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:32
L8	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
L9	3	"12977625"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:40
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;	OR	ON	2008/04/29 10:53

			USOCR; FPRS; EPO; JPO; DERWENT			
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 (anneal\$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 15:16
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	US-PGPUB; USPAT;	OR	ON	2008/10/21 12:58

		(anneal\$3 OR heat NEAR5 treated)	USOCR; FPRS; EPO; JPO; DERWENT			
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; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:13
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;	OR	ON	2009/08/03 13:14

			USOCR; FPRS; EPO; JPO; DERWENT			
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").FN.	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; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:45
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	US-PGPUB; USPAT;	OR	ON	2010/10/07 11:32

		endodontic	USOCR; FPRS; EPO; JPO; DERWENT			
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; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
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-	US-PGPUB; USPAT;	OR	ON	2011/05/12 09:28

		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.	DERWENT			
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 (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
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	US-PGPUB;	OR	ON	2011/05/12

		OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			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 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 10:01
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;	OR	ON	2011/05/23

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT			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; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 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	US-PGPUB;	OR	ON	2011/09/07

		treat\$4) AND atmosphere AND (helium neon argon krypton xenon radon)	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			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; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 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	US-PGPUB;	OR	ON	2012/08/23

EAST Search History


		(medical dental) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium)) AND temperature	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			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

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

8/28/2012 2:22:58 PM

C:\Users\mnelson3\Documents\EAST\Workspaces\13336579 Dental and medical instruments comprising titanium.wsp


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

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

SEARCH NOTES		
Search Notes	Date	Examiner
See EAST search history	8/28/2012	MN
Reviewed parent	8/28/2012	MN

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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

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

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant			<input type="checkbox"/> CPA			<input type="checkbox"/> T.D.			<input type="checkbox"/> R.1.47		
CLAIM		DATE									
Final	Original	08/28/2012									
	1	✓									
	2	✓									
	3	✓									
	4	✓									
	5	✓									
	6	✓									
	7	✓									
	8	✓									
	9	✓									
	10	✓									
	11	✓									
	12	✓									
	13	✓									
	14	✓									
	15	✓									

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

Date: November 30, 2012

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

IN THE UNITED 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

AMENDMENT

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 September 14, 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 ~~or medical~~ instrument or device, the method comprising:
 - (a) providing a dental ~~or medical~~ 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 ~~in an atmosphere consisting essentially of a gas unreactive with the instrument or device,~~
wherein the heat-treated instrument or device has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

2. (Currently Amended) 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.
~~the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon.~~

3. (Currently Amended) The method of claim 2 [[1]] wherein:
the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon.
~~step (a) comprises providing a dental or medical instrument or device comprising a titanium alloy.~~

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. (Original) The method of claim 1 wherein:
the titanium alloy is selected from alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys, and nickel-titanium alloys.

7. (Original) The method of claim 1 wherein:
the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.

8. (Currently Amended) The method of claim 2 [[1]] 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. (Currently Amended) The method of claim 2 [[1]] 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. (Currently Amended) The method of claim 1 wherein:
~~the entire instrument or device is heat treated in step (b) at a single temperature.~~
the angle of permanent deformation is tested in accordance with ISO Standard
3630-1.

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 recite that the heat-treated instrument or device has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion. This language is found in claim 11 of PCT/US05/19947 filed June 7, 2005, which is the parent of the present application. Related tests and data are shown in Example 4 and Figure 6 of the application.

Independent claim 1 has been amended to recite that the dental instrument or device has an elongate shank as described at page 3, line 29 of the application.

The limitations in original claim 1 regarding "medical" instruments and devices have been deleted.

The limitation in original claim 1 regarding heat-treating in an atmosphere consisting essentially of a gas unreactive with the instrument or device has been moved to claim 2.

The limitation in original claim 2 regarding the gas of the heat-treating atmosphere has been moved to claim 3.

In view of the amendments to claims 1 and 2, the dependency of claims 8 and 9 has been changed to claim 2.

Claim 11 has been amended to recite that the deformation test in claim 1 is in accordance with ISO Standard 3630-1 as described at the first sentence of Example 4 of the specification.

Double Patenting Rejection

A terminal disclaimer has been submitted in order to overcome the double patenting rejection.

Claim Rejection - 35 USC § 112

Claims 3 and 11 were rejected under 35 U.S.C. 112, fourth paragraph. The limitations of original claim 3 have been deleted and replaced with the limitations of original claim 2. Claim 11 has been amended to recite that the deformation test in claim 1 is in accordance with ISO Standard 3630-1. It is submitted that these amendments overcome the 35 U.S.C. 112, fourth paragraph, rejection.

Claim Rejection - 35 USC § 103

Claims 1-15 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").

First, independent claim 1 has been amended to recite that the dental instrument or device has an elongate shank. Patel does not show a dental instrument or device having an elongate shank. Patel shows a cardiac harness 10. Likewise, Shiota does not show a dental instrument or device having an elongate shank. Shiota shows a medical guide wire.

Second, independent claim 1 has also been amended to recite that the dental instrument or device has been treated in the method to have an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion. Patel and Shiota do 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 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 plastic 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 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.

Thus, Patel does not teach a method that produces a material having an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion as recited in amended independent claim 1. Shiota does not make up for these deficiencies in Patel. 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 fail to teach or suggest an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion as recited in amended independent claim 1. Accordingly, it is respectfully submitted that independent claim 1 (and claims 2-15 that depend thereon) are patentable over Patel and Shiota.

Conclusion

Claims 1-15 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.

A terminal disclaimer fee has been submitted. If additional fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,
Neill H. Luebke

Dated: November 30, 2012

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

18749156

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. I have reviewed the Office Action of September 14, 2012 in the above-identified patent application.

3. I have reviewed U.S. Patent Application Publication No. 2005/0090844 to Patel *et al.* ("Patel") cited in the Office Action of September 14, 2012.

4. Independent claim 1 of my above-identified patent application after amendment will require that "the heat-treated instrument or device has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion". It is respectfully submitted that the materials of Patel would not undergo this permanent deformation as recited in amended independent claim 1.

5. Attached as Exhibit A is a definition of Flexibility and Elasticity in order to show how one in the dental field would understand these terms. Note from this excerpt from the U.S. Army course that "[f]lexibility is the characteristic of a metal, which allows it to deform temporarily" and the term "elasticity of a metal is used when it returns to its original shape when the load or force is removed". (Underlining added.) Stated in a different way, flexibility and elasticity do not connote permanent deformation (as recited in amended independent claim 1).

6. Superelastic alloys belong to the larger family of shape memory alloys. When mechanically loaded, a superelastic alloy deforms reversibly to very high strains - up to 10% - by the creation of a stress-induced phase. When the load is removed, the new phase becomes unstable and the material regains its original shape.


7. Nickel-Titanium is an example of an alloy exhibiting superelasticity. Superelastic devices take advantage of their large, reversible deformation and include antennas, eyeglass frames, and biomedical stents. Patel is directed to such a superelastic biomedical device. See, paragraphs [0022], [0024], and [0046], and claim 1, line 3, and claim 23, lines 1 and 5 of Patel. This means that the Patel wire material will return to its original shape after deformation as in the definitions of flexibility and elasticity in Exhibit A. The Patel superelastic wire material would not undergo plastic deformation as recited in amended independent claim 1. In contrast, the method of amended independent claim 1 provides a heat-treated instrument or device that

remains bent which is referenced as the angle greater than 10 degrees of permanent deformation in amended independent claim 1.

8. In summary, one skilled in the art when reviewing Patel would understand that the Patel material 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.

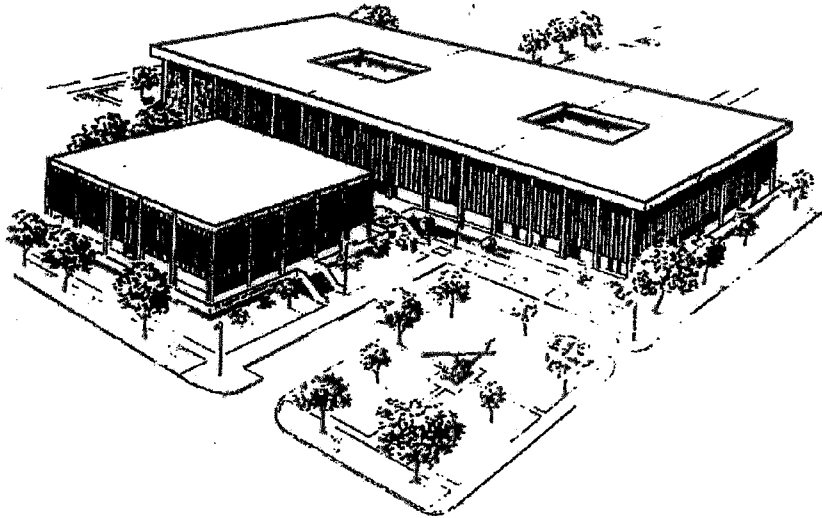
9. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like made are punishable by fine or imprisonment, 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: November 26, 2012



Dr. Neill H. Luebke

U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
FORT SAM HOUSTON, TEXAS 78234-6100



Dental Materials

SUBCOURSE MD0502

EDITION 100

d. Flexibility and Elasticity. These terms differ in their technical definition but they are very closely related. Flexibility is the characteristic of a metal, which allows it to deform temporarily. The elasticity of a metal is used when it returns to its original shape when the load or force is removed.]

e. Fatigue. Fatigue is the property of a metal to tire and to fracture after repeated stressing at loads below its proportional limit.

f. Structure (Crystalline or Grain Structure). Metals are crystalline and many of their physical properties depend largely upon the size and arrangement of their minute crystals called grains.

(1) Grain size. The size of the grains in a solidified metal depends upon the number of nuclei of crystallization present and the rate of crystal growth. In the practical sense, the faster a molten is cooled to solidification, the greater will be the number of nuclei and the smaller will be the grain size. Generally speaking, small grains arranged in an orderly fashion give the most desirable properties.

(2) Grain shape. The shape of the grains is also formed at the time of crystallization. If the metal is poured or forced into a mold before cooling, the grains will be in a flattened state. Metal formed by this method is known as cast metal. If the metal is shaped by rolling, bending, or twisting, the grains are elongated and the metal becomes a wrought wire.

g. Crushing Strength. Crushing strength is the amount of resistance of a material to fracture under compression.

h. Thermal Conductivity. Thermal conductivity is defined as the ability of a material to transmit heat or cold. A low thermal conductivity is desired in restorative materials used on the tooth whereas a high thermal conductivity is desirable where the material covers soft tissue.

1-4. METALLURGICAL TERMS

a. Cold Working. This is the process of changing the shape of a metal by rolling, pounding, bending, or twisting at normal room temperature.

b. Strain Hardening. This occurs when a metal becomes stiffer and harder because of continued or repeated application of a load or force. At this point, no further slippage of the atoms of the metal can occur without fracture.

c. Heat Softening Treatment (Annealing). This treatment is necessary in order to continue manipulating a metal after strain hardening to prevent it from fracturing. The process of annealing consists of heating the metal to the proper temperature (as indicated by the manufacturer's instructions) and cooling it rapidly by immersing in cold water. Annealing relieves stresses and strains caused by cold working and restores slipped atoms within the metal to their regular arrangement.

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STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Neill H. Luebke

Application No./Patent No.: 13/336,579 Filed/Issue Date: December 23, 2011

Titled: Dental and Medical Instruments Comprising Titanium

Gold Standard Instruments, LLC, a Corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

- 1. the assignee of the entire right, title, and interest in;
- 2. an assignee of less than the entire right, title, and interest in (The extent (by percentage) of its ownership interest is _____ %); or
- 3. the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

the patent application/patent identified above, by virtue of either:

A. An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 027273, Frame 0140, or for which a copy therefore is attached.

OR

B. A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

Additional documents in the chain of title are listed on a supplemental sheet(s).

As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Neill H. Luebke
Signature

11-29-12
Date

Neill H. Luebke

President

Printed or Typed Name

Title

This collection of information is required by 37 CFR 3.73(b). 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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18749227

**TERMINAL DISCLAIMER TO OBIATE A DOUBLE PATENTING
REJECTION OVER A "PRIOR" PATENT**

Docket Number (Optional)

115207.00007

In re Application of: Neill H. Luebke

Application No.: 13/336,579

Filed: December 23, 2011

For: Dental and Medical Instruments Comprising Titanium

The owner*, Gold Standard Instruments, LLC, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent No. 8,083,873 as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

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

2. The undersigned is an attorney or agent of record. Reg. No. _____

Neill H. Luebke 11-29-12
Signature Date

Neill H. Luebke
Typed or printed name

Telephone Number _____

- Terminal disclaimer fee under 37 CFR 1.20(d) included.

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.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

This collection of information is required by 37 CFR 1.321. 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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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:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Statutory or terminal disclaimer	2814	1	80	80
Total in USD (\$)				80

Electronic Acknowledgement Receipt

EFS ID:	14356740
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:	30-NOV-2012
Filing Date:	23-DEC-2011
Time Stamp:	17:00:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$80
RAM confirmation Number	5338
Deposit Account	170055
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		Response-11-30-12.pdf	88929 ef61c3c269ca78e281f9bda068f62f182c23c026	yes	8
Multipart Description/PDF files in .zip description					
		Document Description	Start	End	
		Amendment/Req. Reconsideration-After Non-Final Reject	1	1	
		Claims	2	4	
		Applicant Arguments/Remarks Made in an Amendment	5	8	
Warnings:					
Information:					
2	Rule 130, 131 or 132 Affidavits	declaration.pdf	201421 1ff6e269a2dc5ade728a0700ec35163792ff436e	no	5
Warnings:					
Information:					
3	Assignee showing of ownership per 37 CFR 3.73.	Statement.pdf	79091 278ddda1627454eb738d74ad9d76e0e94b27060f	no	1
Warnings:					
Information:					
4	Terminal Disclaimer Filed	TermDisc.pdf	85354 465e9f152012ccc3f4a0e3ef041db723c5b85d3a	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	29992 68a612bd64c363dead6215a3ce83a00e9e0865	no	2
Warnings:					
Information:					
Total Files Size (in bytes):				484787	

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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.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 13/336,579		Filing Date 12/23/2011		<input type="checkbox"/> To be Mailed			
APPLICATION AS FILED – PART I					OTHER THAN						
(Column 1)		(Column 2)		SMALL ENTITY <input checked="" type="checkbox"/> OR		SMALL ENTITY					
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)				
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A					
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A					
<input type="checkbox"/> 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 \$ =					
<input type="checkbox"/> 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).										
<input type="checkbox"/> 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					OTHER THAN						
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR		SMALL ENTITY	
AMENDMENT	11/30/2012	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	• 14	Minus •• 20	= 0	X \$31 =	0	OR	X \$ =			
	Independent (37 CFR 1.16(h))	• 1	Minus ••• 3	= 0	X \$125 =	0	OR	X \$ =			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))						OR				
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR				
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE			
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR		SMALL ENTITY	
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	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 \$ =			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))						OR				
	<input type="checkbox"/> 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.				Legal Instrument Examiner: /MYRTLE LEIGH/							
** 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.											

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Application Number 	Application/Control No. 13/336,579	Applicant(s)/Patent under Reexamination LUEBKE, NEILL, HAMILTON
Document Code - DISQ		Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	<input checked="" type="checkbox"/> APPROVED	<input type="checkbox"/> DISAPPROVED
Date Filed : 30 NOV 2012	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

JAB

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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 12/19/2012 QUARLES & BRADY LLP Attn: IP Docket 411 E. WISCONSIN AVENUE SUITE 2350 MILWAUKEE, WI 53202-4426			EXAMINER NELSON, MATTHEW M	
			ART UNIT 3776	PAPER NUMBER
			NOTIFICATION DATE 12/19/2012	DELIVERY MODE 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	

- 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 30 November 2012.
- 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) 1-14 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) 1-14 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).
a) All b) Some * c) None of:
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 11/30/2012 is acknowledged.

Claim Rejections - 35 USC § 112

- The following is a quotation of 35 U.S.C. 112(a):
(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- Claims 1-14 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 recites the method steps of providing a titanium alloy and subjecting it to heat treatment at a temperature above 400 C and that the resulting deformation after a torque at 45 degrees of flexion would result in greater than 10 degrees of permanent deformation. However, not all titanium alloys subjected to this treatment would result in that degree of deformation. The dependent claims do not provide further steps that would always result in this degree of permanent deformation.

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 negated by the manner in which the invention was made.

- Claims 1-10, 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) 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 (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]). With respect to claim 6, the titanium alloy is selected from nickel-titanium alloys ([0029]). With respect to claim 7, the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium ([0029]).

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.

- Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of Shiota as applied to claim 1 above, and further in view of Heath et al. (US 5,380,200).

- Patel/Shiota discloses the device as previously described above, but fails to show the angle of permanent deformation is tested in accordance with ISO Standard 3630-1.

- Heath teaches titanium alloy dental devices whose physical properties after manufacture are tested by the standard of subjecting the shank to torque at 45 degrees

Art Unit: 3776

of flexion and measuring the results (col. 5, lines 17-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Patel/Shiota's method by including the testing step of Heath in order to determine the end properties of the device and ensure they are as desired.

- It is also noted for reference that Heath shows interchangeability of nickel-titanium, stainless steel, titanium alpha alloy, titanium beta alloy, and titanium alpha beta alloy as materials for construction, which would be advantageously improved by the heat treatment methods of Shiota ([0041] also shows interchangeability of Ni-Ti and stainless steel).

Response to Amendment

- The Declaration under 37 CFR 1.132 filed 11/30/2012 is insufficient to overcome the rejection of claims 1-14 as set forth in the last Office action because: First, the test of how much deformation after 45 degrees of flexion is entirely dependent on the original shape of the device or instrument. It is also of issue that the provided method steps will not result in this degree of deformation for every type of titanium alloy. Special measures not included in this claim and therefore not enabled as explained above would need to be conducted to ensure that every titanium alloy would result in having these properties at the heat-treatments described.

Response to Arguments

- Applicant's arguments filed 11/30/2012 have been fully considered but they are not persuasive.
- Applicant argues that Patel does not show a dental instrument or device having an elongate shank, however Patel clearly shows for instance in [0004] and [0005] dental applications of the invention, such as orthodontic wire (which is an elongate shank). Patel is most broadly directed to long fatigue life nitinol that may be used for many commercial applications such as dentistry.
- Applicant argues with respect to the deformation angle after torque at 45 degrees of flexion. This has been addressed several times above. Most importantly, this test is entirely dependent on the original deformation of the device or instrument. Also, this limitation is not enabled by the current claims since not every titanium alloy would have these results.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to 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.

/MMN/

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

Notice of References Cited	Application/Control No. 13/336,579	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3776	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,490,112 A	12-1984	Tanaka et al.	433/20
*	B	US-5,080,584 A	01-1992	Karabin, Roger J.	433/20
*	C	US-5,380,200 A	01-1995	Heath et al.	433/102
*	D	US-5,653,590 A	08-1997	Heath et al.	433/102
*	E	US-5,775,902 A	07-1998	Matsutani et al.	433/102
*	F	US-6,206,695 B1	03-2001	Wong et al.	433/102
*	G	US-6,375,458 B1	04-2002	Moorlegghem et al.	433/2
*	H	US-6,431,863 B1	08-2002	Sachdeva et al.	433/102
*	I	US-6,428,634 B1	08-2002	Besselink et al.	148/421
*	J	US-2002/0191878 A1	12-2002	Ueda et al.	384/492
*	K	US-2004/0121283 A1	06-2004	Mason, Robert M.	433/102
*	L	US-2004/0129352 A1	07-2004	Shiota, Hiroyuki	148/527
*	M	US-2004/0193246 A1	09-2004	Ferrera, David A.	623/001.15

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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	Examiner MATTHEW NELSON	Art Unit 3776	Page 2 of 2

U.S. PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-2005/0090844 A1	04-2005	Patel et al.	606/151
*	B US-7,137,815 B2	11-2006	Matsutani et al.	433/102
	C US-			
	D US-			
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			

FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	"5380200".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/05 08:39
L2	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
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	US-PGPUB;	OR	ON	2008/04/29

EAST Search History

		NEAR1 Titanium))	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			15:12
S11	29	S8 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	2008/04/29 15:16
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;	OR	ON	2009/02/24

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT			12:26
S24	1092	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:13
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;	OR	ON	2010/03/18

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT			13:12
S34	1112	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:45
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;	OR	ON	2010/10/19

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT			15:56
S44	1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
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 (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
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

EAST Search History

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 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 10:01
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

EAST Search History

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; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 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; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 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

EAST Search History


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 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 13:32
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

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

12/ 5/ 2012 9:41:51 AM


C:\Users\mnelson3\Documents\EAST\Workspaces\13336579 Dental and medical instruments comprising titanium.wsp

Index of Claims 	Application/Control No. 13336579	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON
	Examiner MATTHEW NELSON	Art Unit 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						
	1	✓	✓						
	2	✓	✓						
	3	✓	✓						
	4	✓	✓						
	5	✓	✓						
	6	✓	✓						
	7	✓	✓						
	8	✓	✓						
	9	✓	✓						
	10	✓	✓						
	11	✓	✓						
	12	✓	✓						
	13	✓	✓						
	14	✓	✓						
	15	✓	-						

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

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

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

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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

Date: February 14, 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~~ 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.

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. (Original) The method of claim 1 wherein:

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

8. (Previously Presented) 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. (Previously Presented) The method of claim 1 wherein:
the angle of permanent deformation is tested in accordance with ISO Standard 3630-1.

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 recite that the heat-treated instrument or device comprises a nickel-titanium alloy as recited in original claim 6.

Claim 6 has been cancelled.

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]".

The limitations of original claim 6 regarding the heat-treated instrument or device comprising a nickel-titanium alloy have been added to claim 1. The angle of permanent deformation test of claim 1 was reported in Example 4 and Figure 6 of the present application. In Example 4, the files tested were made from a nickel-titanium alloy. 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 was previously amended to recite that the dental instrument or device has been treated in the method to have an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion. This limitation distinguishes the method of Patel in that the Patel method creates a superelastic material (wire, ribbon, tubing or sheet). Note also the description of Figure 6 at paragraph [0021] of Patel which makes it emphatic that Patel is making wire that is formed into a matrix.

U.S. Patent No. 7,175,655 to Molaci ("Molaci") was cited in an IDS and has been considered by the Office. Molaci explains that "superelasticity or pseudoelasticity refers to the ability of a material to undergo extremely large elastic deformation" (see column 1, lines 27-28 of Molaci). The material created in the Patel method is superelastic (see paragraph [0022] of Patel) and therefore, the material created in the Patel method will undergo an extremely large elastic deformation.

In contrast, the invention of claim 1 "has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion" (underling added). This limitation in claim 1 distinguishes the claimed invention from the material created in the Patel method (which will undergo extremely large elastic deformation).

In order to more fully demonstrate that the present invention will undergo permanent deformation (unlike the material created in the Patel method), the attached Inventor's Declaration shows a test in which the inventor heat-treated an instrument in accordance with independent claim 1 and thereafter deformed the shank after heat-treating. The deformation was permanent. In contrast, the non-heat treated instrument that was deformed returned to its original shape (no permanent deformation) like the material created in the Patel method.

Page 3 of the Office Action alleges 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". The attached Inventor's Declaration rebuts this allegation. In this regard, the attached Inventor's Declaration notes in Item 6 that:

"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."

Thus, the statement at Page 3 of the Office Action that "Patel discusses orthodontic wires in [0004] which would have a predetermined deformation over 10 degrees" is not supported by evidence in Patel and is refuted by the attached Inventor's Declaration.

Items 7-9 of the attached Inventor's Declaration also explain that Patel is performing a sequence of cold working and anneal cycles on the wire and that the final step of Patel was cold working the Nitinol wire, ribbon, tubing or sheet to assure the Nitinol was in a superelastic state. Thus, the statement at Page 3 of the Office Action that "Patel discusses orthodontic wires in [0004] which would have a predetermined deformation over 10 degrees" is not supported by evidence in Patel and is further refuted by Items 7-9 of the attached Inventor's Declaration.

Thus, Patel does not teach a method that produces a material having an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion as recited in amended independent claim 1. Shiota and Heath do not make up for these

deficiencies in Patel. 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 an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion as recited in independent claim 1. Accordingly, it is respectfully submitted that independent claim 1 (and claims 2-5 and 7-14 that depend thereon) are patentable over Patel and Shiota and Heath.

Conclusion

Claims 1-5 and 7-14 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.

No fees are believed to be due. If fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,
Neill H. Luebke

Dated: February 14, 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

19589380

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 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