IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Filed:	Herewith
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.

All of the references cited on the attached Information Disclosure Statement, except for Harmeet Walia *et al.*; "An Initial Investigation of the Bending and Torsional Properties of Nitinol Root Canal Files"; Vol. 14, No. 7, Journal of Endodontics; 346-351 (July, 1988), have already been cited and submitted by the Applicants or cited by the Examiner in U.S. Patent Application No. 14/167,211, filed January 29, 2014, from which the present application claims priority. Therefore, Applicants are only submitting a copy of the Harmeet Walia et al. article 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.

Applicant respectfully requests 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: October 23, 2014

/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

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	
	Examiner Name	
	Attorney Docket Number	115207.00014

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code1	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5171383		1992-12-15	Sagaye et al.	
	2	6149501		2000-11-21	Farzin-Nia et al.	
	3	6485507		2002-11-26	Walak et al.	

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U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code1	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020137008		2002-09-26	McSpadden et al.	

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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number3	Country Code2 i	Kind Code4	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
	1							☐

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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]
	1	Kuhn et al., Fatigue and Mechanical Properties of Nickel-Titanium Endodontic Instruments, Journal of Endodontics, 2002, 28(10), 716-20	☐
	2	Khier et al., Bending properties of superelastic and nonsuperelastic nickeltitanium orthodontic wires, American Journal of Orthodontics and Dentofacial Orthopedics, 1991, 99(4), 310-18	☐
	3	Miura et al., The super-elastic property of the Japanese NiTi alloy wire for use in orthodontics, American Journal of Orthodontics and Dentofacial Orthopedics, 1986, 90(1), 1-10	☐
	4	Relevant aspects in the clinical applications of NiTi shape memory alloys, Journal of Materials Science: Materials in Medicine, 1996, 7, 403-6	☐
	5	F. S. Weine, Endodontic Therapy (6th ed. 2004)	☐
	6	Brantley et al., Differential scanning calorimetric studies of nickel titanium rotary endodontic instruments, Journal of Endodontics, 2002, 28, 567-72	☐
	7	Schafer et al., Relationship between design features of endodontic instruments and their properties. Part 3. Resistance to bending and fracture. Journal of Endodontics, 2001, 27, 299-303	☐
	8	Firstov et al., Surface oxidation of NiTi shape memory alloy, Biomaterials, 2002, 23, 4863-71	☐
	9	Kuhn et al., Influence of structure on NiTi endodontic instruments failure, Journal of Endodontics, 2001, 27(10), 516-20	☐

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	10	"DECLARATION OF NEILL H. LUEBKE, D.D.S., M.S.", inventor of the present application, filed on August 15, 2014 in United States District Court for the Eastern District Of Tennessee Civil Action No. 14-00196	☐
	11	Tepel et al., Properties of endodontic hand instruments used in rotary motion. Part 3. Resistance to bending and fracture. Journal of Endodontics, 1997, 23, 141–5	☐

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CERTIFICATION STATEMENT

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☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2014-10-03
Name/Print	Richard T. Roche	Registration Number	38599

Privacy Act Statement

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

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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.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of References Cited	Application/Control No. 14/167,311	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3732	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	Moorleghem 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

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	N					
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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-			
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	E	US-			
	F	US-			
	G	US-			
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet | of

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

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6783438	10/23/2003	Aloise et al.	
		US-20040171333	09/02/2004	Aloise et al.	
		US-20060014480	01/13/2006	Aloise et al.	
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	First Named Inventor	Neill H. Luebke
	Art Unit	3732
	Examiner Name	Matthew M. Nelson
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U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code1	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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		US-6,431,863	08-13-2002	Lal Sachdeva, et al.	
		US-6,422,865	07-23-2002	Fischer	
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		Copy of International Search Report corresponding to PCT/US2005/019947, under date of mailing of 10 November 2005.	

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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.

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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 record s.

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.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Richard T. Roche/Sandra Szablewski
Attorney Docket Number:	115207.00014

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Pages:				
Claims:				
Claims in Excess of 20	1202	3	80	240
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1840**

Electronic Acknowledgement Receipt

EFS ID:	20500053
Application Number:	14522013
International Application Number:	
Confirmation Number:	9570
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:	115207.00014
Receipt Date:	23-OCT-2014
Filing Date:	
Time Stamp:	15:41:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1840
RAM confirmation Number	1982
Deposit Account	170055
Authorized User	

File Listing:

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

1	Application Data Sheet	Application_Data_Sheet_Luebke.PDF	1286538 ab0d45ce77eb8ca3bf57dd38f6ffb2f4356c2c67	no	7
Warnings:					
Information:					
2		Continuationspec1.pdf	108695 c1936f3d480d0003c38d5deb4655bf57e20ce09c	yes	20
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	15	
	Claims		16	19	
	Abstract		20	20	
Warnings:					
Information:					
3	Drawings-only black and white line drawings	Luebke-00014-Drawings.PDF	339610 a7f4754b26ee288c904f4c0600ff33168e776739	no	7
Warnings:					
Information:					
4	Oath or Declaration filed	luebkedeclaration.pdf	56417 6e1444737c56d49d9188757b9943f4e423a01133	no	1
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	00014_Information_disclosure_statement.PDF	483903 9320aca75ec2b5e6c2f290a12e941d3e0260b94b	no	16
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
6	Non Patent Literature	Walia-Article.PDF	1013371 30b374a0a0fae82f11b2b520688b010576cd1fec	no	6
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	36459 845c8ec626656254488fcfd7525a14b430b1511b	no	2
Warnings:					
Information:					

Total Files Size (in bytes):	3324993

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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	115207.00014
	Application Number	

Title of Invention	Dental and Medical Instruments Comprising Titanium

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	Neill	Hamilton	Luebke	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Brookfield	**State/Province**	WI	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	18010 Continental Drive		
Address 2			
City	Brookfield	**State/Province**	WI
Postal Code	53045-1204	**Country** i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	26710
Email Address	Add Email / Remove Email

Application Information:

Title of the Invention	Dental and Medical Instruments Comprising Titanium		
Attorney Docket Number	115207.00014	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Filing By Reference :

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	115207.00014
	Application Number	
Title of Invention	Dental and Medical Instruments Comprising Titanium	

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country i

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	**Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	26710		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the application number blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	14167311	2014-01-29
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
14167311	Continuation of	134555841	2012-04-25
Prior Application Status	Patented		Remove

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	115207.00014
	Application Number	
Title of Invention	Dental and Medical Instruments Comprising Titanium	

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13455841	Continuation of	13336579	2011-12-23	8562341	2013-10-22
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13336579	Continuation of	12977625	2010-12-23	8083873	2011-12-27
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12977625	Division of	11628933	2006-12-07	8062033	2011-11-22
Prior Application Status	Pending				Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
11628933	a 371 of international	PCT/US05/19947	2005-06-07
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCT/US05/19947	Claims benefit of provisional	60578091	2004-06-08

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) i the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country i	Filing Date (YYYY-MM-DD)	Access Code i (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	115207.00014
	Application Number	
Title of Invention	Dental and Medical Instruments Comprising Titanium	

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	115207.00014
	Application Number	
Title of Invention	Dental and Medical Instruments Comprising Titanium	

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(●) Assignee ◯ Legal Representative under 35 U.S.C. 117 ◯ Joint Inventor

◯ Person to whom the inventor is obligated to assign. ◯ Person who shows sufficient proprietary interest

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☒

Organization Name	Gold Standard Instruments, LLC		
Mailing Address Information:			
Address 1	18010 Continental Drive		
Address 2			
City	Brookfield	**State/Province**	WI
Country i	US	Postal Code	53045
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	115207.00014
	Application Number	

Title of Invention	Dental and Medical Instruments Comprising Titanium

Organization Name	Gold Standard Instruments, LLC

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	18010 Continental Drive		
Address 2			
City	Brookfield	**State/Province**	WI
Country i	US	Postal Code	53045
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications

Signature	/Richard T. Roche/			Date (YYYY-MM-DD)	2014-10-23
First Name	Richard T.	Last Name	Roche	Registration Number	38599

Additional Signature may be generated within this form by selecting the Add button. Add

Privacy Act Statement

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

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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.

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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.

Dental and Medical Instruments Comprising Titanium

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation application of U.S. Patent Application No. 14/167,211 filed January 29, 2014, which is a continuation of U.S. Patent Application No. 13/455,841 filed April 25, 2012, now U.S. Patent No. 8,727,773, which is a continuation of U.S. Patent Application No. 13/336,579 filed December 23, 2011, now U.S. Patent No. 8,562,341, which is a continuation of U.S. Patent Application No. 12/977,625 filed December 23, 2010, now U.S. Patent No. 8,083,873, 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

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.

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.

[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 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.

[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.

[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 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.

[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 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. 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, 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 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).

[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.

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 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. 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 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.

[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.

[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.

[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).

[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).

[0021] Figure 5 is a graph showing the results of 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" for untreated (Control) files, heat-treated files (TT), and titanium nitride coated files (Ti-N).

[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).

[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

[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 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 O_2) 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 O_2) 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 O_2) 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 O_2) 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.

[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 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; 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, 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.

[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 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

[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

[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 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 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

[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". 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, 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 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 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 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 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 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 an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a nickel titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 25° C. up to but not equal to the melting point of the nickel titanium alloy,

wherein the heat treated shank has increased fatigue life compared to an endodontic instrument of same composition and size not treated in accordance with step (b).

2. The method of claim 1 wherein the nickel titanium alloy is superelastic.

3. The method of claim 1 wherein:

the fatigue life is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

4. The method of claim 1 wherein:

the fatigue life is increased by at least 10%.

5. The method of claim 1 wherein:

the fatigue life is increased by at least 30%.

6. The method of claim 1 wherein:

the fatigue life is increased by at least 50%.

7. The method of claim 1 wherein:
the fatigue life is increased by at least 70%.

8. The method of claim 1 wherein:
the fatigue life is increased by at least 230%.

9. The method of claim 1 wherein:
the fatigue life is increased by at least 450%.

10. A method of claim 1 wherein:
the heat treating temperature is at least 250° C.

11. A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 25° C. up to but not equal to the melting point of the titanium alloy,

wherein the heat treated shank has improved cyclic fatigue compared to an endodontic instrument of same composition and size not treated in accordance with step (b).

12. The method of claim 11 wherein the nickel titanium alloy is a superelastic nickel titanium alloy.

13. The method of claim 11 wherein:

the cyclic fatigue is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

14. The method of claim 11 wherein:

the cyclic fatigue revolutions are at least 300.

15. The method of claim 11 wherein:

the cyclic fatigue revolutions are at least 950.

16. The method of claim 11 wherein:

the cyclic fatigue revolutions are at least 1600.

17. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 2000.

18. The method of claim 11 wherein:
the cyclic fatigue revolutions are increased by at least 50%.

19. The method of claim 11 wherein:
the cyclic fatigue revolutions are increased by at least 100%.

20. The method of claim 11 wherein:
the heat-treating temperature is at least 100° C.

21. The method of claim 11 wherein:
the heat treating temperature is at least 200° C.

22. The method of claim 11 wherein:
the heat-treating temperature is at least 300° C.

23. The method of claim 11 wherein:
the heat-treating temperature is at least 400° C.

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.

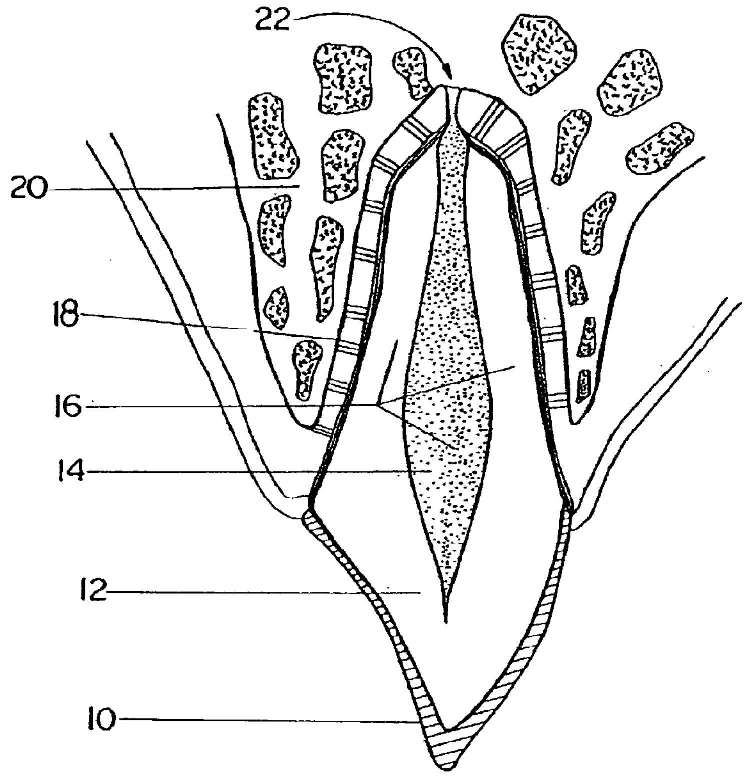
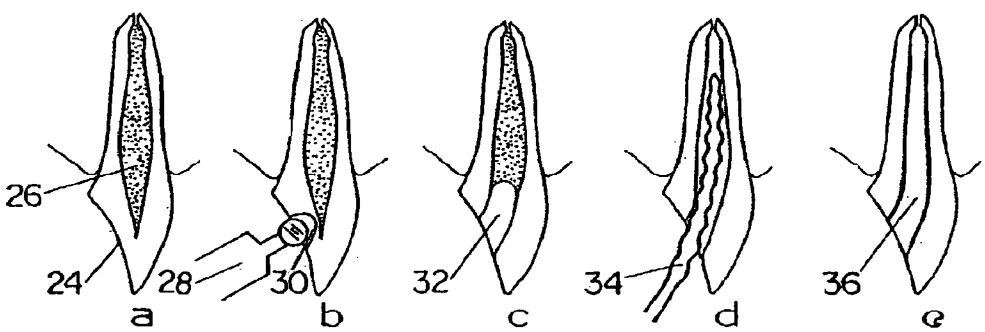


FIG. 1

FIG. 2



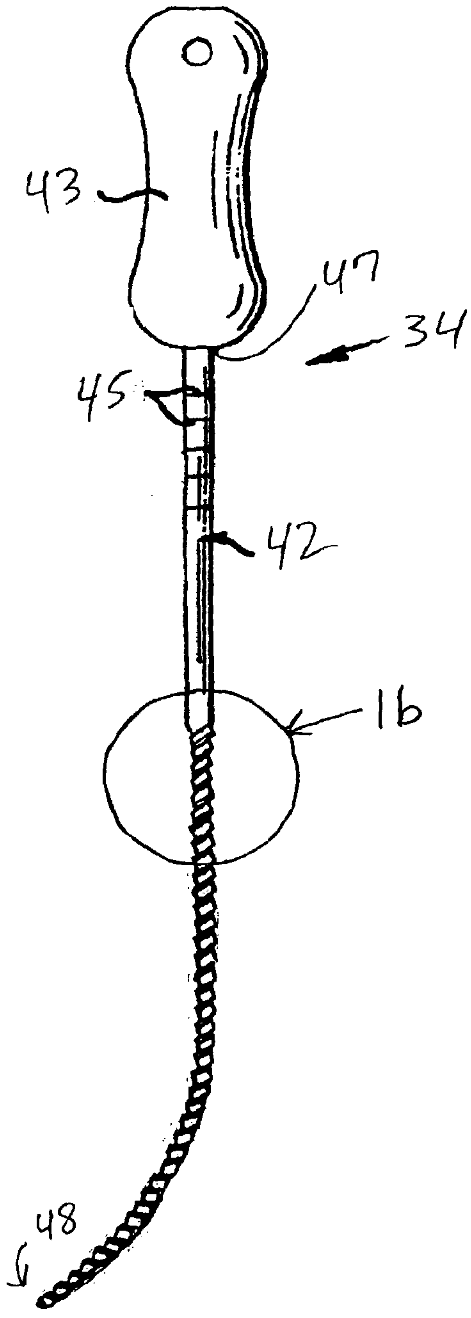


Fig. 1a

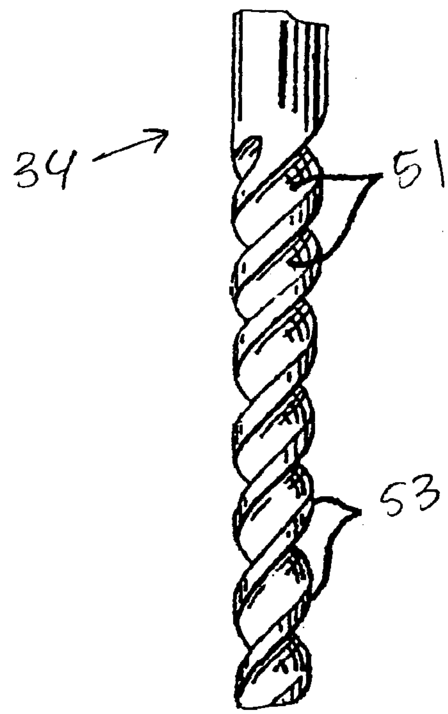


Fig. 1b

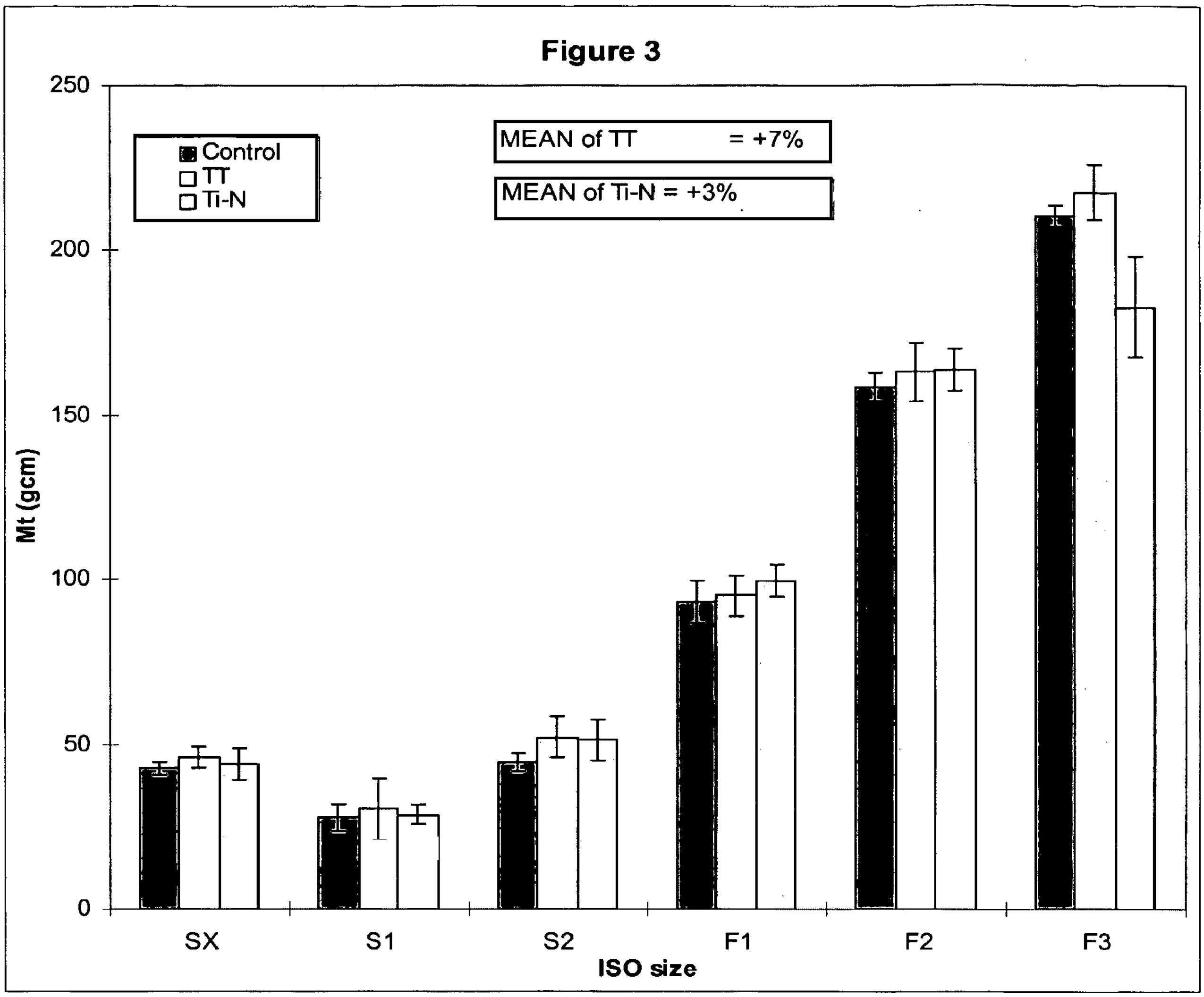


Figure 3
Control
TT
Ti-N
MEAN of TT = +7%
MEAN of Ti-N = +3%
250
200
150
100
50
0
Mt (gcm)
SX
S1
S2
F1
F2
F3
ISO size

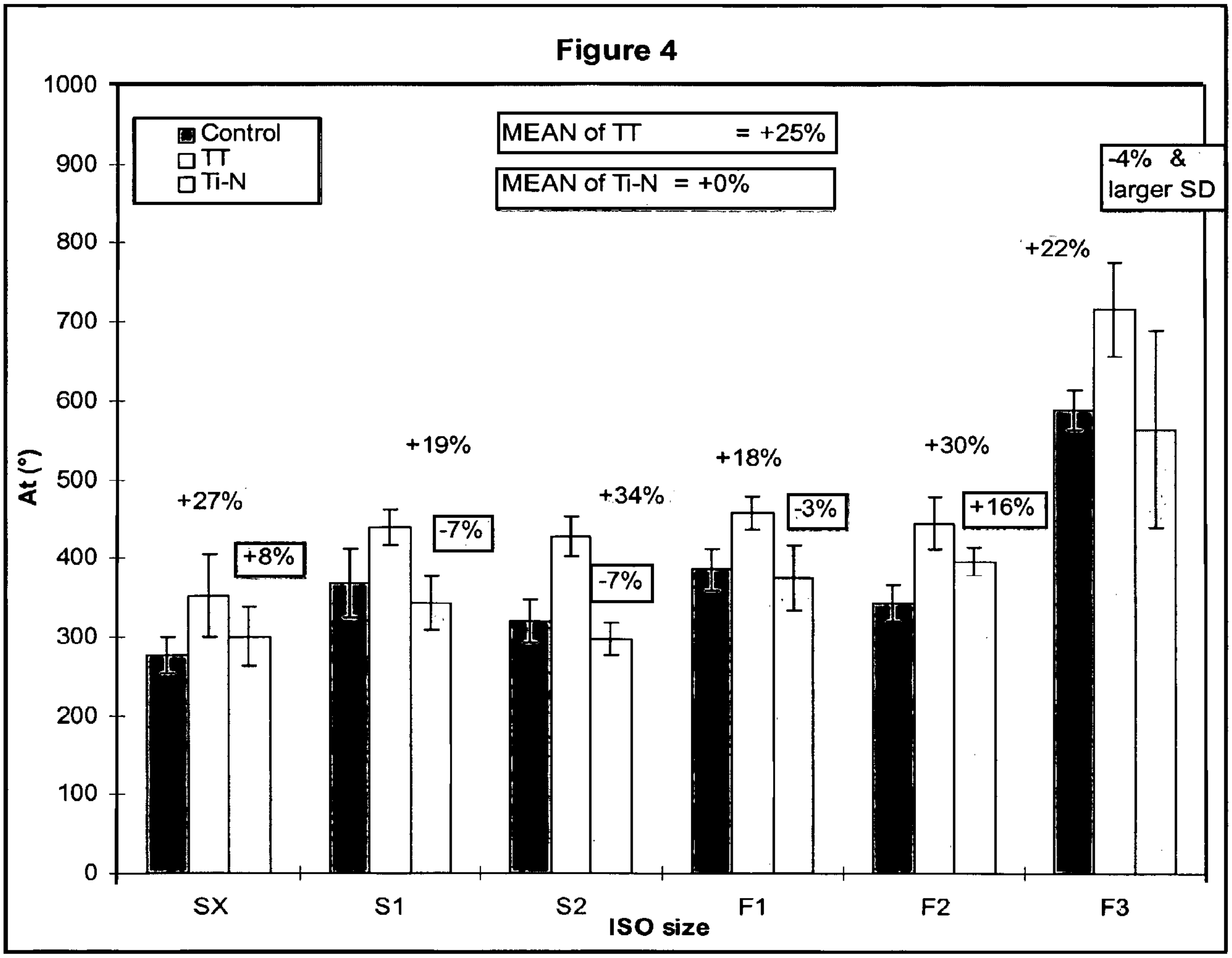
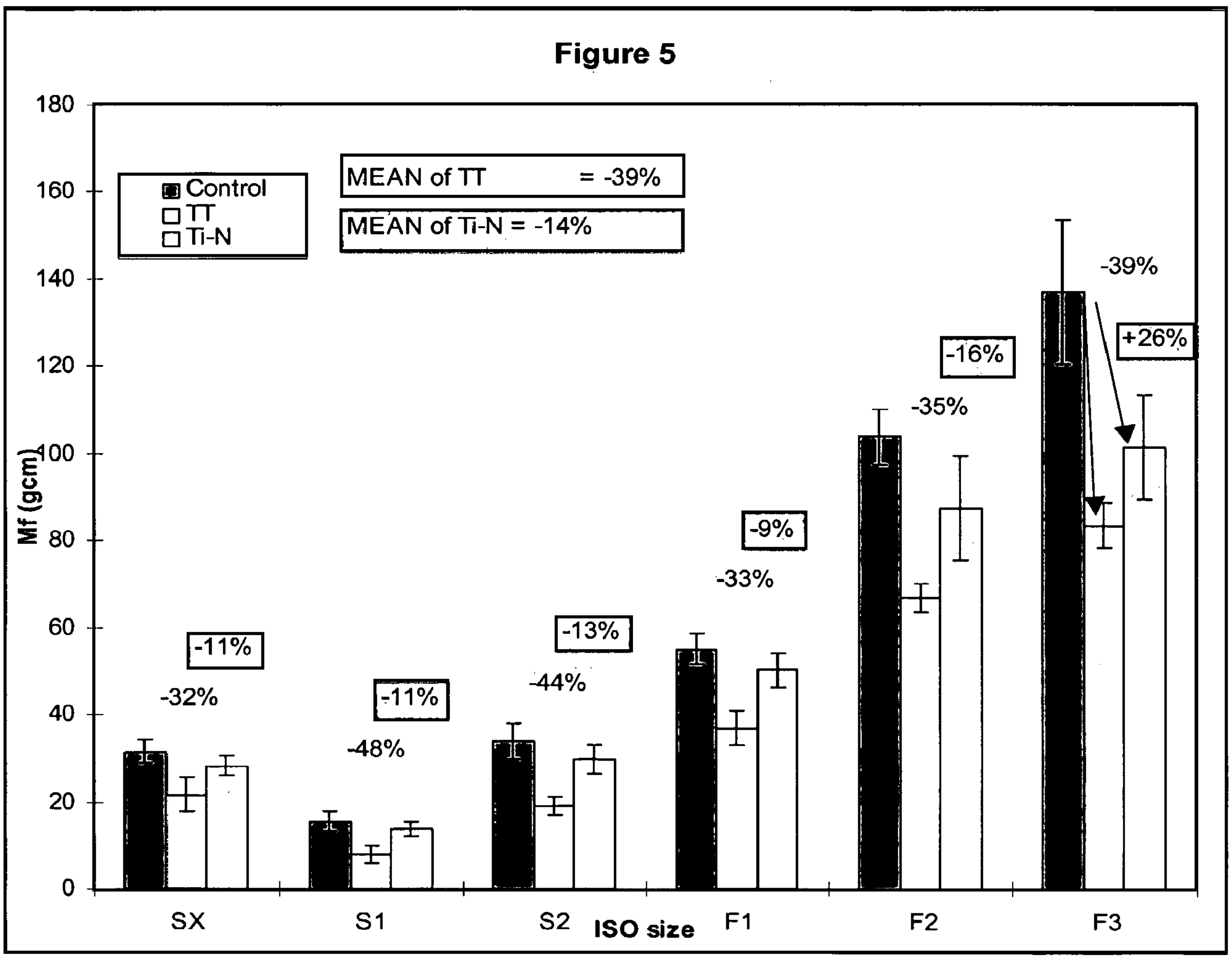


Figure 4
Control
TT
Ti-N
MEAN of TT = +25%
MEAN of Ti-N = +0%
-4% & larger SD
+22%
+27%
+8%
+19%
-7%
+34%
-7%
+18%
-3%
+30%
+16%
At (°)
ISO size
SX
S1
S2
F1
F2
F3
1000
900
800
700
600
500
400
300
200
100
0



180
160
140
120
100
80
60
40
20
0
Mf (gcm)
Control
TT
Ti-N
MEAN of TT = -39%
MEAN of Ti-N = -14%
-11%
-32%
-11%
-48%
-13%
-44%
-9%
-33%
-16%
-35%
-39%
+26%
SX
S1
S2
ISO size
F1
F2
F3

Figure 5

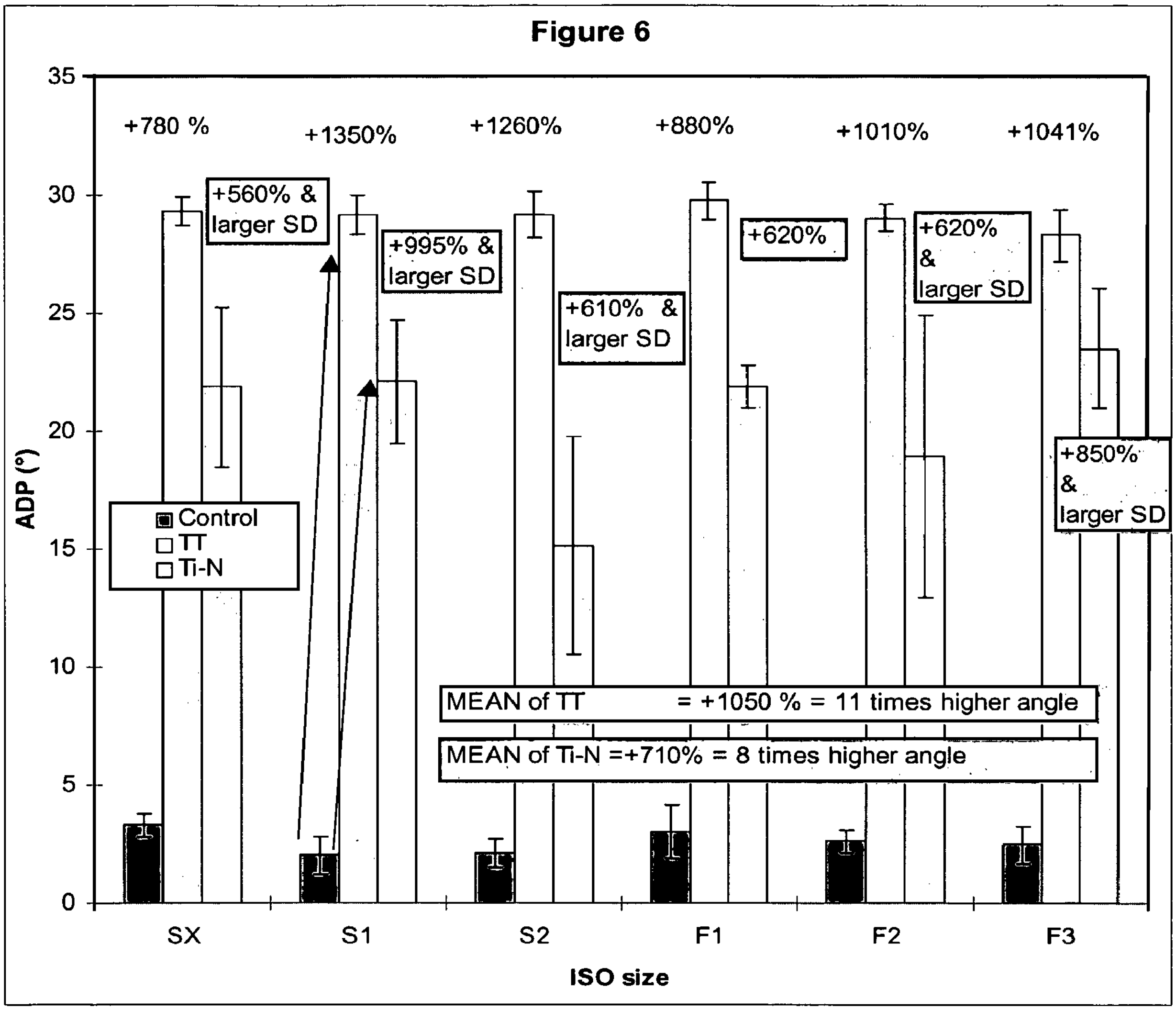


Figure 6
35
30
25
20
15
10
5
0
ADP (°)
+780 %
+1350%
+1260%
+880%
+1010%
+1041%
+560% & larger SD
+995% & larger SD
+610% & larger SD
+620%
+620% & larger SD
+850% & larger SD
Control
TT
Ti-N
MEAN of TT = +1050 % = 11 times higher angle
MEAN of Ti-N =+710% = 8 times higher angle
SX
S1
S2
F1
F2
F3
ISO size

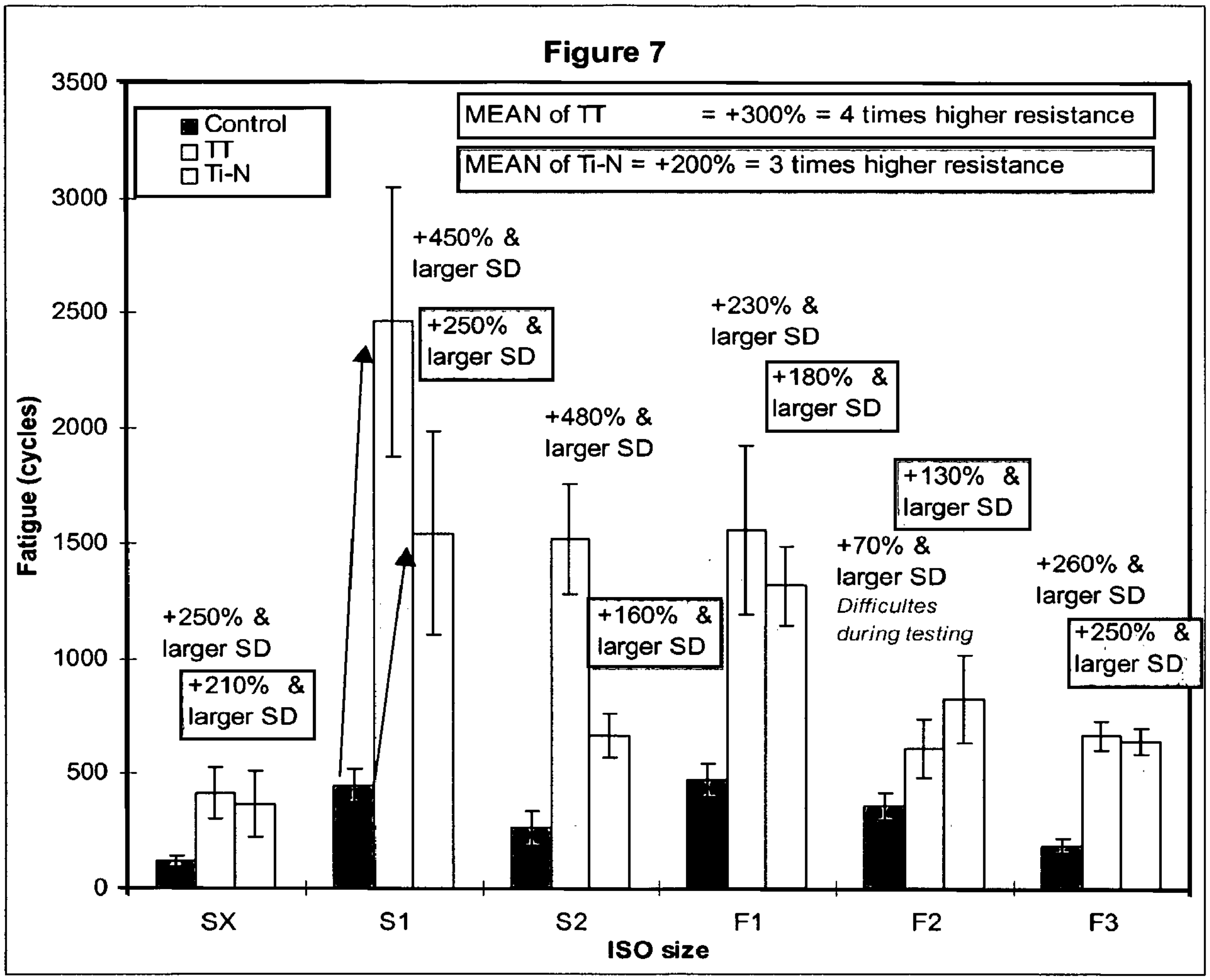


Figure 7
Control
TT
Ti-N
MEAN of TT = +300% = 4 times higher resistance
MEAN of Ti-N = +200% = 3 times higher resistance
Fatigue (cycles)
3500
3000
2500
2000
1500
1000
500
0
+250% & larger SD
+210% & larger SD
+450% & larger SD
+250% & larger SD
+480% & larger SD
+160% & larger SD
+230% & larger SD
+180% & larger SD
+70% & larger SD
Difficultes during testing
+130% & larger SD
+260% & larger SD
+250% & larger SD
SX
S1
S2
F1
F2
F3
ISO size

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Dental and Medical Instruments Comprising Titanium

As the below named inventor, I hereby declare that:

This declaration is directed to:

☑ The attached application, or

☐ United States application or PCT international application number ___________________

filed on _______________________________.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Neill Hamilton Luebke　　Date (Optional) : ___________________

Signature: Neill Luebke

Note: An application data sheet (PTO/AIA/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/SB/AIA01 form for each additional inventor.

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 10/31/2014

ASAHLE	SALE	#00000008	Mailroom Dt:	10/23/2014		170055	14522013
		01	FC : 4011	70.00	DA		
		02	FC : 2111	300.00	DA		
		03	FC : 2311	360.00	DA		
		04	FC : 2202	120.00	DA		

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 10/31/2014

ASAHLE	ADJ #00000001	Mailroom Dt: 10/23/2014				
	Seq No:	1982	Sales Acctg Dt: 10/24/2014	170055	14522013	
	01	FC : 1011	280.00 CR			
	02	FC : 1111	600.00 CR			
	03	FC : 1311	720.00 CR			
	04	FC : 1202	240.00 CR			

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 12/22/2014

MTEKLEMI ADJ #00000010 Mailroom Dt: 10/23/2014
Seq No: 8 Sales Acctg Dt: 10/31/2014 170055 14522013

01	FC : 4011	70.00	CR
02	FC : 2111	300.00	CR
03	FC : 2311	360.00	CR
04	FC : 2202	120.00	CR

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number
14/522,013

APPLICATION AS FILED - PART I

FOR	NUMBER FILED (Column 1)	NUMBER EXTRA (Column 2)	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	23 minus 20 =	* 3	x 40 =	120	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x 210 =	0.00			
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).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
			TOTAL	850		TOTAL	

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

APPLICATION AS AMENDED - PART II

AMENDMENT A

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

AMENDMENT B

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/522,013	10/23/2014	Neill Hamilton Luebke	115207.00014

CONFIRMATION NO. 9570

FORMALITIES LETTER

OC000000071667857

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

Date Mailed: 11/04/2014

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given TWO MONTHS from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

The required item(s) identified below must be timely submitted to avoid abandonment:

- A substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required. The substitute specification must be submitted with markings and be accompanied by a clean version (without markings) as set forth in 37 CFR 1.125(c) and a statement that the substitute specification contains no new matter (see 37 CFR 1.125(b)). The specification, claims, and/or abstract page(s) submitted is not acceptable and cannot be scanned or properly stored because:
  - The application contains drawings, but the specification does not contain a brief description of the several views of the drawings as required by 37 CFR 1.74 and 37 CFR 1.77(b)(9).

The following item(s) appear to have been **omitted** from the application:

- Figure(s) **2A - 2E** described in the specification.

Applicant must reply to this notice within the time period set forth in this notice to avoid abandonment of this application. Applicant must select one of the three following options and the reply must comply with the requirements set forth in the selected option and any other requirements set forth in this notice. The reply should also indicate which option applicant has selected.

I. Petition for date of deposit: Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and the petition fee set forth in 37 CFR 1.17(f) with evidence of such deposit **must** be filed within **TWO MONTHS** of the date of this Notice. The petition fee will be refunded if it is determined that the item(s) was received by the USPTO. **THIS TWO MONTH PERIOD IS EXTENDABLE UNDER 37 CFR 1.136(a) or (b).**

II. Petition for later filing date: Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s), and a petition under 37 CFR 1.182 with the petition fee set forth in 37 CFR 1.17(f) requesting the later filing date **must** be filed within **TWO MONTHS** of the date of this Notice. **THIS TWO MONTH PERIOD IS EXTENDABLE UNDER 37 CFR 1.136(a) or (b).**

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(f)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted item(s) and the petition (and petition fee) requesting the later filing date.

III. Acceptance of application as deposited: Applicant may accept the application as deposited in the USPTO by filing an appropriate amendment as set forth in either (A) or (B) below within **TWO MONTHS** of the date of this Notice. **THIS TWO MONTH PERIOD IS EXTENDABLE UNDER 37 CFR 1.136(a) or (b)** . The application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (i.e., the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit. A petition is not required for this option.

(A) If applicant wants to accept the application as deposited without adding the subject matter that was in the omitted item (e.g., a missing page or figure), applicant is required to submit one or more of the following items without adding any new matter (see 35 U.S.C. 132(a)):

1. For a missing page of the specification,
   a) a substitute specification including claims that amends the specification to renumber the pages consecutively and cancels any incomplete sentences, and
   b) a statement that the substitute specification includes no new matter, in compliance with 37 CFR 1.121(b)(3) and 1.125;
2. For a missing figure of the drawings,
   a) replacement drawing sheets in compliance with 37 CFR 1.121(d) to renumber the drawing figures consecutively (if necessary),
   b) a substitute specification excluding claims that amends the specification to cancel any references to any omitted drawing(s) and corrects the references in the specification to the drawing figures to correspond with any relabeled drawing figures, and
   c) a statement that the substitute specification includes no new matter, in compliance with 37 CFR 1.121(b)(3) and 1.125;
3. For a missing page of the claim listing only, a replacement claim listing with the claims renumbered consecutively or, if amendment to the claims is also necessary, then a complete claim listing in compliance with 37 CFR 1.121(c);
4. For a missing or unreadable compact disc,
   a) a substitute specification (excluding the claims) deleting the reference to the compact disc and the files contained on the compact disc, and
   b) a statement that the substitute specification includes no new matter, in compliance with 37 CFR 1.121(b)(3) and 1.125; and
5. For a missing or unreadable file submitted on a compact disc,
   a) a substitute specification (excluding the claims) deleting the reference to the missing or unreadable file, and a statement that the substitute specification includes no new matter, in compliance with 37 CFR 1.121(b)(3) and 1.125; and
   b) a replacement transmittal letter listing all of the files except the missing or unreadable file in compliance with 37 CFR 1.52(e)(3)(ii).

(B) Alternatively, if applicant wants to accept the application as deposited but wishes to add the subject matter in the omitted item (e.g., a missing page or figure) by relying on an incorporation by reference under 37 CFR 1.57 or other portions of the original disclosure, applicant is required to submit one or more of the following items without adding any new matter (see 35 U.S.C. 132(a)):

1. To add the subject matter in a missing page of specification,
   a) a substitute specification excluding claims and
   b) a statement that the substitute specification includes no new matter, in compliance with 37 CFR 1.121(b)(3) and 1.125;

2. To add a missing figure of the drawings, new and replacement drawing sheets in compliance with 37 CFR 1.121(d);
3. To add the subject matter in a missing page of the claim listing, a complete claim listing in compliance with 37 CFR 1.121(c) (e.g., a claim in the missing page should be submitted as a new claim);
4. To add the subject matter in a missing or unreadable compact disc,
   a) a replacement compact disc and a duplicate copy of the compact disc, in compliance with 37 CFR 1.52(e); and
   b) a statement that the replacement compact disc contains no new matter in compliance with 37 CFR 1.52(e)(4); and,
5. To add the subject matter in a missing or unreadable file submitted on a compact disc,
   a) a replacement compact disc that contains all of the files listed in the specification including the missing or unreadable file and a duplicate copy of the compact disc, in compliance with 37 CFR 1.52(e); and
   b) a statement that the replacement compact disc contains no new matter in compliance with 37 CFR 1.52(e)(4).

If applicant is relying on an incorporation by reference under 37 CFR 1.57 to add the omitted subject matter, then applicant must also comply with the requirements of 37 CFR 1.57.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice". https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/tle/

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/522,013	10/23/2014	3732	850	115207.00014	23	2

CONFIRMATION NO. 9570

FILING RECEIPT

OC000000071667856

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

Date Mailed: 11/04/2014

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**

Inventor(s)

Neill Hamilton Luebke, Brookfield, WI;

Applicant(s)

Gold Standard Instruments, LLC, Brookfield, WI

Assignment For Published Patent Application

GOLD STANDARD INSTRUMENTS, LLC, Brookfield, WI

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 14/167,311 01/29/2014 PAT 8876991
which is a CON of 13/455,841 04/25/2012 PAT 8727773
which is a CON of 13/336,579 12/23/2011 PAT 8562341
which 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 for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 10/31/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/522,013**

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

Dental and Medical Instruments Comprising Titanium

Preliminary Class

433

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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 (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

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

Application Information

Application Number	14/522,013	Confirmation Number	9570	Filing Date	2014-10-23
Attorney Docket Number (optional)	115207.00014	Art Unit	3732	Examiner	
First Named Inventor	Neill Hamilton 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.

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Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2014-12-12
Name	Richard T. Roche	Registration Number	38599

Electronic Acknowledgement Receipt

EFS ID:	20948935
Application Number:	14522013
International Application Number:	
Confirmation Number:	9570
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Customer Number:	26710
Filer:	Richard T. Roche/Sandra Szablewski
Filer Authorized By:	Richard T. Roche
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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 to make special based on Age/ Health	luebkepetition.pdf	45715 31f7d26f4a430615fa882135c7dabbb2d70c b2fa	no	1

Warnings:

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Total Files Size (in bytes):	45715

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New International Application Filed with the USPTO as a Receiving Office
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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

☑ Practitioners associated with Customer Number: 26710

OR

Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications a ssigned only to the undersigned according to the USPTO assignment records or assignments docu ments attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

☐ The address associated with Customer Number:

OR

Firm or Individual Name			
Address			
City			
Country			
Telephone		Email	

Assignee Name and Address: Gold Standard Instruments, LLC
18010 Continental Drive
Brookfield, WI 53045

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/SB/96 or equivalent) is required to be Filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of The practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature	Neill Hamilton Luebke	Date	11-4-14
Name	Neill Hamilton Luebke	Telephone	
Title	President of Gold Standard Instruments, LLC		

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Gold Standard Instruments, LLC

Application No./Patent No.: 14/522,013 Filed/Issue Date: October 23, 2014

Titled: Dental and Medical Instruments Comprising Titanium

Gold Standard Instruments, LLC, a company

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

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

☐ The extent (by percentage) of its ownership interest is ____________%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

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 034021, Frame 0683, or for which a copy thereof is attached.

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: ______________________

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The document was recorded in the United States Patent and Trademark Office at

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STATEMENT UNDER 37 CFR 3.73(c)

3. From: ______________________________ To: ______________________________

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The document was recorded in the United States Patent and Trademark Office at

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

☐ As required by 37 CFR 3.73(c)(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.

/Richard T. Roche/	December 18, 2014
Signature	Date
Richard T. Roche	Reg. No. 38,599
Printed or Typed Name	Title or Registration Number

[Page 2 of 2]

Dental and Medical Instruments Comprising Titanium

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation application of U.S. Patent Application No. 14/167,311 filed January 29, 2014, now U.S. Patent No. 8,876,991, which is a continuation of U.S. Patent Application No. 13/455,841 filed April 25, 2012, now U.S. Patent No. 8,727,773, which is a continuation of U.S. Patent Application No. 13/336,579 filed December 23, 2011, now U.S. Patent No. 8,562,341, which is a continuation of U.S. Patent Application No. 12/977,625 filed December 23, 2010, now U.S. Patent No. 8,083,873, 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

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.

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.

[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 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.

[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.

[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 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.

[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 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. 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, 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 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).

[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.

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 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. 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 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.

[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.

[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] Figure 2a shows a tooth with sound outer structure but diseased pulp which represents a prior art procedure for preparing a tooth for endodontic restoration.

[0019] Figure 2b shows the tooth being cut with conventional or coated dental drill creating a coronal access opening during an endodontic restoration.

[0020] Figure 2c illustrates the void that is formed resulting from 2b.

[0021] Figure 2d shows how the void is enlarged with a file.

[0022] Figure 2e the final result from 2d, a fully excavated cavity.

[0023] 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).

[0024] 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).

[0025] Figure 5 is a graph showing the results of 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" for untreated (Control) files, heat-treated files (TT), and titanium nitride coated files (Ti-N).

[0026] 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).

[0027] 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

[0028] 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 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.

[0029] 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.

[0030] 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 O_2) 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 O_2) 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.

[0031] 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.

[0032] 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 O_2) 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 O_2) 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.

[0033] 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.

[0034] 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 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.

[0035] 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; 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, 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.

[0036] 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 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.

[0037] 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™.

[0038] 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

[0039] 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

[0040] 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$\cdot$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". 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 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 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

[0041] 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". 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

[0042] 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

[0043] 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 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". 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 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 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

[0044] Six groups of thirty ISO size SX, S1, S2, F1, F2 and F3 files were used in a 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 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.

[0045] 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.

[0046] 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 an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a nickel titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 25° C. up to but not equal to the melting point of the nickel titanium alloy,

wherein the heat treated shank has increased fatigue life compared to an endodontic instrument of same composition and size not treated in accordance with step (b).

2. The method of claim 1 wherein the nickel titanium alloy is superelastic.

3. The method of claim 1 wherein:

the fatigue life is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

4. The method of claim 1 wherein:

the fatigue life is increased by at least 10%.

5. The method of claim 1 wherein:

the fatigue life is increased by at least 30%.

6. The method of claim 1 wherein:

the fatigue life is increased by at least 50%.

7. The method of claim 1 wherein:
the fatigue life is increased by at least 70%.

8. The method of claim 1 wherein:
the fatigue life is increased by at least 230%.

9. The method of claim 1 wherein:
the fatigue life is increased by at least 450%.

10. A method of claim 1 wherein:
the heat treating temperature is at least 250° C.

11. A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 25° C. up to but not equal to the melting point of the titanium alloy,

wherein the heat treated shank has improved cyclic fatigue compared to an endodontic instrument of same composition and size not treated in accordance with step (b).

12. The method of claim 11 wherein the nickel titanium alloy is a superelastic nickel titanium alloy.

13. The method of claim 11 wherein:

the cyclic fatigue is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

14. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 300.

15. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 950.

16. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 1600.

17. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 2000.

18. The method of claim 11 wherein:
the cyclic fatigue revolutions are increased by at least 50%.

19. The method of claim 11 wherein:
the cyclic fatigue revolutions are increased by at least 100%.

20. The method of claim 11 wherein:
the heat-treating temperature is at least 100° C.

21. The method of claim 11 wherein:
the heat treating temperature is at least 200° C.

22. The method of claim 11 wherein:
the heat-treating temperature is at least 300° C.

23. The method of claim 11 wherein:
the heat-treating temperature is at least 400° C.

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Neill Hamilton Luebke
Application No: 14/522,013
Filed: October 23, 2014
Confirmation No.: 9570
Attorney Docket: 115207.00014
Invention: Dental and Medical Instruments Comprising Titanium

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CHANGE OF ENTITY STATUS AND PAYMENT OF FEE DEFICIENCY

Dear Sir:

It has been brought to our attention, that this case was paid at large entity but the large entity fees have been refunded for the small entity rates. Large entity is the correct status. Please charge deposit account 170055 the required fee deficiency. Attached is a detailed list of the fees that we are paying the difference for.

The Commissioner is authorized to deduct $990 from Deposit Account Number 17-0055. Applicant requests that the Examiner contact the undersigned if there are any discrepancies with our record and yours.

Respectfully submitted,

Date: December 18, 2014

/Richard T. Roche/

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414.277.5805

Date of Original Fee	Fee Code that was submitted	Amount of Fee Paid as Small Entity	Fee Code that should have been submitted	Amount that should have been paid (large entity)	Difference Applicant is submitting today
10/31/2014	4011	$70	1011	$280	$210
10/31/2014	2111	$300	1111	$600	$300
10/31/2014	2311	$360	1311	$720	$360
10/31/2014	2202	$120	1202	$240	$120
Totals		$850		$1840	**$990**

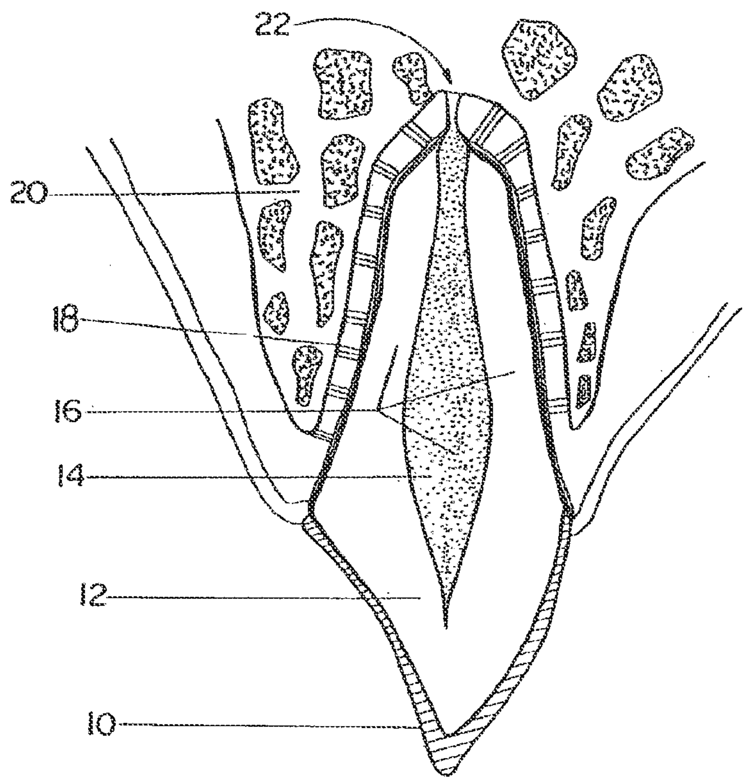

FIG. 1

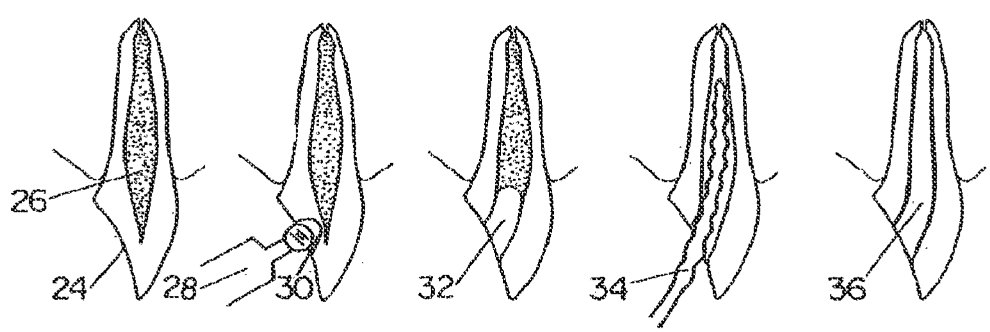

FIG. 2A FIG. 2B FIG. 2C FIG. 2D FIG. 2E

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Dental and Medical Instruments Comprising Titanium

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation application of U.S. Patent Application No. ~~14/167,211~~14/167,311 filed January 29, 2014, now U.S. Patent No. 8,876,991, which is a continuation of U.S. Patent Application No. 13/455,841 filed April 25, 2012, now U.S. Patent No. 8,727,773, which is a continuation of U.S. Patent Application No. 13/336,579 filed December 23, 2011, now U.S. Patent No. 8,562,341, which is a continuation of U.S. Patent Application No. 12/977,625 filed December 23, 2010, now U.S. Patent No. 8,083,873, 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

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.

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.

[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 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.

[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.

[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 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.

[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 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. 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, 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 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).

[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.

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 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. 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 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.

[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.

[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~~Figure 2a shows a tooth with sound outer structure but diseased pulp which represents a prior art procedure for preparing a tooth for endodontic restoration.

[0019] Figure 2b shows the tooth being cut with conventional or coated dental drill creating a coronal access opening during an endodontic restoration.

[0020] Figure 2c illustrates the void that is formed resulting from 2b.

[0021] Figure 2d shows how the void is enlarged with a file.

~~[0018]~~ [0022] Figure 2e the final result from 2d, a fully excavated cavity.

~~[0019]~~ [0023] 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).

~~[0020]~~ [0024] 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).

~~[0021]~~ [0025] Figure 5 is a graph showing the results of 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" for untreated (Control) files, heat-treated files (TT), and titanium nitride coated files (Ti-N).

~~[0022]~~ [0026] 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).

~~[0023]~~ [0027] 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

~~[0024]~~ [0028] 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 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]~~ [0029] 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]~~ [0030] 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 O_2) 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 O_2) 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]~~ [0031] 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]~~ [0032] 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 O_2) 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 O_2) 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]~~ [0033] 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.

~~[0030]~~ [0034] 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 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]~~ [0035] 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; 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, 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.

~~[0032]~~ [0036] 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 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]~~ [0037] 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]~~ [0038] 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

~~[0035]~~ [0039] 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

~~[0036]~~ [0040] 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 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 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

~~[0037]~~ [0041] 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”. 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]~~ [0042] 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]~~ [0043] 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 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". 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 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 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]~~ **[0044]** Six groups of thirty ISO size SX, S1, S2, F1, F2 and F3 files were used in a 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 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]~~ **[0045]** 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]~~ [0046] 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 an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a nickel titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 25° C. up to but not equal to the melting point of the nickel titanium alloy,

wherein the heat treated shank has increased fatigue life compared to an endodontic instrument of same composition and size not treated in accordance with step (b).

2. The method of claim 1 wherein the nickel titanium alloy is superelastic.

3. The method of claim 1 wherein:

the fatigue life is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

4. The method of claim 1 wherein:

the fatigue life is increased by at least 10%.

5. The method of claim 1 wherein:

the fatigue life is increased by at least 30%.

6. The method of claim 1 wherein:

the fatigue life is increased by at least 50%.

7. The method of claim 1 wherein:
the fatigue life is increased by at least 70%.

8. The method of claim 1 wherein:
the fatigue life is increased by at least 230%.

9. The method of claim 1 wherein:
the fatigue life is increased by at least 450%.

10. A method of claim 1 wherein:
the heat treating temperature is at least 250° C.

11. A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 25° C. up to but not equal to the melting point of the titanium alloy,

wherein the heat treated shank has improved cyclic fatigue compared to an endodontic instrument of same composition and size not treated in accordance with step (b).

12. The method of claim 11 wherein the nickel titanium alloy is a superelastic nickel titanium alloy.

13. The method of claim 11 wherein:
the cyclic fatigue is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

14. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 300.

15. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 950.

16. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 1600.

17. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 2000.

18. The method of claim 11 wherein:
the cyclic fatigue revolutions are increased by at least 50%.

19. The method of claim 11 wherein:
the cyclic fatigue revolutions are increased by at least 100%.

20. The method of claim 11 wherein:
the heat-treating temperature is at least 100° C.

21. The method of claim 11 wherein:
the heat treating temperature is at least 200° C.

22. The method of claim 11 wherein:
the heat-treating temperature is at least 300° C.

23. The method of claim 11 wherein:
the heat-treating temperature is at least 400° C.

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	14/522,013
Filing Date:	October 23, 2014
First-named Inventor:	Neil Hamilton Luebke
Attorney Docket No.:	115207.00014
Confirmation No.:	9570
Title:	Dental and Medical Instruments Comprising Titanium

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS
Filing Date Granted

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

Dear Sir:

In a Notice to File Corrected Application Papers mailed November 4, 2014, Applicant was given two months from the mailing date to (1) submit a substitute specification conforming the "Brief Description of the Drawings" section to the figures submitted 2) file a Replacement Sheet for FIGs. 2A-2E and 3) petition for the date of deposit.

Amendments to the Specification are on page 2 of this paper, and include an attached substitute specification in both clean and markup versions.

Amendments to the Drawings are on page 3 of this paper, and include an attached Replacement Sheet.

Remarks begin on page 4 of this paper, and include the required statements of no new matter.

AMENDMENT TO THE SPECIFICATION

Please amend the specification according to the substitute specification (clean and markup copies) submitted herewith. The specification is amended to include the complete label designation for each figure cited and to include other information that was already disclosed in the figures, and no other changed have been made.

AMENDMENT TO THE DRAWINGS

Attached herewith is a replacement sheet clearly identifying FIGs. 2A - 2E. No other changes have been made and no new matter has been added.

Remarks

SUBSTITUTE SPECIFICATION & DRAWINGS

The Office has required applicant to submit a substitute specification, because the application "does not contain a brief description of the several views of the drawings…". A substitute specification (clean and markup) is submitted herewith to cite the complete labels of all the figures cited throughout the description. Also, a Replacement Sheet has been submitted clearly identifying FIGs. 2A-2E.

STATEMENT OF NO NEW MATTER

The concurrently submitted substitute specification clarifies the complete number and letter label for each cited figure. Any other added description was included in the original drawings. Nothing else has been changed. Accordingly, Applicant states that the substitute specification adds no new matter to the specification.

PETITION FOR DATE OF DEPOSIT

Applicants hereby petition for the date of deposit of the nonprovisional application. Applicants have included the descriptions of FIGS. 2A through 2E in the specification to allow a new paragraph for each description which conforms with the formatting of the other Figure descriptions. This clerical error has been corrected without adding any new matter (see above). Accordingly, Applicants respectfully request that this Petition for Date of Deposit be granted.

REQUEST FOR PETITION FEE REFUND

Applicants herewith submit, the $200 petition fee under 37 CFR 1.17(f) (fee code 2462). Applicant respectfully requests that the petition fee be refunded, as the allegedly omitted items were in fact received by the USPTO on the date of filing.

CONCLUSION AND FEES

This response is believed timely, and no extension of time is believed necessary for this response to be entered by the Office. However, should an extension of time or any other fee be due in this or any subsequent response, please consider this paper to be a petition for the appropriate extension of time and a request to charge the extension fee to Deposit Account No. 17-0055.

Respectfully submitted,

Date: December 18, 2014

/Richard T. Roche/

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Electronic Patent Application Fee Transmittal

Application Number:	14522013
Filing Date:	23-Oct-2014
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Richard T. Roche/Sara Kerstein
Attorney Docket Number:	115207.00014

Filed as Large Entity

Filing Fees for **Utility under 35 USC 111(a)**

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Petition fee- 37 CFR 1.17(f) (Group I)	1462	1	400	400
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**400**

Electronic Acknowledgement Receipt

EFS ID:	20999083
Application Number:	14522013
International Application Number:	
Confirmation Number:	9570
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Customer Number:	26710
Filer:	Richard T. Roche/Sara Kerstein
Filer Authorized By:	Richard T. Roche
Attorney Docket Number:	115207.00014
Receipt Date:	18-DEC-2014
Filing Date:	23-OCT-2014
Time Stamp:	10:36:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$400
RAM confirmation Number	8770
Deposit Account	170055
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	POA_Luebke.pdf	580008 9f5a578d3b28ab1d45d6d74acf364b2a931eed09	no	1
Warnings:					
Information:					
2	Assignee showing of ownership per 37 CFR 3.73.	Luebke_14_373.pdf	76114 100b59bae14571ce23bbdee2ab9e8c4e19fea768	no	2
Warnings:					
Information:					
3	Specification	Luebke_14_cleancopy.pdf	109686 cad5ecd86c4630391275855281e4aca1f29edbcc	no	19
Warnings:					
Information:					
4	Notification of loss of entitlement to small entity status	luebke_14_entity.pdf	95602 13d5fe63e7fbf033f73d4733da60cf8939240992	no	1
Warnings:					
Information:					
5	Drawings-only black and white line drawings	luebke_14_figure.pdf	575516 fb4f19f9922e6bb7379771647b1f4b5160f482f7	no	1
Warnings:					
Information:					
6	Specification	luebke_14_marked.pdf	114787 f3119bae27786af1911ecf92f078c669328604de	no	19
Warnings:					
Information:					
7	Applicant Response to Pre-Exam Formalities Notice	Luebke_14_response.pdf	100170 8fa520ce9235ce630af190114a39e4da0dc75c94	no	5
Warnings:					
Information:					

8	Fee Worksheet (SB06)	fee-info.pdf	30383 a43538f771820e67e51b42f88d247e73053bffe7	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	1682266

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.

Electronic Acknowledgement Receipt

EFS ID:	20999083
Application Number:	14522013
International Application Number:	
Confirmation Number:	9570
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Customer Number:	26710
Filer:	Richard T. Roche/Sara Kerstein
Filer Authorized By:	Richard T. Roche
Attorney Docket Number:	115207.00014
Receipt Date:	18-DEC-2014
Filing Date:	23-OCT-2014
Time Stamp:	10:36:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$400
RAM confirmation Number	8770
Deposit Account	170055
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	POA_Luebke.pdf	580008 9f5a578d3b28ab1d45d6d74acf364b2a931eed09	no	1
Warnings:					
Information:					
2	Assignee showing of ownership per 37 CFR 3.73.	Luebke_14_373.pdf	76114 100b59bae14571ce23bbdee2ab9e8c4e19fea768	no	2
Warnings:					
Information:					
3	Specification	Luebke_14_cleancopy.pdf	109686 cad5ecd86c4630391275855281e4aca1f29edbcc	no	19
Warnings:					
Information:					
4	Notification of loss of entitlement to small entity status	luebke_14_entity.pdf	95602 13d5fe63e7fbf033f73d4733da60cf8939240992	no	1
Warnings:					
Information:					
5	Drawings-only black and white line drawings	luebke_14_figure.pdf	575516 fb4f19f9922e6bb7379771647b1f4b5160f482f7	no	1
Warnings:					
Information:					
6	Specification	luebke_14_marked.pdf	114787 f3119bae27786af1911ecf92f078c669328604de	no	19
Warnings:					
Information:					
7	Applicant Response to Pre-Exam Formalities Notice	Luebke_14_response.pdf	100170 8fa520ce9235ce630af190114a39e4da0dc75c94	no	5
Warnings:					
Information:					

8	Fee Worksheet (SB06)	fee-info.pdf	30383 a43538f771820e67e51b42f88d247e73053bffe7	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1682266		

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.

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 12/22/2014

MTEKLEMI	SALE	#00000014	Mailroom Dt:	12/18/2014		170055	14522013
		01	FC : 1011	280.00	DA		
		02	FC : 1111	600.00	DA		
		03	FC : 1311	720.00	DA		
		04	FC : 1202	240.00	DA		

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United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/522,013	10/23/2014	Neill Hamilton Luebke	115207.00014

CONFIRMATION NO. 9570

POA ACCEPTANCE LETTER

OC000000072511423

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

Date Mailed: 12/24/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 12/18/2014.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/dgela/

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number
14/522,013

APPLICATION AS FILED - PART I

FOR	NUMBER FILED (Column 1)	NUMBER EXTRA (Column 2)	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	23 minus 20 =	* 3			OR	x 80 =	240
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 420 =	0.00
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).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
			TOTAL			TOTAL	1840

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

APPLICATION AS AMENDED - PART II

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

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/522,013	10/23/2014	3732	1840	115207.00014	23	2

CONFIRMATION NO. 9570

UPDATED FILING RECEIPT

OC000000072518266

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

Date Mailed: 12/24/2014

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**

Inventor(s)

Neill Hamilton Luebke, Brookfield, WI;

Applicant(s)

Gold Standard Instruments, LLC, Brookfield, WI

Assignment For Published Patent Application

GOLD STANDARD INSTRUMENTS, LLC, Brookfield, WI

Power of Attorney: The patent practitioners associated with Customer Number 26710

Domestic Priority data as claimed by applicant

This application is a CON of 14/167,311 01/29/2014 PAT 8876991
which is a CON of 13/455,841 04/25/2012 PAT 8727773
which is a CON of 13/336,579 12/23/2011 PAT 8562341
which 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 for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 10/31/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/522,013**

Projected Publication Date: 04/02/2015

Non-Publication Request: No

Early Publication Request: No
Title

Dental and Medical Instruments Comprising Titanium

Preliminary Class

433

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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 (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/522,013	10/23/2014	Neill Hamilton Luebke	115207.00014

CONFIRMATION NO. 9570

PUBLICATION NOTICE

OC000000074377654

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

Title: Dental and Medical Instruments Comprising Titanium

Publication No. US-2015-0089810-A1
Publication Date: 04/02/2015

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 Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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SUITE 2350
MILWAUKEE WI 53202-4426

MAILED
MAY 28 2015
OFFICE OF PETITIONS

In re Application of	:	
Neill Hamilton Luebke	:	
Application No. 14/522,013	:	DECISION ON PETITION
Filed: October 23, 2014	:	TO MAKE SPECIAL UNDER
Attorney Docket No. 115207.00014	:	37 CFR 1.102(c)(1)
	:	

This is a decision on the petition under 37 CFR 1.102(c)(1), filed December 12, 2014, to make the above-identified application special based on applicant's age as set forth in M.P.E.P. § 708.02, Section IV.

The petition is **GRANTED**.

A grantable petition to make an application special under 37 CFR 1.102(c)(1) and MPEP § 708.02, Section IV: Applicant's Age must be accompanied by evidence showing that at least one of the applicants is 65 years of age, or more, such as a birth certificate or a statement by applicant. No fee is required

The instant petition includes a certification by registered attorney, Richard T. Roche, that he is in possession of evidence that the inventor is 65 years of age or more. Accordingly, the above-identified application has been accorded "special" status.

Telephone inquiries concerning this decision should be directed to Shelly A Chase at 571-272-3816.

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

The application is being forwarded to the Technology Center Art Unit 3732 for action on the merits commensurate with this decision.

David Bucci
Petitions Examiner
Office of Petitions

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/522,013	10/23/2014	Neill Hamilton Luebke	115207.00014	9570

26710 7590 06/03/2015

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
06/03/2015	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

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No. 14/522,013	Applicant(s) LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3732	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS 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 *12/18/2014*.

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

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

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

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

Disposition of Claims*

5)☒ Claim(s) *1-23* 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) *1-23* 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 *12/18/2014* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

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

4) ☐ Other: _____.

- The present application is being examined under the pre-AIA first to invent provisions.

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 double patenting rejection is appropriate where the claims at issue 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 reference 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. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

- Claims 1-23 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 8,876,991. Although the claims at issue are not identical, they are not patentably distinct from each other because both applications are directed to the same invention other than what property is compared.
- Claims 1-23 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,727,773. Although the claims at issue are not identical, they are not patentably distinct from each other because both applications are directed to the same invention other than what property is compared.
- Claims 1-23 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 8,562,341. Although the claims at issue are not identical, they are not patentably distinct from each other because both applications are directed to the same invention other than what property is compared.
- Claims 1-23 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 8,083,873. Although the claims at

issue are not identical, they are not patentably distinct from each other because both applications are directed to the same invention other than what property is compared.

Claim Objections

- Claims 1 and 11 are objected to because of the following informalities: Claims 1 and 11 have a period after "25° C". A claim must be only one sentence long. Appropriate correction is required.

Claim Rejections - 35 USC § 112

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

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

- Claims 1-23 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. Claims 1-23 recite the method steps of providing a titanium or nickel titanium alloy and subjecting it to heat treatment at a temperature above 25 C and that the resulting fatigue life and cyclic fatigue are improved to varying degrees. However, not all titanium and nickel titanium alloys subjected to this treatment (particularly at low temperatures of 25 C for short periods of time) would result in that degree of change in fatigue life and cyclic fatigue. A similar rejection was made previously in parent application 13/336,579 and was overcome by making it clear that the heat treatment was done on a "**superelastic** nickel titanium alloy" (emphasis added). Present claims 2 and 12 mention superelastic alloys, but do not make it clear at what step of the method they are superelastic.

- The following is a quotation of 35 U.S.C. 112(b):
  (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

  The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claim 12 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

- Claim 12 recites the limitation "the nickel titanium alloy" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

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

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (US 2005/0090844) in view of Matsutani (US 7,137,815).

- Patel shows a method for manufacturing or modifying a dental instrument, the method comprising providing a dental elongate shank comprising a titanium or nickel titanium alloy ([0029]; 10) and heat-treating the entire instrument or device at a temperature from 25/250/100/200/300/400 degrees Celsius up to but not equal to the melting point of the titanium or nickel titanium alloy ([0041]-[0042]), wherein the heat-treated shank has improved cyclic fatigue and therefore increased fatigue life by at least 10/30/50/70/100/230/450% or revolutions at least 300/950/1600/2000 compared to an instrument of the same composition not treated ([0036] shows the increased revolution cycles and life up to millions of cycles resulting in 1500% increase [48 million cycles divided by 32 thousand cycles]). With respect to claims 2 and 12, the nickel titanium alloy is a superelastic nickel titanium alloy at some point ([0042]). However, Patel fails to show the dental instrument is specifically an endodontic instrument having a cutting edge extending from a distal end of the shank along an axial length of the shank.

- Matsutani teaches a similar heat treatment process conducted on an endodontic instrument elongate shank (6 and 7 in Fig. 1) having a cutting edge (at 4 in Fig. 1) extending from a distal end of the shank along an axial length of the shank (Fig. 1). 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 choosing an endodontic instrument as the dental instrument as taught by Matsutani since it is well known in the art to conduct heat treatments on endodontic instruments. With respect to claims 3 and 13, the cyclic fatigue and fatigue life are determined on an analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers (The test would be done on a root canal enlarger such as that taught by Patel/Matsutani and would therefore be at least somewhat based on the ISO Standard for root canal enlargers; More importantly, it is noted that the claim is not specific as to what portions of the ISO Standard are included in the analysis and the claims are not positively reciting the comparison or analysis as part of the method).

Conclusion

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

If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, Cris Rodriguez, *at* (571) 272-4964**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/Matthew M. Nelson/

Notice of References Cited	Application/Control No. 14/522,013	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3732	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	Moorleghem 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.

Notice of References Cited	Application/Control No. 14/522,013	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3732	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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	S					
	T					

NON-PATENT DOCUMENTS

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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.

Index of Claims	**Application/Control No.** 14522013	**Applicant(s)/Patent Under Reexamination** LUEBKE, NEILL HAMILTON
	Examiner MATTHEW NELSON	**Art Unit** 3732

✓	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	05/29/2015								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
	10	✓								
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	14	✓								
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	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								
	21	✓								
	22	✓								
	23	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14522013	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	MATTHEW NELSON	3732

CPC- SEARCHED

Symbol	Date	Examiner
A61C5/023; A61C2201/007; C22F1/006,10,004; C22C14/00; C22C19/03	5/29/2015	MN

CPC COMBINATION SETS - SEARCHED

Symbol	Date	Examiner

US CLASSIFICATION SEARCHED

Class	Subclass	Date	Examiner
29	896.1, 896.11	5/29/2015	MN
148	402, 421, 426	5/29/2015	MN
433	102, 224	5/29/2015	MN

SEARCH NOTES

Search Notes	Date	Examiner
See EAST search history	5/29/2015	MN

INTERFERENCE SEARCH

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

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	38	(US-20070184406-$ or US-20070072147-$ or US-20040121283-$ or US-20080032260-$ or US-20050003325-$ or US-20030077553-$ or US-20020137008-$ or US-20020157806-$ or US-20020191878-$ or US-20020036057-$ or US-20050090844-$ or US-20050011596-$ or US-20040129352-$ or US-20030188810-$ or US-20020185200-$ or US-20040193246-$).did. or (US-6431863-$ or US-6428634-$ or US-4490112-$ or US-6375458-$ or US-5921775-$ or US-5897316-$ or US-5882198-$ or US-5775902-$ or US-5080584-$ or US-6206695-$ or US-7137815-$ or US-5941760-$ or US-5653590-$ or US-7779542-$ or US-6087640-$ or US-6783438-$ or US-6540849-$ or US-5380200-$ or US-7207111-$ or US-5092941-$ or US-5984679-$ or US-6988887-$).did. or (US-6422865-B-$).did.	US-PGPUB; USPAT; DERWENT	OR	ON	2015/05/29 10:21
L3	8	L1 AND ((cyclic ADJ fatigue) fatigue cyclic)	US-PGPUB; USPAT; DERWENT	OR	ON	2015/05/29 10:22
L4	2821	(A61C5/023 OR A61C2201/007).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/05/29 11:23
L5	15842	(C22F1/006 OR C22F1/10 OR C22F1/004).CPC. (C22C14/00 OR C22C19/03).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/05/29 11:24
L6	16	luebke-neill.in. luebke-neill-$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/05/29 11:24
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;	OR	ON	2008/04/29

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT			10:53
S6	544	Ni adj Ti AND anneal$2 AND time AND hour	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S7	16	Ni adj Ti AND anneal$2 AND time AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:54
S8	876	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:54
S9	53	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:55
S10	183	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 15:12
S11	29	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (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	US-PGPUB;	OR	ON	2008/10/21

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

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT			13:14
S29	192	S28 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S30	1099	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:33
S31	18	S30 AND microstructure	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:34
S32	200	S30 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:35
S33	2	("7175655").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/18 13:12
S34	1112	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; 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	US-PGPUB;	OR	ON	2010/10/07

		Ti) (Nickel WITH Titanium)) AND endodontic	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			11:32
S39	83	("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel WITH Titanium)) AND endodontic AND deformation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/07 11:33
S40	1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:02
S41	226	S40 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:02
S42	52	S41 AND ((shape NEAR1 memory) (permanent NEAR1 deformation))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:34
S43	2	"5843244".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:56
S44	1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; 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-	US-PGPUB;	OR	ON	2011/05/12

		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.	USPAT; DERWENT			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
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
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
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
S103	2	"5380200".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/05 08:39

S104	2819	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/12/05 09:41
S105	2834	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/01/10 09:57
S106	2	"8048345".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/01/10 11:03
S107	2876	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/06/04 10:10
S108	2	"8083873".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S109	0	"8562341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S110	2	"13336579"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S111	3097	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/10/17 09:51
S114	3276	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	2014/04/04 09:31
S115	8472	(C22C14/00 OR C22C19/03).CPC.	US-PGPUB; USPAT; USOCR;	OR	ON	2014/04/04 09:42

			FPRS; EPO; JPO; DERWENT			
S116	2592	(A61C5/023 OR A61C2201/007).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:44
S117	608	superelastic ADJ nickel ADJ titanium AND heat$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:47
S118	178	superelastic ADJ nickel ADJ titanium SAME heat$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:48
S119	6221	(C22F1/006 OR C22F1/10 OR C22F1/004).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:51
S120	1414	(C22F1/006).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:52
S122	1109	(C22F1/006).CPC. AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:52
S123	22	(C22F1/006).CPC. AND (dental dentistry "433".clas.) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:53
S124	7	(C22F1/006).CPC. AND superelastic AND (dental dentistry "433".clas.) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:55
S125	36	(US-20070184406-$ or US-20070072147-$ or US-20040121283-$ or US-20080032260-$ or US-20050003325-$ or US-20030077553-$ or US-20020137008-$ or US-20020157806-$ or US-20020191878-$ or US-20020036057-$ or US-20050090844-$ or US-20050011596-$ or US-20040129352-$ or US-20030188810-$ or US-20020185200-$	US-PGPUB; USPAT; DERWENT	OR	ON	2014/07/16 10:50

		or US-20040193246-$).did. or (US-6431863-$ or US-6428634-$ or US-4490112-$ or US-6375458-$ or US-5921775-$ or US-5897316-$ or US-5882198-$ or US-5775902-$ or US-5080584-$ or US-6206695-$ or US-7137815-$ or US-5941760-$ or US-5653590-$ or US-7779542-$ or US-6087640-$ or US-6783438-$ or US-6540849-$ or US-5380200-$ or US-7207111-$ or US-5092941-$).did. or (US-6422865-B-$).did.				
S126	19	S125 AND superelastic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/16 10:50
S127	2	"5984679".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/16 10:53
S128	20857	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) AND (martensit$3 OR deform$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:58
S129	8052	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (martensit$3 OR deform$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:58
S130	91	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (martensit$3 OR deform$3) AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:58
S131	45	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (martensit$3 OR deform$3) AND "433".clas. AND @ad<="20050607"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:59

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
S113	1	(433/102).CCLS.	UPAD	OR	OFF	2014/02/08 08:20

5/29/2015 11:27:29 AM
C:\Users\mnelson3\Documents\EAST\EAST Workspaces\14522013 Dental and medical

instruments comprising titanium.wsp

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	
	Examiner Name	
	Attorney Docket Number	115207.00014

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code1	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5171383		1992-12-15	Sagaye et al.	
	2	6149501		2000-11-21	Farzin-Nia et al.	
	3	6485507		2002-11-26	Walak et al.	

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U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code1	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020137008		2002-09-26	McSpadden et al.	

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Examiner Initial*	Cite No	Foreign Document Number3	Country Code2 i	Kind Code4	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
	1							☐

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

Receipt date: 10/23/2014	Application Number		14522013 - GAU: 3732
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date		
	First Named Inventor	Neill H. Luebke	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	115207.00014	

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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]
	1	Kuhn et al., Fatigue and Mechanical Properties of Nickel-Titanium Endodontic Instruments, Journal of Endodontics, 2002, 28(10), 716-20	☐
	2	Khier et al., Bending properties of superelastic and nonsuperelastic nickeltitanium orthodontic wires, American Journal of Orthodontics and Dentofacial Orthopedics, 1991, 99(4), 310-18	☐
	3	Miura et al., The super-elastic property of the Japanese NiTi alloy wire for use in orthodontics, American Journal of Orthodontics and Dentofacial Orthopedics, 1986, 90(1), 1-10	☐
	4	Relevant aspects in the clinical applications of NiTi shape memory alloys, Journal of Materials Science: Materials in Medicine, 1996, 7, 403-6	☐
	5	F. S. Weine, Endodontic Therapy (6th ed. 2004)	☐
	6	Brantley et al., Differential scanning calorimetric studies of nickel titanium rotary endodontic instruments, Journal of Endodontics, 2002, 28, 567-72	☐
	7	Schafer et al., Relationship between design features of endodontic instruments and their properties. Part 3. Resistance to bending and fracture. Journal of Endodontics, 2001, 27, 299-303	☐
	8	Firstov et al., Surface oxidation of NiTi shape memory alloy, Biomaterials, 2002, 23, 4863-71	☐
	9	Kuhn et al., Influence of structure on NiTi endodontic instruments failure, Journal of Endodontics, 2001, 27(10), 516-20	☐

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Receipt date: 10/23/2014	Application Number	14522013 - GAU: 3732
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Neill H. Luebke
	Art Unit	
	Examiner Name	
	Attorney Docket Number	115207.00014

	10	"DECLARATION OF NEILL H. LUEBKE, D.D.S., M.S.", inventor of the present application, filed on August 15, 2014 in United States District Court for the Eastern District Of Tennessee Civil Action No. 14-00196	☐
	11	Tepel et al., Properties of endodontic hand instruments used in rotary motion. Part 3. Resistance to bending and fracture. Journal of Endodontics, 1997, 23, 141–5	☐

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EXAMINER SIGNATURE

Examiner Signature	/Matthew Nelson/	Date Considered	05/29/2015

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Notice of References Cited	Application/Control No. 14/167,311	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3732	Page 1 of 2

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*	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
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*	F	US-6,206,695 B1	03-2001	Wong et al.	433/102
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Notice of References Cited	Application/Control No. 14/167,311	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3732	Page 2 of 2

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

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Doc description: Information Disclosure Statement (IDS) Filed

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	

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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
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Application Number	
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First Named Inventor	LUEBKE, Neill Hamilton
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		US-6,431,863	08-13-2002	Lal Sachdeva, et al.	
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First Named Inventor	LUEBKE, Neill Hamilton
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		Copy of International Search Report corresponding to PCT/US2005/019947, under date of mailing of 10 November 2005.	

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	Application Number	
	Filing Date	
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	
	Examiner Name	
	Attorney Docket Number	115207.00014

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Receipt date: 10/23/2014	Application Number	14522013 - GAU: 3732
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	
	Examiner Name	
	Attorney Docket Number	115207.00014

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CONFIRMATION NO. 9570

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/522,013	10/23/2014 RULE	433	3732	115207.00014

APPLICANTS
Gold Standard Instruments, LLC, Brookfield, WI;

INVENTORS
Neill Hamilton Luebke, Brookfield, WI;

** **CONTINUING DATA** *************************
This application is a CON of 14/167,311 01/29/2014 PAT 8876991
which is a CON of 13/455,841 04/25/2012 PAT 8727773
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which claims benefit of 60/578,091 06/08/2004

** **FOREIGN APPLICATIONS** *************************

** **IF REQUIRED, FOREIGN FILING LICENSE GRANTED** **
10/31/2014

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

Dental and Medical Instruments Comprising Titanium

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
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	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

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	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

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	1	2006149675	JP	A	2006-06-15	Mani K.K.		☐
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	Attorney Docket Number	115207.00014

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	14	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-00632, U.S. Patent No. 8,727,773, Petition for Inter Partes Review, January 30, 2015	☐
	15	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-00632, U.S. Patent No. 8,727,773, Declaration of A. Jon Goldberg, January 30, 2015	☐
	16	IN THE U.S. DISTRICT COURT, EASTERN DISTRICT OF TENNESSEE, Dentsply International, Inc. v. US Endodontics, LLC, Civil Action No. 2:14-cv-00196, Complaint for Patent Infringement, June 24, 2014	☐
	17	IN THE U.S. DISTRICT COURT, EASTERN DISTRICT OF TENNESSEE, Dentsply International, Inc. v. US Endodontics, LLC, Civil Action No. 2:14-cv-00196, Defendant US Endodontics, LLC's Answer and Counterclaims, August 6, 2014	☐
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	21	IN THE U.S. DISTRICT COURT, EASTERN DISTRICT OF TENNESSEE, Dentsply International, Inc. v. US Endodontics, LLC, Civil Action No. 2:14-cv-00196, Answer to Counterclaims, September 19, 2014	☐
	22	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-01476, U.S. Patent No. 8,727,773, Petition for Inter Partes Review, June 25, 2015	☐
	23	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-01476, U.S. Patent No. 8,727,773, Declaration of A. Jon Goldberg, June 25, 2015	☐

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	Attorney Docket Number	115207.00014

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	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
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CERTIFICATION STATEMENT

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☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2015-07-24
Name/Print	Richard T. Roche	Registration Number	38,599

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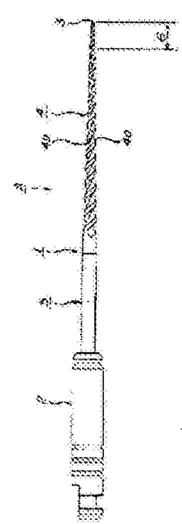
(54) (TITLE OF THE INVENTION) Root canal treatment apparatus

(57) (ABSTRACT)
(PROBLEM) Provide a highly durable root canal treatment apparatus that is unlikely to become damaged in the event that flex acts upon it while rotating during root canal formation.
(MEANS FOR SOLVING) Work portion 4 of a designated length from tip 3 is formed on file A serving as the root canal treatment apparatus, which has a shaft-shaped needle portion 1 made of nickel-titanium alloy on which a shank 5 is formed continuously with work portion 4, and at least a portion or the entirety of work portion 4 is subjected to heat treatment focused on resistance to rotating fatigue.
(SELECTED DRAWING) Fig. 1



(SCOPE OF PATENT CLAIMS)
(CLAIM 1) Shaft-shaped root canal treatment apparatus made of nickel-titanium alloy, on which a work portion of a designated length from the tip is formed and on which a shank is formed continuously with said work portion, which root canal treatment apparatus is characterized in that at least a portion or the entirety of the work portion is subjected to heat treatment focused on resistance to rotating fatigue.
(DETAILED DESCRIPTION OF THE INVENTION)
(TECHNICAL FIELD)
(0001)
This invention relates to a root canal treatment apparatus for dental care, particularly to a root canal treatment apparatus that has improved resistance to wear arising from rotation of a root canal treatment apparatus that performs the intended treatment by rotating, entering and exiting in the length direction, or repeatedly switching between forward and reverse by roughly 1/4 of a rotation.
(BACKGROUND ART)
(0002)
Examples of apparatuses for the treatment of the root canal of a tooth by rotation that shape the root canal by cutting include a file and a reamer. These root canal treatment apparatuses are comprised of a member shaped by forming a work portion provided with a cutting edge or projection on a finely tapered axial rod in accordance with the treatment objective, or forming a work portion by shaping a tapered axial rod into a spiral shape. Furthermore, depending on the model, a handle or grip allowing the doctor to grasp and operate the apparatus may be integrally attached to the end of the aforesaid member to allow the doctor to directly operate the apparatus or grip the apparatus by means of the chuck of a handpiece or the like.
(0003)
Root canals are very fine and there is considerable disparity in their shape and thickness from person to person. For this reason, even the same model of root canal treatment apparatus comes in a variety of models of differing thickness. For example, if using a file to form the root canal by cutting, it is necessary to deform the file according to the shape of the root canal in order to keep from damaging the tissue surrounding the root canal, i.e. it is necessary for the file to have appropriate elasticity.
(0004)
The technology in Patent Literature 1 has been proposed as a root canal treatment apparatus with high elasticity and shape restorability of the kind described above. This technology relates to a root canal treatment apparatus manufactured by forming a work portion on shape memory-treated axial rod material having superelastic property by performing removal processing while retaining at below the shape memory treatment temperature.
(0005)
In the aforesaid root canal treatment apparatus, the axial rod on which a work portion has been formed deforms supply according to applied external force and rapidly regains its original shape when the external force is removed. For this reason, it is able to follow the shape of the root canal very closely, making it possible to form a root canal to a high level of precision.
(0006)
(PATENT LITERATURE 1) Japanese Patent Publication No. 3375765
(DISCLOSURE OF THE INVENTION)
(PROBLEM TO BE SOLVED BY THE INVENTION)
(0007)
In the root canal treatment apparatus in the aforesaid Patent Literature 1, the entire length of the work portion has uniform superelastic property, for which reason when the work portion is bent, the work portion on the free end attempts to return to its original shape, producing stress as the tip is inserted into the root canal and bent during root canal treatment. In particular, when shaping the root canal, because rotation occurs with primarily the tip of the work portion bent, flex stress acts on the work portion, producing an issue whereby there is a higher likelihood of damaging the narrow tip portion.
(0008)
The objective of this invention is to provide a root canal treatment apparatus that is unlikely to become damaged in the event that flex acts upon it while rotating during root canal formation, i.e. that is highly durable.
(MEANS OF SOLVING THE PROBLEM)
(0009)

To solve the aforesaid problem, the root canal treatment apparatus in this invention is a shaft-shaped root canal treatment apparatus made of nickel-titanium alloy, on which a work portion of a designated length from the tip is formed and on which a shank is formed continuously with said work portion, in which root canal treatment apparatus at least a portion or the entirety of the work portion is subjected to heat treatment focused on resistance to rotating fatigue.

(EFFECT OF THE INVENTION)

(0010)

In the root canal treatment apparatus in this invention, subjecting at least a portion or the entirety of the work portion to heat treatment focused on resistance to rotating fatigue makes it possible to achieve high resistance to flex occurring as a result of rotation during root canal treatment.

(PREFERRED EMBODIMENT OF THE INVENTION)

(0011)

The root canal treatment apparatus in this invention is an apparatus for the treatment of a root canal by rotation, and applies to all apparatuses made using axial-shaped material made of nickel-titanium (Ni-Ti) alloy. In root canal treatment apparatuses of this kind, a work portion having a shape most suited to the intended treatment is formed on one end, and an operation portion operated by the doctor is formed on the other end. This operating portion is formed into a handle if directly operated by hand by the doctor, or is furnished with a handle in a shape most suited to the structure of the grip of said apparatus in the event that an apparatus such as a handpiece is used.

(0012)

In particular, subjecting at least a portion or the entirety of the work portion to heat treatment focused on resistance improves the durability of the site on which flex acts during root canal treatment, making it possible to eliminate the risk of breakage.

(EMBODIMENT 1)

(0013)

Preferred embodiments of the root canal treatment apparatus in this invention will be described below using the drawings. Fig. 1 is a drawing showing a file that is a representative example of a root canal treatment apparatus. Fig. 2 is a schematic drawing illustrating the composition when performing a fatigue rupture test for the tip of the file.

(0014)

The shape of file A will be described by means of Fig. 1 to represent the aforesaid root canal treatment apparatus. File A is an apparatus that cuts the wall of the root canal, and is comprised of a needle 1 and handle 2.

(0015)

A tapered work portion 4 is formed on needle 1 over a span of a designated length from tip 3, and a straight shank 5 is formed continuously with work portion 4. Work portion 4 can have a rectangular, triangular or square shape depending on the type, each of which is constituted in such a way as to be able to exert its own unique functions.

(0016)

In File A in this embodiment, forming the rectangular cross-section into a spiral shape along work portion 4 produces a groove 4a and cutting edge 4b along said groove 4a.

(0017)

Shank 5 has the function of being attached to handle 2. As indicated in Fig. 2, a handle can be constituted in such a way as to be gripped by the chuck of a handpiece or allow a doctor to grip it while operating the apparatus, with each formed into a shape and from a material corresponding to its function.

(0018)

For example, the handle 2 shown in the drawing is made of a metal such as stainless steel, and shank 5 is inserted into a hole formed in the axis and fastened by bonding. If forming a handle operated by having a doctor grip it by hand, shank 5 is sometimes fastened by integrally insert-molding by injection-molding with a synthetic resin.

(0019)

Needle 1 is made of nickel-titanium (Ni-Ti) alloy and is formed using a wire having a diameter corresponding to the diameter of needle 1 comprising file A, with portion 6, which is a portion of work portion 4, being subjected to heat treatment focused on resistance to rotating fatigue (hereinafter referred to as "durability heat treatment").

(0020)

Moreover, in this embodiment, durability heat treatment of file A is performed only on portion 6 from tip 3 of work portion 4, but naturally, it is also acceptable to perform durability heat treatment over the entirety of work portion 4 in this invention.

(0021)

There is no particular restriction on the length of portion 6 of work portion 4. In tests of this invention and the like, there were many instances of breakage at the region 2 mm to 3 mm from the tip when the entirety of the work portion was made to have superelastic property. For this reason, the length of portion 6 of work portion 4 must be at least 2 mm from tip 3, and at most the full length of work portion 4. The range for the preferable length of portion 6 is on the order of 3 mm to 10 mm from tip 3 when the length of work portion 4 is 16 mm, 3 mm or 4 mm being particularly preferable.

(0022)

Furthermore, the length of portion 6 may be altered to correspond to the taper of file A. For example, if the taper is 2/100, the portion furthest from tip 3 of work portion 4 (base) will not have a large diameter, so by using a designated length range from tip 3 for portion 6 and giving the other portions superelastic property, it is possible to retain the strength of the base. If the taper is 4/100 or 6/100, the diameter of the base is large, so the strength of the base will be retained even if the entirety of work portion 4 is subjected to durability heat treatment, and operability will be good.

(0023)

Durability heat treatment of portion 6 of work portion 4 is performed by heating the portion intended for durability heat treatment (portion 6 or the entirety of work portion 4) to a temperature obtained by testing to be described below, and retaining the raised temperature for a length of time obtained by testing. This durability heat treatment sets the Af temperature of the Ni-Ti alloy serving as the material of the file to a temperature greater than normal temperature, thereby making the site of portion 6 able to exert shape memory function.

(0024)

In a file A comprised in the manner set forth above, prior to treatment, a doctor is able to pre-curve portion 6 in accordance with the shape of the root canal or the shape of the apical foramen. By thus performing pre-curving, it becomes possible for tip 3 and portion 6 to closely follow the root canal when tip 3 is inserted into the root canal while performing treatment. Subsequent to completion of treatment and removal from the root canal, the doctor can apply force to cause it to regain its original shape, or heating can be performed to a temperature greater than the Af temperature set by durability heat treatment to cause it to regain its original shape.

(0025)

The aforesaid portion 6 is extremely flexible, which makes it possible to extend the length of time until breakage when work portion 4 is rotated while bent while tip 3 is inserted into the root canal, or when entering and exiting in the length direction, or when repeatedly switching between forward and reverse by roughly 1/4 of a rotation.

(0026)

In particular, because work portion 4 is formed in a tapered shape, when work portion 4 is bent with tip 3 as the fulcrum, shank 5 will remain essentially straight, making shank 5 of work portion 4 an arc shape with a small curvature, while the curvature increases moving towards portion 6 such that the arc becomes more prominently curved, and portion 6 will be significantly bent. In short, work portion 4 is not bent uniformly, but is rather bent in accordance with the taper. When the bending of work portion 4 is released, sections other than portion 6 return to their original shape (for example straight) and portion 6 retains its bent shape.

(0027)

Next, the testing method for setting the heat treatment temperature and retention time (heat treatment conditions) when performing heat treatment focused on resistance to rotating fatigue over either portion 6, which is a portion of work portion 4, or the entirety of work portion 4, will be described together with results thereof.

(0028)
The objective of this testing is to investigate the heat treatment conditions most conducive to achieving high durability in file A, assuming the most extreme rotation during root canal treatment involving rotating, entering and exiting in the length direction or repeatedly switching between forward and reverse by roughly 1/4 of a rotation, as well as to investigate the heat treatment conditions common to different Ni-Ti alloys.
(0029)
For this reason, this testing was performed by producing files A with the same specifications using as raw material a plurality of types of Ni-Ti alloy wire, performing fatigue rupture test on a plurality of samples subjected to heat treatment under different temperature and retention times using the device shown in Fig. 2, measuring the time until rupture, and comparing the measured results, thereby discovering the heat treatment conditions focused on durability to rotating fatigue.
(0030)
It is best for the time until occurrence of fatigue rupture in file A to be as long as possible. However, because there must be some benchmark in order to make a judgment, in this test, the benchmark was set to roughly 20 minutes without the occurrence of fatigue rupture when tested with the fatigue rupture tester described below.
(0031)
Using a wire with a diameter of roughly 1.0 mm composed of Ni: 55.76 wt%, remainder Ti (material 1), Ni: 55.91 wt%, remainder Ti (material 2), Ni: 55.97 wt%, remainder Ti (material 3), Ni: 55.90 wt%, remainder Ti (material 4) and Ni: 55.89 wt%, remainder Ti (material 5) as the material comprising file A, a plurality of no. 30 files were produced, each having a tip diameter of roughly 0.3 mm, taper 4/100, rectangular cross-sectional shape, roughly 25 mm length of needle projecting from handle 2 and roughly 15 mm length of work portion.
(0032)
Next, samples were produced from the files A produced from materials 1 to 5, one not subjected to heat treatment (untreated), one heat treated by retaining at 300°C for 30 minutes (heat treatment condition 1), one heat treated by retaining at 400°C for 30 minutes (heat treatment condition 2), one heat treated by retaining at 500°C for 30 minutes (heat treatment condition 3), and one heat treated by retaining at 600°C for 15 minutes (heat treatment condition 4), and a fatigue rupture test (durability) was performed, with a bending test and torsion test performed corroboratively.
(0033)
Moreover, during each test, in one sample, heat treatment was performed by inserting the needle 1 made of Ni-Ti alloy into an electric furnace and subjecting the entirety of work portion 4 to heat treatment, while in another sample, heat treatment was performed only for portion 6 from tip 3. Five samples were tested under the same conditions. Indicated values are a summary of test data.
(0034)
First, the bending test method and results will be described. The bending test was performed using a sample in which the entirety of needle 1 was heat treated, by bending to 45° while grasping a location 3 mm from the tip 3 of work portion 4 and measuring the maximum torque. The results of the bending test for untreated samples 1 to 5 were within the range of 40gf-cm to 50gf-cm, for heat treatment condition 1 samples 1 to 5 within the range of 40gf-cm to 55gf-cm, for heat treatment condition 2 samples 1 to 5 within the range of 35gf-cm to 40gf-cm, for heat treatment condition 3 samples 1 to 5 within the range of 30gf-cm to 40gf-cm, and for heat treatment condition 4 samples 1 to 5 within the range of 35gf-cm to 40gf-cm, showing no significant difference.
(0035)
Next, the torsion test method and results will be described. The torsion test was performed using a sample in which the entirety of needle 1 was heat treated, by grasping a location 3 mm from the tip 3 of work portion 4 and rotating, and measuring the maximum torque and angle at the time of rupture. The results of the torsion test for the untreated condition samples 1 to 5 were within the range of maximum torque 70gf-cm to 80gf-cm and angle 400° to 500°, for heat treatment condition 1 samples 1 to 5

within the range of maximum torque 70gf-cm to 80gf-cm and angle 400° to 500°, for heat treatment condition 2 samples 1 to 5 within the range of maximum torque 80gf-cm to 120gf-cm and angle 400° to 600°, for heat treatment condition 3 samples 1 to 5 within the range of maximum torque 70gf-cm to 100gf-cm and angle 450° to 700°, and for heat treatment condition 4 samples 1 to 5 within the range of maximum torque 70gf-cm to 90gf-cm and angle 800° to 1100°, revealing that although the test results for heat treatment condition 4 were significant compared to the other conditions, there was no significant difference between the other heat treatment conditions.

(0036)

Next, the fatigue rupture test method and results will be described. The fatigue rupture test was performed using a sample in which the entirety of needle 1 was heat treated using the device shown in Fig. 2. In short, using a device furnished with a pair of pins 21, 22 having a groove 21a, 22a capable of receiving the tip 3 of work portion 4, one of the pins 21 was set in such a way that the center thereof corresponded to a position 4 mm from the tip 3 of work portion 4 and tip 3 was inserted into the groove 22a of the other pin 22, thereby bending portion 6 of work portion 4 by roughly 45 degrees, this state was maintained while rotating 200 times per minute, and time until rupture was measured.

(0037)

The results of this fatigue rupture test revealed that time until fatigue rupture changes significantly depending on heat treatment conditions. In short, time until fatigue rupture was roughly 18 minutes in material 2, which had the highest durability among the untreated condition, within the range of 5 to 10 minutes in the case of heat treatment condition 1, within the range of 4 to 11 minutes in the case of heat treatment condition 3, and within the range of 3 to 5 minutes in the case of heat treatment condition 4, whereas time until fatigue rupture was within the range of 8 to 56 minutes in the case of heat treatment condition 2 (400°C – 30 minutes), revealing a significant increase in the time until fatigue rupture compared to the other heat treatment conditions.

(0038)

In short, when heat treatment is performed under heat treatment condition 2, there is significant lengthening effect on the fatigue rupture time, indicating that this heat treatment is capable of imparting a high level of durability.

(0039)

As indicated above, it was found that performing heat treatment of Ni-Ti alloy material while retaining for 30 minutes at 400°C improved durability. However, it is not clear whether or not the condition of 400°C – 30 minutes is ideal. For this reason, a fatigue rupture test was performed by using a single material and processing time and changing the temperature.

(0040)

The material used in the test was the aforesaid material 2 having a composition of Ni: 55.91 wt%, remainder Ti. A fatigue rupture test was performed for samples heat treated, respectively, at a temperature of 250°C, 300°C, 350°C, 375°C, 400°C, 410°C, 420°C, 425°C, 430°C, 440°C, 450°C, 475°C, 500°C and 550°C.

(0041)

The results of the aforesaid rupture tests are shown in Fig. 3. As shown in this diagram, results show that time until fatigue rupture exceeds 15 minutes when heat treatment temperature is within the range of 400°C to 450°C and exceeds 20 minutes when heat treatment temperature is within the range of 430°C to 440°C. Based on these test results, it can be said that heat treatment focused on resistance to rotating fatigue can be performed over the entirety of the work portion by performing heat treatment at a heat treatment temperature within the range of 400°C to 450°C and retaining for 30 minutes.

(0042)

Next, using a partial heating device not shown in the drawings[,] with the heat treatment range within the range of roughly 5 mm from tip 3 of work portion 4 or within the range of roughly 10 mm from tip 3, the aforesaid material 2 composed of Ni: 55.91 wt%, remainder Ti as the material, 400°C (350°C, 340°C), 425°C (370°C, 360°C), 450°C (390°C, 375°C), 475°C (410°C, 390°C), 500°C (440°C, 420°C), 525°C (460°C, 430°C), 550°C (480°C, 440[°C]) as the heat treatment temperature – partial heating device temperature setting, and 45 minutes (fixed) as the retention time, a fatigue rupture test was performed on a sample subjected to heat treatment at a temperature selected from among the aforesaid conditions. As a comparative example, a fatigue rupture test was performed on a sample that was heat-treated at 400°C for 45 minutes using a drier.

(0043)
Moreover, heat treatment of a range roughly 5 mm and roughly 10 mm from the tip of work portion 4 was performed on a very fine axial bolt within a limited range, so it is not possible to prescribe clear dimensions. For this reason, it is difficult to express the length range from tip 3 as a precise numeral value, and hence the range must be expressed as a range of on the order of roughly 5 mm or roughly 10 mm.
(0044)
When performing heat treatment using partial heating device, there is no guarantee that the temperature setting of the partial heating device and the actual temperature of the sample will match precisely. When heat treatment was actually performed with a partial heating device, a difference was found between the measured surface temperature of the sample and the temperature setting. In short, the first temperature in parentheses is the surface temperature of the sample as measured when a range of roughly 5 mm from the tip was heated, and the second temperature is the surface temperature of the sample as measured when a range of roughly 10 mm from the tip was heated, versus the aforesaid temperature setting of the partial heating device. Thus, the surface temperature of the sample during heat treatment was measured to be a temperature lower than the temperature setting of the partial heating device.
(0045)
As a result of the aforesaid tests, it was found that in the case of a heat treatment range of roughly 5 mm, the time until occurrence of fatigue rupture was roughly 29 minutes when the heat treatment temperature was set to 425°C, whereas in the case of other heat treatment conditions fatigue rupture occurred after 20 minutes or less.
(0046)
In the case of a heat treatment range of roughly 10 mm, the time until occurrence of fatigue rupture exceeded 20 minutes when the heat treatment temperature was within a range of 425°C to 500°C. In the case of a heat treatment temperature of 525°C, fatigue rupture occurred at roughly 19 minutes.
(0047)
In the comparative example, the time until occurrence of fatigue rupture was roughly 35 minutes.
(0048)
For practical purposes, it is adequate for the time until occurrence of fatigue rupture to be on the order of roughly 20 minutes or greater, for which reason it can be said that heat treatment focused on resistance to rotating fatigue over a portion of the work portion can be applied by performing heat treatment under heat treatment conditions of 425°C – 45 minutes in a file A that was heat-treated within a range of roughly 5 mm from the tip, and under heat treatment conditions of 425°C – 45 minutes to 525°C – 45 minutes in a file A that was heat-treated within a range of roughly 10 mm from the tip.
(0049)
As set forth above, putting together the results of fatigue rupture tests of samples wherein the entirety of the work portion 4 was heat-treated and fatigue rupture [tests] of samples in which a range of 5 mm and 10 mm from the tip of the work portion was heat-treated, it can be said to be possible to apply heat treatment focused on resistance to rotating fatigue over a portion or the entirety of the work portion by performing heat treatment with the heat treatment temperature set to within the range of 400°C to 450°C and retaining for 30 minutes to 45 minutes.
(0050)
In a file A of the kind described above, by gripping handle 2 in the chuck of a handpiece not shown in the drawings and having the doctor hold this handpiece, once portion 6 formed on work portion 4 has been pre-bent into a shape corresponding to the shape of the root canal of the patient, it is possible to shape the root canal by cutting the walls of said root canal by inserting tip 3 into the root canal and rotating in the direction of cutting edge 4b while displacing axially.
(0051)
Moreover, although in this embodiment a cutting edge 4b was formed because a file A was taken as an example of the root canal treatment apparatus, a cutting edge 4b will not necessarily be formed in the work portion 4 of all root canal treatment apparatuses; in some cases, a pointed projection or tapered coil will be formed. Even in the case of root canal treatment apparatuses of this kind, it is possible to achieve high durability by performing heat durability heat treatment over portion 6 of work portion 4 or over the entirety of work portion 4 as long as the root canal treatment apparatus treats a root canal by rotation.
(0052)
As set forth above, there is no particular restriction on the method of manufacturing a file A; however, representative methods will be described briefly. The first manufacturing method involves forming a work portion by performing metal removal

processing on material previously granted superelasticity, and subsequently subjecting a portion or the entirety of the tip of the work portion to durability heat treatment.

(0053)

In short, axial bolt-shaped material is formed by cutting wire made of Ni-Ti alloy granted superelasticity in advance and having a diameter corresponding to the thickness of the intended file to the length of said file, and then a needle portion is formed by tapering this material, machining the groove and cutting edge, machining the tip, and machining the work portion and shank. At this time, because it is impossible to perform plastic working on the material due to its superelasticity, the various processes performed on the material are performed by means of processes involving the removal of metal including grinding.

(0054)

Next, a portion subjected to durability heat treatment is formed over a range of a designated length from the tip of the work portion or over the entirety of work portion 4. This process is performed by using refrigerant to cool the sections of the needle already formed into a prescribed shape that do not correspond to the sections intended to be subjected to durability heat treatment, and then heating according to pre-set heat treatment conditions for temperature and retention time. There is no particular restriction on the refrigerant used at this time; for example, water can be used.

(0055)

The intended file can then be manufactured by inserting the shank of the needle provided with a portion 6 subjected to durability heat treatment over a range of a designated length from the tip of the work portion or over the entirety of the work portion in the manner set forth above into the handle and bonding the two together.

(0056)

A second manufacturing method involves manufacturing the intended file by subjecting a range of a designated length corresponding to the portion subjected to durability heat treatment, or a portion corresponding to the entirety of the work portion, to durability heat treatment from one end at the stage where the material is formed, and subsequently performing processing involving the removal of metal from the material to form a work portion with a groove and cutting edge.

(0057)

In the second manufacturing method described above, a segment subjected to durability heat treatment at the material stage and a section having superelasticity are formed, with the work portion being formed by subjecting this material to metal removal processing. Accordingly, a needle shape is remembered by, and a groove and cutting edge continuous with the superelastic portion are formed on, the portion subjected to durability heat treatment.

(0058)

The intended file can then be manufactured by subjecting material furnished in the manner set forth above with a segment corresponding to the portion subjected to durability heat treatment and a segment corresponding to the superelastic portion to processing involving metal removal so as to form a needle comprised of a work portion and shank, and subsequently inserting the shank in the handle and bonding the two together.

(INDUSTRIAL APPLICABILITY)

(0059)

The root canal treatment apparatus in this invention proffers the advantage of making it possible to prolong the length of time until occurrence of rupture when treating a root canal by inserting the tip portion thereof into a root canal with a complicated shape and rotating, even when fatigue occurs as a result of this rotation.

(BRIEF DESCRIPTION OF THE DRAWINGS)

(0060)

(FIG. 1) Drawing showing a file serving as a representative example of a root canal treatment apparatus.

(FIG. 2) Schematic drawing illustrating the composition when performing a fatigue rupture test for the tip of the file.

(FIG. 3) Diagram showing the test results for fatigue rupture time when the same material was heat-treated at a different temperature.

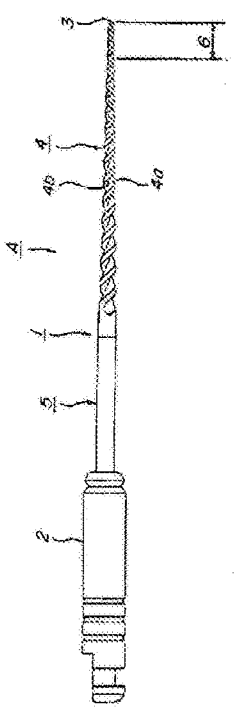
(EXPLANATION OF REFERENCES)

(0061)

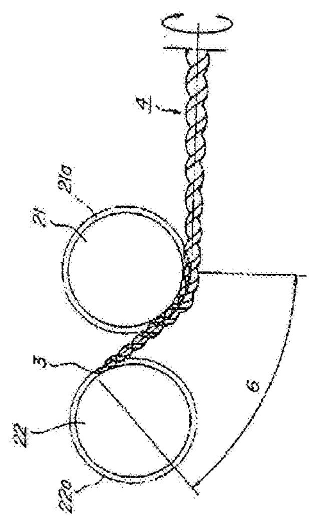
A	File
1	Needle
2	Handle

3	Tip
4	Work portion
4a	Groove
4b	Cutting edge
5	Shank
6	Portion
21, 211	Pin
21a, 22a	Groove

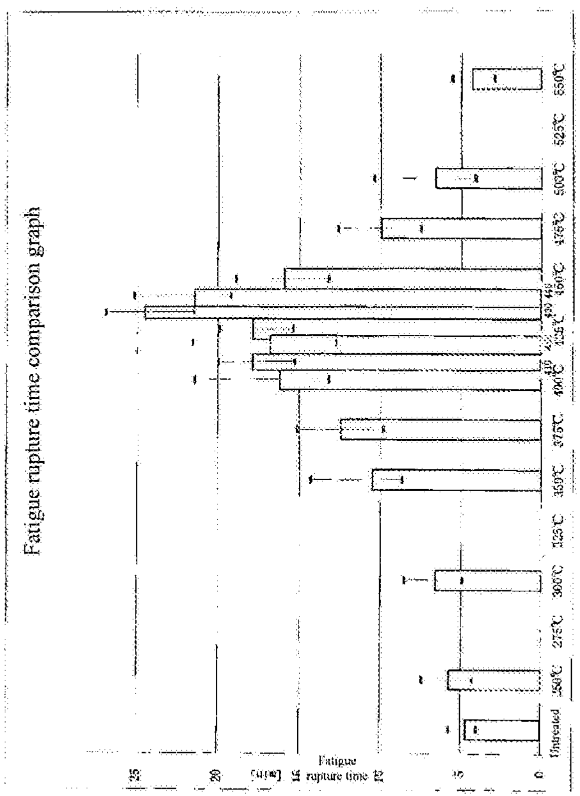
(Fig. 1)



(Fig. 2)



(Fig. 3)


Fatigue rupture time comparison graph
Fatigue rupture time [min]
25
20
15
10
5
0
Untreated
250℃
275℃
300℃
325℃
350℃
375℃
400℃
425℃
450℃
475℃
500℃
525℃
550℃

Continued from the front page

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F-terms (reference) 4C052 AA16 DD10

TRANSPERFECT

State of New York)
County of New York) ss.:

Affidavit

Miyako Inoue-Herrera, being duly sworn, hereby deposes and says:

I possess advanced knowledge of the Japanese and English languages. My qualifications are as follows:

Bilingual Japanese/English
Certified Japanese into English Quality Manager
Six years of experience as a Quality Manager

I have reviewed the attached translation and compared it to the original "JPA_2006149675." The attached is, to the best of my knowledge and belief, a true and accurate translation from Japanese to English of said original "JPA_2006149675."

Miyako Inoue-Herrera
TransPerfect Translations International, Inc.

Sworn to before me this January 23, 2015

Signature, Notary Public

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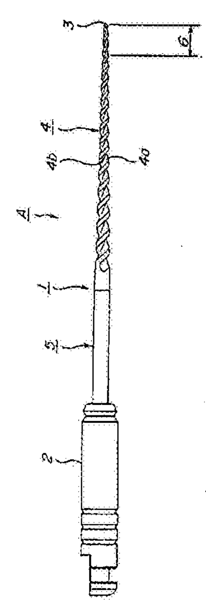
(54)【発明の名称】根管治療器具

(57)【要約】
【課題】根管成形の際に回転させることに伴う繰り返し曲げが作用しても破損する虞の低い、高い耐久性を有する根管治療器具を提供する。
【解決手段】根管治療器具となるファイルAは、先端3から所定長さの作業部4が形成され、作業部4に連続してシャンク5が形成されたニッケルーチタン合金からなる軸状の針部1を有し、少なくとも作業部4の一部又は全部に於いて回転疲労に対する耐久性に着目した熱処理が施されている。
【選択図】 図1



【特許請求の範囲】
【請求項１】
先端から所定長さの作業部が形成されると共に該作業部に連続してシャンクが形成されたニッケル－チタン合金からなる軸状の根管治療器具であって、少なくとも作業部の一部又は全部に於いて回転疲労に対する耐久性に着目した熱処理が施されていることを特徴とする根管治療器具。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、歯科治療用の根管治療器具に関し、特に、回転させたり、長さ方向に出し入れしたり、１／４回転くらいの正逆転を繰り返すことをさせて目的の治療を施す根管治療器具の回転に伴う疲労に対する耐久性を向上させた根管治療器具に関するものである。
【背景技術】
【０００２】
回転させつつ歯の根管を治療するための器具として、根管を切削して成形するファイル，リーマがある。この根管治療器具は、細いテーパ状の軸棒に治療目的に対応させて切刃や突部を設けた作業部を形成し、或いはテーパ状の軸棒をスパイラル状に成形して作業部を形成した部材によって構成されている。また機種によっては、前記部材の端部に医師が把持して操作するハンドルや柄を一体的に取り付けて、ハンドピース等のチャックに把持させたり、医師が直接操作し得るようにしたりして構成されている。
【０００３】
根管は極めて細く、且つ形状や太さは多様であり個人差も大きい。このため、同一機種の根管治療器具であっても、異なる太さを持つ多数のものが提供される。例えばファイルを用いて根管を切削して成形するような場合、根管の周囲を傷めることがないようにファイルは根管の形状に沿って変形すること、即ち、適度な弾性を有することが必要である。
【０００４】
上記の如き極めて高い弾性と形状の復元性を持つ根管治療器具として特許文献１の技術が提案されている。この技術は、記憶熱処理した超弾性特性を有する軸棒素材を記憶処理温度以下に保持しながら除去加工を施して作業部を形成して製造された根管治療器具に関するものである。
【０００５】
上記根管治療器具では、作業部が形成された軸棒は、作用する外力に応じてしなやかに変形し、且つ外力が除去されるのに伴って速やかに元の形状に復元する。このため、根管の形状に対して極めて高い追従性を発揮して精度の良い根管成形を行うことが出来る。
【０００６】
【特許文献１】特許第３３７５７６５号公報
【発明の開示】
【発明が解決しようとする課題】
【０００７】
上記特許文献１に係る根管治療器具では作業部の全長にわたって均等な超弾性特性を有するため、作業部を曲げたとき、自由端である先端部分にも元の形状に戻ろうとする作用があり、根管の治療に際し先端を根管に挿入して曲げるのに伴って応力が発生する。特に、根管成形に際し、作業部の主に先端部が曲がった状態で回転させることから、作業部には繰り返し曲げ応力が作用することとなり、細い先端部分が棄損する可能性が高くなるという問題がある。
【０００８】
本発明の目的は、根管成形の際に回転させることに伴う繰り返し曲げが作用しても棄損する虞の低い、即ち、高い耐久性を有する根管治療器具を提供することにある。
【課題を解決するための手段】
【０００９】

上記課題を解決するために本発明に係る根管治療器具は、先端から所定長さの作業部が形成されると共に該作業部に連続してシャンクが形成されたニッケル－チタン合金からなる軸状の根管治療器具であって、少なくとも作業部の一部又は全部に於いて回転疲労に対する耐久性に着目した熱処理が施されているものである。

【発明の効果】

【００１０】

本発明に係る根管治療器具では、少なくとも作業部の一部又は全部に於いて回転疲労に対する耐久性に着目した熱処理が施されていることによって、根管を治療する際に回転させた場合に生じる繰り返し曲げに対し、高い耐久性を発揮することが出来る。

【発明を実施するための最良の形態】

【００１１】

本発明に係る根管治療器具は、回転に伴って根管を治療するための器具であって、ニッケル－チタン（Ｎｉ－Ｔｉ）合金からなる軸状の材を用いて形成される全ての器具を対象としている。このような根管治療器具は、一方側の端部に目的の治療を最も合理的に行うことが可能な形状を持った作業部が形成され、他方側の端部に医師が操作する操作部が形成されている。この操作部は医師が手で直接操作する場合はハンドルが形成され、ハンドピースのような器具を用いる場合は該器具の把持部の構造に最適な形状を持った柄が設けられる。

【００１２】

特に、作業部の一部又は全部に対し耐久性に着目した熱処理を施すことによって、根管の治療に際し繰り返し曲げが作用する部位の耐久性の向上をはかり、破断の虞を排除し得るようにしたものである。

【実施例１】

【００１３】

以下本発明に係る根管治療器具の好ましい実施形態について図を用いて説明する。図１は根管治療器具を代表する例としてのファイルを示す図である。図２はファイルの先端部分の疲労破断試験を行う際の構成を説明する模式図である。

【００１４】

上記根管治療器具を代表してファイルＡの形状について図１により説明する。ファイルＡは根管に於ける根管壁を切削する器具であり、針部１と柄２とによって構成されている。

【００１５】

針部１には先端３から所定長さ範囲にわたるテーパ状の作業部４が形成されており、作業部４に連続してストレート状のシャンク５が形成されている。作業部４は、ファイルの種類に応じて断面が長方形のものや、三角形或いは四角形のものが提供され、夫々独自の機能を発揮し得るように構成されている。

【００１６】

本実施例に於けるファイルＡでは、長方形の断面が作業部４に沿ってスパイラル状に形成されることで、溝４ａ，該溝４ａに沿った切刃４ｂが形成されている。

【００１７】

シャンク５は柄２に取り付けられる機能を有している。柄２は図に示すようにハンドピースのチャックに把持されるように構成されたものや、医師が手で把持して操作し得るようにしたものがあり、夫々の機能に対応した形状と材質を持って形成されている。

【００１８】

例えば、図に示す柄２は、ステンレス鋼等の金属からなり、軸心に形成された穴にシャンク５を挿通して接着により固定されている。また医師が手で把持して操作する柄を形成する場合、合成樹脂の射出成形によりシャンク５をインサート成形して一体化させて固定されることもある。

【００１９】

針部１はニッケル－チタン（Ｎｉ－Ｔｉ）合金からなり且つファイルＡを構成する針部

１の径に対応した径を有する線材を用いて形成されており、作業部４の一部である部分６に於いて回転疲労に対する耐久性に着目した熱処理（以下、「耐久熱処理」という）が施されている。

【００２０】

尚、本実施例では、ファイルＡに対する耐久熱処理を作業部４に於ける先端３からの部分６に対してのみ行っているが、本発明に於いて作業部４の全部に対して耐久熱処理を行って良いことは当然である。

【００２１】

作業部４に於ける部分６の長さは特に限定するものではない。本件発明者等の実験では、作業部全体を超弾性特性としたとき、先端から２ｍｍ～３ｍｍの部位で乗損する例が多かった。このため、作業部４に於ける部分６の長さは、最低でも先端３から２ｍｍは必要であり、最大は作業部４の全長である。また部分６の特に好ましい長さ範囲は、作業部４の長さが１６ｍｍである場合は先端３から３ｍｍ～１０ｍｍ程度であり、３ｍｍ，４ｍｍ程度であることがより好ましい。

【００２２】

また、ファイルＡのテーパに対応させて部分６の長さを変化させても良い。例えばテーパが２／１００の場合は、作業部４の先端３から離れた部分（元部側）に於いても大きな径にはならないため、部分６は先端３から所定の長さ範囲とし、その他の部分は超弾性特性にすれば、元部側の強さを保持することが可能である。テーパが４／１００、６／１００の場合、元部側の径が大きくなるため、作業部４の全部に対して耐久熱処理を施した場合でも元部側の強さは保持されており、操作性は良い。

【００２３】

作業部４に於ける部分６に対する耐久熱処理は，耐久熱処理すべき部位（部分６や作業部４の全部）を、後述する試験によって得られた温度に上昇させると共に、上昇させた温度を試験によって得られた時間保持することで行われる。この耐久熱処理は、ファイルの材料となるＮｉ－Ｔｉ合金のＡｆ温度を常温よりも高い温度とするものであり、部分６を形状記憶機能を発揮し得る部位に設定するものである。

【００２４】

上記の如く構成されたファイルＡでは、治療に際し、医師が患者の根管の形状、或いは根尖口の形状に対応させて予め部分６を曲げておく（プレカーブ）ことが可能となる。このようにプレカーブを形成しておくことで、先端３を根管に挿入して治療を行う際に、先端３及び部分６が根管に対して高い追従性を発揮することが可能となる。そして治療が終了して根管から取り出した後、医師が力を加えて初期の形状に変形させることが可能であり、また耐久熱処理によって設定されたＡｆ温度以上に上昇させることで初期の形状を回復することが可能である。

【００２５】

上記部分６は柔軟性に富み、先端３を根管に挿入した状態で作業部４を曲げて回転させたり、長さ方向に出し入れしたり、１／４回転くらいの正逆転を繰り返すことをさせたとき、破断に至る時間を長くすることが可能である。

【００２６】

特に、作業部４がテーパ状に形成されているため、先端３を支点として作業部４を曲げたとき、シャンク５は略直線を維持し、作業部４のシャンク５側は曲率の小さい弧状となり、部分６側に接近するに従って曲率が大きくなって強く曲げられた弧状となり、更に、部分６はより強く曲げられる。即ち、作業部４は一様に曲げられるものではなく、テーパに対応して曲げられる。そして作業部４の曲げを解除すると、部分６以外の部位は元の形状（例えば直針状）に復元し、部分６は曲げられた形状を維持する。

【００２７】

次に、作業部４の一部である部分６、又は作業部４の全部に於いて回転疲労に対する耐久性に着目した熱処理を施す際の熱処理温度及び保持時間（熱処理条件）を設定するための試験方法と、結果について説明する。

【００２８】
この試験の目的は、回転させたり、長さ方向に出し入れしたり、１／４回転くらいの正逆転を繰り返すことをさせて治療するうち、最も過酷な回転させて根管の治療を行う場合を想定して、ファイルＡが最も高い耐久性を発揮し得る熱処理条件を調査すると共に、異なるＮｉ－Ｔｉ合金に対して共通性を持った熱処理条件を調査することにある。
【００２９】
このため、本実験は、複数の種類のＮｉ－Ｔｉ合金の線材を材料として同一仕様のファイルＡを構成し、異なる温度と保持時間を設定して熱処理した複数のサンプルを図２に示す装置を用いて疲労破断試験を行って、破断に至る時間を計測し、計測された結果を比較することで、回転疲労に対する耐久性に着目した熱処理条件を見いだすようにしたものである。
【００３０】
ファイルＡとしての疲労破断に至る時間は長時間であることにこしたことはない。しかし、一応の基準を設けないと判定のしようがないため、本試験では、後述する疲労破断試験機を用いた試験で約２０分疲労破断を起こさないことを基準として設定した。
【００３１】
ファイルＡを構成する素材として、材料組成が、Ｎｉ：５５．７６重量％、残部Ｔｉ（材料１）、Ｎｉ：５５．９１重量％、残部Ｔｉ（材料２）、Ｎｉ：５５．９７重量％、残部Ｔｉ（材料３）、Ｎｉ：５５．９０重量％、残部Ｔｉ（材料４）、Ｎｉ：５５．８９重量％、残部Ｔｉ（材料５）で、直径が約１．０ｍｍの線を用いて、３０番のファイルで、先端部分の径が約０．３ｍｍ、テーパが４／１００、断面形状が長方形、柄２から突出している針部の長さ約２５ｍｍ、作業部の長さ約１５ｍｍの形状を持ったものを夫々複数本作成した。
【００３２】
次に、材料１～５によって作成したファイルＡを、熱処理を施さないもの（未処理）、３００℃で３０分保持して熱処理したもの（熱処理条件１）、４００℃で３０分保持して熱処理したもの（熱処理条件２）、５００℃で３０分保持して熱処理したもの（熱処理条件３）、６００℃で１５分保持して熱処理したもの（熱処理条件４）のサンプルを作成して疲労破断試験（耐久性）の実験を行うと共に、付随的に曲げ試験，捩じり試験を行った。
【００３３】
尚、各試験に於いて、熱処理はＮｉ－Ｔｉ合金からなる針部１を電気炉に挿入して作業部４の全体に熱処理が施されているものと、先端３からの部分６に対応させて熱処理したものとがある。また同一の条件の試験に対するサンプル数は５とした。更に、記載した数値は試験データをまとめたものである。
【００３４】
先ず、曲げ試験の方法と結果について説明する。曲げ試験は、針部１の全体を熱処理したものを用い、作業部４の先端３から３ｍｍの位置を把持して４５°まで曲げたときの最大トルクを計測することで行った。曲げ試験の結果、未処理条件の材料１～５は４０ｇｆ－ｃｍ～５０ｇｆ－ｃｍの範囲、熱処理条件１の材料１～５は４０ｇｆ－ｃｍ～５５ｇｆ－ｃｍの範囲、熱処理条件２の材料１～５は３５ｇｆ－ｃｍ～４０ｇｆ－ｃｍの範囲、熱処理条件３の材料１～５は３０ｇｆ－ｃｍ～４０ｇｆ－ｃｍの範囲、熱処理条件４の材料１～５は３５ｇｆ－ｃｍ～４０ｇｆ－ｃｍの範囲、に入っており、有意な差が生じているとは認められない、という結果を得た。
【００３５】
次に、捩じり試験の方法と結果について説明する。捩じり試験は、針部１の全体を熱処理したものを用い、作業部４の先端３から３ｍｍの位置を把持して回転させ、破断したときの最大トルクと角度を計測することで行った。捩じり試験の結果、未処理条件の材料１～５は最大トルク７０ｇｆ－ｃｍ～８０ｇｆ－ｃｍ，角度；４００°～５００°の範囲、熱処理条件１の材料１～５は最大トルク７０ｇｆ－ｃｍ～８０ｇｆ－ｃｍ，角度；４００

°～５００°の範囲、熱処理条件２の材料１～５は最大トルク８０ｇｆ－ｃｍ～１２０ｇｆ－ｃｍ，角度；４００°～６００°の範囲、熱処理条件３の材料１～５は最大トルク７０ｇｆ－ｃｍ～１００ｇｆ－ｃｍ，角度；４５０°～７００°の範囲、熱処理条件４の材料１～５は最大トルク７０ｇｆ－ｃｍ～９０ｇｆ－ｃｍ，角度；８００°～１１００°の範囲、に入っており、熱処理条件４の試験結果は他の条件のものと比較して有利であるものの、他の熱処理条件では有意な差が生じているとは認められない、という結果を得た。

【００３６】

次に、疲労破断試験の方法と結果について説明する。疲労破断試験は、針部１の全体を熱処理したものを用い、図２に示す装置を用いて行った。即ち、作業部４の先端３側を受け入れることが可能な溝２１ａ，２２ａを有する一対のピン２１，２２を配置した装置を用い、一方のピン２１の中心に作業部４の先端３から４mmの位置が対応するようにセットすると共に先端３を他方のピン２２の溝２２ａに挿入することで、作業部４に於ける部分６を略４５度に曲げ、この曲げ状態を維持して毎分２００回転させて破断に至る時間を計測した。

【００３７】

この疲労破断試験の結果、疲労破断に至る時間は熱処理条件に応じて大きく変化していることがわかった。即ち、未処理条件の場合最も耐久性の高い材料２でも約１８分であり、熱処理条件１の場合５分～１０分の範囲、熱処理条件３の場合４分～１１分の範囲、熱処理条件４の場合３分～５分の範囲であるのに対し、熱処理条件２（４００℃－３０分）では、約８分～約５６分の範囲と、他の熱処理条件の疲労破断に至る時間と比較して大幅に延長されている。

【００３８】

即ち、熱処理条件２の熱処理を施した場合、疲労破断時間に大幅な延長効果が見られ、高い耐久性を発揮することが可能な熱処理であると言える。

【００３９】

上記の如くしてＮｉ－Ｔｉ合金の素材を温度４００℃で３０分保持する熱処理を行うことで耐久性が向上することが判明した。しかし、４００℃－３０分の条件が最適であるか否かは明確ではない。このため、材料を特定し、且つ処理時間を一定にした上で温度を変化させて疲労破断試験を行った。

【００４０】

試験に供する材料は、Ｎｉ：５５．９１重量％、残部Ｔｉの組成を持つ前述の材料２とした。また熱処理温度を２５０℃，３００℃，３５０℃，３７５℃，４００℃，４１０℃，４２０℃，４２５℃，４３０℃，４４０℃，４５０℃，４７５℃，５００℃，５５０℃とし、夫々の温度で熱処理したサンプルの疲労破断試験を行った。

【００４１】

上記破断試験の結果を図３に示す。同図に示すように、熱処理温度が４００℃～４５０℃の範囲である場合、疲労破断に至る時間は１５分を越えており、４３０℃及び４４０℃では２０分を越えているという結果を得た。この試験結果から、熱処理温度を４００℃～４５０℃の範囲に設定して３０分保持する熱処理を行うことで作業部の全部に於いて回転疲労に対する耐久性に着目した熱処理を施すことが可能であるといえる。

【００４２】

次に、図示しない部分加熱装置を用い。熱処理の範囲を作業部４の先端３から約５ｍｍの範囲、先端３から約１０ｍｍの範囲とし、材料をＮｉ：５５．９１重量％、残部Ｔｉの組成を持つ前述の材料２とし、熱処理温度－部分加熱装置の設定温度を４００℃（３５０℃，３４０℃），４２５℃（３７０℃，３６０℃），４５０℃（３９０℃，３７５℃），４７５℃（４１０℃，３９０℃），５００℃（４４０℃，４２０℃），５２５℃（４６０℃，４３０℃），５５０℃（４８０℃，４４０）とし、保持時間を４５分（一定）とし、前記条件の中から選択した温度で熱処理したサンプルの疲労破断試験を行った。また比較例としてドライヤーを用いて４００℃－４５分で熱処理したサンプルの疲労破断試験も行った。

【００４３】
尚、作業部４の先端から約５ｍｍ，約１０ｍｍの範囲に対する熱処理は、極めて細い軸棒に対して範囲を限定して実施するものであり、明確な寸法を規定し得るものでもない。このため、先端３からの長さ範囲を正確な数値で表すことは困難であり、約５ｍｍ，約１０ｍｍ程度の範囲との表現にならざるを得ない。
【００４４】
部分加熱装置を用いて熱処理を行う場合、部分加熱装置の設定温度とサンプルの実際の温度とが正確に一致することの保証はない。実際に部分加熱装置による熱処理を行っているときに、サンプルの表面温度を測定したところ、設定温度との間に開きがあった。即ち、上記部分加熱装置の設定温度に対し、かっこ内の前側の温度は先端から約５ｍｍの範囲を加熱したときに計測したサンプルの表面温度であり、後側の温度は先端から約１０ｍｍの範囲を加熱したときに計測したサンプルの表面温度である。このように、熱処理中のサンプルの表面温度は、部分加熱装置の設定温度よりも低い温度として測定されている。
【００４５】
上記試験の結果、熱処理の範囲が約５ｍｍの場合、熱処理温度を４２５℃に設定したとき疲労破断に至る時間が約２９分となり、他の熱処理条件の場合には２０分以下の時間で疲労破断した。
【００４６】
熱処理の範囲が約１０ｍｍの場合、熱処理温度が４２５℃～５００℃の範囲で疲労破断に至る時間が２０分を越えた。また熱処理温度が５２５℃の場合、約１９分で疲労破断している。
【００４７】
また比較例では、疲労破断に至る時間は約３５分であった。
【００４８】
実用上、疲労破断に至る時間は約２０分程度以上であれば良く、従って、先端から約５ｍｍの範囲を熱処理したファイルＡでは４２５℃－４５分の熱処理条件で、先端から約１０ｍｍの範囲を熱処理したファイルＡでは４２５℃－４５分～５２５℃－４５分の熱処理条件で熱処理を行うことで作業部の一部に於いて回転疲労に対する耐久性に着目した熱処理を施すことが可能であるといえる。
【００４９】
上記の如く、作業部４の全体を熱処理したサンプルの疲労破断試験、及び作業部の先端から５ｍｍ，１０ｍｍの範囲を熱処理したサンプルの疲労破断の結果から総合して、熱処理温度を４００℃～４５０℃の範囲に設定して３０分～４５分保持する熱処理を行うことで作業部の一部又は全部に於いて回転疲労に対する耐久性に着目した熱処理を施すことが可能であるといえる。
【００５０】
上記の如きファイルＡでは、柄２を図示しないハンドピースのチャックに把持させると共に医師がこのハンドピースを持ち、作業部４に形成された部分６を予め患者の根管の形状に対応させて曲げた後、先端３を根管に挿入して切刃４ｂの方向に回転させつつ軸方向に移動させることで、根管壁を切削して該根管を成形することが可能である。
【００５１】
尚、本実施例では根管治療器具としてのファイルＡを例としたため、切刃４ｂが形成されているが、全ての根管治療器具に於ける作業部４に必ず切刃４ｂが形成されているものでもなく、刺状の突起やテーパを持ったコイル状に形成されたものもある。そして、このような根管治療器具であっても、回転によって根管を治療する根管治療器具であれば、作業部４の部分６又は作業部４の全部に耐久熱処理を施すことによって、高い耐久性を発揮させせることが可能である。
【００５２】
上記の如き、ファイルＡを製造する方法は特に限定するものではないが、代表的な方法について簡単に説明する。第１の製造方法は、予め超弾性特性を持たせた素材から金属除

去加工を行って作業部を形成し、その後、作業部の先端側の一部又は作業部の全部を耐久熱処理したものである。

【００５３】

即ち、予め超弾性特性を持たせたＮｉ－Ｔｉ合金の線材であって目的のファイルの太さに対応する径を持った線材を、該ファイルの長さに対応させて切断することで軸棒状の素材を形成し、この素材に対し、テーパ加工、溝と切刃の加工、先端の加工、作業部及びシャンクの加工を行って、針部を形成する。このとき、素材が超弾性特性を有することから塑性加工を施すことが不可能であるため、素材に対する各加工は研削加工を含む金属の除去を伴う加工によって行われる。

【００５４】

次いで、作業部の先端から所定の長さ範囲、又は作業部４全体に耐久熱処理を施した部分を形成する。この工程は、既に所定の形状に形成されている針材に於ける耐久熱処理を施す部分に対応する部位以外の部位を冷媒によって冷却しておき、予め設定されている温度と保持時間からなる熱処理条件に基づいて加熱することで行われる。このとき用いる冷媒としては特に限定するものではなく、例えば水を用いることが可能である。

【００５５】

上記の如くして作業部の先端から所定長さ範囲、又は作業部の全体に耐久熱処理を施した部分６を設けた針部のシャンクを柄に挿通すると共に両者を接着することで、目的のファイルを製造することが可能である。

【００５６】

また第２の製造方法は、素材を形成した段階で一方側の端部から耐久熱処理を施した部分に対応する所定長さ範囲、又は作業部の全体に対応する部分に、耐久熱処理を施し、その後、素材に対して金属の除去を伴う加工を行って、溝，切刃を有する作業部を形成することで目的のファイルを製造するものである。

【００５７】

上記第２の製造方法では、素材の段階で耐久熱処理を施した部位と、超弾性特性を有する部位とが形成され、この素材に対して金属除去加工を施して作業部を形成することになる。従って、耐久熱処理を施した部分には、直針状の形状が記憶されると共に、超弾性部と連続した溝，切刃が形成されることとなる。

【００５８】

上記の如くして耐久熱処理を施した部分に対応する部位と、超弾性部に対応する部位を設けた素材に金属除去を伴う加工を施すことで作業部，シャンクからなる針部を形成し、その後、シャンクを柄に挿通して両者を接着することで、目的のファイルを製造することが可能である。

【産業上の利用可能性】

【００５９】

本発明の根管治療器具は、先端部分が複雑な湾曲形状を持った根管に挿入されると共に回転して根管の治療を行ったとき、この回転に伴って疲労が生じた場合でも、破断に至る時間を延長することが可能となり有利である。

【図面の簡単な説明】

【００６０】

【図１】根管治療器具を代表する例としてのファイルを示す図である。

【図２】ファイルの先端部分の疲労破断試験を行う際の構成を説明する模式図である。

【図３】同一の材料に対し異なる温度で熱処理したときの疲労破断時間の試験結果を示す図である。

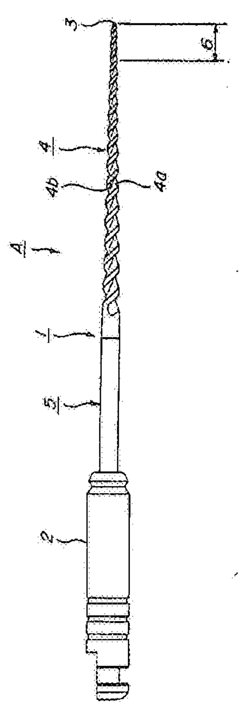
【符号の説明】

【００６１】

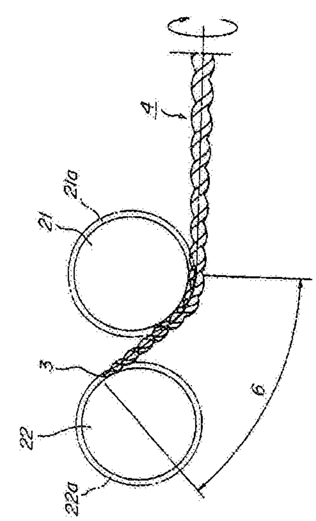
A	ファイル
1	針部
2	柄

3	先端
4	作業部
4 a	溝
4 b	切刃
5	シャンク
6	部分
2 1, 2 2	ピン
2 1 a, 2 2 a	溝

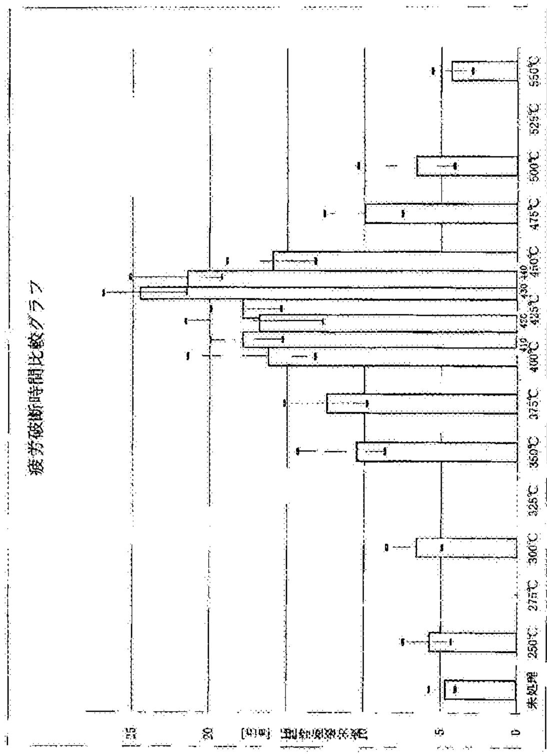
【図1】



【図2】



【図３】


疲労破断時間比較グラフ
未処理
250℃
275℃
300℃
325℃
350℃
375℃
400℃
425℃
450℃
475℃
500℃
525℃
550℃
0
5
20
25

フロントページの続き

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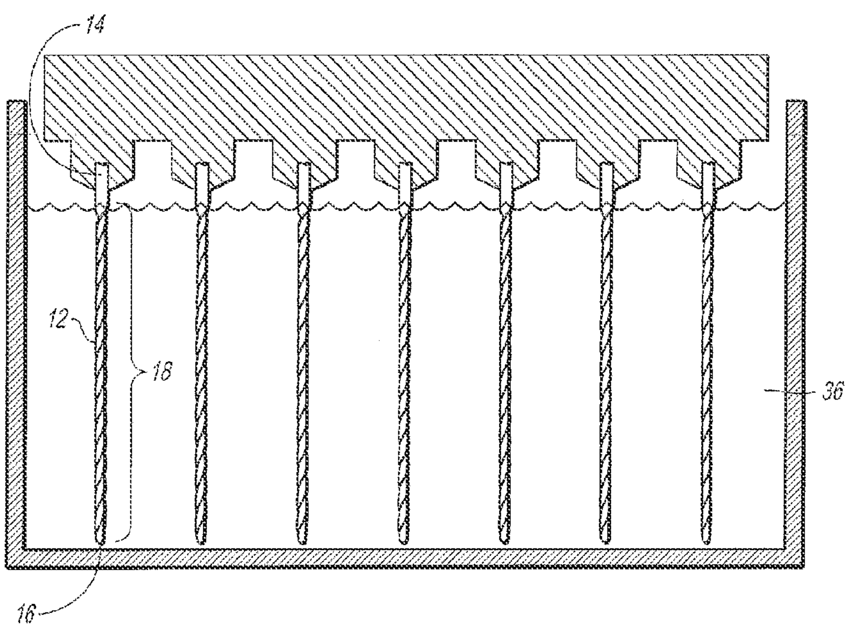
[Continued on next page]

(54) Title: METHODS FOR MANUFACTURING ENDODONTIC INSTRUMENTS



(57) Abstract: A method of manufacturing endodontic files involves a chemical milling process to yield endodontic files having a desired taper. The process involves the steps of (a) providing a metallic rod having a cutting portion with a polygonal cross section; (b) torsioning the rod so as to form helical cutting surfaces in the cutting portion of the metallic rod; and (c) chemically milling the cutting portion of the rod so as to taper the cutting portion. The rod may be formed of any desirable metallic material, for example stainless steel or a nickel-titanium alloy.

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METHODS FOR MANUFACTURING ENDODONTIC INSTRUMENTS

BACKGROUND OF THE INVENTION

1. The Field of the Invention

The invention is in the field of endodontics and particularly to endodontic instruments for use in preparing root canals to receive a filling material such as gutta percha. More particularly, the invention is in the field of processes for manufacturing endodontic files.

2. The Relevant Technology

When a root canal of a living tooth becomes infected or abscessed, discomfort and, in many cases, severe pain can result. In the early days of dentistry the only solution was to pull the tooth. More recently, however, dental practitioners have learned to successfully remove the pulp material forming the nerve of the tooth that has become infected and, after careful preparation of the canal that contained the nerve material, refill the canal with an inert filling material, such as gutta percha, permitting a patient to retain the tooth.

In order to achieve a successful root canal restoration, the dental practitioner must carefully and, as completely as possible, remove the infected pulp material of the tooth to prevent continued or future infection of surrounding tissues. The removal process typically includes shaping of the root canal so that it can be effectively and successfully filled and sealed with an inert material to eliminate the possibility of further infection occurring within the cleaned and shaped root canal.

Cleaning and shaping the root canal in preparation to filling with a material such as gutta percha is achieved by the use of metal files that include cutting surfaces for removing tissue in the root canal. The cutting surfaces are typically formed by helical flutes formed in the file. One or more helical cutting surfaces may be provided, which may be axially spaced as desired.

Some existing endodontic instruments and manufacturing methods are described in U.S. Pat. No. 4,934,934, U.S. Pat. No. 5,653,590, and U.S. Pat. No. 5,762,541.

Since root canals are seldom straight, often having bends and twists, at least some endodontic files are advantageously flexible. Currently preferred materials of construction include stainless steel, and more recently, nickel-titanium (Ni-Ti) alloys. Such materials, especially Ni-Ti alloys, exhibit good flexibility, resilience and strength, and are not likely to fail during use. Flexibility and strength are important to avoid file breakage during the cleaning process.

Endodontic instruments may be designed to be manually manipulated or to be fitted to a powered handpiece that provides rotation of the file during its use. An endodontic instrument that is intended for hand use is typically provided with an enlarged diameter plastic handle attached to the proximal end of the instrument, configured for easy manipulation between the thumb and forefinger of the dental practitioner. An instrument intended for use with a powered handpiece has a stem at the instrument proximal end configured to be removably received within a chuck of the powered handpiece, by which the instrument may then be rotated as desired by a dental practitioner.

One current method of manufacturing existing endodontic files is by a grinding operation. In the grinding operation, a metallic (typically a titanium alloy) rod is advanced past a rotating grinding wheel at a relatively slow feed rate. The depth of cut may be varied along the length of the rod in order to produce a tapered endodontic file. Such a method is disclosed in U.S. Patent No. 5,762,541.

Tapering and grinding the rod in this way requires complex and precise machining equipment with many moving parts to perform the grinding, rotating, and tapering of the rod. The method is quite complex and relatively expensive.

It would be an improvement in the art to provide an alternative method of manufacture capable of producing tapered endodontic instruments at a reasonable cost using machinery of reduced complexity.

BRIEF SUMMARY OF THE INVENTION

The present invention provides a method for manufacturing endodontic instruments. In one embodiment, the invention involves the steps of (a) providing a metallic rod having a cutting portion with a polygonal cross section; (b) torsioning the rod so as to form helical cutting surfaces in the cutting portion of the metallic rod; and

(c) chemically milling the cutting portion of the rod so as to form a cutting portion having a desired taper.

The metallic rod may have any of various polygonal cross sections, such as triangular, square, or any of various regular or irregular shapes bounded by straight or curved sides. The cutting portion of the metallic rod is typically torsioned, which may be accomplished by holding one end of the cutting portion stationary while twisting the opposite end. Torsioning the rod causes the apices of the polygon to be twisted to form helical cutting surfaces along the cutting portion of the rod.

It will be appreciated that cutting surfaces can be formed in any manner known in the art. For example, a non-tapered file (or even a file having an initial taper) can be formed by any known method (*e.g.*, grinding, cutting, particulate blasting, machining, laser micromachining, and the like) and then tapered using a chemical milling process to yield an endodontic instrument having a desired final taper.

Once an intermediate instrument having a cutting surface is formed, the cutting portion of the intermediate instrument is tapered by a chemical milling process. In one embodiment, the intermediate instrument is placed in a chemical bath. The bath composition may include hydrofluoric acid, nitric acid, water and a wetting agent. The longer the time that any specific portion of the file is in contact with the chemical milling solution, the greater will be the amount of metallic material stripped or removed from that portion. In one embodiment, at least the cutting portion of the metallic rod is submerged within the chemical milling composition and allowed to soak in the chemical milling solution. Allowing a soak time allows the chemical milling solution to remove the outer metal oxide layers of the cutting portion. Afterwards, the cutting portion is progressively withdrawn at a predetermined rate so as to result in a tapered cutting portion having a desired angle of taper. In another embodiment, no soak time is required, and the cutting portion may be progressively inserted and/or progressively withdrawn from the chemical milling solution, so as to result in a tapered cutting portion having a desired angle of taper.

Specific soak times (optional) and rates of insertion and/or withdrawal from the chemical milling composition depend on the chemical milling composition used, what type of material the intermediate file is formed from, the starting thickness of the rod, and the taper to be realized. When used, soak times preferably range from about 1 minute to about 1 hour, more preferably from about 3 minutes to about 30 minutes, and most preferably from about 5 minutes to about 20 minutes. Soaking removes the metal oxide layers that may otherwise interfere with the formation of a smooth taper.

Preferred rates of insertion and/or withdrawal range from about 0.1 mm per minute to about 6 mm per minute, more preferably from about 0.5 mm per minute to about 3 mm per minute and most preferably about 0.8 mm per minute to about 1.2 mm per minute.

These and other benefits, advantages and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the manner in which the above recited and other benefits, advantages and features of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 is a cross sectional view of a tooth having two roots, with an endodontic instrument being positioned in one of the roots;

Figure 2 is a perspective view of the cutting portion of an exemplary endodontic instrument;

Figures 3A-3G illustrates several different polygonal transverse cross sections through several exemplary endodontic instruments manufactured according to the method of the present invention;

Figure 4 is an exploded view of an apparatus for torsioning metallic rods for manufacturing endodontic instruments according to the present invention;

Figures 5A-5E depict exemplary torsioned metallic rods being chemically milled to taper the cutting portions of the metallic rods; and

Figures 6A and 6B depict exemplary tapered metallic rods.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A detailed description of the invention endodontic instruments and manufacturing methods will now be provided, with specific reference to figures illustrating preferred embodiments of the invention. It will be appreciated that like structures will be provided with like reference designations. To provide context for interpreting the scope of the invention, certain terms used throughout the application will now be defined.

As used herein, the terms endodontic "instrument" and endodontic "instruments" refer to endodontic files and other instruments used in a root canal or other endodontic procedure. The terms "intermediate file" or "intermediate instruments" shall refer to metallic substrates before being chemically milled.

As used herein, the terms "polygon" and "polygonal" refer to a shape that is closed and bounded by straight or curved sides. Non-limiting examples include a triangle, a square, a rectangle, a pentagon, a spherical triangle, or any other of various regular or irregular shapes.

As used herein, the terms "chemical milling," "stripping" and "etching" refer to a procedure whereby a material is worked or shaped by exposure to a chemical bath. While exposed to the chemical bath, the shaping occurs as bits of material are "stripped" or "etched" off because of the chemical action of the bath.

As used herein, the term "soak time" refers to the amount of time that the metallic rod is exposed to the chemical milling composition of the chemical bath while in a stationary state. Soaking the metallic rod is optional and removes metal oxide layers that may otherwise interfere with the formation of a smooth taper.

I. Exemplary Endodontic Instruments

Referring to Figures 1 and 2, an endodontic instrument 10 is illustrated which comprises a metallic rod 12 having a proximal end 14, and a distal end 16. At least a portion of the metallic rod 12 comprises a cutting portion 18 of the endodontic instrument, which is disposed between the proximal end 14 and the distal end 16. In this embodiment, the cutting portion 18 includes at least one helical cutting edge 20 that extends helically around metallic rod 12. A handle 19 may be provided adjacent the proximal end 14 of the metallic rod 12 in order to facilitate gripping of the endodontic instrument 10 by the user or a dental hand piece (*e.g.*, a reciprocating hand piece).

The cutting portion 18 is preferably tapered between the proximal end 14 and the distal end 16, with decreasing diameter or width toward the distal end 16. The taper may be continuous or incremental (i.e. stair stepped). The taper may be any amount desired, but is preferably between about 0.02 mm/mm and about 0.06 mm/mm. The specific taper of any instrument will depend on the intended use and dental practitioner preference. For example, a taper of 0.0225 mm/mm may be preferred when preparing a root canal that is to receive a gutta percha cone having a taper of about 0.02 mm/mm.

The cutting portion 18 may have a length of about 2 mm up to the full length of the rod 12, which may be as much as about 30 mm or more. In the illustrated embodiment, the cutting portion 18 has a length sufficient to extend substantially the full depth of a tooth root canal as illustrated in Figure 1. It will be appreciated, however, that the cutting portion may terminate before reaching the tip 16, as in a coronal file, or comprise a small length near the tip 16 as in an apical file.

The cross sectional configuration of the cutting portion 18 of the instrument illustrated in Figures 1 and 2 is triangular and is composed of three linear sides, as best seen in Figure 3A. The apices 22a of the triangle form cutting edges 20. The cutting portion 18 may be of any polygonal cross section such that when the rod is torsioned, cutting edges 20 are formed.

Several non-limiting examples of suitable polygonal cross sections are illustrated in figures 3A-3G. Figure 3A illustrates a triangular cross section in which apices 22a form three cutting edges 20. Figure 3B illustrates a square cross section in which line intersections 22b form four cutting edges. Figure 3C illustrates a cross section bounded by four curved sides, two of which are concave and two of which are convex. The intersections 22c between the convex and concave sides form four cutting edges.

Figures 3D and 3E illustrate alternative spherical triangular cross sections, with the triangle cross section of Figure 3D having concave surfaces between the apices 22d of the triangle and with the triangle cross section of Figure 3E having convex surfaces between apices 22e of the triangle.

Figure 3F illustrates a cross section bounded by a combination of four concavely curved sides separated by four straight sides. The intersection 22f between the straight and curved sides form eight cutting edges. Figure 3G illustrates a cross section of an irregular polygon bounded by three concavely curved sides separated by three convexly curved sides. The intersections 22g between the six curved sides yield six cutting surfaces.

When torsioned, the apices or edges 22a-g of the various cross sections form helical cutting edges 20.

II. Method of Manufacture

Figures 4 and 5A-5E illustrate an exemplary method of manufacturing endodontic instruments according to the present invention. As will be further described below, the method involves a unique process which has been found to efficiently produce endodontic instruments of the type described, from a metallic wire. The metallic wire may be formed of any suitable metallic material, for example stainless steel, a nickel-titanium alloy (Ni-Ti), nickel-titanium-chromium alloy, a nickel-titanium-copper alloy, a nickel-titanium-niobium alloy, or any other superelastic metallic material. Although any suitable metallic material may be used, nickel-titanium alloys are preferred because they are strong yet flexible and resilient. The Ni-Ti alloy preferably has a titanium content in a range of about 20% to about 80%, more preferably in a range of about 30% to about 70%, and most preferably in a range of about 40% to about 60%. In one embodiment, the balance of the alloy may comprise nickel and small amounts of other ingredients which do not adversely affect the suitability of the material for use as an endodontic instrument.

The wire from which the endodontic instrument is to be manufactured may be supplied already drawn in a selected polygonal cross sectional shape. Alternatively, the wire may be supplied in a circular cross section and then shaped to the desired cross section by processes known to those of skill in the art. With regard to wire thickness, endodontic instruments are sized in accordance with established standards, which range from a thickness at the distal end 16 of 1.4 mm (size 140) to a thickness at the distal end 16 of 0.06 mm (size 06).

Figure 4 depicts an exemplary apparatus (in exploded view) for performing the first steps of an exemplary method of manufacture. The exemplary apparatus includes a collet 26, housing cap 28, insert 30, insert housing 32, and coil assembly 34. The continuous wire is first cut to a desired length. The wire length 24 is positioned to extend out of collet 26, which may be of well known construction. Wire length 24 extends out collet 26 and into insert 30, which is nearly surrounded by housing cap 28. In order to receive wire 24, insert 30 includes a passage through its center having the same cross section shape as wire 24. The passage is slightly larger than wire 24 so as to allow clearance for the wire 24 to be received within insert 30. The ends of the passage may be flared so as to facilitate inserting the wire 24 through the passage.

Insert 30 is formed of a hard material, preferably a ceramic such as cermet. The insert 30 and housing cap 28 are received within insert housing 32. Coil assembly 34 (for heating) surrounds the insert housing and insert. The wire 24 is heated, and then torsioned. Torsion is accomplished by turning and retracting the collet 26.

The wire 24 may be heated by any known method prior to torsioning. Examples of suitable heating methods include electrical resistive heating, convection heating, direct heating by a torch, or RF high frequency induction heating. RF high frequency induction heating is a preferred heating method. In RF high frequency induction heating, the wire 24 is heated while positioned through coil assembly 34 into which an electrical current is fed. The electrical current and coil assembly 34 create a heating field that may be focused on the wire 24 as it is positioned through the coil assembly 34. Heating wire 24 makes it easier to subsequently torsion the wire.

In order to avoid oxidation of the metal wire 24 while heating, when possible, the heating is preferably performed in an inert environment, such as under a noble gas environment. Examples of inert gases that may be used include, but are not limited to, helium, argon and even nitrogen in those cases where the heated metal does not adversely react with nitrogen to form a brittle product. Because allows of titanium can react with nitrogen to form titanium nitride, which is brittle, it may not be advantageous to use nitrogen gas when manufacturing an endodontic file from titanium alloys. Nitrogen works well with other metals, such as stainless steel.

Insert 30 and collet 26 function together to torsion wire 24. While both ends of the wire 24 are gripped, collet 26 turns, which twists the wire 24 about its longitudinal axis. This causes the apices or intersections 22 of the polygonal cross section of the wire 24 to form helical cutting edges 20 as described above with respect to Figures 1 and 2. Collet 26 is retracted either during or after turning, removing wire 24 from insert 30.

Once a length of wire 24 has been cut and torsioned to form a metallic rod 12, the rod is ready to be tapered. Although the current example tapers the rod after torsioning, the order is not critical, and the torsioning process could be performed after tapering. In either case, the cutting portion 18 is tapered by chemically milling at least the cutting portion 18 of the metallic rod 12. The cutting portion 18 of rod 12 is chemically milled by placing the cutting portion 18 in a chemical milling composition. The composition may contain an acid, water, and a wetting agent. Suitable acids include hydrofluoric acid and nitric acid. One currently preferred composition includes about 10% hydrofluoric acid, about 20% nitric acid, about 0.8% Dapco 6001, a wetting agent, and the balance water. Percentages are given as percent by volume.

It is preferable to maintain the chemical milling solution at a temperature between about 15° and about 105°C, more preferably about 25° and about 90°C, and most preferably about 35° and about 65°C.

In addition, it is preferable to stir the chemical milling solution. Suitable stirring rates include about 1 to 1200 RPM.

The cutting portion 18 of each rod 12 is tapered by progressively inserting and/or withdrawing the cutting portion 18 from the chemical milling composition 36. Figures 5A-5E illustrate tapering by progressively withdrawing the cutting portion 18. The rate at which the rod 12 is inserted and/or withdrawn from the composition 36 will depend on the chemical milling composition 36 used, what type of material the rod 12 is formed of, the starting thickness of the rod 12, and the taper to be realized. Slower rates of insertion and/or withdrawal result in longer treatment times, which generally result in greater tapering of the cutting portion 18.

In one embodiment, it may be desirable to soak at least said cutting portion in said chemical milling composition for a predetermined soak time prior to withdrawal from the chemical milling composition. When used, preferably soak times are from between about 1 minute and about 60 minutes, more preferably 3 minutes to about 30 minutes, and most preferably about 5 minutes to about 20 minutes. Soaking strips off the outer metal oxide layers, which may result in a smoother taper.

The amount of metallic material stripped away by the milling composition is proportional to the treatment time of any specific portion of the metallic rod. In order to strip or etch more metal from the distal end 16 of the endodontic file 10, the distal end 16 of the endodontic instrument 10 will be submerged longer in the composition 36 than the rest of the cutting portion 18 of rod 12. The cutting portion 18 of rod 12 is progressively inserted and/or withdrawn from the composition 36 at a predetermined rate, resulting in a metallic rod with a tapered cutting portion 18.

The metallic rod 12 may be inserted and/or withdrawn at any desired rate, although it is preferable to insert and/or withdraw the rod 12 at a rate of between about 0.1 mm per minute to about 6 mm per minute, more preferably about 0.5 mm per minute to about 3 mm per minute and most preferably about 0.8 mm per minute to about 1.2 mm per minute. The specific rate of insertion and/or withdrawal depends on the actual chemical milling composition 36 used, what type of material the rod 12 is formed of, the starting thickness of the rod 12, and the taper to be realized. One of ordinary skill will be able to select a rate that will yield a desired taper for a given metallic rod.

The metallic rod 12 is preferably inserted and/or withdrawn continuously from the chemical milling composition 36 so as to form a smooth taper, although the rod 12 could alternately be inserted and/or withdrawn incrementally from the chemical milling composition. Incremental insertion and/or withdrawal results in a stepped taper rather than a smooth taper, which may be desirable in some applications.

Figures 5A-5E illustrate different stages during the chemical milling process where the rod 12 is progressively withdrawn from the milling composition 36. Figure 5A illustrates a state at the beginning of the chemical milling process where the entire cutting portion 18 of each metallic rod 12 is submerged in the composition 36. Figure 5B illustrates an intermediate stage during the chemical milling process where the cutting portion 18 of rod 12 has been partially withdrawn from milling composition 36. Figure 5C illustrates a more advanced intermediate stage where cutting portion 18 has been further withdrawn, while figure 5D illustrates a yet more advanced intermediate stage where cutting portion 18 has been almost completely withdrawn. Figure 5E illustrates a stage where the cutting portion 18 has been completely withdrawn from milling composition 36.

Figures 6A-6B illustrate exemplary endodontic instruments 10 having continuous tapered cutting portions 18. The instrument illustrated in figure 6A includes a taper of about 0.02 mm/mm while that illustrated in figure 6B includes a taper of about 0.06 mm/mm.

After chemical milling, the rod 12 is then further processed in a conventional manner to form the completed instrument as illustrated for example in Figure 1 (*e.g.* fitting a handle or stem 19 to proximal end 14, optionally surface finishing the rod 12, etc). The process as described and claimed has been found to produce inexpensive high quality endodontic instruments. In addition, with at least some polygonal cross sections, tapering by chemical milling has been found to result in cutting surfaces which sharpen as they are chemically milled. The process is suitable for commercial application to manufacture as few or as many instruments at a time as desired, and does not require the complex mechanical milling machinery required by existing manufacturing methods.

It will be appreciated that the cutting surfaces or edges of the endodontic instruments may be formed by other means known in the art instead of torsioning. For example, they may be formed by cutting, grinding, grit blasting, machining, laser micromachining, and the like.

It will also be appreciated that the present claimed invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A method of manufacturing an endodontic instrument for use in performing an endodontic procedure, comprising:

(a) providing an intermediate instrument having a cutting portion; and

(b) chemically milling at least said cutting portion of said intermediate instrument so as to yield an endodontic instrument having a desired taper.

2. The method as recited in claim 1, wherein at least a portion of said cutting portion is formed by (c) torsioning a metallic rod having a polygonal cross section so as to form helical cutting edges in said cutting portion.

3. The method as recited in claim 2, wherein said polygonal cross section is at least one of a square, a triangle, a polygon having straight surfaces, a polygon having concave surfaces, or a polygon having convex surfaces.

4. The method as recited in claim 2, wherein said metallic rod is heated prior to and/or during torsioning.

5. The method as recited in claim 4, wherein said metallic rod is heated by RF high frequency induction heating.

6. The method as recited in claim 4, wherein said heating is performed in an inert environment.

7. The method as recited in claim 6, wherein said inert environment comprises at least one noble gas.

8. The method as recited in claim 2, wherein (c) is performed prior to (b).

9. The method as recited in claim 2, wherein (b) is performed prior to (c).

10. The method as recited in claim 1, wherein at least a portion of said cutting portion is formed by at least one of cutting, grinding, laser micromachining, machining, or grit blasting.

11. The method as recited in claim 1, wherein said chemical milling is performed by progressively inserting and/or withdrawing said cutting portion from said chemical milling composition at a predetermined rate.

12. The method as recited in claim 11, wherein said chemical milling composition is acidic.

13. The method as recited in claim 12, wherein said chemical milling composition comprises one or more of hydrofluoric acid, nitric acid, water, and a wetting agent.

14. The method as recited in claim 11, wherein said chemical milling composition is maintained at a temperature between about 15° and about 105°C.

15. The method as recited in claim 11, wherein said chemical milling composition is maintained at a temperature between about 25° and about 90°C.

16. The method as recited in claim 11, wherein said chemical milling composition is maintained at a temperature between about 35° and about 65°C.

17. The method as recited in claim 11, further comprising soaking at least said cutting portion in said chemical milling composition for a predetermined soak time of between about 1 minute and about 60 minutes.

18. The method as recited in claim 17, wherein said soak time is between about 3 minutes and about 30 minutes.

19. The method as recited in claim 17, wherein said soak time is between about 5 minutes and about 20 minutes.

20. The method as recited in claim 11, wherein said cutting portion of said rod is inserted and/or withdrawn from said chemical milling composition at a rate of between about 0.1 mm per minute and about 6 mm per minute.

21. The method as recited in claim 11, wherein said cutting portion of said rod is inserted and/or withdrawn from said chemical milling composition at a rate of between about 0.5 mm per minute and about 3 mm per minute.

22. The method as recited in claim 11, wherein said cutting portion of said rod is inserted and/or withdrawn from said chemical milling composition at a rate of between about 0.8 mm per minute and about 1.2 mm per minute.

23. The method as recited in claim 1, wherein said chemically milling produces a cutting portion taper of between about 0.02 mm/mm and about 0.06 mm/mm.

24. The method as recited in claim 23, wherein said chemically milling produces a cutting portion taper of about 0.0225 mm/mm.

25. The method as recited in claim 1, wherein said chemically milling sharpens the cutting surfaces as they are chemically milled.

26. The method as recited in claim 1, wherein said chemically milling comprises chemically milling a plurality of intermediate instruments simultaneously.

27. An endodontic instrument adapted for use in performing an endodontic procedure manufactured according to claim 1.

28. An endodontic instrument adapted for use in performing an endodontic procedure, comprising:

a metallic rod, said rod having a proximal end and a distal end so as to define a tapered cutting portion adjacent said distal end; and

at least one helical cutting surface extending around said cutting portion,

said endodontic instrument formed by:

(a) providing a metallic rod having a cutting portion with a polygonal cross section;

(b) torsioning said rod so as to form helical cutting edges in said cutting portion with a polygonal cross section; and

(c) chemically milling said cutting portion of said rod so as to taper said cutting portion.

29. An endodontic instrument as recited in claim 28, wherein said instrument is formed of a nickel-titanium alloy.

30. An endodontic instrument as recited in claim 29, wherein said nickel-titanium alloy has a titanium content between about 20% and about 80%.

31. An endodontic instrument as recited in claim 29, wherein said nickel-titanium alloy has a titanium content between about 30% and about 70%.

32. An endodontic instrument as recited in claim 29, wherein said nickel-titanium alloy has a titanium content between about 40% and about 60%.

33. An endodontic instrument as recited in claim 28, wherein said polygonal cross section is triangular.

34. An endodontic instrument as recited in claim 28, wherein said polygonal cross section is square.

35. An endodontic instrument as recited in claim 28, wherein said polygonal cross section is a spherical triangle.

36. An endodontic instrument as recited in claim 28, wherein said polygonal cross section is bounded by a plurality of curved sides.

37. An endodontic instrument as recited in claim 28, wherein said polygonal cross section is bounded by a combination of curved and straight sides.

38. An endodontic instrument as recited in claim 28, wherein said polygonal cross section is an irregular polygon bounded by at least one of concavely or convexly curved sides.

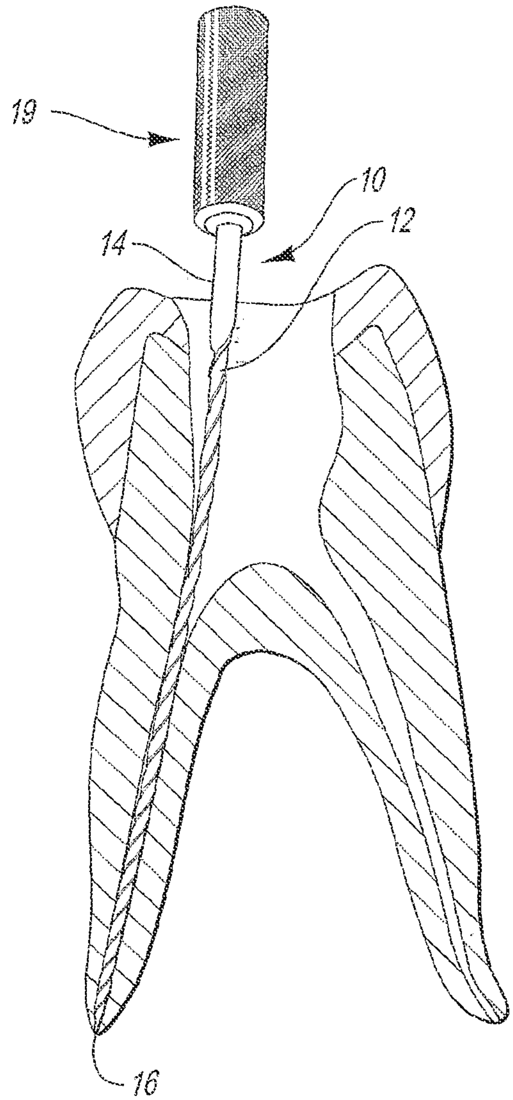

FIG. 1

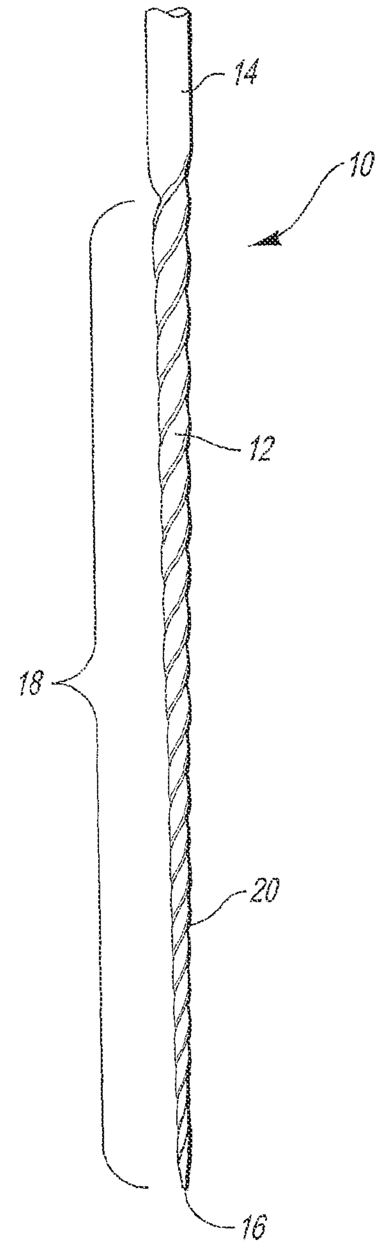

FIG. 2

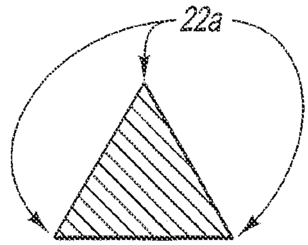

FIG. 3A

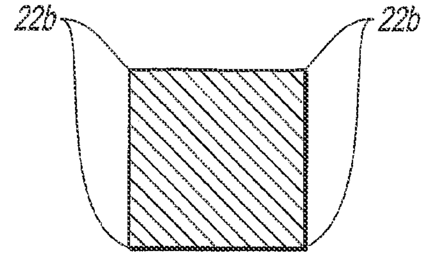

FIG. 3B

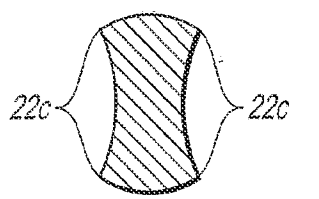

FIG. 3C

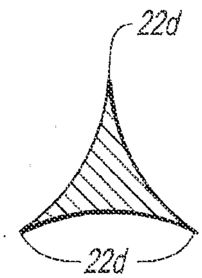

FIG. 3D

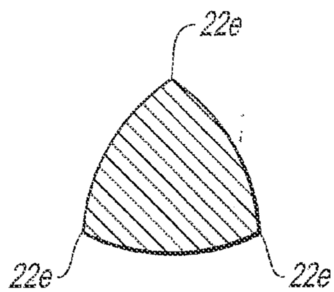

FIG. 3E

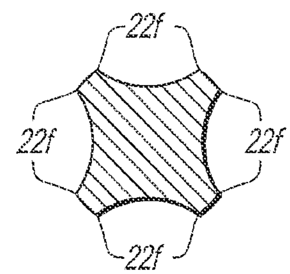

FIG. 3F

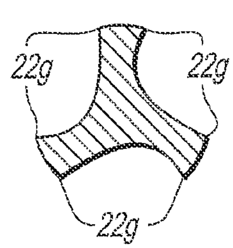

FIG. 3G

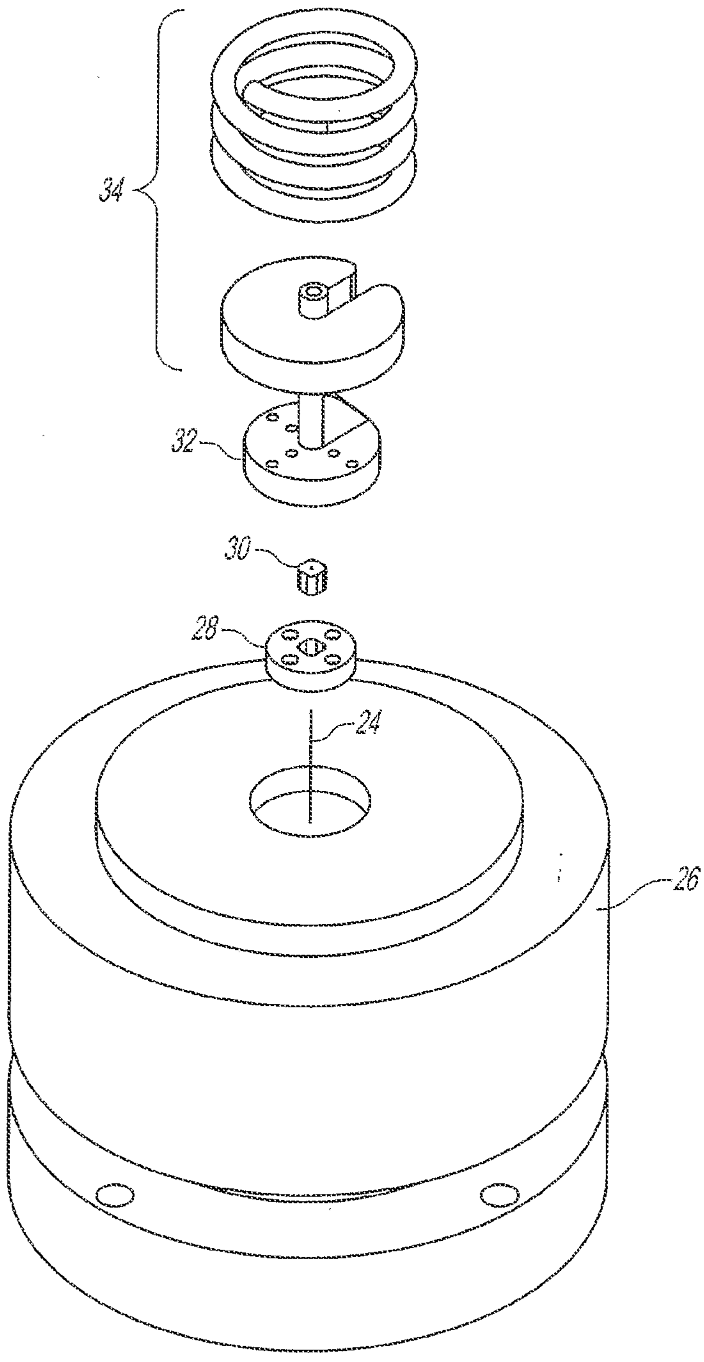

FIG. 4

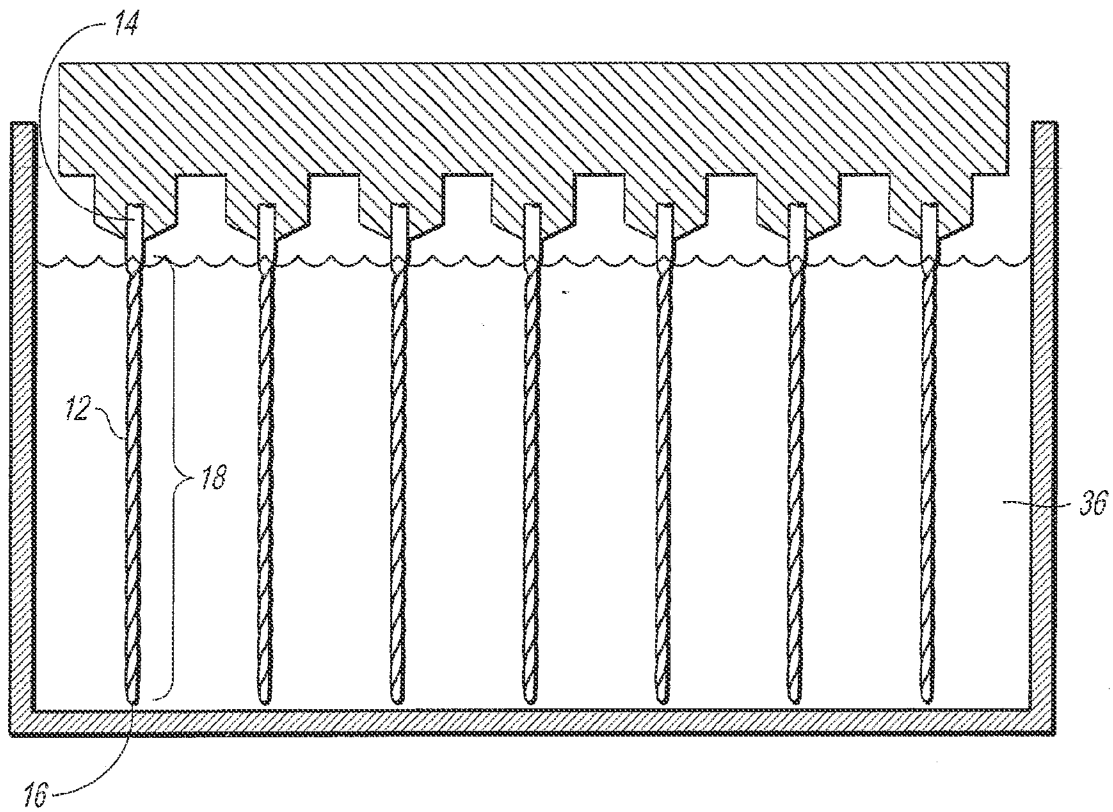

FIG. 5A

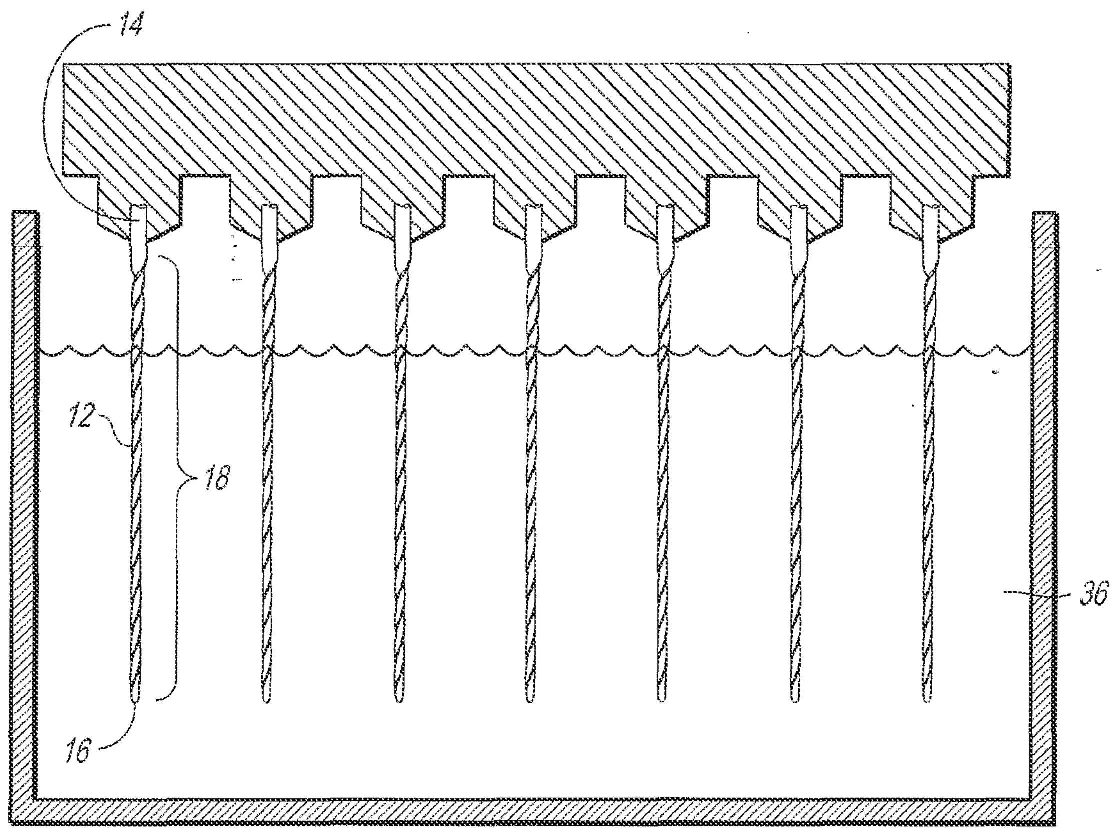

FIG. 5B

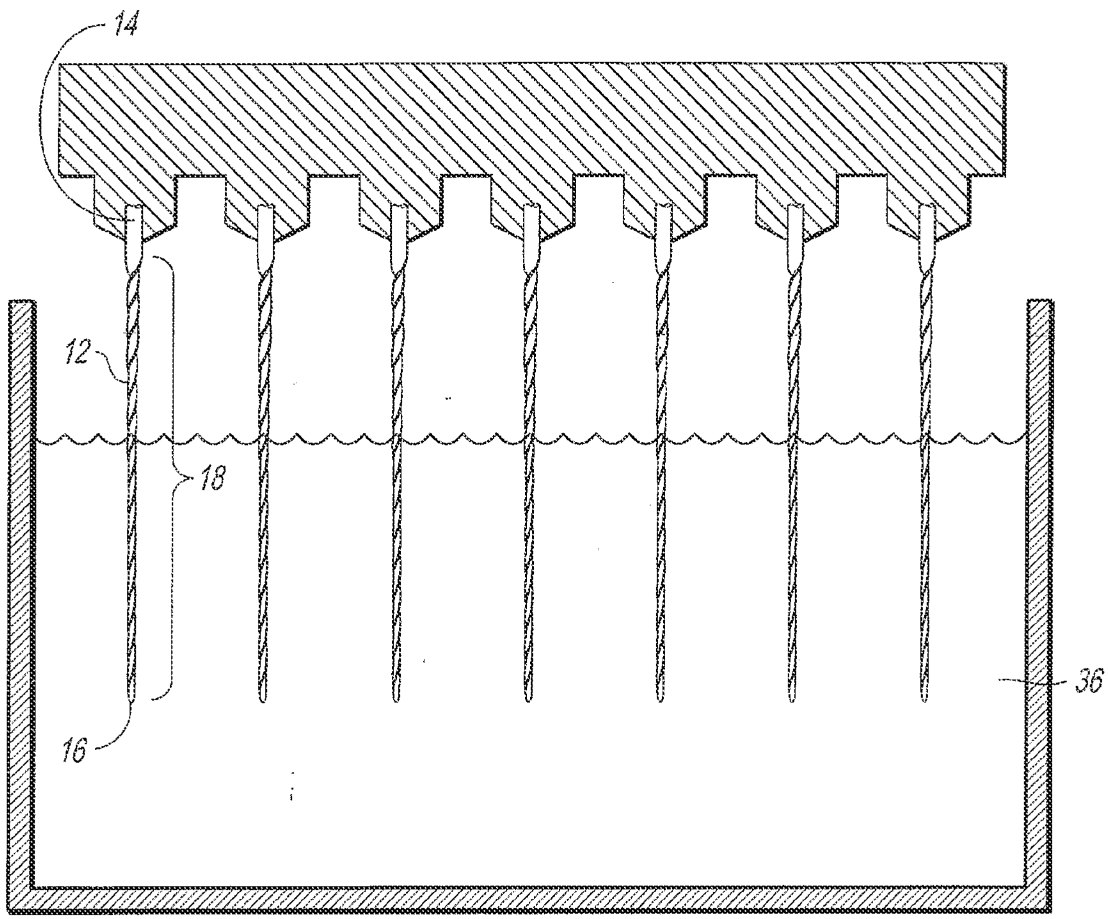

FIG. 5C

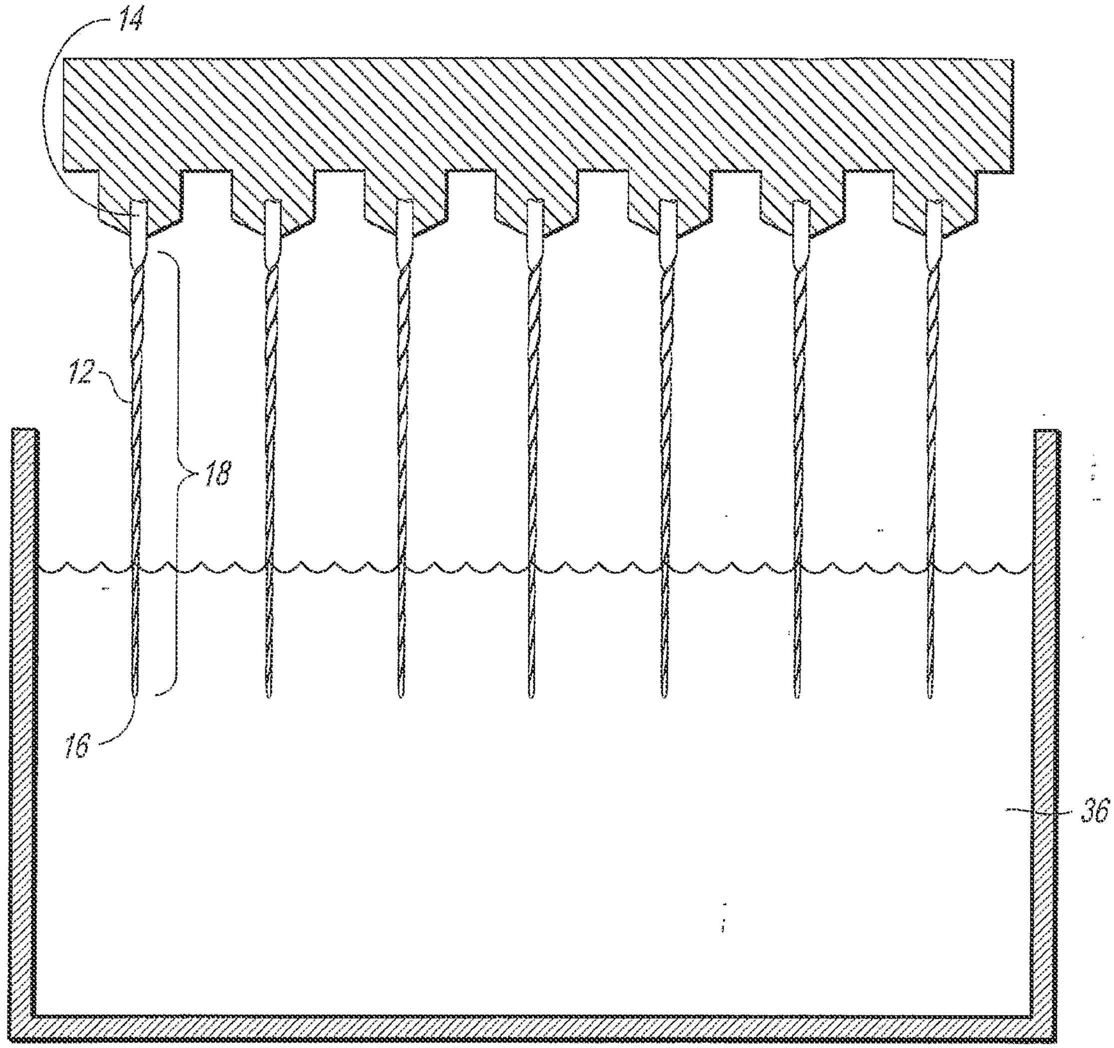

FIG. 5D

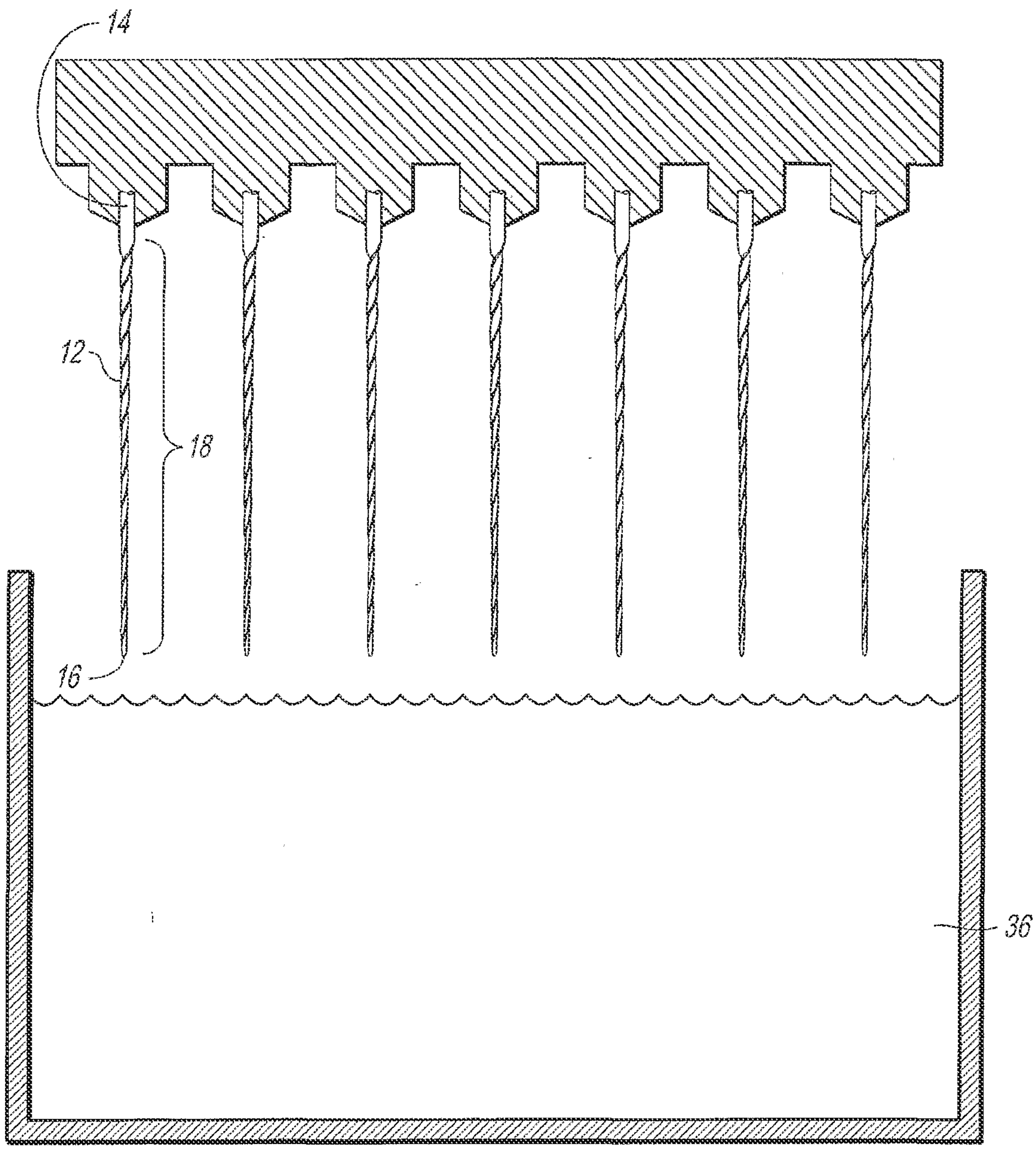

FIG. 5E

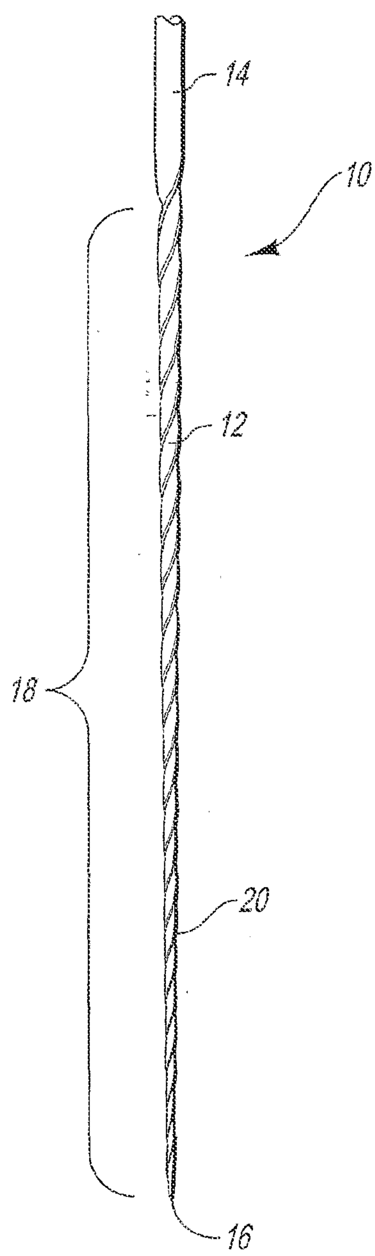

FIG. 6A

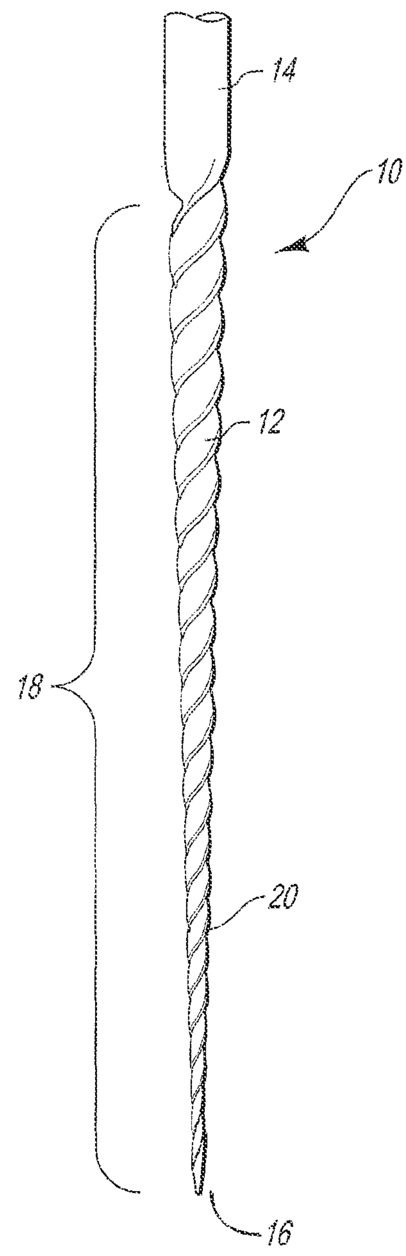

FIG. 6B

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 115207.00002	**FOR FURTHER ACTION** See item 4 below	
International application No. PCT/US2005/019947	International filing date *(day/month/year)* 07 June 2005 (07.06.2005)	Priority date *(day/month/year)* 08 June 2004 (08.06.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant LUEBKE, Neil, Hamilton		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

   - [x] Box No. I — Basis of the report
   - [ ] Box No. II — Priority
   - [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV — Lack of unity of invention
   - [x] Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI — Certain documents cited
   - [ ] Box No. VII — Certain defects in the international application
   - [ ] Box No. VIII — Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 08 December 2006 (08.12.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 14 NOV 2005
WIPO PCT

To:
RICHARD T. ROCHE
QUARLES & BRADY LLP
411 EAST WISCONSIN AVENUE
MILWAUKEE, WI 53202

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference 115207.00002		Date of mailing (*day/month/year*) 10 NOV 2005 **FOR FURTHER ACTION** See paragraph 2 below
International application No. PCT/US05/19947	International filing date (*day/month/year*) 07 June 2005 (07.06.2005)	Priority date (*day/month/year*) 08 June 2004 (08.06.2004)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61C 5/02 and US Cl.: 433/102		
Applicant LUEBKE, NEIL HAMILTON		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis(b)* that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	03 November 2005 (03.11.2005)	For Kevin P Shaver Telephone No. (571) 272-4720

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/19947

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into ______, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in electronic form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Form PCT/ISA/237(Box No. I) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/19947

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-19	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-19	NO
Industrial applicability (IA)	Claims 1-19	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-3, 6, 10, 13, 15-17, and 19 lack an inventive step under PCT Article 33(3) as being obvious over Sachdeva in view of Fishcer. Sachdeva discloses the claimed endodontic instrument except that the heat-treatment of the shank occurring in an atmosphere of essentially un-reactive gas. (See Specifcation).

Claims 4-5, 7-9, 12, 14, and 18 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Besselink et al. Sachdeva in view of Fishcer discloses the claimed invention with the exception of the range of values associated with diameter of the shank,temperature of heat treatment, time for heat treatment, and ratio of titanium to nickel. (See specification)

Claim 11 lacks an inventive step under PCT Article 33(3) as being obvious over Sachdeva in view of Fischer. Sachdeva in view of Fischer discloses the claimed invention with the exception of the angle of the shank. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shank so that it maintains a deformation of greater than 10 degrees after a 45 degree torque, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 1-19 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Electronic Patent Application Fee Transmittal

Application Number:	14522013
Filing Date:	23-Oct-2014
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Richard T. Roche/Beth Erlitz
Attorney Docket Number:	115207.00014

Filed as Large Entity

Filing Fees for **Utility under 35 USC 111(a)**

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($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
	Total in USD ($)			**180**

Electronic Acknowledgement Receipt

EFS ID:	23012147
Application Number:	14522013
International Application Number:	
Confirmation Number:	9570
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Customer Number:	26710
Filer:	Richard T. Roche/Beth Erlitz
Filer Authorized By:	Richard T. Roche
Attorney Docket Number:	115207.00014
Receipt Date:	24-JUL-2015
Filing Date:	23-OCT-2014
Time Stamp:	09:48:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	8117
Deposit Account	170055
Authorized User	ROCHE, RICHARD T.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	11520700014SupplDSJuly2015.pdf	614227 87d11e383e7ad59a915bc46047eb5a90e0afc8a2	no	7
Warnings:					
Information:					
2	Foreign Reference	JP2006149675.pdf	8376580 d1a1d4ac6f6cde25e1cafeabfdb12ea307007afc	no	23
Warnings:					
Information:					
3	Foreign Reference	WO2004100818.pdf	23204715 dde3566fa9d930ba444c7da6c157022d1b28527d	no	26
Warnings:					
Information:					
4	Non Patent Literature	Alpati2006.pdf	4951673 0c7541d2d3feb23c2366649794b73b99b934fe35	no	76
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5	Non Patent Literature	Endo1994.pdf	11199875 bad34d4499d1054511000131cf572b97a3060a12	no	14
Warnings:					
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6	Non Patent Literature	Lugscheider2002.pdf	702179 bf83d0d65d682a97360afc9938714f4dcb441008	no	6
Warnings:					
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7	Non Patent Literature	Miyazaki1982.pdf	2676294 4c77a1be51c72d203cbecc7d6841c1f07bbb568e	no	6
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8	Non Patent Literature	Pelton2000.pdf	1609400 3dc69c734e69a1b2892c8385d26656fe078dabf5	no	12
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Information:					
9	Non Patent Literature	Schafer2003.pdf	3789627 91c944306590a2a56adc74f559d24e48c42c0186	no	7
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Information:					
10	Non Patent Literature	Stokes1999.pdf	7209983 eef2885505bd90180d3108b2e6b66289cb582b74	no	4
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Information:					
11	Non Patent Literature	Tripi2003.pdf	917409 d030b1f1395e497e73ac37f4c5ff31eb28f3da0f	no	3
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Information:					
12	Non Patent Literature	ISO3630-1-1992.pdf	5614160 be055b39fa72fa217f658bd525f7ebf06d64afab	no	28
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13	Non Patent Literature	ISO3630-1-2008.pdf	6482198 0ea51ca4e39f8486858f667d7a0176aa6391ec70	no	26
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14	Other Reference-Patent/App/Search documents	PCTUS2005019947IPRP20061208.pdf	1862390 7de0125d25021ae4c63a0d5cd29e1053c72433b4	no	4
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15	Other Reference-Patent/App/Search documents	EP05756629SupplSearchReport20121026.pdf	5230470 69eca15570455f79971906c84ae432ef7fbcaef2	no	6
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16	Other Reference-Patent/App/Search documents	EP05756629ExamReport20130124.pdf	1752541 f2eab58bf311df7723dcd3caeaa0b9109300522e	no	8
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17	Other Reference-Patent/App/Search documents	PetitionforInterPartesReviewIPR201500632Jan2015.pdf	475196 a8e544d08be45e9897e6e55617ccd34cc78093db	no	67
Warnings:					
Information:					
18	Other Reference-Patent/App/Search documents	DeclarationGoldberg20150130.pdf	4702124 94a7988dd526aeb131ff393bd7b6b3da58d3f493	no	100
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Information:					
19	Other Reference-Patent/App/Search documents	USDCTennesseeAnswerAndCounterclaims20140806.pdf	163922 bfb45015edb529069eb5f45d4ad49ea2d0176adb	no	13
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20	Other Reference-Patent/App/Search documents	USDCTennesseeComplaintPatentInfringement20140624.pdf	184693 8d6e0d70018e35f5a9e3338285fc6e22ce8fa5d5	no	9
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21	Other Reference-Patent/App/Search documents	USDCTennesseeAnswerToCounterclaims20140902.pdf	172030 d355bc2a469c5886a60db2d9d60dae3beec4adcb	no	5
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22	Other Reference-Patent/App/Search documents	USDCTennesseeAnswerToCounterclaims20140919.pdf	174769 6edb15833ba7d438f9f0f7a1d5b6152aab1009c4	no	5
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23	Other Reference-Patent/App/Search documents	PetitionforInterPartesReviewIPR201501476June2015.pdf	221028 e50c047ca09211c6994b983e31e446b9c39f3a1a	no	32
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24	Other Reference-Patent/App/Search documents	DeclarationGoldberg20150625.pdf	715981 4b6aeade8bb931be38fd4f1428eb88b263a9a4b9	no	39
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25	Other Reference-Patent/App/Search documents	USDCTennesseeAmendedComplaintPatentInfringement20140815.pdf	189008 06c53ed220fc56059c55d01dbad3d6c18acba513	no	10
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26	Other Reference-Patent/App/Search documents	USDCTennesseeAnswerToAmendedComplaintCounterclaims20140902.pdf	147749 4144e350e6e9172013dd8d3d5172a08a1232a07e	no	13
Warnings:					
Information:					
27	Fee Worksheet (SB06)	fee-info.pdf	30432 695ba5cb1c3fd803d1e3aafa94c74184b0811d67	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	93370653	

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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.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14522013
	Filing Date	2014-10-23
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

U.S.PATENTS Remove

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
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	1	20060115786	A1	2006-06-01	Matsutani et al.	

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	1	2004344717	JP	A	2004-11-29	Mani, Inc.		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Application Number	14522013
	Filing Date	2014-10-23
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

	1	BAHIA, et al., Fatigue Behaviour of Nickel-Titanium Superelastic Wires and Endodontic Instruments, Fatigue & Fracture of Engineering Materials & Structures, 2006, 29(7):518-523	☐
	2	DREXEL, et al., The Effects of Cold Work and Heat Treatment on the Properties of Nitinol Wire, Proceedings of the International Conference on Shape Memory and Superelastic Technologies, May 7-11, 2006, pp. 447-454	☐
	3	PELTON, et al., The Physical Metallurgy of Nitinol for Medical Applications, JOM, 2003, 55(5):33-37	☐
	4	TESTARELLI, et al., Bending Properties of a New Nickel-Titanium Alloy with a Lower Percent by Weight of Nickel, Journal of Endodontics, 2011, 37(9):1293-1295	☐
	5	ProFile ISO Rotary Files Product Information and Material Safety Data Sheet for Nickel Titanium Wire: 'NITINOL 55', http://www.tulsadentalspecialties.com/default/endodontics/RotaryFiles/ProFileISO.aspx [Exhibit 1035 to the Petition for Post-Grant Review, Case No. PGR2015-00019, website was accessed July 22, 2015]	☐
	6	Petition for Post-Grant Review of U.S. Patent No. 8,876,991 B2, in the United States Patent and Trademark Office Before the Patent Trial and Appeal Board, Case No. PGR2015-00019, August 3, 2015	☐
	7	Declaration of A. Jon Goldberg, Exhibit 1002 to the Petition for Post-Grant Review of U.S. Patent No. 8,876,991 B2, in the United States Patent and Trademark Office Before the Patent Trial and Appeal Board, Case No. PGR2015-00019, August 3, 2015	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14522013
	Filing Date	2014-10-23
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2015-08-24
Name/Print	Richard T. Roche	Registration Number	38,599

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JAPAN PATENT OFFICE

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Application Number:	2004-344717
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is	JP 2004-344717
Applicant(s):	Mani, Inc.

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December 9, 2005

Commissioner,
Japan Patent Office

Makoto Nakajima

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[Document name]	Scope of patent claim 1
[Document name]	Detailed description 1
[Document name]	Drawing 1
[Document name]	Abstract 1
[General power of attorney no.]	9007482

[Document Name] Scope of Patent Claims

(CLAIM 1)
Shaft-shaped root canal treatment apparatus made of nickel-titanium alloy, on which a work portion of a designated length from the tip is formed and on which a shank is formed continuously with said work portion, the root canal treatment apparatus is characterized in that at least a portion or the entirety of the work portion is subjected to heat treatment focused on resistance to rotating fatigue.

[Document name] DETAILED DESCRIPTION OF THE INVENTION
[Title of the invention] Root Canal Treatment Apparatus
(TECHNICAL FIELD)
(0001)
This invention relates to a root canal treatment apparatus for dental care, particularly to a root canal treatment apparatus that has improved resistance to wear arising from rotation of a root canal treatment apparatus that performs the intended treatment by rotating, entering and exiting in the length direction, or repeatedly switching between forward and reverse by roughly 1/4 of a rotation.
(BACKGROUND ART)
(0002)
Examples of apparatuses for the treatment of the root canal of a tooth by rotation that shape the root canal by cutting include a file and a reamer. These root canal treatment apparatuses are comprised of a member shaped by forming a work portion provided with a cutting edge or projection on a finely tapered axial rod in accordance with the treatment objective, or forming a work portion by shaping a tapered axial rod into a spiral shape. Furthermore, depending on the model, a handle or grip allowing the doctor to grasp and operate the apparatus may be integrally attached to the end of the aforesaid member to allow the doctor to directly operate the apparatus or grip the apparatus by means of the chuck of a handpiece or the like.
(0003)
Root canals are very fine, and there is considerable disparity in their shape and thickness from person to person. For this reason, even the same model of root canal treatment apparatus comes in a variety of models of differing thickness. For example, if using a file to form the root canal by cutting, it is necessary to deform the file according to the shape of the root canal in order to keep from damaging the tissue surrounding the root canal, i.e. it is necessary for the file to have appropriate elasticity.
(0004)
The technology in Patent Literature 1 has been proposed as a root canal treatment apparatus with high elasticity and shape restorability of the kind described above. This technology relates to a root canal treatment apparatus manufactured by forming a work portion on shape memory-treated axial rod material having superelastic property by performing removal processing while retaining at below the shape memory treatment temperature.
(0005)
In the aforesaid root canal treatment apparatus, the axial rod on which a work portion has been formed flexibly deforms supply according to applied external force and rapidly regains its original shape when the external force is removed. For this reason, it is able to follow the shape of the root canal very closely, making it possible to form a root canal to a high level of precision.
(0006)
(PATENT LITERATURE 1) Japanese Patent Publication No. 3375765
(DISCLOSURE OF THE INVENTION)
(PROBLEM TO BE SOLVED BY THE INVENTION)
(0007)
In the root canal treatment apparatus in the aforesaid Patent Literature 1, the entire length of the work portion has uniform superelastic property, for which reason when the work portion is bent, the work portion on the free end attempts to return to its original shape, producing stress as the tip is inserted into the root canal and bent during root canal treatment. In particular, when shaping the root canal, because rotation occurs with primarily the tip of the work portion bent, flex stress acts on the work portion, producing an issue whereby there is a higher likelihood of damaging the narrow tip portion.
(0008)
The objective of this invention is to provide a root canal treatment apparatus that is unlikely to become damaged in the event that flex acts upon it while rotating during root canal formation, i.e. that is highly durable.
(MEANS OF SOLVING THE PROBLEM)
(0009)
To solve the aforesaid problem, the root canal treatment apparatus in this invention is a shaft-shaped root canal treatment apparatus made of nickel-titanium alloy, on which a work portion of a designated length from the tip is formed and on which a shank is formed continuously with said work portion, in which root canal treatment apparatus at least a portion or the entirety of the work portion is subjected to heat treatment focused on resistance to rotating fatigue.
(EFFECT OF THE INVENTION)

(0010)
In the root canal treatment apparatus in this invention, subjecting at least a portion or the entirety of the work portion to heat treatment focused on resistance to rotating fatigue makes it possible to achieve high resistance to flex occurring as a result of rotation during root canal treatment.
(PREFERRED EMBODIMENT OF THE INVENTION)
(0011)
The root canal treatment apparatus in this invention is an apparatus for the treatment of a root canal by rotation, and applies to all apparatuses made using axial-shaped material made of nickel-titanium (Ni-Ti) alloy. In root canal treatment apparatuses of this kind, a work portion having a shape most suited to the intended treatment is formed on one end, and an operation portion operated by the doctor is formed on the other end. This operating portion is formed into a handle if directly operated by hand by the doctor, or is furnished with a handle in a shape most suited to the structure of the grip of said apparatus in the event that an apparatus such as a handpiece is used.
(0012)
In particular, subjecting at least a portion or the entirety of the work portion to heat treatment focused on resistance improves the durability of the site on which flex acts during root canal treatment, making it possible to eliminate the risk of breakage.
(EMBODIMENT 1)
(0013)
Preferred embodiments of the root canal treatment apparatus in this invention will be described below using the drawings. Fig. 1 is a drawing showing a file that is a representative example of a root canal treatment apparatus. Fig. 2 is a schematic drawing illustrating the composition when performing a fatigue rupture test for the tip of the file.
(0014)
The shape of file A will be described by means of Fig. 1 to represent the aforesaid root canal treatment apparatus. File A is an apparatus that cuts the wall of the root canal, and is comprised of a needle 1 and handle 2.
(0015)
A tapered work portion 4 is formed on needle 1 over a span of a designated length from tip 3, and a straight shank 5 is formed continuously with work portion 4. Work portion 4 can have a rectangular, triangular or square shape depending on the type of file, each of which is constituted in such a way as to be able to exert its own unique functions.
(0016)
In File A in this embodiment, forming the rectangular cross-section into a spiral shape along work portion 4 produces a groove 4a and cutting edge 4b along said groove 4a.
(0017)
Shank 5 has the function of being attached to handle 2. As indicated in the drawing, handle 2 can be constituted in such a way as to be gripped by the chuck of a handpiece or allow a doctor to grip it by hand while operating the apparatus, with each formed into a shape and from a material corresponding to its function.
(0018)
For example, the handle 2 shown in the drawing is made of a metal such as stainless steel, and shank 5 is inserted into a hole formed in the axis and fastened by bonding. If forming a handle operated by having a doctor grip it by hand, shank 5 is sometimes fastened by integrally insert-molding by injection-molding with a synthetic resin.
(0019)
Needle 1 is made of nickel-titanium (Ni-Ti) alloy and is formed using a wire having a diameter corresponding to the diameter of needle 1 comprising file A, with portion 6, which is a portion of work portion 4, being subjected to heat treatment focused on resistance to rotating fatigue (hereinafter referred to as "durability heat treatment").
(0020)
Moreover, in this embodiment, durability heat treatment of file A is performed only on portion 6 from tip 3 of

work portion 4, but naturally, it is also acceptable to perform durability heat treatment over the entirety of work portion 4 in this invention.

(0021)

There is no particular restriction on the length of portion 6 of work portion 4. In tests by the inventors of this invention and the like, there were many instances of breakage at the region 2 mm to 3 mm from the tip when the entirety of the work portion was made to have superelastic property. For this reason, the length of portion 6 of work portion 4 must be at least 2 mm from tip 3, and at most the full length of work portion 4. The range for the preferable length of portion 6 is on the order of 3 mm to 10 mm from tip 3 when the length of work portion 4 is 16 mm, with 3 mm or 4 mm being particularly preferable.

(0022)

Furthermore, the length of portion 6 may be altered to correspond to the taper of file A. For example, if the taper is 2/100, the portion furthest from tip 3 of work portion 4 (base) will not have a large diameter, so by using a designated length range from tip 3 for portion 6 and giving the other portions superelastic property, it is possible to retain the strength of the base. If the taper is 4/100 or 6/100, the diameter of the base is large, so the strength of the base will be retained even if the entirety of work portion 4 is subjected to durability heat treatment, and operability will be good.

(0023)

Durability heat treatment of portion 6 of work portion 4 is performed by heating the portion intended for durability heat treatment (portion 6 or the entirety of work portion 4) to a temperature obtained by testing to be described below, and retaining the raised temperature for a length of time obtained by testing. This durability heat treatment sets the Af temperature of the Ni-Ti alloy serving as the material of the file to a temperature greater than normal temperature, thereby making the site of portion 6 able to exert shape memory function.

(0024)

In a file A comprised in the manner set forth above, prior to treatment, a doctor is able to pre-curve portion 6 in accordance with the shape of the root canal or the shape of the apical foramen of the patient. By thus performing pre-curving, it becomes possible for tip 3 and portion 6 to closely follow the root canal when tip 3 is inserted into the root canal while performing treatment. Subsequent to completion of treatment and removal from the root canal, the doctor can apply force to cause it to regain its original shape, or heating can be performed to a temperature greater than the Af temperature set by durability heat treatment to cause it to regain its original shape.

(0025)

The aforesaid portion 6 is extremely flexible, which makes it possible to extend the length of time until breakage when work portion 4 is rotated while bent while tip 3 is inserted into the root canal, or when entering and exiting in the length direction, or when repeatedly switching between forward and reverse by roughly 1/4 of a rotation.

(0026)

In particular, because work portion 4 is formed in a tapered shape, when work portion 4 is bent with tip 3 as the fulcrum, shank 5 will remain essentially straight, making shank 5 of work portion 4 an arc shape with a small curvature, while the curvature increases moving towards portion 6 such that the arc becomes more prominently curved, and portion 6 will be significantly bent. In short, work portion 4 is not bent uniformly, but is rather bent in accordance with the taper. When the bending of work portion 4 is released, sections other than portion 6 return to their original shape (for example straight) and portion 6 retains its bent shape.

(0027)

Next, the testing method for setting the heat treatment temperature and retention time (heat treatment conditions) when performing heat treatment focused on resistance to rotating fatigue over either portion 6, which is a portion of work portion 4, or the entirety of work portion 4, will be described together with results thereof.

(0028)

The objective of this testing is to investigate the heat treatment conditions most conducive to achieving high durability in file A, assuming the most extreme rotation during root canal treatment involving rotating, entering and exiting in the length direction or repeatedly switching between forward and reverse by roughly 1/4 of a rotation, as well as to investigate the heat treatment conditions common to different Ni-Ti alloys.

(0029)
For this reason, this testing was performed by producing files A with the same specifications using as raw material a plurality of types of Ni-Ti alloy wire, performing fatigue rupture test on a plurality of samples subjected to heat treatment under different temperature and retention times using the device shown in Fig. 2, measuring the time until rupture, and comparing the measured results, thereby discovering the heat treatment conditions focused on durability to rotating fatigue.
(0030)
It is best for the time until occurrence of fatigue rupture in file A to be as long as possible. However, because there must be some benchmark in order to make a judgment, in this test, the benchmark was set to roughly 20 minutes without the occurrence of fatigue rupture when tested with the fatigue rupture tester described below.
(0031)
Using a wire with a diameter of roughly 1.0 mm composed of Ni: 55.76 wt%, remainder Ti (material 1), Ni: 55.91 wt%, remainder Ti (material 2), Ni: 55.97 wt%, remainder Ti (material 3), Ni: 55.90 wt%, remainder Ti (material 4) and Ni: 55.89 wt%, remainder Ti (material 5) as the material comprising file A, a plurality of no. 30 files were produced, each having a tip diameter of roughly 0.3 mm, taper 4/100, rectangular cross-sectional shape, roughly 25 mm length of needle projecting from handle 2 and roughly 15 mm length of work portion.
(0032)
Next, samples were produced from the files A produced from materials 1 to 5, one not subjected to heat treatment (untreated), one heat treated by retaining at 300°C for 30 minutes (heat treatment condition 1), one heat treated by retaining at 400°C for 30 minutes (heat treatment condition 2), one heat treated by retaining at 500°C for 30 minutes (heat treatment condition 3), and one heat treated by retaining at 600°C for 15 minutes (heat treatment condition 4), and a fatigue rupture test (durability) was performed, with a bending test and torsion test performed corroboratively.
(0033)
Moreover, during each test, in one sample, heat treatment was performed by inserting the needle 1 made of Ni-Ti alloy into an electric furnace and subjecting the entirety of work portion 4 to heat treatment, while in another sample, heat treatment was performed only for portion 6 from tip 3. Five samples were tested under the same conditions. Indicated values are a summary of test data.
(0034)
First, the bending test method and results will be described. The bending test was performed using a sample in which the entirety of needle 1 was heat treated, by bending to 45° while grasping a location 3 mm from the tip 3 of work portion 4 and measuring the maximum torque. The results of the bending test for untreated samples 1 to 5 were within the range of 40 gf-cm to 50 gf-cm, for heat treatment condition 1 samples 1 to 5 within the range of 40 gf-cm to 55 gf-cm, for heat treatment condition 2 samples 1 to 5 within the range of 35 gf-cm to 40 gf-cm, for heat treatment condition 3 samples 1 to 5 within the range of 30 gf-cm to 40 gf-cm, and for heat treatment condition 4 samples 1 to 5 within the range of 35 gf-cm to 40 gf-cm, showing no significant difference.
(0035)
Next, the torsion test method and results will be described. The torsion test was performed using a sample in which the entirety of needle 1 was heat treated, by grasping a location 3 mm from the tip 3 of work portion 4 and rotating, and measuring the maximum torque and angle at the time of rupture. The results of the torsion test for the untreated condition samples 1 to 5 were within the range of maximum torque 70 gf-cm to 80 gf-cm and angle 400° to 500°, for heat treatment condition 1 samples 1 to 5 within the range of maximum torque 70 gf-cm to 80 gf-cm and angle 400° to 500°, for heat treatment condition 2 samples 1 to 5 within the range of maximum torque 80 gf-cm to 120 gf-cm and angle 400° to 600°, for heat treatment condition 3 samples 1 to 5 within the range of maximum torque 70 gf-cm to 100 gf-cm and angle 450° to 700°, and for heat treatment condition 4 samples 1 to 5 within the range of maximum torque 70 gf-cm to 90 gf-cm and angle 800° to 1100°, revealing that although the test results for heat treatment condition 4 were significant compared to the other conditions, there was no significant difference

between the other heat treatment conditions.

(0036)

Next, the fatigue rupture test method and results will be described. The fatigue rupture test was performed using a sample in which the entirety of needle 1 was heat treated using the device shown in Fig. 2. In short, using a device furnished with a pair of pins 21, 22 having a groove 21a, 22a capable of receiving the tip 3 of work portion 4, one of the pins 21 was set in such a way that the center thereof corresponded to a position 4 mm from the tip 3 of work portion 4 and tip 3 was inserted into the groove 22a of the other pin 22, thereby bending portion 6 of work portion 4 by roughly 45 degrees, this state was maintained while rotating 200 times per minute, and time until rupture was measured.

(0037)

The results of this fatigue rupture test revealed that time until fatigue rupture changes significantly depending on heat treatment conditions. In short, the time until fatigue rupture was roughly 18 minutes in material 2, which had the highest durability among the untreated condition, within the range of 5 to 10 minutes in the case of heat treatment condition 1, within the range of 4 to 11 minutes in the case of heat treatment condition 3, and within the range of 3 to 5 minutes in the case of heat treatment condition 4, whereas the time until fatigue rupture was within the range of 8 to 56 minutes in the case of heat treatment condition 2 (400°C-30 minutes), revealing a significant increase in the time until fatigue rupture compared to the other heat treatment conditions.

(0038)

In short, when heat treatment is performed under heat treatment condition 2, there is significant lengthening effect on the fatigue rupture time, indicating that this heat treatment is capable of imparting a high level of durability.

(0039)

As indicated above, it was found that performing heat treatment of Ni-Ti alloy material while maintaining the temperature at 400°C for 30 minutes improved durability. However, it is not clear whether or not the condition of 400°C-30 minutes is ideal. For this reason, a fatigue rupture test was performed by using a single material and setting the processing time to be constant and changing the temperature.

(0040)

The material used in the test was the aforesaid material 2 having a composition of Ni: 55.91 wt%, remainder Ti. A fatigue rupture test was performed for samples heat treated, respectively, at a temperature of 250°C, 300°C, 350°C, 375°C, 400°C, 410°C, 420°C, 425°C, 430°C, 440°C, 450°C, 475°C, 500°C and 550°C.

(0041)

The results of the aforesaid rupture tests are shown in Fig. 3. As shown in this diagram, results show that time until fatigue rupture exceeds 15 minutes when heat treatment temperature is within the range of 400°C to 450°C and exceeds 20 minutes when heat treatment temperature is within the range of 430°C to 440°C. Based on these test results, it can be said that heat treatment focused on resistance to rotating fatigue can be performed over the entirety of the work portion by performing heat treatment at a heat treatment temperature within the range of 400°C to 450°C and retaining for 30 minutes.

(0042)

Next, using a partial heating device not shown in the drawings[,] with the heat treatment range within the range of roughly 5 mm from tip 3 of work portion 4 or within the range of roughly 10 mm from tip 3, the aforesaid material 2 composed of Ni: 55.91 wt%, remainder Ti as the material, 400°C (350°C, 340°C), 425°C (370°C, 360°C), 450°C (390°C, 375°C), 475°C (410°C, 390°C), 500°C (440°C, 420°C), 525°C (460°C, 430°C), 550°C (480°C, 440[°C]) as the heat treatment temperature-partial heating device temperature setting, and 45 minutes (fixed) as the retention time, a fatigue rupture test was performed on a sample subjected to heat treatment at a temperature selected from among the aforesaid conditions. As a comparative example, a fatigue rupture test was performed on a sample that was heat-treated at 400°C for 45 minutes using a drier.

(0043)

Moreover, heat treatment of a range roughly 5 mm and roughly 10 mm from the tip of work portion 4 was performed on a very fine axial bolt within a limited range, so it is not possible to prescribe clear dimensions. For this reason, it is difficult to express the length range from tip 3 as a precise numeral value, and hence the range must be expressed as a range of on the order of roughly 5 mm or roughly 10 mm.

(0044)

When performing heat treatment using a partial heating device, there is no guarantee that the temperature setting of the partial heating device and the actual temperature of the sample will match precisely. When heat treatment was actually performed with a partial heating device, a difference was found between the measured surface temperature of the sample and the temperature setting. In short, the first temperature in parentheses is the surface temperature of the sample as measured when a range of roughly 5 mm from the tip was heated, and the second temperature is the surface temperature of the sample as measured when a range of roughly 10 mm from the tip was heated, versus the aforesaid temperature setting of the partial heating device. Thus, the surface temperature of the sample during heat treatment was measured to be a temperature lower than the temperature setting of the partial heating device.

(0045)

As a result of the aforesaid tests, it was found that in the case of a heat treatment range of roughly 5 mm, the time until occurrence of fatigue rupture was roughly 29 minutes when the heat treatment temperature was set to 425°C, whereas in the case of other heat treatment conditions, fatigue rupture occurred after 20 minutes or less.

(0046)

In the case of a heat treatment range of roughly 10 mm, the time until occurrence of fatigue rupture exceeded 20 minutes when the heat treatment temperature was within a range of 425°C to 500°C. In the case of a heat treatment temperature of 525°C, fatigue rupture occurred at roughly 19 minutes.

(0047)

In the comparative example, the time until occurrence of fatigue rupture was roughly 35 minutes.

(0048)

For practical purposes, it is adequate for the time until occurrence of fatigue rupture to be on the order of roughly 20 minutes or greater, for which reason it can be said that heat treatment focused on resistance to rotating fatigue over a portion of the work portion can be applied by performing heat treatment under heat treatment conditions of 425°C-45 minutes in a file A that was heat-treated within a range of roughly 5 mm from the tip, and under heat treatment conditions of 425°C-45 minutes to 525°C-45 minutes in a file A that was heat-treated within a range of roughly 10 mm from the tip.

(0049)

As set forth above, putting together the results of fatigue rupture tests of samples wherein the entirety of the work portion 4 was heat-treated and fatigue rupture [tests] of samples in which a range of 5 mm and 10 mm from the tip of the work portion was heat-treated, it can be said to be possible to apply heat treatment focused on resistance to rotating fatigue over a portion or the entirety of the work portion by performing heat treatment with the heat treatment temperature set to within the range of 400°C to 450°C and retaining for 30 minutes to 45 minutes.

(0050)

In a file A of the kind described above, by gripping handle 2 in the chuck of a handpiece not shown in the drawings and having the doctor hold this handpiece, once portion 6 formed on work portion 4 has been pre-bent into a shape corresponding to the shape of the root canal of the patient, it is possible to shape the root canal by cutting the walls of said root canal by inserting tip 3 into the root canal and rotating in the direction of cutting edge 4b while displacing axially.

(0051)

Moreover, although in this embodiment a cutting edge 4b was formed because a file A was taken as an example of the root canal treatment apparatus, a cutting edge 4b will not necessarily be formed in the work portion 4 of all root canal treatment apparatuses; in some cases, a pointed projection or tapered coil will be formed. Even in the case of root canal treatment apparatuses of this kind, it is possible to achieve high durability by performing heat durability heat treatment over portion 6 of work portion 4 or over the entirety of work portion 4 as long as the root canal treatment apparatus treats a root canal by rotation.

(0052)

As set forth above, there is no particular restriction on the method of manufacturing a file A; however, representative methods will be described briefly. The first manufacturing method involves forming a work portion by performing metal removal processing on material previously granted superelasticity, and subsequently subjecting a portion or the entirety of the tip of the work portion to durability heat treatment.

(0053)

In short, axial bolt-shaped material is formed by cutting wire made of Ni-Ti alloy granted superelasticity in advance and having a diameter corresponding to the thickness of the intended file to the length of said file, and then a needle portion is formed by tapering this material, machining the groove and cutting edge, machining the tip, and machining the work portion and shank. At this time, because it is impossible to perform plastic working on the material due to its superelasticity, the various processes performed on the material are performed by means of processes involving the removal of metal including grinding.

(0054)

Next, a portion subjected to durability heat treatment is formed over a range of a designated length from the tip of the work portion or over the entirety of work portion 4. This process is performed by using a refrigerant to cool the sections of the needle already formed into a prescribed shape that do not correspond to the sections intended to be subjected to durability heat treatment, and then heating according to pre-set heat treatment conditions for temperature and retention time. There is no particular restriction on the refrigerant used at this time; for example, water can be used.

(0055)

The intended file can then be manufactured by inserting the shank of the needle provided with a portion 6 subjected to durability heat treatment over a range of a designated length from the tip of the work portion or over the entirety of the work portion in the manner set forth above into the handle and bonding the two together.

(0056)

A second manufacturing method involves manufacturing the intended file by subjecting a range of a designated length corresponding to the portion subjected to durability heat treatment, or a portion corresponding to the entirety of the work portion, to durability heat treatment from one end at the stage where the material is formed, and subsequently performing processing involving the removal of metal from the material to form a work portion with a groove and cutting edge.

(0057)

In the second manufacturing method described above, a segment subjected to durability heat treatment at the material stage and a section having superelasticity are formed, with the work portion being formed by subjecting this material to metal removal processing. Accordingly, a needle shape is remembered by, and a groove and cutting edge continuous with the superelastic portion are formed on the portion subjected to durability heat treatment.

(0058)

The intended file can then be manufactured by subjecting material furnished in the manner set forth above with a segment corresponding to the portion subjected to durability heat treatment and a segment corresponding to the superelastic portion to processing involving metal removal so as to form a needle comprised of a work portion and shank, and subsequently inserting the shank in the handle and bonding the two together.

(INDUSTRIAL APPLICABILITY)

(0059)

The root canal treatment apparatus in this invention proffers the advantage of making it possible to prolong the length of time until occurrence of rupture when treating a root canal by inserting the tip portion thereof into a root canal with a complicated shape and rotating, even when fatigue occurs as a result of this rotation.

(BRIEF DESCRIPTION OF THE DRAWINGS)

(0060)

(FIG. 1) Drawing showing a file serving as a representative example of a root canal treatment apparatus.

(FIG. 2) Schematic drawing illustrating the composition when performing a fatigue rupture test for the tip of the file.

(FIG. 3) Diagram showing the test results for fatigue rupture time when the same material was heat-treated at a different temperature.

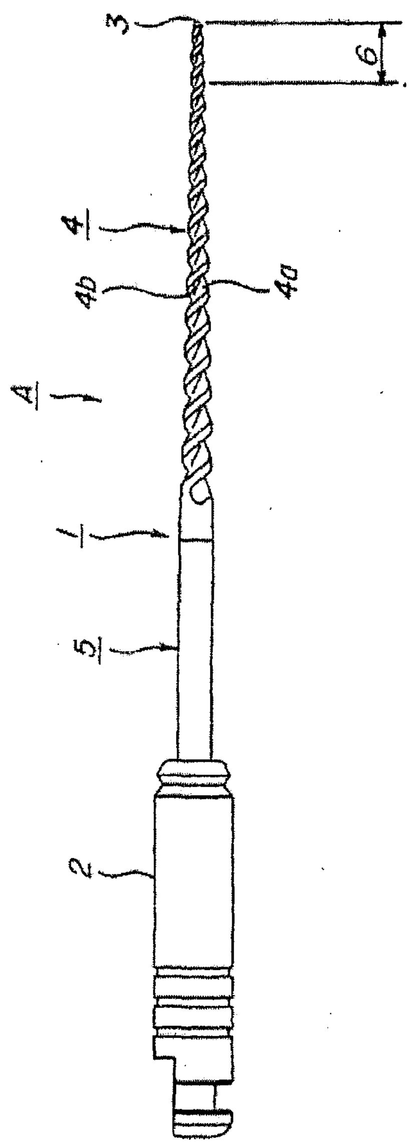
(EXPLANATION OF REFERENCES)

(0061)

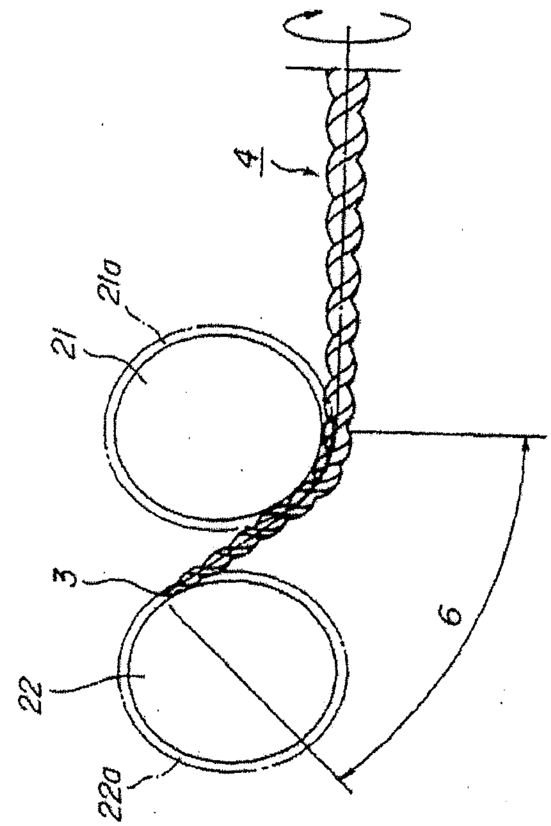
A	File
1	Needle
2	Handle
3	Tip
4	Work portion
4a	Groove
4b	Cutting edge

5	Shank
6	Portion
21, 211	Pin
21a, 22a	Groove

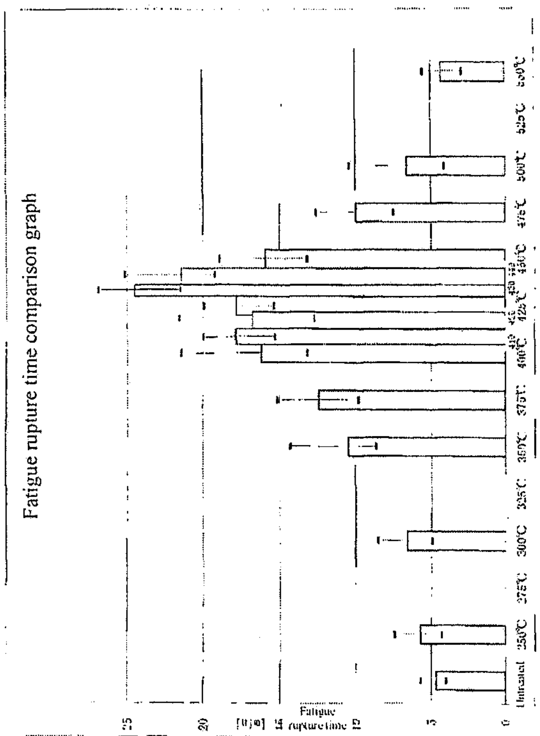
[Document name] Drawings
(Fig. 1)



(Fig. 2)



(Fig. 3)



(ABSTRACT)
(PROBLEM) Provide a highly durable root canal treatment apparatus that is unlikely to become damaged in the event that flex acts upon it while rotating during root canal formation.
(MEANS FOR SOLVING) Work portion 4 of a designated length from tip 3 is formed on file A serving as the root canal treatment apparatus, which has a shaft-shaped needle portion 1 made of nickel-titanium alloy on which a shank 5 is formed continuously with work portion 4, and at least a portion or the entirety of work portion 4 is subjected to heat treatment focused on resistance to rotating fatigue.
(SELECTED DRAWING) Fig. 1

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[Reason of change]	Change of name
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Affidavit

Natalia Lehmann, being duly sworn, hereby deposes and says:

I possess advanced knowledge of the Japanese and English languages. My qualifications are as follows:

Bilingual Japanese/English
Fifteen years of experience as a Japanese-to-English translator
Nine years of experience as a Japanese-to-English editor and proofreader

I have reviewed the attached translation and compared it to the original "Japanese Patent Application No. 2004-344717." The attached is, to the best of my knowledge and belief, a true and accurate translation from Japanese to English of said original "Japanese Patent Application No. 2004-344717."

Natalia Lehmann
TransPerfect Translations International, Inc.

Sworn to before me this July 27, 2015

Signature, Notary Public

SUZANNE TAYLOR
Notary Public
STATE OF TEXAS
My Comm. Exp. 01-30-2019

Stamp, Notary Public

日本国特許庁
JAPAN PATENT OFFICE

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This is to certify that the annexed is a true copy of the following application as filed with this Office.

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is JP2004−344717

出願人
Applicant(s): マニー株式会社

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出証特２００５－３１０２０６７

【書類名】特許請求の範囲
【請求項１】
先端から所定長さの作業部が形成されると共に該作業部に連続してシャンクが形成されたニッケルーチタン合金からなる軸状の根管治療器具であって、少なくとも作業部の一部又は全部に於いて回転疲労に対する耐久性に着目した熱処理が施されていることを特徴とする根管治療器具。

【書類名】明細書
【発明の名称】根管治療器具
【技術分野】
【０００１】
本発明は、歯科治療用の根管治療器具に関し、特に、回転させたり、長さ方向に出し入れしたり、１／４回転くらいの正逆転を繰り返すことをさせて目的の治療を施す根管治療器具の回転に伴う疲労に対する耐久性を向上させた根管治療器具に関するものである。
【背景技術】
【０００２】
回転させつつ歯の根管を治療するための器具として、根管を切削して成形するファイル，リーマがある。この根管治療器具は、細いテーパ状の軸棒に治療目的に対応させて切刃や突部を設けた作業部を形成し、或いはテーパ状の軸棒をスパイラル状に成形して作業部を形成した部材によって構成されている。また機種によっては、前記部材の端部に医師が把持して操作するハンドルや柄を一体的に取り付けて、ハンドピース等のチャックに把持させたり、医師が直接操作し得るようにしたりして構成されている。
【０００３】
根管は極めて細く、且つ形状や太さは多様であり個人差も大きい。このため、同一機種の根管治療器具であっても、異なる太さを持つ多数のものが提供される。例えばファイルを用いて根管を切削して成形するような場合、根管の周囲を傷めることがないようにファイルは根管の形状に沿って変形すること、即ち、適度な弾性を有することが必要である。
【０００４】
上記の如き極めて高い弾性と形状の復元性を持つ根管治療器具として特許文献１の技術が提案されている。この技術は、記憶熱処理した超弾性特性を有する軸棒素材を記憶処理温度以下に保持しながら除去加工を施して作業部を形成して製造された根管治療器具に関するものである。
【０００５】
上記根管治療器具では、作業部が形成された軸棒は、作用する外力に応じてしなやかに変形し、且つ外力が除去されるのに伴って速やかに元の形状に復元する。このため、根管の形状に対して極めて高い追従性を発揮して精度の良い根管成形を行うことが出来る。
【０００６】
【特許文献１】特許第３３７５７６５号公報
【発明の開示】
【発明が解決しようとする課題】
【０００７】
上記特許文献１に係る根管治療器具では作業部の全長にわたって均等な超弾性特性を有するため、作業部を曲げたとき、自由端である先端部分にも元の形状に戻ろうとする作用があり、根管の治療に際し先端を根管に挿入して曲げるのに伴って応力が発生する。特に、根管成形に際し、作業部の主に先端部が曲がった状態で回転させることから、作業部には繰り返し曲げ応力が作用することとなり、細い先端部分が棄損する可能性が高くなるという問題がある。
【０００８】
本発明の目的は、根管成形の際に回転させることに伴う繰り返し曲げが作用しても棄損する虞の低い、即ち、高い耐久性を有する根管治療器具を提供することにある。
【課題を解決するための手段】
【０００９】
上記課題を解決するために本発明に係る根管治療器具は、先端から所定長さの作業部が形成されると共に該作業部に連続してシャンクが形成されたニッケルーチタン合金からなる軸状の根管治療器具であって、少なくとも作業部の一部又は全部に於いて回転疲労に対する耐久性に着目した熱処理が施されているものである。
【発明の効果】

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【００１０】
本発明に係る根管治療器具では、少なくとも作業部の一部又は全部に於いて回転疲労に対する耐久性に着目した熱処理が施されていることによって、根管を治療する際に回転させた場合に生じる繰り返し曲げに対し、高い耐久性を発揮することが出来る。
【発明を実施するための最良の形態】
【００１１】
本発明に係る根管治療器具は、回転に伴って根管を治療するための器具であって、ニッケルーチタン（Ｎｉ－Ｔｉ）合金からなる軸状の材を用いて形成される全ての器具を対象としている。このような根管治療器具は、一方側の端部に目的の治療を最も合理的に行うことが可能な形状を持った作業部が形成され、他方側の端部に医師が操作する操作部が形成されている。この操作部は医師が手で直接操作する場合はハンドルが形成され、ハンドピースのような器具を用いる場合は該器具の把持部の構造に最適な形状を持った柄が設けられる。
【００１２】
特に、作業部の一部又は全部に対し耐久性に着目した熱処理を施すことによって、根管の治療に際し繰り返し曲げが作用する部位の耐久性の向上をはかり、破断の虞を排除し得るようにしたものである。
【実施例１】
【００１３】
以下本発明に係る根管治療器具の好ましい実施形態について図を用いて説明する。図１は根管治療器具を代表する例としてのファイルを示す図である。図２はファイルの先端部分の疲労破断試験を行う際の構成を説明する模式図である。
【００１４】
上記根管治療器具を代表してファイルＡの形状について図１により説明する。ファイルＡは根管に於ける根管壁を切削する器具であり、針部１と柄２とによって構成されている。
【００１５】
針部１には先端３から所定長さ範囲にわたるテーパ状の作業部４が形成されており、作業部４に連続してストレート状のシャンク５が形成されている。作業部４は、ファイルの種類に応じて断面が長方形のものや、三角形或いは四角形のものが提供され、夫々独自の機能を発揮し得るように構成されている。
【００１６】
本実施例に於けるファイルＡでは、長方形の断面が作業部４に沿ってスパイラル状に形成されることで、溝４ａ，該溝４ａに沿った切刃４ｂが形成されている。
【００１７】
シャンク５は柄２に取り付けられる機能を有している。柄２は図に示すようにハンドピースのチャックに把持されるように構成されたものや、医師が手で把持して操作し得るようにしたものがあり、夫々の機能に対応した形状と材質を持って形成されている。
【００１８】
例えば、図に示す柄２は、ステンレス鋼等の金属からなり、軸心に形成された穴にシャンク５を挿通して接着により固定されている。また医師が手で把持して操作する柄を形成する場合、合成樹脂の射出成形によりシャンク５をインサート成形して一体化させて固定されることもある。
【００１９】
針部１はニッケルーチタン（Ｎｉ－Ｔｉ）合金からなり且つファイルＡを構成する針部１の径に対応した径を有する線材を用いて形成されており、作業部４の一部である部分６に於いて回転疲労に対する耐久性に着目した熱処理（以下、「耐久熱処理」という）が施されている。
【００２０】
尚、本実施例では、ファイルＡに対する耐久熱処理を作業部４に於ける先端３からの部

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分６に対してのみ行っているが、本発明に於いて作業部４の全部に対して耐久熱処理を行って良いことは当然である。

【００２１】

作業部４に於ける部分６の長さは特に限定するものではない。本件発明者等の実験では、作業部全体を超弾性特性としたとき、先端から２ｍｍ～３ｍｍの部位で棄損する例が多かった。このため、作業部４に於ける部分６の長さは、最低でも先端３から２ｍｍは必要であり、最大は作業部４の全長である。また部分６の特に好ましい長さ範囲は、作業部４の長さが１６ｍｍである場合は先端３から３ｍｍ～１０ｍｍ程度であり、３ｍｍ，４ｍｍ程度であることがより好ましい。

【００２２】

また、ファイルＡのテーパに対応させて部分６の長さを変化させても良い。例えばテーパが２／１００の場合は、作業部４の先端３から離れた部分（元部側）に於いても大きな径にはならないため、部分６は先端３から所定の長さ範囲とし、その他の部分は超弾性特性にすれば、元部側の強さを保持することが可能である。テーパが４／１００、６／１００の場合、元部側の径が大きくなるため、作業部４の全部に対して耐久熱処理を施した場合でも元部側の強さは保持されており、操作性は良い。

【００２３】

作業部４に於ける部分６に対する耐久熱処理は、耐久熱処理すべき部位（部分６や作業部４の全部）を、後述する試験によって得られた温度に上昇させると共に、上昇させた温度を試験によって得られた時間保持することで行われる。この耐久熱処理は、ファイルの材料となるＮｉ－Ｔｉ合金のＡｆ温度を常温よりも高い温度とするものであり、部分６を形状記憶機能を発揮し得る部位に設定するものである。

【００２４】

上記の如く構成されたファイルＡでは、治療に際し、医師が患者の根管の形状、或いは根尖口の形状に対応させて予め部分６を曲げておく（プレカーブ）ことが可能となる。このようにプレカーブを形成しておくことで、先端３を根管に挿入して治療を行う際に、先端３及び部分６が根管に対して高い追従性を発揮することが可能となる。そして治療が終了して根管から取り出した後、医師が力を加えて初期の形状に変形させることが可能であり、また耐久熱処理によって設定されたＡｆ温度以上に上昇させることで初期の形状を回復することが可能である。

【００２５】

上記部分６は柔軟性に富み、先端３を根管に挿入した状態で作業部４を曲げて回転させたり、長さ方向に出し入れしたり、１／４回転くらいの正逆転を繰り返すことをさせたとき、破断に至る時間を長くすることが可能である。

【００２６】

特に、作業部４がテーパ状に形成されているため、先端３を支点として作業部４を曲げたとき、シャンク５は略直線を維持し、作業部４のシャンク５側は曲率の小さい弧状となり、部分６側に接近するに従って曲率が大きくなって強く曲げられた弧状となり、更に、部分６はより強く曲げられる。即ち、作業部４は一様に曲げられるものではなく、テーパに対応して曲げられる。そして作業部４の曲げを解除すると、部分６以外の部位は元の形状（例えば直針状）に復元し、部分６は曲げられた形状を維持する。

【００２７】

次に、作業部４の一部である部分６、又は作業部４の全部に於いて回転疲労に対する耐久性に着目した熱処理を施す際の熱処理温度及び保持時間（熱処理条件）を設定するための試験方法と、結果について説明する。

【００２８】

この試験の目的は、回転させたり、長さ方向に出し入れしたり、１／４回転くらいの正逆転を繰り返すことをさせて治療するうち、最も過酷な回転させて根管の治療を行う場合を想定して、ファイルＡが最も高い耐久性を発揮し得る熱処理条件を調査すると共に、異なるＮｉ－Ｔｉ合金に対して共通性を持った熱処理条件を調査することにある。

【００２９】
このため、本実験は、複数の種類のＮｉ－Ｔｉ合金の線材を材料として同一仕様のファイルＡを構成し、異なる温度と保持時間を設定して熱処理した複数のサンプルを図２に示す装置を用いて疲労破断試験を行って、破断に至る時間を計測し、計測された結果を比較することで、回転疲労に対する耐久性に着目した熱処理条件を見いだすようにしたものである。

【００３０】
ファイルＡとしての疲労破断に至る時間は長時間であることにこしたことはない。しかし、一応の基準を設けないと判定のしようがないため、本試験では、後述する疲労破断試験機を用いた試験で約２０分疲労破断を起こさないことを基準として設定した。

【００３１】
ファイルＡを構成する素材として、材料組成が、Ｎｉ：５５．７６重量％、残部Ｔｉ（材料１）、Ｎｉ：５５．９１重量％、残部Ｔｉ（材料２）、Ｎｉ：５５．９７重量％、残部Ｔｉ（材料３）、Ｎｉ：５５．９０重量％、残部Ｔｉ（材料４）、Ｎｉ：５５．８９重量％、残部Ｔｉ（材料５）で、直径が約１．０ｍｍの線を用いて、３０番のファイルで、先端部分の径が約０．３ｍｍ、テーパが４／１００、断面形状が長方形、柄２から突出している針部の長さ約２５ｍｍ、作業部の長さ約１５ｍｍの形状を持ったものを夫々複数本作成した。

【００３２】
次に、材料１～５によって作成したファイルＡを、熱処理を施さないもの（未処理）、３００℃で３０分保持して熱処理したもの（熱処理条件１）、４００℃で３０分保持して熱処理したもの（熱処理条件２）、５００℃で３０分保持して熱処理したもの（熱処理条件３）、６００℃で１５分保持して熱処理したもの（熱処理条件４）のサンプルを作成して疲労破断試験（耐久性）の実験を行うと共に、付随的に曲げ試験，捩じり試験を行った。

【００３３】
尚、各試験に於いて、熱処理はＮｉ－Ｔｉ合金からなる針部１を電気炉に挿入して作業部４の全体に熱処理が施されているものと、先端３からの部分６に対応させて熱処理したものとがある。また同一の条件の試験に対するサンプル数は５とした。更に、記載した数値は試験データをまとめたものである。

【００３４】
先ず、曲げ試験の方法と結果について説明する。曲げ試験は、針部１の全体を熱処理したものを用い、作業部４の先端３から３ｍｍの位置を把持して４５°まで曲げたときの最大トルクを計測することで行った。曲げ試験の結果、未処理条件の材料１～５は４０ｇｆ－ｃｍ～５０ｇｆ－ｃｍの範囲、熱処理条件１の材料１～５は４０ｇｆ－ｃｍ～５５ｇｆ－ｃｍの範囲、熱処理条件２の材料１～５は３５ｇｆ－ｃｍ～４０ｇｆ－ｃｍの範囲、熱処理条件３の材料１～５は３０ｇｆ－ｃｍ～４０ｇｆ－ｃｍの範囲、熱処理条件４の材料１～５は３５ｇｆ－ｃｍ～４０ｇｆ－ｃｍの範囲、に入っており、有意な差が生じているとは認められない、という結果を得た。

【００３５】
次に、捩じり試験の方法と結果について説明する。捩じり試験は、針部１の全体を熱処理したものを用い、作業部４の先端３から３ｍｍの位置を把持して回転させ、破断したときの最大トルクと角度を計測することで行った。捩じり試験の結果、未処理条件の材料１～５は最大トルク７０ｇｆ－ｃｍ～８０ｇｆ－ｃｍ，角度；４００°～５００°の範囲、熱処理条件１の材料１～５は最大トルク７０ｇｆ－ｃｍ～８０ｇｆ－ｃｍ，角度；４００°～５００°の範囲、熱処理条件２の材料１～５は最大トルク８０ｇｆ－ｃｍ～１２０ｇｆ－ｃｍ，角度；４００°～６００°の範囲、熱処理条件３の材料１～５は最大トルク７０ｇｆ－ｃｍ～１００ｇｆ－ｃｍ，角度；４５０°～７００°の範囲、熱処理条件４の材料１～５は最大トルク７０ｇｆ－ｃｍ～９０ｇｆ－ｃｍ，角度；８００°～１１００°の範囲、に入っており、熱処理条件４の試験結果は他の条件のものと比較して有利であるも

のの、他の熱処理条件では有意な差が生じているとは認められない、という結果を得た。

【００３６】

次に、疲労破断試験の方法と結果について説明する。疲労破断試験は、針部１の全体を熱処理したものを用い、図２に示す装置を用いて行った。即ち、作業部４の先端３側を受け入れることが可能な溝２１ａ，２２ａを有する一対のピン２１，２２を配置した装置を用い、一方のピン２１の中心に作業部４の先端３から４㎜の位置が対応するようにセットすると共に先端３を他方のピン２２の溝２２ａに挿入することで、作業部４に於ける部分６を略４５度に曲げ、この曲げ状態を維持して毎分２００回転させて破断に至る時間を計測した。

【００３７】

この疲労破断試験の結果、疲労破断に至る時間は熱処理条件に応じて大きく変化していることがわかった。即ち、未処理条件の場合最も耐久性の高い材料２でも約１８分であり、熱処理条件１の場合５分～１０分の範囲、熱処理条件３の場合４分～１１分の範囲、熱処理条件４の場合３分～５分の範囲であるのに対し、熱処理条件２（４００℃－３０分）では、約８分～約５６分の範囲と、他の熱処理条件の疲労破断に至る時間と比較して大幅に延長されている。

【００３８】

即ち、熱処理条件２の熱処理を施した場合、疲労破断時間に大幅な延長効果が見られ、高い耐久性を発揮することが可能な熱処理であると言える。

【００３９】

上記の如くしてＮｉ－Ｔｉ合金の素材を温度４００℃で３０分保持する熱処理を行うことで耐久性が向上することが判明した。しかし、４００℃－３０分の条件が最適であるか否かは明確ではない。このため、材料を特定し、且つ処理時間を一定にした上で温度を変化させて疲労破断試験を行った。

【００４０】

試験に供する材料は、Ｎｉ：５５．９１重量％、残部Ｔｉの組成を持つ前述の材料２とした。また熱処理温度を２５０℃，３００℃，３５０℃，３７５℃，４００℃，４１０℃，４２０℃，４２５℃，４３０℃，４４０℃，４５０℃，４７５℃，５００℃，５５０℃とし、夫々の温度で熱処理したサンプルの疲労破断試験を行った。

【００４１】

上記破断試験の結果を図３に示す。同図に示すように、熱処理温度が４００℃～４５０℃の範囲である場合、疲労破断に至る時間は１５分を越えており、４３０℃及び４４０℃では２０分を越えているという結果を得た。この試験結果から、熱処理温度を４００℃～４５０℃の範囲に設定して３０分保持する熱処理を行うことで作業部の全部に於いて回転疲労に対する耐久性に着目した熱処理を施すことが可能であるといえる。

【００４２】

次に、図示しない部分加熱装置を用い。熱処理の範囲を作業部４の先端３から約５ｍｍの範囲、先端３から約１０ｍｍの範囲とし、材料をＮｉ：５５．９１重量％、残部Ｔｉの組成を持つ前述の材料２とし、熱処理温度－部分加熱装置の設定温度を４００℃（３５０℃，３４０℃），４２５℃（３７０℃，３６０℃），４５０℃（３９０℃，３７５℃），４７５℃（４１０℃，３９０℃），５００℃（４４０℃，４２０℃），５２５℃（４６０℃，４３０℃），５５０℃（４８０℃，４４０）とし、保持時間を４５分（一定）とし、前記条件の中から選択した温度で熱処理したサンプルの疲労破断試験を行った。また比較例としてドライヤーを用いて４００℃－４５分で熱処理したサンプルの疲労破断試験も行った。

【００４３】

尚、作業部４の先端から約５ｍｍ，約１０ｍｍの範囲に対する熱処理は、極めて細い軸棒に対して範囲を限定して実施するものであり、明確な寸法を規定し得るものでもない。このため、先端３からの長さ範囲を正確な数値で表すことは困難であり、約５ｍｍ，約１０ｍｍ程度の範囲との表現にならざるを得ない。

【００４４】
部分加熱装置を用いて熱処理を行う場合、部分加熱装置の設定温度とサンプルの実際の温度とが正確に一致することの保証はない。実際に部分加熱装置による熱処理を行っているときに、サンプルの表面温度を測定したところ、設定温度との間に開きがあった。即ち、上記部分加熱装置の設定温度に対し、かっこ内の前側の温度は先端から約５ｍｍの範囲を加熱したときに計測したサンプルの表面温度であり、後側の温度は先端から約１０ｍｍの範囲を加熱したときに計測したサンプルの表面温度である。このように、熱処理中のサンプルの表面温度は、部分加熱装置の設定温度よりも低い温度として測定されている。
【００４５】
上記試験の結果、熱処理の範囲が約５ｍｍの場合、熱処理温度を４２５℃に設定したとき疲労破断に至る時間が約２９分となり、他の熱処理条件の場合には２０分以下の時間で疲労破断した。
【００４６】
熱処理の範囲が約１０ｍｍの場合、熱処理温度が４２５℃～５００℃の範囲で疲労破断に至る時間が２０分を越えた。また熱処理温度が５２５℃の場合、約１９分で疲労破断している。
【００４７】
また比較例では、疲労破断に至る時間は約３５分であった。
【００４８】
実用上、疲労破断に至る時間は約２０分程度以上であれば良く、従って、先端から約５ｍｍの範囲を熱処理したファイルＡでは４２５℃－４５分の熱処理条件で、先端から約１０ｍｍの範囲を熱処理したファイルＡでは４２５℃－４５分～５２５℃－４５分の熱処理条件で熱処理を行うことで作業部の一部に於いて回転疲労に対する耐久性に着目した熱処理を施すことが可能であるといえる。
【００４９】
上記の如く、作業部４の全体を熱処理したサンプルの疲労破断試験、及び作業部の先端から５ｍｍ，１０ｍｍの範囲を熱処理したサンプルの疲労破断の結果から総合して、熱処理温度を４００℃～４５０℃の範囲に設定して３０分～４５分保持する熱処理を行うことで作業部の一部又は全部に於いて回転疲労に対する耐久性に着目した熱処理を施すことが可能であるといえる。
【００５０】
上記の如きファイルＡでは、柄２を図示しないハンドピースのチャックに把持させると共に医師がこのハンドピースを持ち、作業部４に形成された部分６を予め患者の根管の形状に対応させて曲げた後、先端３を根管に挿入して切刃４ｂの方向に回転させつつ軸方向に移動させることで、根管壁を切削して該根管を成形することが可能である。
【００５１】
尚、本実施例では根管治療器具としてのファイルＡを例としたため、切刃４ｂが形成されているが、全ての根管治療器具に於ける作業部４に必ず切刃４ｂが形成されているものでもなく、刺状の突起やテーパを持ったコイル状に形成されたものもある。そして、このような根管治療器具であっても、回転によって根管を治療する根管治療器具であれば、作業部４の部分６又は作業部４の全部に耐久熱処理を施すことによって、高い耐久性を発揮させることが可能である。
【００５２】
上記の如き、ファイルＡを製造する方法は特に限定するものではないが、代表的な方法について簡単に説明する。第１の製造方法は、予め超弾性特性を持たせた素材から金属除去加工を行って作業部を形成し、その後、作業部の先端側の一部又は作業部の全部を耐久熱処理したものである。
【００５３】
即ち、予め超弾性特性を持たせたＮｉ－Ｔｉ合金の線材であって目的のファイルの太さに対応する径を持った線材を、該ファイルの長さに対応させて切断することで軸棒状の素

材を形成し、この素材に対し、テーパ加工、溝と切刃の加工、先端の加工、作業部及びシャンクの加工を行って、針部を形成する。このとき、素材が超弾性特性を有することから塑性加工を施すことが不可能であるため、素材に対する各加工は研削加工を含む金属の除去を伴う加工によって行われる。

【００５４】

次いで、作業部の先端から所定の長さ範囲、又は作業部４全体に耐久熱処理を施した部分を形成する。この工程は、既に所定の形状に形成されている針材に於ける耐久熱処理を施す部分に対応する部位以外の部位を冷媒によって冷却しておき、予め設定されている温度と保持時間からなる熱処理条件に基づいて加熱することで行われる。このとき用いる冷媒としては特に限定するものではなく、例えば水を用いることが可能である。

【００５５】

上記の如くして作業部の先端から所定長さ範囲、又は作業部の全体に耐久熱処理を施した部分６を設けた針部のシャンクを柄に挿通すると共に両者を接着することで、目的のファイルを製造することが可能である。

【００５６】

また第２の製造方法は、素材を形成した段階で一方側の端部から耐久熱処理を施した部分に対応する所定長さ範囲、又は作業部の全体に対応する部分に、耐久熱処理を施し、その後、素材に対して金属の除去を伴う加工を行って、溝，切刃を有する作業部を形成することで目的のファイルを製造するものである。

【００５７】

上記第２の製造方法では、素材の段階で耐久熱処理を施した部位と、超弾性特性を有する部位とが形成され、この素材に対して金属除去加工を施して作業部を形成することになる。従って、耐久熱処理を施した部分には、直針状の形状が記憶されると共に、超弾性部と連続した溝，切刃が形成されることとなる。

【００５８】

上記の如くして耐久熱処理を施した部分に対応する部位と、超弾性部に対応する部位を設けた素材に金属除去を伴う加工を施すことで作業部，シャンクからなる針部を形成し、その後、シャンクを柄に挿通して両者を接着することで、目的のファイルを製造することが可能である。

【産業上の利用可能性】

【００５９】

本発明の根管治療器具は、先端部分が複雑な湾曲形状を持った根管に挿入されると共に回転して根管の治療を行ったとき、この回転に伴って疲労が生じた場合でも、破断に至る時間を延長することが可能となり有利である。

【図面の簡単な説明】

【００６０】

【図１】根管治療器具を代表する例としてのファイルを示す図である。

【図２】ファイルの先端部分の疲労破断試験を行う際の構成を説明する模式図である。

【図３】同一の材料に対し異なる温度で熱処理したときの疲労破断時間の試験結果を示す図である。

【符号の説明】

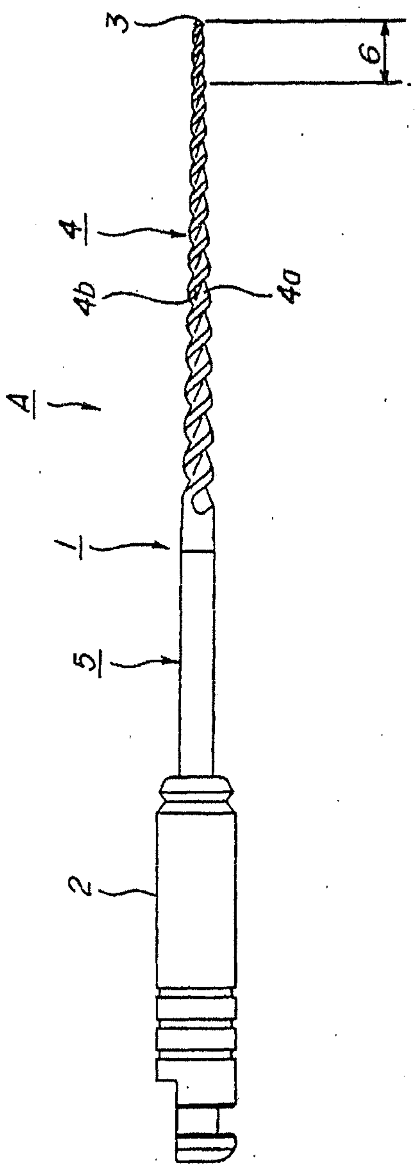
【００６１】

A	ファイル
1	針部
2	柄
3	先端
4	作業部
4 a	溝
4 b	切刃

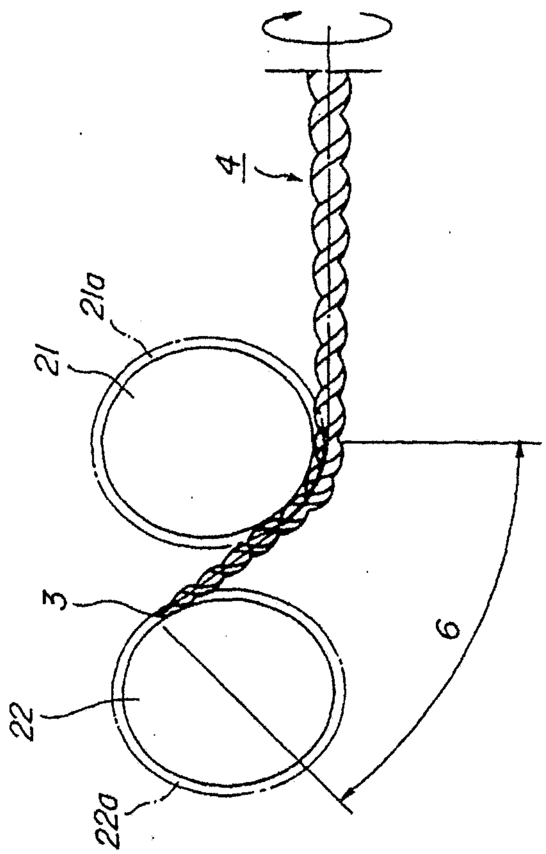
出証特２００５－３１０２０６７

5	シャンク
6	部分
２１，２２	ピン
２１ａ，２２ａ	溝

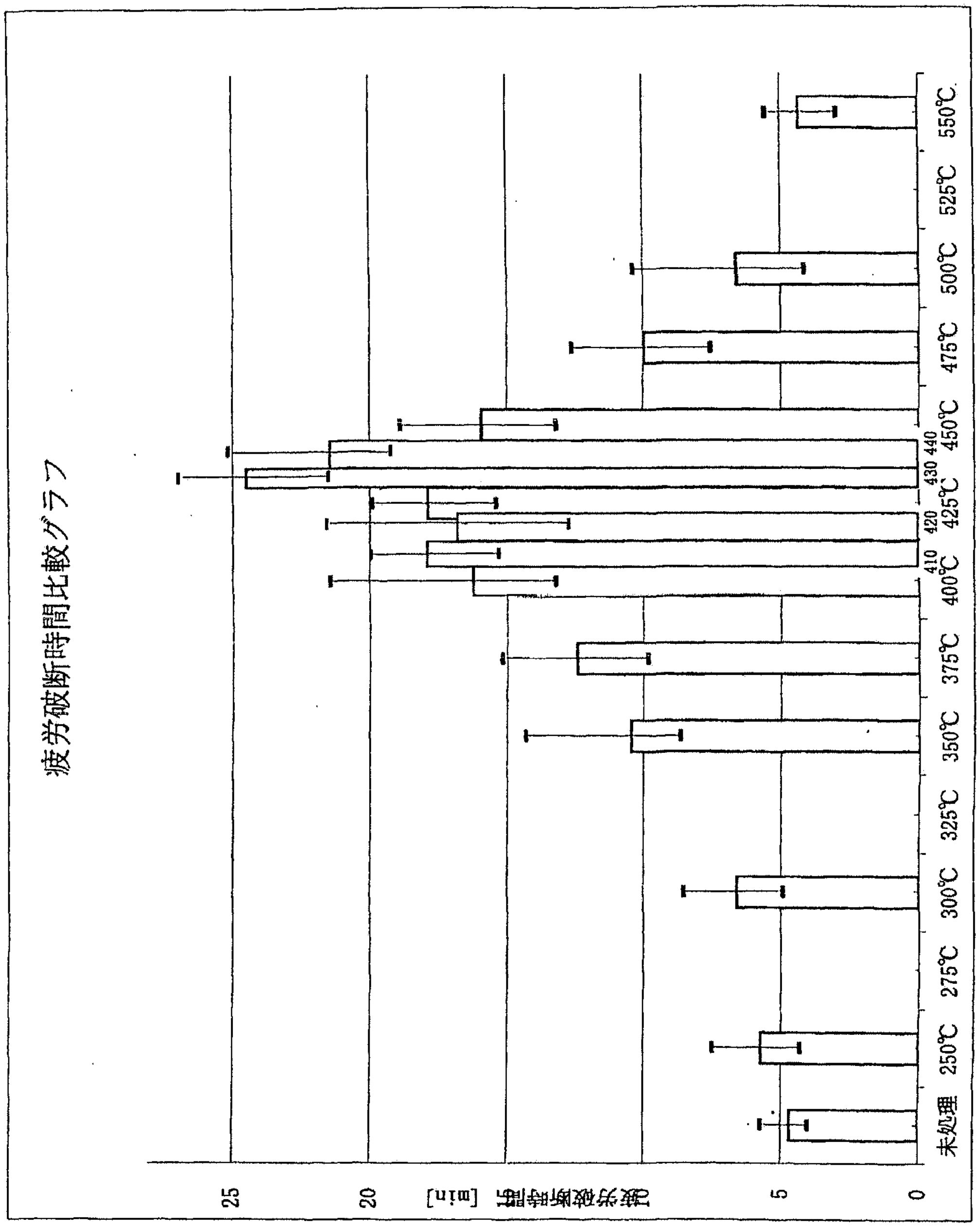
【書類名】図面
【図１】



【図２】



【図３】


疲労破断時間比較グラフ
疲労破断時間 [min]
0
5
20
25
未処理
250℃
275℃
300℃
325℃
350℃
375℃
400℃
410
420
425℃
430
440
450℃
475℃
500℃
525℃
550℃

【書類名】要約書
【要約】
【課題】根管成形の際に回転させることに伴う繰り返し曲げが作用しても破損する虞の低い、高い耐久性を有する根管治療器具を提供する。
【解決手段】根管治療器具となるファイルＡは、先端３から所定長さの作業部４が形成され、作業部４に連続してシャンク５が形成されたニッケル－チタン合金からなる軸状の針部１を有し、少なくとも作業部４の一部又は全部に於いて回転疲労に対する耐久性に着目した熱処理が施されている。
【選択図】　　図１

特願２００４－３４４７１７

出　願　人　履　歴　情　報

識別番号　［３９０００３２２９］

１．変更年月日　１９９６年　５月２４日
［変更理由］　名称変更
住　所　栃木県塩谷郡高根沢町大字中阿久津７４３
氏　名　マニー株式会社

出証番号　出証特２００５－３１０２０６７

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Customer Number:	26710
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	11520700014SuppIDSAug2015.pdf	613248 a53549c8c70375e61f0d487fe6056307c3f88564	no	4

Warnings:

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Date: August 25, 2015

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

IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	14/522,013
Filing Date:	October 23, 2014
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	9570
Art Unit:	3732
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 June 3, 2015.

Please amend the above-identified patent application as follows:

A Listing of the Claims begins 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 an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic nickel titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 25° C[[.]] up to but not equal to the melting point of the nickel titanium alloy,

wherein the heat treated shank has increased fatigue life compared to an endodontic instrument of same composition and size not treated in accordance with step (b) , and

wherein the heat treated shank exhibits permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1.

2. (Cancelled)

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

the fatigue life is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

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

the fatigue life is increased by at least 10%.

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

the fatigue life is increased by at least 30%.

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

the fatigue life is increased by at least 50%.

7. (Original) The method of claim 1 wherein:
the fatigue life is increased by at least 70%.

8. (Original) The method of claim 1 wherein:
the fatigue life is increased by at least 230%.

9. (Original) The method of claim 1 wherein:
the fatigue life is increased by at least 450%.

10. (Original) A method of claim 1 wherein:
the heat treating temperature is at least 250° C.

11. (Currently Amended) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 25° C[[.]] up to but not equal to the melting point of the titanium alloy,

wherein the heat treated shank has improved cyclic fatigue compared to an endodontic instrument of same composition and size not treated in accordance with step (b), and

wherein the heat treated shank exhibits permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1.

12. (Currently Amended) The method of claim 11 wherein the ~~nickel~~ titanium alloy is a ~~superelastic~~ nickel titanium alloy.

13. (Original) The method of claim 11 wherein:

the cyclic fatigue is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

14. (Original) The method of claim 11 wherein:

the cyclic fatigue revolutions are at least 300.

15. (Original) The method of claim 11 wherein:

the cyclic fatigue revolutions are at least 950.

16. (Original) The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 1600.

17. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 2000.

18. (Original) The method of claim 11 wherein:
the cyclic fatigue revolutions are increased by at least 50%.

19. (Original) The method of claim 11 wherein:
the cyclic fatigue revolutions are increased by at least 100%.

20. (Original) The method of claim 11 wherein:
the heat-treating temperature is at least 100° C.

21. (Original) The method of claim 11 wherein:
the heat treating temperature is at least 200° C.

22. (Original) The method of claim 11 wherein:
the heat-treating temperature is at least 300° C.

23. (Original) The method of claim 11 wherein:
the heat-treating temperature is at least 400° C.

REMARKS

Supplemental Information Disclosure Statements

Supplemental Information Disclosure Statements were filed July 24, 2015 and August 24, 2015 for Office consideration.

The present application, U.S. Patent Application No. 14/522,013, is a continuation of U.S. Patent Application No. 14/167,311, now U.S. Patent No. 8,876,991, which is a continuation of U.S. Patent Application No. 13/455,841, now U.S. Patent No. 8,727,773.

U.S. Patent No. 8,727,773 is involved in a proceeding before the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office. The Case Number is IPR2015-00632.

U.S. Patent No. 8,727,773 is involved in another proceeding before the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office. The Case Number is IPR2015-01476.

U.S. Patent No. 8,727,773 is involved in litigation in the United States District Court for the Eastern District Of Tennessee. The litigation is *Dentsply International, Inc. v. U.S. Endodontics, LLC*, Civil Action No. 14-00196, filed June 24, 2014.

U.S. Patent No. 8,876,991 is involved in a proceeding before the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office. The Case Number is PGR2015-00019.

Claim Amendments

Claim 1 has been amended to recite a superelastic nickel titanium alloy. This has a basis in claim 2, which has been cancelled.

Claim 11 has been amended to recite a superelastic titanium alloy. This has a basis in claim 12, which has been amended to delete the term "superelastic".

Independent claims 1 and 11 has been amended to recite "wherein the heat treated shank exhibits permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1". This limitation has a basis at Example 4 and Figure 6 of the specification.

Claim Objections

Claims 1 and 11 were objected to because of an extra period after "25° C". Claims 1 and 11 have been amended to correct this informality.

35 U.S.C. § 112 Rejection

Claims 1-23 were rejected under 35 U.S.C. § 112. The term "superelastic" has been added to independent claims 1 and 11 in order to overcome this rejection as suggested in the Office Action.

Claim 12 was rejected under 35 U.S.C. § 112. The term "nickel" has been deleted from claim 12 in order to overcome this rejection.

35 U.S.C. § 103 Rejection

Claims 1-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Patel et al. (US 2005/0090844) in view of Matsutani (US 7,137,815).

Patel conducts the heat treatment described on a nickel-titanium alloy for annealing and shape setting purposes to arrive at a superelastic device, whereas the present invention is conducting the heat treatment on a superelastic shank (rather than as part of the forming of a superelastic device) resulting in non-superelastic properties that allow for permanent deformation. Amended independent claims 1 and 11 recite these differences between Patel and the claimed invention. Specifically, amended independent claims 1 and 11: (i) recite in step (a), a shank comprising a superelastic alloy; (ii) recite in step (b), heat-treating the shank comprising the superelastic alloy after step (a); and (iii) recite that the heat treated shank exhibits permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1.

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

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

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

Thus, Patel conducts the heat treatment described on a nickel-titanium alloy for annealing and shape setting purposes to arrive at a superelastic device as confirmed in the technical literature. Amended independent claims 1 and 1 now make it clear that the present invention is conducting the heat treatment on a superelastic shank rather than as part of the forming a superelastic device as in Patel.

Looking at U.S. Patent No. 7,137,815 to Matsutani *et al.*, there is described a root canal treatment tool that includes a work portion having a shape memory characteristic in the range of a predetermined length from the tip and a superelastic characteristic in a remaining portion (see column 2, lines 11-24 of Matsutani). In one manufacturing method for the Matsutani root canal treatment tool, "a raw material previously provided with a superelastic characteristic is subjected to a working of removing metal to form a work portion, and by which the tip side of the work portion is again subjected to a heat treatment to provide the tip side with a shape memory characteristic" (see column 6, lines 18-23 of Matsutani). Still referring to Matsutani, it is stated that "the length of the shape memory portion 6 in the work portion 4 needs to be at least 2 mm from the tip 3 [, and] [a]lthough the maximum length is not limited to a special length, the maximum length is about 3/4 of the whole length of the work portion 4" (see column 5, lines 25-29 of Matsutani). Thus, Matsutani heat treats only the tip of the instrument to create a shape memory portion at the tip and a superelastic portion for the remainder of the instrument. In contrast, independent claims 1 and 11 require heat-treating the entire shank.

Summarizing, Patel and Matsutani do not teach a method that heat treats an entire shank comprising a superelastic nickel titanium alloy or a superelastic titanium alloy to produce a dental instrument that exhibits permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 as recited in amended independent claims 1 and 11. It is well settled that in order to establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Accordingly, it is submitted that independent claim 1 (and claims 3-10 that depend thereon) and independent claim 11 (and claims 12-23 that depend thereon) are patentable over Patel and Matsutani.

Double Patenting Rejections

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 8,876,991.

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,727,773.

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 8,562,341.

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 8,083,873.

It is requested that the double patenting rejections be held in abeyance until allowable subject matter is indicated.

Conclusion

Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

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

Respectfully submitted,

Neill H. Luebke

Dated: August 25, 2015

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QB\35764169.1

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

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Abstract

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

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

1. INTRODUCTION

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

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

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

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

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

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

2. EXPERIMENT

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

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

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

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

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

3. RESULTS AND DISCUSSION

3.1 Structure and surface

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

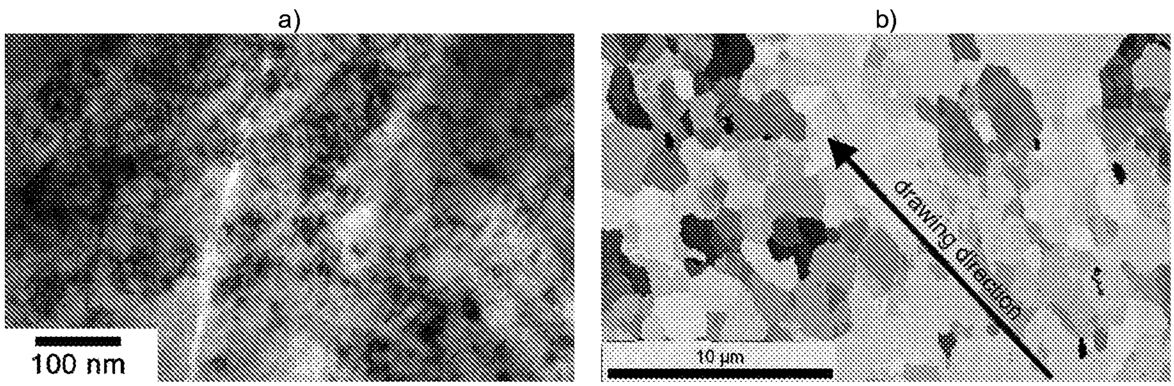

Fig. 1: Structures of the wire: a) as-prepared (TEM), b) heat-treated at 600°C/10 min (EBSD)

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

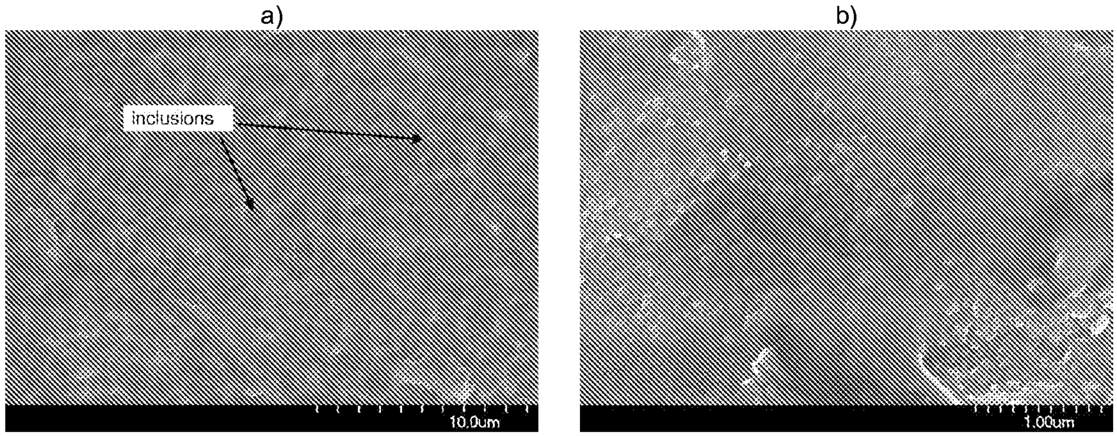

Fig. 2: Surface of the as-prepared wire (a) and the wire heat-treated at 600°C/10 min (b).

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

3.2 Mechanical and fatigue properties

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

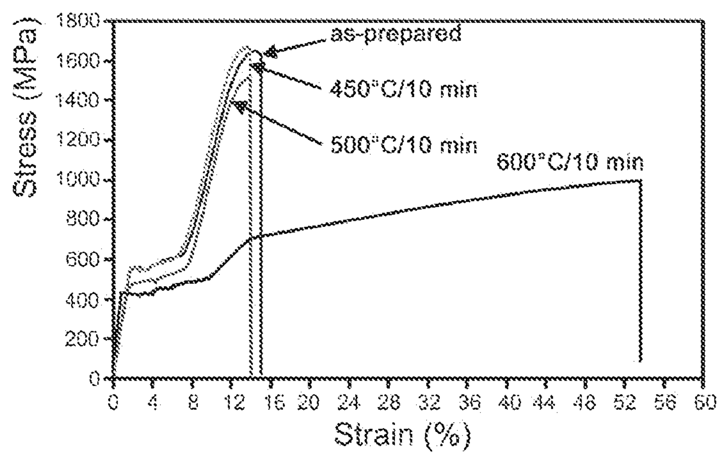

Fig. 3: Stress-strain curves of the wires treated by various regimes.

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

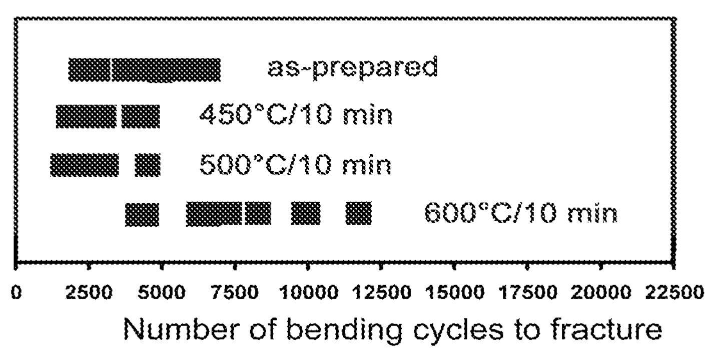

Fig. 4: The fatigue lives of the wires expressed as the numbers of bending cycles to fracture (each state is represented by ten measurements).

3.3 Corrosion resistance

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

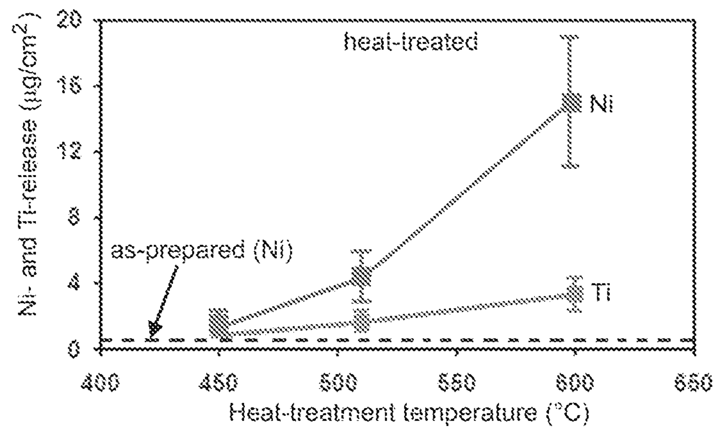

Fig.5: Ti and Ni release into the corrosive medium as a function of heat treatment temperature.

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

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

4. CONCLUSIONS

It is demonstrated in the present work that the functional properties of NiTi wire are modified considerably by 10-min heat treatments at moderate temperatures of 450-600°C. These modifications should be taken into account when the shape-setting treatment of stents is performed. Modifications of the tensile properties occurring mainly after treatment at 600°C can be attributed to recrystallization processes in the work-hardened wire. It is clear that lower heat treatment temperatures up to 500°C do not considerably affect the tensile strength. The fatigue as well as the corrosion properties are influenced by the heat treatment of the wire. Fatigue life is found to improve with increasing heat treatment temperature. The reason for this is that the heat treatment induces structural changes beneficial for the formation of plastic stress-induced martensite at the crack tip, which increases the crack growth resistance. The effect of heat treatment on the corrosion resistance is negative due to the formation of thick and defect-containing oxide layers which worsen the protective effect.

ACKNOWLEDGEMENTS

Research of the NiTi alloys is financially supported by research projects no. MSM6046137302, MSMT NO. 21/2011, IAA200100902 and KAN300100801.

REFERENCES

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Electronic Acknowledgement Receipt

EFS ID:	23308495
Application Number:	14522013
International Application Number:	
Confirmation Number:	9570
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:	115207.00014
Receipt Date:	25-AUG-2015
Filing Date:	23-OCT-2014
Time Stamp:	17:11:21
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		Luebkeamendment.pdf	2004486 04000fc82f32b695be3a281e7b93914909992857	yes	19

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	19

Warnings:

Information:

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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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/522,013	Filing Date 10/23/2014	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT 08/25/2015	CLAIMS REMAINING AFTER AMENDMENT (Column 1)		HIGHEST NUMBER PREVIOUSLY PAID FOR (Column 2)	PRESENT EXTRA (Column 3)	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 22	Minus	** 23	= 0	x $80 =	0
Independent (37 CFR 1.16(h))	* 2	Minus	***2	= 0	x $420 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/CHERYL CLARK/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/522,013	10/23/2014	Neill Hamilton Luebke	115207.00014	9570

26710 7590 09/04/2015
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
09/04/2015	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

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No. 14/522,013	Applicant(s) LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3732	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTHS 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 _8/25/2015_.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

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

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

Disposition of Claims*

5)☒ Claim(s) _1 and 3-23_ 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 and 3-23_ is/are rejected.
8)☐ Claim(s) _____ is/are objected to.
9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

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

Application Papers

10)☐ The specification is objected to by the Examiner.
11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a)☐ All b)☐ Some** c)☐ None of the:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.
3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
4) ☐ Other: _____.

1) The present application is being examined under the pre-AIA first to invent provisions.

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 double patenting rejection is appropriate where the claims at issue 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 reference 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. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more

information about eTerminal Disclaimers, refer to
http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

- Claims 1-23 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 8,876,991. Although the claims at issue are not identical, they are not patentably distinct from each other because both applications are directed to the same invention other than what property is compared.
- Claims 1-23 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,727,773. Although the claims at issue are not identical, they are not patentably distinct from each other because both applications are directed to the same invention other than what property is compared.
- Claims 1-23 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 8,562,341. Although the claims at issue are not identical, they are not patentably distinct from each other because both applications are directed to the same invention other than what property is compared.
- Claims 1-23 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 8,083,873. Although the claims at issue are not identical, they are not patentably distinct from each other because both applications are directed to the same invention other than what property is compared.

Claim Rejections - 35 USC § 112

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

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

- Claims 1-23 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. Claims 1 and 11 recites the method steps of providing a superelastic (nickel) titanium alloy and subjecting it to a heat treatment at a temperature above 25 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 superelastic (nickel) titanium alloys subjected to a heat treatment at these low of temperatures would appear to result in that degree of deformation. The dependent claims do not provide further steps that would always result in this degree of permanent deformation.
- The Examples provided in the specification only relate to heat treatments at 500 degrees C for about 1 to 2 hours, and do not provide any guidance on how a heat treatment at 25 degrees C (the lower boundary temperature) could result in the same amount of deformation after a bending test. It is noted that 25 C is less than the

temperature of the mouth, which is typically around 37 C, and within Merriam Webster's definition of room temperature, between 15 to 25 degrees C. This method would then be broad enough to encompass placing a superelastic endodontic instrument in a patient's mouth or leaving a superelastic endodontic instrument in a room at room temperature, however one would not expect the resulting deformation after doing so, and therein lies the 112 issue.

- It is suggested to provide an example heat treatment at 25 degrees C that would result in the claimed permanent deformation if Applicant believes this would only require routine experimentation. At present, it is unclear how such a low temperature, and those temperatures below the Example temperature, could be used to achieve the claimed result.

Conclusion

- 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, Cris Rodriguez, *at* (571) 272-4964**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/Matthew M. Nelson/

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

Index of Claims	Application/Control No. 14522013	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON
	Examiner MATTHEW NELSON	Art Unit 3732

✓	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	05/29/2015	08/31/2015							
	1	✓	✓							
	2	✓	-							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
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	16	✓	✓							
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	19	✓	✓							
	20	✓	✓							
	21	✓	✓							
	22	✓	✓							
	23	✓	✓							

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	7	"8876991".pn. "8727773".pn. "8562341".pn. "8083873".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/08/31 09:02
L2	3	"20060115786".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/08/31 09:30
L3	3730	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	2015/08/31 10:23
L4	2934	(A61C5/023 OR A61C2201/007).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/08/31 10:23
L5	16533	(C22F1/006 OR C22F1/10 OR C22F1/004).CPC. (C22C14/00 OR C22C19/03).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/08/31 10:23
L6	19290	(L4 L5)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/08/31 10:23
S2	6	"6431863".pn. "6422865".pn. "6428634".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 07:56
S5	1068	Ni adj Ti AND anneal$2 AND time	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53

S6	544	Ni adj Ti AND anneal$2 AND time AND hour	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S7	16	Ni adj Ti AND anneal$2 AND time AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:54
S8	876	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:54
S9	53	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:55
S10	183	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 15:12
S11	29	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (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; 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; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14

S29	192	S28 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S30	1099	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:33
S31	18	S30 AND microstructure	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:34
S32	200	S30 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:35
S33	2	("7175655").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/18 13:12
S34	1112	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; 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; 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-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
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
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
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
S103	2	"5380200".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/05 08:39
S104	2819	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/12/05 09:41

S105	2834	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/01/10 09:57
S106	2	"8048345".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/01/10 11:03
S107	2876	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/06/04 10:10
S108	2	"8083873".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S109	0	"8562341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S110	2	"13336579"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S111	3097	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/10/17 09:51
S114	3276	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	2014/04/04 09:31
S115	8472	(C22C14/00 OR C22C19/03).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:42
S116	2592	(A61C5/023 OR A61C2201/007).CPC.	US-PGPUB; USPAT; USOCR;	OR	ON	2014/04/04 09:44

			FPRS; EPO; JPO; DERWENT			
S117	608	superelastic ADJ nickel ADJ titanium AND heat$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:47
S118	178	superelastic ADJ nickel ADJ titanium SAME heat$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:48
S119	6221	(C22F1/006 OR C22F1/10 OR C22F1/004).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:51
S120	1414	(C22F1/006).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:52
S122	1109	(C22F1/006).CPC. AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:52
S123	22	(C22F1/006).CPC. AND (dental dentistry "433".clas.) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:53
S124	7	(C22F1/006).CPC. AND superelastic AND (dental dentistry "433".clas.) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:55
S125	36	(US-20070184406-$ or US-20070072147-$ or US-20040121283-$ or US-20080032260-$ or US-20050003325-$ or US-20030077553-$ or US-20020137008-$ or US-20020157806-$ or US-20020191878-$ or US-20020036057-$ or US-20050090844-$ or US-20050011596-$ or US-20040129352-$ or US-20030188810-$ or US-20020185200-$ or US-20040193246-$).did. or (US-6431863-$ or US-6428634-$ or US-4490112-$ or US-6375458-$ or US-5921775-$ or US-5897316-$ or US-5882198-$ or US-5775902-$ or US-5080584-$ or US-6206695-$ or US-7137815-$ or US-5941760-$ or US-	US-PGPUB; USPAT; DERWENT	OR	ON	2014/07/16 10:50

		5653590-$ or US-7779542-$ or US-6087640-$ or US-6783438-$ or US-6540849-$ or US-5380200-$ or US-7207111-$ or US-5092941-$).did. or (US-6422865-B-$).did.				
S126	19	S125 AND superelastic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/16 10:50
S127	2	"5984679".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/16 10:53
S128	20857	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) AND (martensit$3 OR deform$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:58
S129	8052	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (martensit$3 OR deform$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:58
S130	91	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (martensit$3 OR deform$3) AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:58
S131	45	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (martensit$3 OR deform$3) AND "433".clas. AND @ad<="20050607"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:59
S132	38	(US-20070184406-$ or US-20070072147-$ or US-20040121283-$ or US-20080032260-$ or US-20050003325-$ or US-20030077553-$ or US-20020137008-$ or US-20020157806-$ or US-20020191878-$ or US-20020036057-$ or US-20050090844-$ or US-20050011596-$ or US-20040129352-$ or US-20030188810-$ or US-20020185200-$ or US-20040193246-$).did. or (US-6431863-$ or US-6428634-$ or US-4490112-$ or US-6375458-$ or US-5921775-$ or US-5897316-$ or US-5882198-$ or US-5775902-$ or US-5080584-$ or US-6206695-$ or US-7137815-$ or US-5941760-$ or US-5653590-$ or US-7779542-$ or US-6087640-$ or US-6783438-$ or US-6540849-$ or US-5380200-$ or US-	US-PGPUB; USPAT; DERWENT	OR	ON	2015/05/29 10:21

		7207111-$ or US-5092941-$ or US-5984679-$ or US-6988887-$).did. or (US-6422865-B-$).did.				
S133	8	S132 AND ((cyclic ADJ fatigue) fatigue cyclic)	US-PGPUB; USPAT; DERWENT	OR	ON	2015/05/29 10:22
S134	2821	(A61C5/023 OR A61C2201/007).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/05/29 11:23
S135	15842	(C22F1/006 OR C22F1/10 OR C22F1/004).CPC. (C22C14/00 OR C22C19/03).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/05/29 11:24
S136	16	luebke-neill.in. luebke-neill-$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/05/29 11:24
S137	3624	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	2015/05/29 11:30

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
S113	1	(433/102).CCLS.	UPAD	OR	OFF	2014/02/08 08:20

8/31/2015 10:25:24 AM
C:\Users\mnelson3\Documents\EAST\EAST Workspaces\14522013 Dental and medical instruments comprising titanium.wsp

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14522013
	Filing Date	2014-10-23
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

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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	5464362		1995-11-07	Heath et al.	
	2	5628674		1997-05-13	Heath et al.	
	3	5697906		1997-12-16	Ariola et al.	
	4	8062033	B2	2011-11-22	Luebke	
	5	8083873	B2	2011-12-27	Luebke	
	6	8562341	B2	2013-10-22	Luebke	
	7	8727773	B2	2014-05-20	Luebke	
	8	8876991	B2	2014-11-04	Luebke	

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	1	20080032260	A1	2008-02-07	Luebke	
	2	20110271529	A1	2011-11-10	Gao et al.	

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	1	2006149675	JP	A	2006-06-15	Mani K.K.		☐
	2	2004100818	WO	A2	2004-11-25	Ultradent Products Inc.		☐

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	1	ALAPATI, An Investigation of Phase Transformation Mechanisms for Nickel-Titanium Rotary Endodontic Instruments, Dissertation, Ohio State University, 2006, 76 pages	☐
	2	ENDO, et al., Effects of Titanium Nitride Coatings on Surface and Corrosion Characteristics of Ni-Ti Alloy, Dental Materials Journal, 1994, 13(2):228-239	☐

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	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

	3	LUGSCHEIDER, et al., Investigation of the Residual Stresses and Mechanical Properties of (Cr,A1)N Arc PVD Coatings Used for Semi-Solid Metal (SSM) Forming Dies, Thin Solid Films, 2002, 420-421:318-323	☐
	4	MIYAZAKI, et al., Characteristics of Deformation and Transformation Pseudoelasticity in Ti-Ni Alloys, Journal de Physique, 1982, 43:C4-255 - C4-260	☐
	5	PELTON, et al., Optimisation of Processing and Properties of Medical Grade Nitinol Wire, Min. Invas. Ther. & Allied Technol., 2000, 9(1):107-118	☐
	6	SCHAFER, et al., Bending Properties of Rotary Nickel-Titanium Instruments, Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod., 2003, 96:757-763	☐
	7	STOKES, et al., Corrosion in Stainless-Steel and Nickel-Titanium Files, Journal of Endodontics, 1999, 25(1):17-20	☐
	8	TRIPI, et al., Fabrication of Hard Coatings on NiTi Instruments, Journal of Endodontics, 2003, 29(2):132-134	☐
	9	International Standard, ISO 3630-1, First Edition, 1992-12-15, Dental Root-Canal Instruments -- Part 1: Files, Reamers, Barbed Broaches, Rasps, Paste Carriers, Explorers and Cotton Broaches, 28 pages	☐
	10	International Standard, ISO 3630-1, Second Edition, 2008-02-01, Dentistry - Root-Canal Instruments - Part 1: General Requirements and Test Methods, 26 pages	☐
	11	PCT International Preliminary Report on Patentability, PCT/US2005/019947, December 8, 2006, 4 pages	☐
	12	EUROPEAN PATENT OFFICE, Supplementary European Search Report, Application Number EP 05756629, October 26, 2012, 6 pages	☐
	13	EUROPEAN PATENT OFFICE, Examination Report, Application Number EP 05756629, January 24, 2013, 8 pages	☐

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	14	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-00632, U.S. Patent No. 8,727,773, Petition for Inter Partes Review, January 30, 2015	☐
	15	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-00632, U.S. Patent No. 8,727,773, Declaration of A. Jon Goldberg, January 30, 2015	☐
	16	IN THE U.S. DISTRICT COURT, EASTERN DISTRICT OF TENNESSEE, Dentsply International, Inc. v. US Endodontics, LLC, Civil Action No. 2:14-cv-00196, Complaint for Patent Infringement, June 24, 2014	☐
	17	IN THE U.S. DISTRICT COURT, EASTERN DISTRICT OF TENNESSEE, Dentsply International, Inc. v. US Endodontics, LLC, Civil Action No. 2:14-cv-00196, Defendant US Endodontics, LLC's Answer and Counterclaims, August 6, 2014	☐
	18	IN THE U.S. DISTRICT COURT, EASTERN DISTRICT OF TENNESSEE, Dentsply International, Inc. v. US Endodontics, LLC, Civil Action No. 2:14-cv-00196, Answer to Counterclaims, September 2, 2014	☐
	19	IN THE U.S. DISTRICT COURT, EASTERN DISTRICT OF TENNESSEE, Dentsply International, Inc. v. US Endodontics, LLC, Civil Action No. 2:14-cv-00196, Amended Complaint for Patent Infringement, August 15, 2014	☐
	20	IN THE U.S. DISTRICT COURT, EASTERN DISTRICT OF TENNESSEE, Dentsply International, Inc. v. US Endodontics, LLC, Civil Action No. 2:14-cv-00196, Defendant US Endodontics LLC's Answer to Amended Complaint and Counterclaims, September 2, 2014	☐
	21	IN THE U.S. DISTRICT COURT, EASTERN DISTRICT OF TENNESSEE, Dentsply International, Inc. v. US Endodontics, LLC, Civil Action No. 2:14-cv-00196, Answer to Counterclaims, September 19, 2014	☐
	22	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-01476, U.S. Patent No. 8,727,773, Petition for Inter Partes Review, June 25, 2015	☐
	23	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-01476, U.S. Patent No. 8,727,773, Declaration of A. Jon Goldberg, June 25, 2015	☐

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	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

EXAMINER SIGNATURE			
Examiner Signature	/Matthew Nelson/	Date Considered	08/31/2015

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	Filing Date	2014-10-23
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2015-07-24
Name/Print	Richard T. Roche	Registration Number	38,599

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	Application Number	14522013
	Filing Date	2014-10-23
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

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	1	20060115786	A1	2006-06-01	Matsutani et al.	

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	1	2004344717	JP	A	2004-11-29	Mani, Inc.		☐

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	1	BAHIA, et al., Fatigue Behaviour of Nickel-Titanium Superelastic Wires and Endodontic Instruments, Fatigue & Fracture of Engineering Materials & Structures, 2006, 29(7):518-523	☐
	2	DREXEL, et al., The Effects of Cold Work and Heat Treatment on the Properties of Nitinol Wire, Proceedings of the International Conference on Shape Memory and Superelastic Technologies, May 7-11, 2006, pp. 447-454	☐
	3	PELTON, et al., The Physical Metallurgy of Nitinol for Medical Applications, JOM, 2003, 55(5):33-37	☐
	4	TESTARELLI, et al., Bending Properties of a New Nickel-Titanium Alloy with a Lower Percent by Weight of Nickel, Journal of Endodontics, 2011, 37(9):1293-1295	☐
	5	ProFile ISO Rotary Files Product Information and Material Safety Data Sheet for Nickel Titanium Wire: 'NITINOL 55', http://www.tulsadentalspecialties.com/default/endodontics/RotaryFiles/ProFileISO.aspx [Exhibit 1035 to the Petition for Post-Grant Review, Case No. PGR2015-00019, website was accessed July 22, 2015]	☐
	6	Petition for Post-Grant Review of U.S. Patent No. 8,876,991 B2, in the United States Patent and Trademark Office Before the Patent Trial and Appeal Board, Case No. PGR2015-00019, August 3, 2015	☐
	7	Declaration of A. Jon Goldberg, Exhibit 1002 to the Petition for Post-Grant Review of U.S. Patent No. 8,876,991 B2, in the United States Patent and Trademark Office Before the Patent Trial and Appeal Board, Case No. PGR2015-00019, August 3, 2015	☐

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

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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.

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14522013	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	MATTHEW NELSON	3732

CPC- SEARCHED

Symbol	Date	Examiner
A61C5/023; A61C2201/007; C22F1/006,10,004; C22C14/00; C22C19/03	5/29/2015	MN
A61C5/023; A61C2201/007; C22F1/006,10,004; C22C14/00; C22C19/03	8/31/2015	MN

CPC COMBINATION SETS - SEARCHED

Symbol	Date	Examiner

US CLASSIFICATION SEARCHED

Class	Subclass	Date	Examiner
29	896.1, 896.11	5/29/2015	MN
148	402, 421, 426	5/29/2015	MN
433	102, 224	5/29/2015	MN
29, 148, 433	Updated	8/31/2015	MN

SEARCH NOTES

Search Notes	Date	Examiner
See EAST search history	5/29/2015	MN
Updated EAST search	8/31/2015	MN

INTERFERENCE SEARCH

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

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
115207.00014	14/522,013	October 23, 2014
First Named Inventor: Neill H. Luebke	Title: Dental and Medical Instruments Comprising Titanium	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:

- Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
- The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
  - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
  - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
    - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
    - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/Richard T. Roche/	September 28, 2015
Name (Print/Typed) Richard T. Roche	Practitioner Registration No. 38599

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

☑ * Total of 1 forms are submitted.

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

Date: September 28, 2015

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

IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	14/522,013
Filing Date:	October 23, 2014
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	9570
Art Unit:	3732
Examiner:	Matthew M. Nelson

AMENDMENT AFTER FINAL ACTION

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

Sir or Madam:

This amendment is in response to the Final Office Action mailed September 4, 2015.

Submitted herewith is a Certification and Request for Consideration under the After Final Consideration Pilot Program 2.0.

A Listing of the Claims begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

Amendments To The Claims

1. (Currently Amended) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic nickel titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from above 25° C up to but not equal to the melting point of the nickel titanium alloy,

wherein the heat treated shank has increased fatigue life compared to an endodontic instrument of same composition and size not treated in accordance with step (b) , and

wherein the heat treated shank exhibits permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1.

2. (Cancelled)

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

the fatigue life is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

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

the fatigue life is increased by at least 10%.

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

the fatigue life is increased by at least 30%.

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

the fatigue life is increased by at least 50%.

7. (Original) The method of claim 1 wherein:
the fatigue life is increased by at least 70%.

8. (Original) The method of claim 1 wherein:
the fatigue life is increased by at least 230%.

9. (Original) The method of claim 1 wherein:
the fatigue life is increased by at least 450%.

10. (Original) A method of claim 1 wherein:
the heat treating temperature is at least 250° C.

11. (Currently Amended) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from above 25° C up to but not equal to the melting point of the titanium alloy,

wherein the heat treated shank has improved cyclic fatigue compared to an endodontic instrument of same composition and size not treated in accordance with step (b), and

wherein the heat treated shank exhibits permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1.

12. (Previously Presented) The method of claim 11 wherein the titanium alloy is a nickel titanium alloy.

13. (Original) The method of claim 11 wherein:

the cyclic fatigue is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

14. (Original) The method of claim 11 wherein:

the cyclic fatigue revolutions are at least 300.

15. (Original) The method of claim 11 wherein:

the cyclic fatigue revolutions are at least 950.

16. (Original) The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 1600.

17. The method of claim 11 wherein:
the cyclic fatigue revolutions are at least 2000.

18. (Original) The method of claim 11 wherein:
the cyclic fatigue revolutions are increased by at least 50%.

19. (Original) The method of claim 11 wherein:
the cyclic fatigue revolutions are increased by at least 100%.

20. (Original) The method of claim 11 wherein:
the heat-treating temperature is at least 100° C.

21. (Original) The method of claim 11 wherein:
the heat treating temperature is at least 200° C.

22. (Original) The method of claim 11 wherein:
the heat-treating temperature is at least 300° C.

23. (Original) The method of claim 11 wherein:
the heat-treating temperature is at least 400° C.

REMARKS

Claim Amendments

Claim 1 and claim 11 have been amended to recite that the temperature is above 25°C. This limitation has a basis at page 4, lines 7-8, of the specification.

35 U.S.C. § 112 Rejection

Claims 1-23 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Applicant acknowledges that a patent must contain a description that enables one skilled in the art to make and use the claimed invention. *See*, *Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, (Fed.Cir.1984). However, a patent specification can be enabling even if some experimentation is necessary to make the patented invention work. *Id* at 1576. "That some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive." *Id* at 1576. Furthermore, a considerable amount of experimentation is not unduly extensive if it is merely routine. *In re Wands*, 858 F.2d 731, 737 (Fed.Cir.1988).

It is submitted that the Office Action has not provided the evidence necessary to demonstrate that one of ordinary skill in the art would be forced to experiment unduly in order to practice the claimed invention. Example 4 of the present application describes how ISO size 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. The results are shown in Figure 6. While Example 4 of the present application uses a non-limiting example temperature, one skilled in the art could readily rerun Example 4 using other temperatures within the scope of independent claims 1 and

11. Merely changing heat treat temperature in the method described in Example 4 of the present application could be characterized as routine experimentation. Thus, this amount of experimentation is not unduly extensive. *In re Wands*, 858 F.2d at 737.

However, in order to expedite prosecution, attached as Exhibit 1 is an Inventor's Declaration under 37 C.F.R. 1.132 that was filed in U.S. Patent Application No. 14/167,311 filed January 29, 2014, now U.S. Patent No. 8,876,991, from which the present application claims priority. (Exhibit 1 submitted herewith was Exhibit 2 of U.S. Patent Application No. 14/167,311.) Exhibit 1 demonstrates that one skilled in the art could readily rerun Example 4 using other temperatures within the scope of independent claims 1 and 11. Exhibit 1 describes how endodontic files were heat treated at 375°C.

At the paragraph bridging pages 4 and 5, the Office Action appears to allege that the claims include inoperative species. However, as set forth in *Atlas Powder Co.*, 750 F.2d at 1576-77:

> Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude … possible inoperative substances …." (citations omitted).

Thus, one skilled in the art could determine the proper combination of temperature conditions, and the claim need not specifically exclude all combinations that could possibly be inoperable.

To the extent that the paragraph bridging pages 4 and 5 of the Office Action is alleging that the claims include inoperative species, Item 9 of the Exhibit 1 Inventor's Declaration points out that orthodontic wire (which is superelastic) activates in the patient's mouth and that permanent deformation is not the process that creates orthodontic movement. Thus, the superelastic wire referenced in the paragraph bridging pages 4 and 5 of the Office Action works in a completely different manner compared to instruments produced by the claimed methods of the present patent application which exhibit permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 as recited in pending independent claims 1 and 11.

Accordingly, it is respectfully requested that the enablement rejection under 35 USC § 112, first paragraph, be withdrawn.

Double Patenting Rejections

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 8,876,991.

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,727,773.

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 8,562,341.

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 8,083,873.

Terminal disclaimers are submitted herewith in order to overcome the double patenting rejections.

Conclusion

Terminal disclaimer fees are submitted herewith. If any other fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: September 28, 2015

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

QB\36793437.1

Exhibit 1

Docket Number: 115207.00011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	14/167,311
Filing Date:	January 29, 2014
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	8000
Art Unit:	3732
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 noted the paragraph at page 5 of the Office Action of April 11, 2014 which states:

> "Specifically, in the arguments filed in the parent case 12/977,625 on 8/26/2011, Applicant showed the criticality of the temperature being over 400 C (where the claims only differ by the temperature between the parent and present invention). "The Inventor's Declaration explains that the angular deflection was significantly larger for the files heat-treated at 500°C, that the cyclic fatigue data demonstrate the remarkable property of passive flexibility in the files heat-treated at 500°C compared to the files heat-treated at 375°C, that the torque data indicates that the heat did not degrade the metal in the files heat-treated at 500°C. and that the bend test data shows that the files heat-treated at 500°C have improved flexibility compared to the files heat- treated at 375°C. Thus, heat treatment within the claimed range was critical to improving the beneficial properties of the endodontic instruments." It is unclear how these temperatures are now sufficient when they had previously been established outside the critical range."

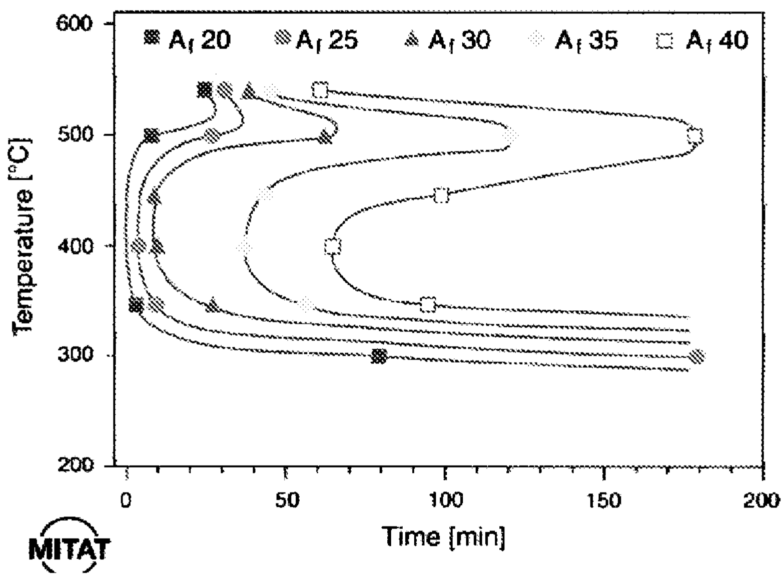
3. The data from the Inventor's Declaration referred to in the paragraph cited in Item 2 above pertains to: (i) Torque at Failure, (ii) Angular Deflection at Failure, (iii) Bend Test, and (iv) Cyclic Fatigue at 375°C and 500°C. The data from the Inventor's Declaration does not show angles of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 as in pending independent claims 1, 6 and 11 of my present application. Thus, none of the tests in the Inventor's Declaration referred to in the paragraph from the Office Action cited in Item 2 was directed to the above feature noted in pending independent claims 1, 6 and 11.

4. I conducted a study to show that endodontic instruments heat treated at 375°C will have an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 as recited in pending independent claims 1, 6 and 11 of my present patent application. I obtained endodontic instruments 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. I heat-treated a first batch of these instruments in a furnace at 375°C for 120 minutes. I heat-treated a second batch of these instruments in a furnace at 400°C for 120 minutes. I heat-treated a third batch of these instruments in a furnace at 500°C for 90 minutes. I used differential scanning calorimetry (DSC) on these heat-treated endodontic instruments to determine the phase of these heat treated endodontic instruments.

5. The DSC of the endodontic instruments heat-treated at 375°C, 400°C, and 500°C all showed that the endodontic instruments were in the martensitic phase. These DSC results are attached as Exhibits A and B and C. This indicates that the endodontic instruments heat treated at 375°C, 400°C and 500°C will all have an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 as recited in pending independent claims 1, 6 and 11 of my patent application.

6. The results of my DSC tests corroborate a study that was published after the filing date of my application. Specifically, M.H. Elahinia *et al.* show in Figure 4 (below) of "Manufacturing and processing of NiTi implants: A review", *Progress in Materials Science*, 57: 911-46, June 2012, that instruments heat-treated between 300°C and 400°C will have a phase such that an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 will be achieved.

M.H. Elahinia et al. / Progress in Materials Science 57 (2012) 911–946



7. It should be noted that pending independent claims 1, 6 and 11 of my present patent application recite "greater than 10 degrees of permanent deformation". Thus, while the Inventor's Declaration referred to in the paragraph from the Office Action cited in Item 2 reports different data between the 500°C and the 375°C samples, the samples heat treated at 375°C merely need to meet a "greater than 10 degrees of permanent deformation" limitation. While the instruments heated to 375°C may have permanent deformation not quite as large as the instruments heated at 500°C, we are not looking for statistical differences, just the permanent deformation of the instrument after heat-treatment in accordance with pending independent claims 1, 6 and 11 of my present patent application.

8. I have noted the paragraph bridging pages 5 and 6 of the Office Action of April 11, 2014 which states:

It is further noted that 25 C is less than the temperature of the mouth, which is typically around 37 C. This method would then be broad enough to encompass placing a superelastic nickel titanium archwire in a patient's mouth, however one would not expect the resulting deformation after doing so, and therein lies the 112 issue.

9. The austenite finish (A_f) temperature for orthodontic wire is such that the wire will activate in the patient's mouth. Permanent deformation is not the process that creates orthodontic movement. The orthodontic wire works as a shape memory alloy (SMA) and is activated in the mouth by the temperature in the mouth. The A_f temperature of the orthodontic wire is usually in the range of 25°C and hence the activation of the SMA movement or force. In the instance of the present patent application, I am attempting to create a martensitic alloy (instrument or device) that is <u>not activated</u> (underlining added) at mouth temperature (37°C) but still displays permanent deformation at 37°C.

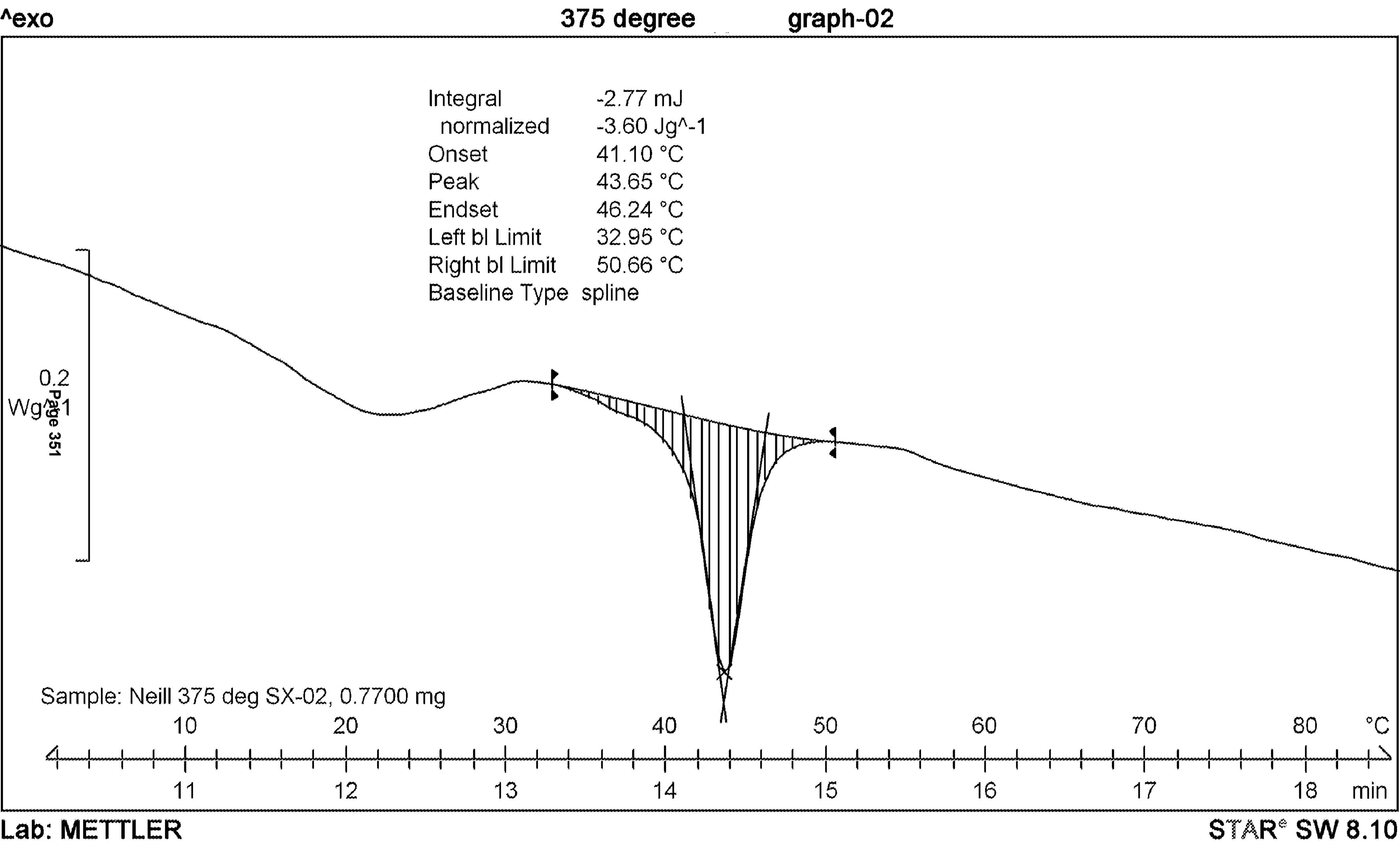
10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like made are punishable by fine or imprisonment,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

Neill H. Luebke

Dr. Neill H. Luebke

Dated: July 9, 2014

Exhibit A



^exo
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normalized -3.60 Jg^-1
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Peak 43.65 °C
Endset 46.24 °C
Left bl Limit 32.95 °C
Right bl Limit 50.66 °C
Baseline Type spline
0.2
Wg^-1
Page 351
Sample: Neill 375 deg SX-02, 0.7700 mg
10
20
30
40
50
60
70
80
°C
11
12
13
14
15
16
17
18
min
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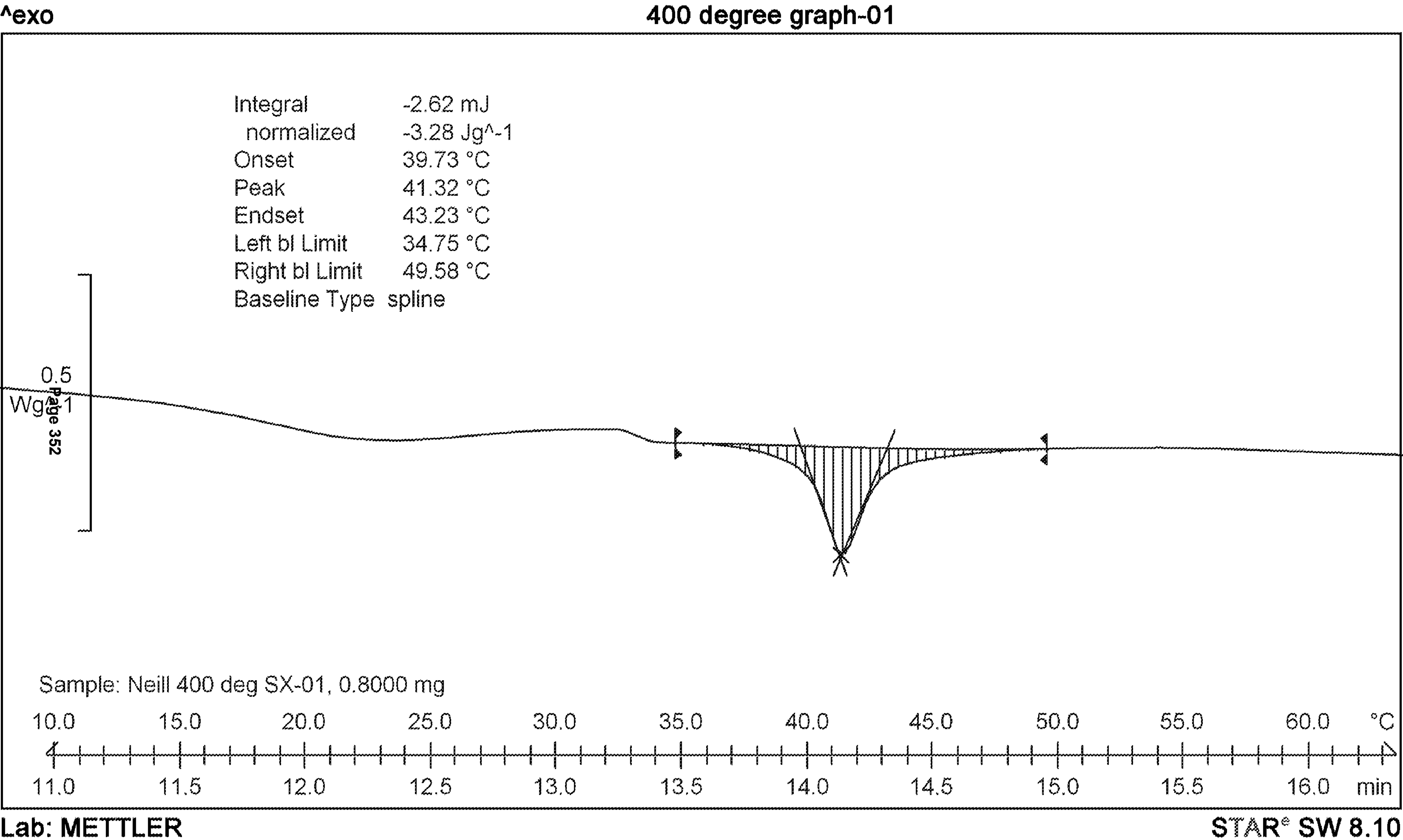
STAR® SW 8.10

Exhibit B


^exo
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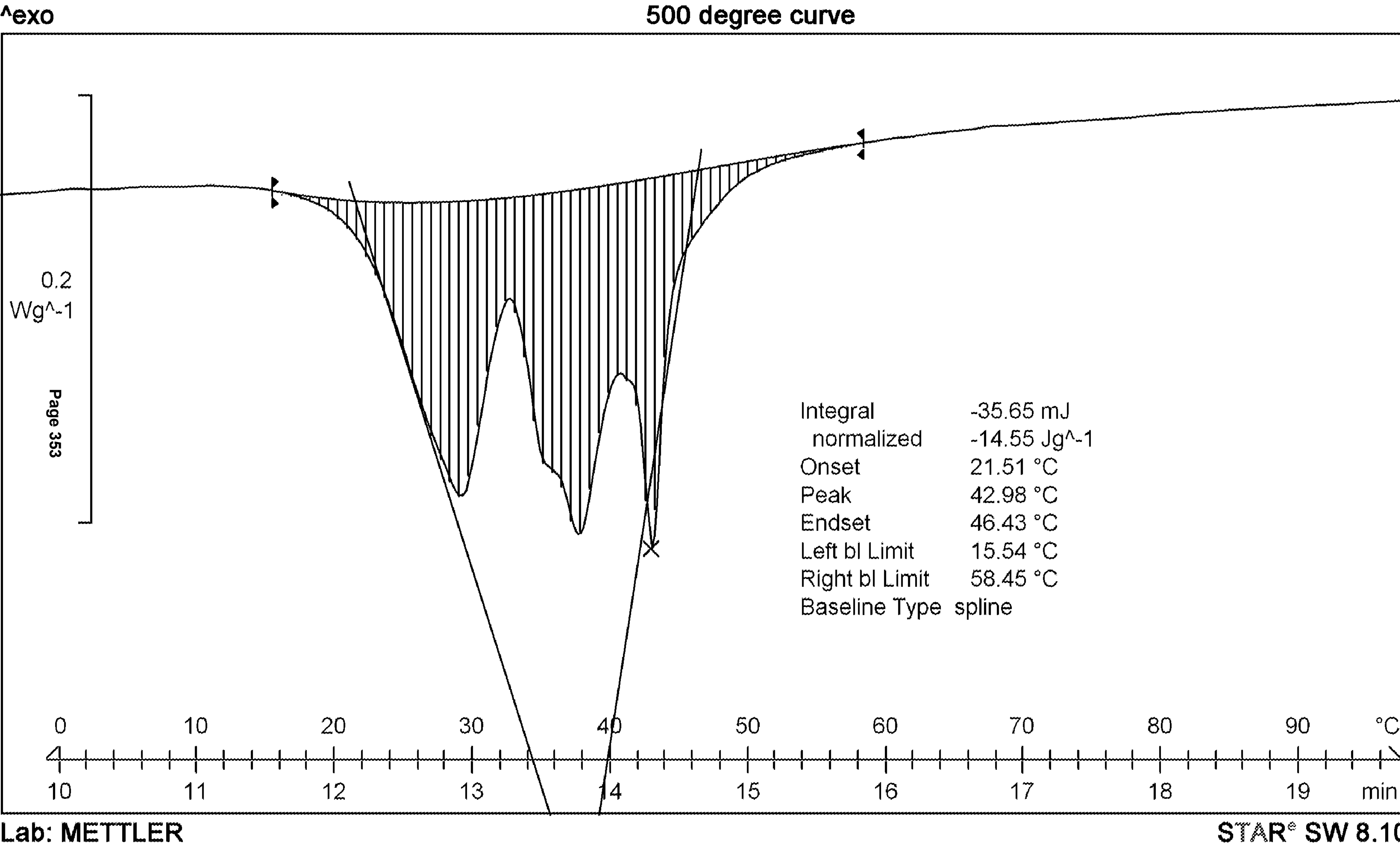
normalized -3.28 Jg^-1
Onset 39.73 °C
Peak 41.32 °C
Endset 43.23 °C
Left bl Limit 34.75 °C
Right bl Limit 49.58 °C
Baseline Type spline
0.5
Wg^-1
Page 352
Sample: Neill 400 deg SX-01, 0.8000 mg
10.0 15.0 20.0 25.0 30.0 35.0 40.0 45.0 50.0 55.0 60.0 °C
11.0 11.5 12.0 12.5 13.0 13.5 14.0 14.5 15.0 15.5 16.0 min
Lab: METTLER
STAR^e SW 8.10

Exhibit C



^exo
500 degree curve
0.2
Wg^-1
Page 353
Integral -35.65 mJ
normalized -14.55 Jg^-1
Onset 21.51 °C
Peak 42.98 °C
Endset 46.43 °C
Left bl Limit 15.54 °C
Right bl Limit 58.45 °C
Baseline Type spline
0 10 20 30 40 50 60 70 80 90 °C
10 11 12 13 14 15 16 17 18 19 min
Lab: METTLER
STAR^e SW 8.10

Electronic Acknowledgement Receipt

EFS ID:	23618429
Application Number:	14522013
International Application Number:	
Confirmation Number:	9570
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Customer Number:	26710
Filer:	Daniel James Ark/Richard Roche
Filer Authorized By:	Daniel James Ark
Attorney Docket Number:	115207.00014
Receipt Date:	28-SEP-2015
Filing Date:	23-OCT-2014
Time Stamp:	12:27:39
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	After Final Consideration Program Request	After_Final_Consideration_Luebke.pdf	177813 d1e33c411dd283f3c46553b4a22be34e7351ef57	no	1

Warnings:

Information:

2		AfterFinalAmendment-9-28-2015.pdf	1556274 be5475469b0d404a7dfff504243a525827dc ab9c	yes	17

Multipart Description/PDF files in .zip description

Document Description	Start	End
Response After Final Action	1	1
Claims	2	5
Applicant Arguments/Remarks Made in an Amendment	6	17

Warnings:

Information:

Total Files Size (in bytes):	1734087

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

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

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

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

PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 115207.00014

In re Application of: Neill H. Luebke

Application No.: 14/522,013

Filed: October 23, 2014

For: Dental and Medical Instruments Comprising Titanium

The applicant, Gold Standard Instruments, LLC, owner 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. 8,876,991 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant 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 applicant 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. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 38599

/Richard T. Roche/ — Signature

09-28-2015 — Date

Richard T. Roche — Typed or printed name

Title

414-277-5805 — 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.

PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 115207.00014

In re Application of: Neill H. Luebke

Application No.: 14/522,013

Filed: October 23, 2014

For: Dental and Medical Instruments Comprising Titanium

The applicant, Gold Standard Instruments, LLC, owner 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. 8,727,773 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant 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.

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- 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;
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/Richard T. Roche/ — Signature
09-28-2015 — Date

Richard T. Roche — Typed or printed name

Title

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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 115207.00014

In re Application of: Neill H. Luebke

Application No.: 14/522,013

Filed: October 23, 2014

For: Dental and Medical Instruments Comprising Titanium

The applicant, Gold Standard Instruments, LLC, owner 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. 8,562,341 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant 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.

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- 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;
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- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

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1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

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2. ☑ The undersigned is an attorney or agent of record. Reg. No. 38599

/Richard T. Roche/ — Signature

09-28-2015 — Date

Richard T. Roche — Typed or printed name

Title

414-277-5805 — 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.

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 115207.00014

In re Application of: Neill H. Luebke

Application No.: 14/522,013

Filed: October 23, 2014

For: Dental and Medical Instruments Comprising Titanium

The applicant, Gold Standard Instruments, LLC, owner 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 applicant 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.

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2. ☑ The undersigned is an attorney or agent of record. Reg. No. 38599

/Richard T. Roche/ — Signature

09-28-2015 — Date

Richard T. Roche — Typed or printed name

Title

414-277-5805 — 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.

Electronic Patent Application Fee Transmittal

Application Number:	14522013
Filing Date:	23-Oct-2014
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Daniel James Ark/Richard T. Roche
Attorney Docket Number:	115207.00014

Filed as Large Entity

Filing Fees for **Utility under 35 USC 111(a)**

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($)
Miscellaneous:				
Statutory or Terminal Disclaimer	1814	4	160	640
		Total in USD ($)		**640**

Electronic Acknowledgement Receipt

EFS ID:	23620432
Application Number:	14522013
International Application Number:	
Confirmation Number:	9570
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Customer Number:	26710
Filer:	Daniel James Ark/Richard T. Roche
Filer Authorized By:	Daniel James Ark
Attorney Docket Number:	115207.00014
Receipt Date:	28-SEP-2015
Filing Date:	23-OCT-2014
Time Stamp:	14:12:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$640
RAM confirmation Number	459
Deposit Account	170055
Authorized User	ROCHE, RICHARD T.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	Terminal_Disclimer_Forms.pdf	1888482 7f3caefed294a1cf3c4e4a332317cedece6dc015	no	4
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30337 ef9de5235dd327b295fde94bd91f5f5c7e53d743	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1918819		

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.

<u>New Applications Under 35 U.S.C. 111</u>
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.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

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

PTO/SB/06 (09-11)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/522,013	Filing Date 10/23/2014	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT	09/28/2015	CLAIMS REMAINING AFTER AMENDMENT (Column 1)		HIGHEST NUMBER PREVIOUSLY PAID FOR (Column 2)	PRESENT EXTRA (Column 3)	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 22	Minus	** 23	= 0	x $80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	x $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**0**

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/DORRETTA BROOKS/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/522,013	10/23/2014	Neill Hamilton Luebke	115207.00014	9570

26710 7590 10/13/2015

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
10/13/2015	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

PTOL-90A (Rev. 04/07)

Advisory Action Before the Filing of an Appeal Brief	Application No. 14/522,013	Applicant(s) LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3732	AIA (First Inventor to File) Status No

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

THE REPLY FILED 28 September 2015 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires ______months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

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

NOTICE OF APPEAL

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

AMENDMENTS

3. ☒ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): ______.
6. ☐ Newly proposed or amended claim(s) ______ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): (a) ☒ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ______.
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: ______.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). ______
14. ☒ Other: PTO-2323.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: .
   Claim(s) objected to: .
   Claim(s) rejected: 1 and 3-23.
   Claim(s) withdrawn from consideration: .

	/MATTHEW NELSON/ Examiner, Art Unit 3732

Continuation of 3. NOTE: The new issues raised include the temperature being above 25 degrees C.

AFCP 2.0 Decision	**Application No.** 14/522,013	**Applicant(s)** LUEBKE, NEILL HAMILTON
	Examiner MATTHEW NELSON	**Art Unit** 3732

This is in response to the After Final Consideration Pilot request filed 28 September 2015.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

   ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.

   ☐ A non-broadening amendment to at least one independent claim was not submitted.

   ☐ A proper AFCP 2.0 request was submitted in response to the most recent final rejection.

   ☐ Other:

2. **Proper Request**

   A. After final amendment submitted with the request will not be treated under AFCP 2.0.
   The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

   ☒ The after final amendment will be treated under pre-pilot procedure.

   B. Updated search and/or completed additional consideration.
   The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

   ☐ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.

   ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action. See attached interview summary for further details.

   ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.

   ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.

   ☐ 5. Other:

Examiner Note: Please attach an interview summary when necessary as described above.

DO NOT ENTER: /M.N./

10/07/2015

Docket No.: 115207.00014

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

Date: September 28, 2015

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

IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	14/522,013
Filing Date:	October 23, 2014
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	9570
Art Unit:	3732
Examiner:	Matthew M. Nelson

AMENDMENT AFTER FINAL ACTION

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

Sir or Madam:

This amendment is in response to the Final Office Action mailed September 4, 2015.

Submitted herewith is a Certification and Request for Consideration under the After Final Consideration Pilot Program 2.0.

A Listing of the Claims begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

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

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

Application Number	14522013	Filing Date	2014-10-23	Docket Number (if applicable)	115207.00014	Art Unit	3732
First Named Inventor	Neill H. Luebke			Examiner Name	Matthew M. Nelson		

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

SUBMISSION REQUIRED UNDER 37 CFR 1.114

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

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

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

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☒ Affidavit(s)/ Declaration(s)
- ☒ Other 3 Month Extension of Time Request

MISCELLANEOUS

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

☐ Other ____________

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 170055

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

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

Signature of Registered U.S. Patent Practitioner			
Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2016-03-03
Name	Richard T. Roche	Registration Number	38599

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

Date: March 3, 2016

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

IN THE UNITED PATENT STATES AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	14/522,013
Filing Date:	October 23, 2014
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	9570
Art Unit:	3732
Examiner:	Matthew M. Nelson

AMENDMENT ACCOMPANYING REQUEST FOR CONTINUED EXAMINATiON

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

Sir or Madam:

This amendment is in response to the Final Office Action mailed September 4, 2015.

A Listing of the Claims begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

Amendments To The Claims

1. (Currently Amended) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic nickel titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 300°C ~~25° C~~ up to but not equal to the melting point of the nickel titanium alloy,

~~wherein the heat treated shank has increased fatigue life compared to an endodontic instrument of same composition and size not treated in accordance with step (b) , and~~

~~wherein the heat treated shank exhibits permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1~~

wherein the heat-treated instrument has an angle greater than 6 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1.

2. (Cancelled)

3. (Currently Amended) The method of claim 1 wherein:

the heat treated shank has increased fatigue life compared to an endodontic instrument of same composition and size not treated in accordance with step (b) , and

the fatigue life is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

4. (Currently Amended) The method of claim 3 [[1]] wherein:

the fatigue life is increased by at least 10%.

5. (Currently Amended) The method of claim 3 [[1]] wherein: the fatigue life is increased by at least 30%.

6. (Currently Amended) The method of claim 3 [[1]] wherein: the fatigue life is increased by at least 50%.

7. (Currently Amended) The method of claim 3 [[1]] wherein: the fatigue life is increased by at least 70%.

8. (Currently Amended) The method of claim 3 [[1]] wherein: the fatigue life is increased by at least 230%.

9. (Currently Amended) The method of claim 3 [[1]] wherein: the fatigue life is increased by at least 450%.

10. (Cancelled)

11. (Currently Amended) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 300°C ~~25° C~~ up to but not equal to the melting point of the titanium alloy,

~~wherein the heat treated shank has improved cyclic fatigue compared to an endodontic instrument of same composition and size not treated in accordance with step (b), and~~

~~wherein the heat treated shank exhibits permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1~~

wherein the heat-treated instrument has an angle greater than 6 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1.

12. (Previously Presented) The method of claim 11 wherein the titanium alloy is a nickel titanium alloy.

13. (Currently Amended) The method of claim 11 wherein:

the heat treated shank has improved cyclic fatigue compared to an endodontic instrument of same composition and size not treated in accordance with step (b), and

the cyclic fatigue is determined by a cyclic fatigue analysis based on ISO Standard 3630-2 Dental root-canal instruments—Part 2: Enlargers and ANSI/ADA Specification No. 95, for Root canal enlargers.

14. (Currently Amended) The method of claim 13 [[11]] wherein:

the cyclic fatigue revolutions are at least 300.

15. (Currently Amended) The method of claim 13 [[11]] wherein:
the cyclic fatigue revolutions are at least 950.

16. (Currently Amended) The method of claim 13 [[11]] wherein:
the cyclic fatigue revolutions are at least 1600.

17. (Currently Amended) The method of claim 13 [[11]] wherein:
the cyclic fatigue revolutions are at least 2000.

18. (Currently Amended) The method of claim 13 [[11]] wherein:
the cyclic fatigue revolutions are increased by at least 50%.

19. (Currently Amended) The method of claim 13 [[11]] wherein:
the cyclic fatigue revolutions are increased by at least 100%.

20. (Cancelled)

21. (Cancelled)

22. (Cancelled)

23. (Cancelled)

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

the heat-treated instrument has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements.

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

the heat-treated instrument has an angle greater than 13 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements.

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

the heat-treated instrument has an angle greater than 15 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements.

27. (New) The method of claim 11 wherein:

the heat-treated instrument has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements.

28. (New) The method of claim 11 wherein:

the heat-treated instrument has an angle greater than 13 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements.

29. (New) The method of claim 11 wherein:

the heat-treated instrument has an angle greater than 15 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements.

REMARKS

Claim Amendments

Claim 1 has been amended to recite the heat treating temperature as 300°C as in original claim 22. Claim 1 has also been amended to recite that the heat-treated instrument has an angle greater than 6 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 as shown in Figure 6 of the application. The third paragraph of the body of original claim 1 has been moved to claim 3, and the dependencies of claims 4-9 have been amended accordingly. It is noted that prior art was not cited against independent claim 1 in the Office Action and therefore, the amendments to claim 1 are not made to overcome prior art.

Claim 10 has been cancelled.

Claim 11 has been amended to recite the heat treating temperature as 300°C as in original claim 22. Claim 11 has also been amended to recite that the heat-treated instrument has an angle greater than 6 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 as shown in Figure 6 of the application. The third paragraph of the body of original claim 11 has been moved to claim 13, and the dependencies of claims 14-19 have been amended accordingly. It is noted that prior art was not cited against independent claim 11 in the Office Action and therefore, the amendments to claim 1 are not made to overcome prior art.

Claim 20-23 have been cancelled.

New claims 24-29 have a basis in Figure 6 of the application.

Advisory Action

The Advisory Action of October 13, 2015 indicated that the amendment submitted September 28, 2015 was not entered.

Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement is submitted herewith.

Applicant wishes to point out that although the Inventor's Declaration submitted September 28, 2015 in the present application was not entered, paragraphs 47 to 58 of my November 4, 2015 Declaration in Case IPR2015-00632 (listed on the IDS form and submitted herewith) are related to the non-entered Inventor's Declaration submitted September 28, 2015.

Double Patenting Rejections

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 8,876,991.

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,727,773.

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 8,562,341.

Claims 1-23 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 8,083,873.

Terminal disclaimers were submitted September 28, 2015 in order to overcome the double patenting rejections. Review and approval of these terminal disclaimers is respectfully requested.

35 U.S.C. § 112 Rejection

Claims 1-23 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Page 5 of the Office Action suggested that the Applicant provide an example heat treatment that would result in the claimed permanent deformation in order to overcome the rejection under 35 U.S.C. § 112, first paragraph. Applicant thanks the Examiner for this helpful recommendation.

Attached is an Inventor's Declaration under 37 C.F.R. 1.132. The Inventor's Declaration reports a study demonstrating that endodontic instruments heat treated at 300°C will have an angle greater than 6 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 as recited in amended independent claims 1 and 11.

Accordingly, it is respectfully requested that the enablement rejection under 35 USC § 112, first paragraph, be withdrawn.

Conclusion

An RCE fee and an extension fee and extra claims fees are submitted herewith. If any other fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,
Neill H. Luebke

Dated: March 3, 2016

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

QB\38812573.1

Docket Number: 115207.00014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	14/522,013
Filing Date:	October 23, 2014
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	9570
Art Unit:	3732
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 noted the paragraph at page 5 of the Office Action mailed September 4, 2015 suggesting that I provide an example heat treatment that would result in the claimed permanent deformation in order to overcome the rejection under 35 U.S.C. § 112, first paragraph.

3. I conducted a study to show that endodontic instruments heat treated at 300°C will have an angle greater than 6 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 as recited in amended independent claims 1 and 11 submitted herewith in my present patent application.

4. I obtained ten endodontic instruments 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. I instructed Bodycote Thermal Processing of Sturtevant, Wisconsin to heat treat these ten endodontic instruments in a furnace at 300°C for 24 hours in air.

5. After the heat treatment at 300°C for 24 hours in air, the ten heat treated endodontic instruments were sent to Knight Mechanical Testing in Fort Wayne, Indiana for testing in accordance with ISO Standard 3630-1 as recited in amended independent claims 1 and 11 submitted herewith in my present patent application. A report from Knight Mechanical Testing is attached as Exhibit A. Page 7 of Exhibit A shows that the ten heat treated endodontic instruments (S1 to S10) had an angle of permanent deformation after torque at 45° of flexion ranging from 12.5 to 15.1 degrees when tested in accordance with ISO Standard 3630-1.

6. Thus, a heat treatment of endodontic instruments at 300°C for 24 hours in air results in the claimed permanent deformation recited in amended independent claims 1 and 11 submitted herewith in my present patent application.

7. 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: March 3, 2016

Neill H. Luebke

Dr. Neill H. Luebke

QB\38821181.1

KMT
KNIGHT MECHANICAL TESTING
3205 Clairmont Ct. Suite B
Fort Wayne, IN 46808
Phone: (260) 489-1444
Fax: (260) 818-2036

Gold Standard Nitinol Files ISO 3630-1 Section 7.5 Stiffness Testing Final Report

KMT Report Number:	TR1139-001
Final Report Date:	3/2/2016
Revision Level:	Initial
Revision Date:	3/2/2016
Customer:	Dr. Neill Luebke Gold Standard Instruments LLC 18010 Continental Drive, Suite 800 Brookfield, WI 53045

Reported By: Nick Chadd - Test Engineer **Date: 3/2/2016**

Reviewed By: Nolan Knight - Engineering Manager **Date: 3/2/2016**

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REVISION / REVIEW HISTORY

Revision Level	Revision / Review Date	Change	Approved by	Date Approved
Initial	3/2/2016	Initial release	NK	3/2/2016

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Contents

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1 Subject

Nitinol Endodontic File Supplied by Bodycote Thermal Processing – Sturtevant, WI

2 Objective

Perform ISO 3630-1 Section 7.5 Stiffness testing on the endodontic files.

3 Background

3.1 Job Summary

KMT Job Number:	1139GSI
Test Method/Protocol:	ISO 3630-1:2008(E) Section 7.5 Stiffness
Test Material Provided by:	Bodycote Thermal Processing – Sturtevant, WI

Table 1: Job Summary

3.2 Testing Summary

Test Method	KMT Project Number	KMT Load Frame (s)	Test Start Date	Test Completion Date
ISO 3630-1 Section 7.5 Stiffness	1139GSI3080	LF16	2/26/2016	2/26/2016

Table 2: Testing Summary

4 Test Material

4.1 ISO 3630-1 Section 7.5 Stiffness Test Material

Description	Part Number	Lot Number	Quantity
Nitinol Endodontic Files	misc	na	10

Table 3: ISO 3630-1 Section 7.5 Stiffness Test Material

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Fax: (260) 818-2036

5 Equipment

5.1 Calibrated Test Equipment

Asset Tag	Description	Manufacturer	Serial #	Calibrated	Calibration Due
KMT ADT 06	Trans-Tek Angular Displacement Transducer, Model 0605-0001	Trans-Tek	E0018	4/6/2015	4/30/2016
KMT CNTR 12	Omega CSC32 Temperature Controller calibrated to 100C	Omega Engineering, Inc.	616580040 055	12/31/2015	12/31/2016
KMT LC 52	Futek Model MBA500 - axial/torque; 100 lb, 100 inlb	Futek	561224	11/13/2015	11/30/2016
KMT MT 13	Wixey Digital Protractor WR 410	Wixey	KMTMT13	1/21/2016	1/31/2017
KMT TP 6	Type K thermocouple probe TJ36-CASS-18U-6-OSTW-M	Omega Engineering, Inc.	KMTTP6	12/31/2015	12/31/2016

Table 4: Calibrated Test Equipment

5.2 Load Frames and Controllers

Asset Tag	Description	Manufacturer	Serial #
KMT LF 16	MTS Model 359.02 load frame, 25 kN capacity	MTS	1027931
KMT CTL 01	MTS Model 493.10 FlexTest GT Controller	MTS	02022807A

Table 5: Load Frames and Controllers

5.3 Fixturing

KMT ISO 3630 Fixture, 0.65" Lever Arm

Table 6: Fixturing

6 Method

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Fax: (260) 818-2036

6.1 ISO 3630-1 Section 7.5 Stiffness Test Setup

The tip of endodontic file was clamped in the KMT ISO 3630 fixture perpendicular to the axis of the rotary actuator, to a depth of 3mm. The fixture was rigidly attached to the torque cell which was clamped to the load frame baseplate. A catch pin was mounted to the rotary actuator. The actuator was rotated until the catch pin was lightly touching the specimen and the angular displacement was set to zero. The actuator was then rotated until it reached an angular displacement of 45°. The applied torque was recorded for each file. See Figure 1 for a photograph of the test setup.

6.2 ISO 3630-1 Section 7.5 Stiffness Test Parameters

Test Rate:	2 rpm
Data Recording Rate:	128 Hz
Test Environment:	Ambient air maintained at 23°C ±2°C

Table 7: ISO 3630-1 Section 7.5 Stiffness Test Parameters

7 Test Results

7.1 ISO 3630-1 Section 7.5 Stiffness Test Results

Sample	Torque @ 45° Angular Displacement (mN-m)	Posttest Permanent Deformation Angle (deg)
S1	14.6	14.5
S2	14.7	14.9
S3	14.0	12.9
S4	12.8	14.1
S5	14.9	13.4
S6	13.1	13.1
S7	14.9	13.0
S8	12.9	14.9
S9	13.3	12.5
S10	12.4	15.1
Avg.	**13.8**	**13.8**
Std. Dev.	**0.9**	**1.0**

Table 8: ISO 3630-1 Section 7.5 Stiffness Test Results

See Appendix A for a torque vs. angular displacement plot for the stiffness test. See Figure 2 for a post-test photograph of the test specimens.

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8 Photographs

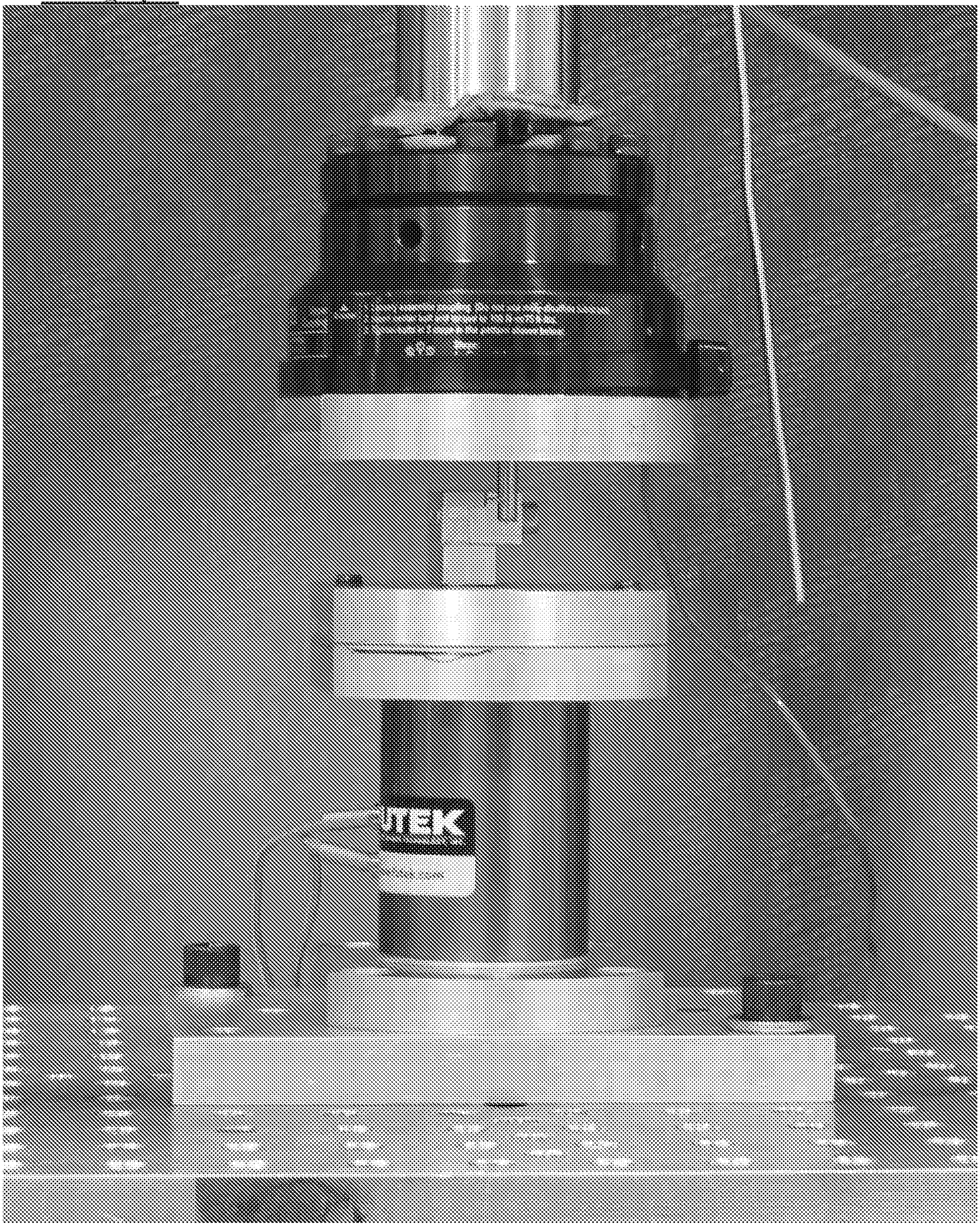

Figure 1: ISO 3630-1 Section 7.5 Stiffness Test Setup

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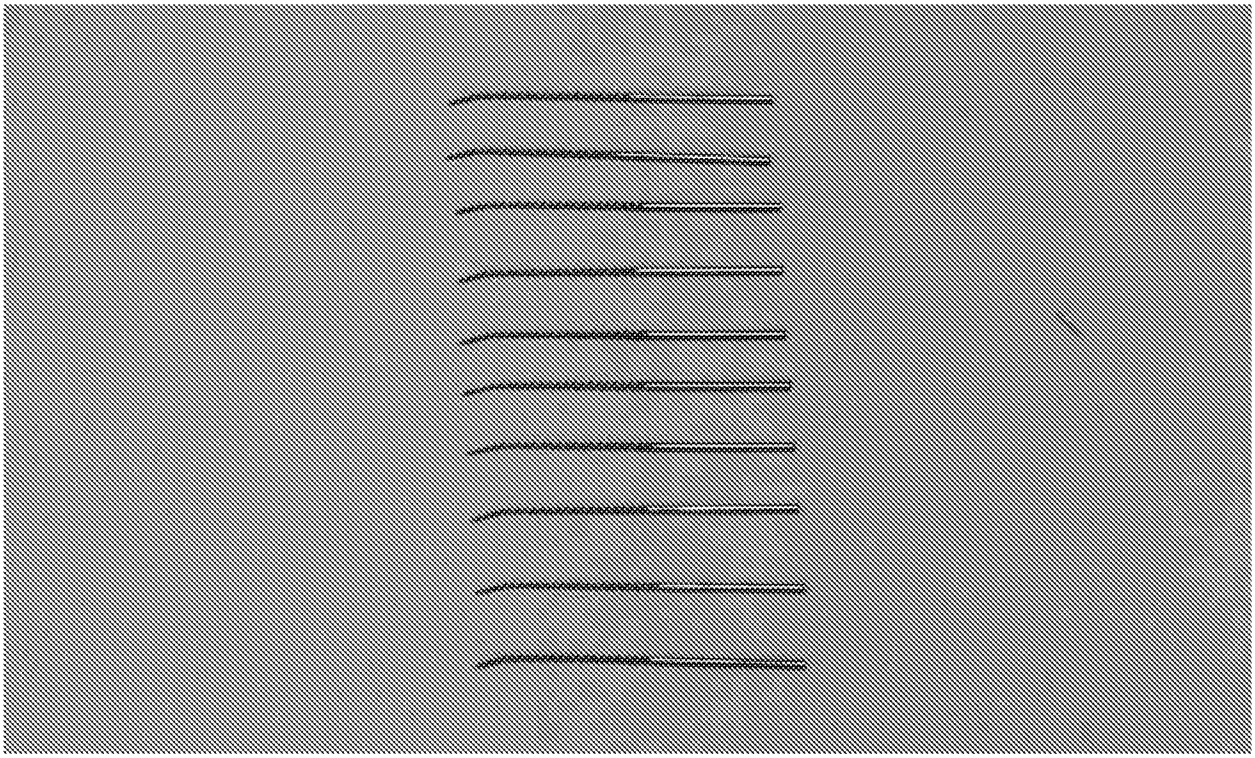

Figure 2: Posttest S1 through S10 from top to bottom

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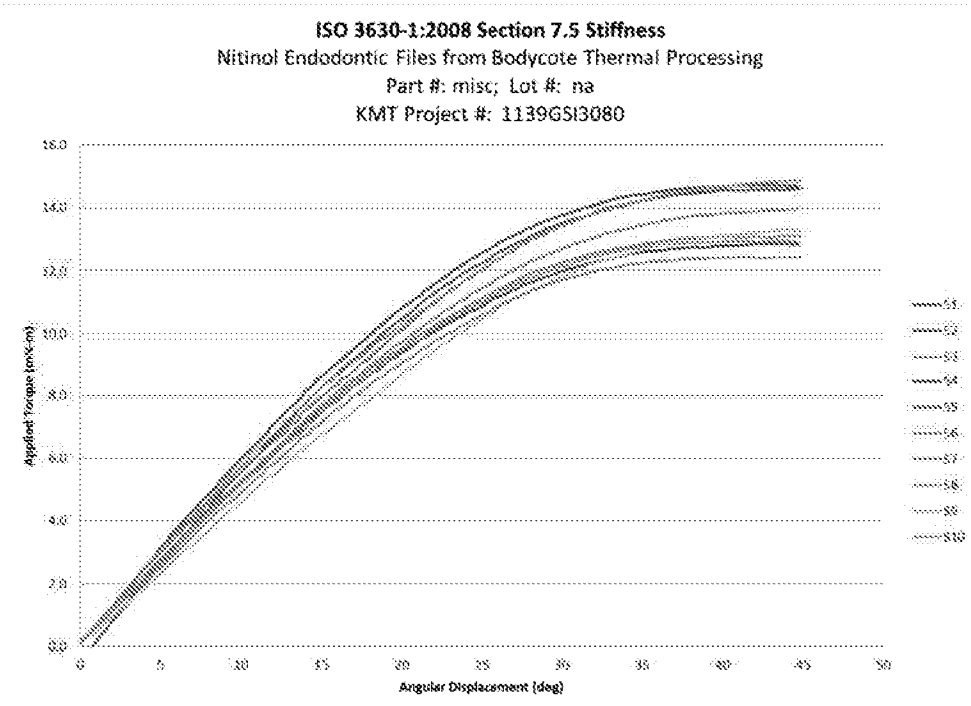
Phone: (260) 489-1444
Fax: (260) 818-2036

9 Appendix A: Test Plots



PTO/AIA/22 (03-13)
Approved for use through 3/31/2013. OMB 0651-0031
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) 115207.00014
Application Number 14/522,013	Filed October 23, 2014
For Dental and Medical Instruments Comprising Titanium	
Art Unit 3732	Examiner Matthew M. Nelson

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

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

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

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

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

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

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

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

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 17-0055.

☐ Payment made via EFS-Web.

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

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 38599.

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

/Richard T. Roche/	3-3-2016
Signature	Date
Richard T. Roche	414-277-5805
Typed or printed name	Telephone Number

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

☑ * Total of 2 forms are submitted.

Electronic Patent Application Fee Transmittal

Application Number:	14522013
Filing Date:	23-Oct-2014
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Richard T. Roche
Attorney Docket Number:	115207.00014

Filed as Large Entity

Filing Fees for **Utility under 35 USC 111(a)**

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in Excess of 20	1202	3	80	240
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 3 months with $0 paid	1253	1	1400	1400
Miscellaneous:				
Request for Continued Examination	1801	1	1200	1200
		Total in USD ($)		**2840**

Electronic Acknowledgement Receipt

EFS ID:	25061413
Application Number:	14522013
International Application Number:	
Confirmation Number:	9570
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:	115207.00014
Receipt Date:	03-MAR-2016
Filing Date:	23-OCT-2014
Time Stamp:	09:53:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$2840
RAM confirmation Number	10782
Deposit Account	170055
Authorized User	ROCHE, RICHARD T.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	11520700014SuppIDSMar2016.pdf	612869 7232316bfce36cd3bc995d1ab27ce4731f5c0e44	no	4
Warnings:					
Information:					
2	Other Reference-Patent/App/Search documents	DecisionInstitutionOfIPR2015-00632Aug2015_.pdf	691821 02d21b326525e2c8b25a883902ebc06ac0e55abb	no	33
Warnings:					
Information:					
3	Other Reference-Patent/App/Search documents	DeclarationLuebkeIPR2015-00632Nov2015.pdf	2067010 b4b3febdea7690758625ab5cf33ff2de54939f18	no	29
Warnings:					
Information:					
4	Other Reference-Patent/App/Search documents	PatentOwnerPrelimRespToPetitionForIPR2015-01476July2015_.pdf	330940 d7dedc809597a176306a3d69df39c2fcf13a802d	no	44
Warnings:					
Information:					
5	Other Reference-Patent/App/Search documents	DecisionDenyingInstitutionOfIPR2015-01476Oct2015_.pdf	139953 0e505a82bc657178ffb146c2bbd4f45e43d7d570	no	11
Warnings:					
Information:					
6	Other Reference-Patent/App/Search documents	PatentOwnerPrelimRespToPetitionForPGR2015-00019Nov2015_.pdf	377596 31aef021cb63f4f627399be11492f8b004af0409	no	91
Warnings:					
Information:					
7	Other Reference-Patent/App/Search documents	DecisionInstitutionOfPGR2015-00019Jan2016_.pdf	359216 2f7a37dd01bacdd6e44aade06feaa9b757564eea	no	39
Warnings:					
Information:					

8	Non Patent Literature	GuhringCoatingServices.pdf	8492129 bf84c0f6fbfd80c5426e46202d650d15d3f2b9a2	no	5
Warnings:					
Information:					
9	Request for Continued Examination (RCE)	Request_for_Continued_Examination_0014.pdf	1323538 414b8ab4601d66a788835616200c5ad240151cb7	no	2
Warnings:					
Information:					
10		luebkeamendment.pdf	79929 cb22a1b0019ddc9f63154a6110cb71df2cf1adba	yes	9

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment Submitted/Entered with Filing of CPA/RCE	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	9

Warnings:					
Information:					
11	Affidavit-traversing rejectns or objectns rule 132	Inventor-Luebke-Declaration-March-3-2016.pdf	964086 47456cc03fcf7a33383d3d976751afdff5079b79	no	13
Warnings:					
Information:					
12	Extension of Time	Extension_of_time_request_0014.pdf	140873 61d48d57dc0dbb56e971900e7dcac861e07ee517	no	1
Warnings:					
Information:					
13	Fee Worksheet (SB06)	fee-info.pdf	33671 3e9efc2cd11915695fc4ffc0e8b6c427123ca39b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	15613631	

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

New Applications Under 35 U.S.C. 111

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

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(**Not for submission under 37 CFR 1.99**)

Application Number	14522013
Filing Date	2014-10-23
First Named Inventor	Neill Hamilton Luebke
Art Unit	3732
Examiner Name	Nelson, Matthew M.
Attorney Docket Number	115207.00014

U.S.PATENTS

Remove

Examiner Initial*	Cite No	Patent Number	Kind Code1	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4850867		1989-07-25	Senia et al.	
	2	5843244		1998-12-01	Pelton et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS

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Examiner Initial*	Cite No	Publication Number	Kind Code1	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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FOREIGN PATENT DOCUMENTS

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Examiner Initial*	Cite No	Foreign Document Number3	Country Code2 i	Kind Code4	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
	1							

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NON-PATENT LITERATURE DOCUMENTS

Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14522013
	Filing Date	2014-10-23
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

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.	T5
	1	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-00632, U.S. Patent No. 8,727,773, Decision - Institution of Inter Partes Review, August 5, 2015	
	2	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-00632, U.S. Patent No. 8,727,773, Declaration of Neill H. Luebke, D.D.S., M.S., November 4, 2015	
	3	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-01476, U.S. Patent No. 8,727,773, Patent Owner's Preliminary Response to Petition for Inter Partes Review, July 30, 2015	
	4	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-01476, U.S. Patent No. 8,727,773, Decision Denying Institution of Inter Partes Review, October 26, 2015	
	5	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case PRG2015-00019, U.S. Patent No. 8,876,991, Patent Owner's Preliminary Response to Petition for Post-Grant Review, November 19, 2015	
	6	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case PRG2015-00019, U.S. Patent No. 8,876,991, Decision - Institution of Post-Grant Review, January 29, 2016	
	7	GUHRING COATING SERVICES, High Performance Thin-Film Coatings for Cutting Tools & Wear Parts, Product Brochure, Copyright Guhring, Inc. 2003	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	14522013
	Filing Date	2014-10-23
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2016-03-01
Name/Print	Richard T. Roche	Registration Number	38,599

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 1 hour 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.**

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
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.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	
14/522,013	10/23/2014	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT	03/03/2016	CLAIMS REMAINING AFTER AMENDMENT (Column 1)		HIGHEST NUMBER PREVIOUSLY PAID FOR (Column 2)	PRESENT EXTRA (Column 3)	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 23	Minus	** 26	= 0	x $80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	x $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**0**

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/THUY TA/

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

26710 7590 03/14/2016

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

EXAMINER	
NELSON, MATTHEW M	
ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 03/14/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/522,013	10/23/2014	Neill Hamilton Luebke	115207.00014	9570

TITLE OF INVENTION: Dental and Medical Instruments Comprising Titanium

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	06/14/2016

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

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

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

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

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

26710 7590 03/14/2016

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

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/522,013	10/23/2014	Neill Hamilton Luebke	115207.00014	9570

TITLE OF INVENTION: Dental and Medical Instruments Comprising Titanium

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	06/14/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
NELSON, MATTHEW M	3732	433-102000

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

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

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

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

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

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

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

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

5. **Change in Entity Status** (from status indicated above)
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ☐ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ☐ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature ______________________ Date ______________________

Typed or printed name ______________________ Registration No. ______________________

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/522,013	10/23/2014	Neill Hamilton Luebke	115207.00014	9570

26710 7590 03/14/2016

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

EXAMINER	
NELSON, MATTHEW M	
ART UNIT	**PAPER NUMBER**
3732	

DATE MAILED: 03/14/2016

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

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

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

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

<table>
<tr><td rowspan="2">Notice of Allowability</td><td>Application No.
14/522,013</td><td colspan="2">Applicant(s)
LUEBKE, NEILL HAMILTON</td></tr>
<tr><td>Examiner
MATTHEW NELSON</td><td>Art Unit
3732</td><td>AIA (First Inventor to File) Status
No</td></tr>
</table>

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *amendment filed on 3/3/2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on______.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1,3-9,11,13-19 and 24-29*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. ______ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

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

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

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

Attachment(s)

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

/MATTHEW NELSON/
Examiner, Art Unit 3732

- The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

EXAMINER'S AMENDMENT

- An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claim 1, line 8: Replace "the nickel titanium alloy" with "the superelastic nickel titanium alloy".

Claim 11, line 8: Replace "the titanium alloy" with "the superelastic titanium alloy".

Cancel claim 12.

Allowable Subject Matter

- Claims 1, 3-9, 11, 13-19, 24-29 are allowed.
- The following is an examiner's statement of reasons for allowance: A method of manufacturing or modifying an endodontic instrument which is provided having an elongated shank of superelastic titanium alloy and then subsequently heat-treating the entire instrument or device at 300 C or above but not the melting temperature, resulting in a device with shape memory characteristics in that an angle greater than 6 degrees

of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 was neither taught nor suggested by the prior art as a whole, either alone or in combination, and in combination with the elements set forth in the claims. The closest prior art does not tend to heat treat entire instruments, nor does it more importantly perform these heat treatments on superelastic dental instruments or devices. Rather, the prior art is interested in heat-treating in order to arrive at a superelastic instrument. So what the present invention is essentially doing is taking a completed superelastic instrument (the prior art) and then conducting further heat-treatment in order to arrive at a shape memory alloy with the prescribed deformation characteristics. Based on prior art and consultation with class 148 regarding the properties of the alloys and heat-treatment, it was understood that while a titanium alloy will not always result in the above properties, a shape memory titanium alloy will result from the claimed method distinguished from the superelastic properties of the prior art.

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

Response to Amendment

- The affidavit under 37 CFR 1.132 filed 3/3/2016 is sufficient to overcome the previous 112 rejection by establishing a higher temperature.

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, Cris Rodriguez,** ***at*** **(571) 272-4964**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/Matthew M. Nelson/

Examiner, Art Unit 3732

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14522013	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3732

CPC- SEARCHED

Symbol	Date	Examiner
A61C5/023; A61C2201/007; C22F1/006,10,004; C22C14/00; C22C19/03	5/29/2015	MN
A61C5/023; A61C2201/007; C22F1/006,10,004; C22C14/00; C22C19/03	8/31/2015	MN
Updated	3/5/2016	MN

CPC COMBINATION SETS - SEARCHED

Symbol	Date	Examiner

US CLASSIFICATION SEARCHED

Class	Subclass	Date	Examiner
29	896.1, 896.11	5/29/2015	MN
148	402, 421, 426	5/29/2015	MN
433	102, 224	5/29/2015	MN
29, 148, 433	Updated	8/31/2015	MN
Updated		3/5/2016	MN

SEARCH NOTES

Search Notes	Date	Examiner
See EAST search history	5/29/2015	MN
Updated EAST search	8/31/2015	MN
Updated EAST search	3/5/2016	MN

INTERFERENCE SEARCH

US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
148	563	3/5/2016	MN
C22F	1/006	3/5/2016	MN

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3792	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	2016/03/05 11:49
L2	3038	(A61C5/023 OR A61C2201/007).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2016/03/05 11:49
L3	17411	(C22F1/006 OR C22F1/10 OR C22F1/004).CPC. (C22C14/00 OR C22C19/03).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2016/03/05 11:49
L4	22717	L1 L2 L3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2016/03/05 11:49
L5	19	luebke-neill.in. luebke-neill-$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2016/03/05 11:49
L7	447	148/563	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2016/03/05 12:12
L8	450	148/563.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2016/03/05 12:12
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").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/18 13:12
S34	1112	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; 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

		(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
S96	282	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:06
S97	184	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:07
S98	71	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) AND (inert gas) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:25
S99	18	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated) SAME (inert gas) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:26
S100	13	"148".clas. AND ((shape ADJ 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
S103	2	"5380200".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/05 08:39

S104	2819	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/12/05 09:41
S105	2834	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/01/10 09:57
S106	2	"8048345".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/01/10 11:03
S107	2876	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/06/04 10:10
S108	2	"8083873".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S109	0	"8562341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S110	2	"13336579"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S111	3097	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/10/17 09:51
S114	3276	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	2014/04/04 09:31
S115	8472	(C22C14/00 OR C22C19/03).CPC.	US-PGPUB; USPAT; USOCR;	OR	ON	2014/04/04 09:42

			FPRS; EPO; JPO; DERWENT			
S116	2592	(A61C5/023 OR A61C2201/007).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:44
S117	608	superelastic ADJ nickel ADJ titanium AND heat$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:47
S118	178	superelastic ADJ nickel ADJ titanium SAME heat$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:48
S119	6221	(C22F1/006 OR C22F1/10 OR C22F1/004).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:51
S120	1414	(C22F1/006).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:52
S122	1109	(C22F1/006).CPC. AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:52
S123	22	(C22F1/006).CPC. AND (dental dentistry "433".clas.) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:53
S124	7	(C22F1/006).CPC. AND superelastic AND (dental dentistry "433".clas.) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/04/04 09:55
S125	36	(US-20070184406-$ or US-20070072147-$ or US-20040121283-$ or US-20080032260-$ or US-20050003325-$ or US-20030077553-$ or US-20020137008-$ or US-20020157806-$ or US-20020191878-$ or US-20020036057-$ or US-20050090844-$ or US-20050011596-$ or US-20040129352-$ or US-20030188810-$ or US-20020185200-$ or US-20040193246-$).did. or (US-	US-PGPUB; USPAT; DERWENT	OR	ON	2014/07/16 10:50

		6431863-$ or US-6428634-$ or US-4490112-$ or US-6375458-$ or US-5921775-$ or US-5897316-$ or US-5882198-$ or US-5775902-$ or US-5080584-$ or US-6206695-$ or US-7137815-$ or US-5941760-$ or US-5653590-$ or US-7779542-$ or US-6087640-$ or US-6783438-$ or US-6540849-$ or US-5380200-$ or US-7207111-$ or US-5092941-$).did. or (US-6422865-B-$).did.				
S126	19	S125 AND superelastic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/16 10:50
S127	2	"5984679".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/16 10:53
S128	20857	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) AND (martensit$3 OR deform$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:58
S129	8052	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (martensit$3 OR deform$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:58
S130	91	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (martensit$3 OR deform$3) AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:58
S131	45	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal$3 OR heat NEAR5 treated OR heat) SAME (martensit$3 OR deform$3) AND "433".clas. AND @ad<="20050607"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/07/16 11:59
S132	38	(US-20070184406-$ or US-20070072147-$ or US-20040121283-$ or US-20080032260-$ or US-20050003325-$ or US-20030077553-$ or US-20020137008-$ or US-20020157806-$ or US-20020191878-$ or US-20020036057-$ or US-20050090844-$ or US-20050011596-$ or US-20040129352-$ or US-20030188810-$ or US-20020185200-$ or US-20040193246-$).did. or (US-6431863-$ or US-6428634-$ or US-4490112-$ or US-6375458-$ or US-5921775-$ or US-5897316-$ or US-	US-PGPUB; USPAT; DERWENT	OR	ON	2015/05/29 10:21

		5882198-$ or US-5775902-$ or US-5080584-$ or US-6206695-$ or US-7137815-$ or US-5941760-$ or US-5653590-$ or US-7779542-$ or US-6087640-$ or US-6783438-$ or US-6540849-$ or US-5380200-$ or US-7207111-$ or US-5092941-$ or US-5984679-$ or US-6988887-$).did. or (US-6422865-B-$).did.				
S133	8	S132 AND ((cyclic ADJ fatigue) fatigue cyclic)	US-PGPUB; USPAT; DERWENT	OR	ON	2015/05/29 10:22
S134	2821	(A61C5/023 OR A61C2201/007).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/05/29 11:23
S135	15842	(C22F1/006 OR C22F1/10 OR C22F1/004).CPC. (C22C14/00 OR C22C19/03).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/05/29 11:24
S136	16	luebke-neill.in. luebke-neill-$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/05/29 11:24
S137	3624	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	2015/05/29 11:30
S138	7	"8876991".pn. "8727773".pn. "8562341".pn. "8083873".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/08/31 09:02
S139	3	"20060115786".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/08/31 09:30
S140	3730	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	2015/08/31 10:23
S141	2934	(A61C5/023 OR A61C2201/007).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2015/08/31 10:23

			DERWENT			
S142	16533	(C22F1/006 OR C22F1/10 OR C22F1/004).CPC. (C22C14/00 OR C22C19/03).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/08/31 10:23
S143	19290	(S141 S142)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2015/08/31 10:23

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L9	291	(148/563).CCLS.	US-PGPUB; USPAT	OR	OFF	2016/03/05 12:13
L10	0	(C22F1/006).IPCR.	US-PGPUB; USPAT	OR	OFF	2016/03/05 12:13
L11	19	(titanium WITH heat WITH deformation).clm.	US-PGPUB; USPAT	OR	ON	2016/03/05 12:13
L12	4	(titanium WITH heat WITH deformation WITH superelastic).clm.	US-PGPUB; USPAT	OR	ON	2016/03/05 12:15
S88	0	(29/896.1,896.11).CCLS.	* No UPAD	OR	OFF	2011/09/07 14:33
S91	0	(148/669).CCLS.	* No UPAD	OR	OFF	2011/09/07 15:04
S113	1	(433/102).CCLS.	* No UPAD	OR	OFF	2014/02/08 08:20

3/5/2016 12:16:31 PM
C:\Users\mnelson3\Documents\EAST\EAST Workspaces\14522013 Dental and medical instruments comprising titanium.wsp

Index of Claims	Application/Control No. 14522013	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON
	Examiner MATTHEW NELSON	Art Unit 3732

✓	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	05/29/2015	08/31/2015	03/05/2016						
	1	✓	✓	✓						
	2	✓	-	-						
	3	✓	✓	✓						
	4	✓	✓	✓						
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	7	✓	✓	✓						
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	26			✓						
	27			✓						
	28			✓						
	29			✓						

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
14522013	LUEBKE, NEILL HAMILTON
Examiner	**Art Unit**
MATTHEW NELSON	3732

CPC

Symbol					Type	Version
A61C		5	/	023	F	2013-01-01
Y10T		29	/	49567	A	2015-01-15
Y10T		29	/	49568	A	2015-01-15
B21F		45	/	008	I	2013-01-01
C22C		14	/	00	I	2013-01-01
C22F		1	/	183	I	2013-01-01
C23C		8	/	24	I	2013-01-01
C23C		8	/	30	I	2013-01-01
C23C		16	/	00	I	2013-01-01
C23C		18	/	1637	I	2013-01-01
C25F		3	/	16	I	2013-01-01
C22F		1	/	004	I	2013-01-01
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			/			

CPC Combination Sets

Symbol					Type	Set	Ranking	Version
			/					
			/					

		Total Claims Allowed:	
(Assistant Examiner)	(Date)	22	
/MATTHEW NELSON/ Examiner.Art Unit 3732 (Primary Examiner)	3/5/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1a

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Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
14522013	LUEBKE, NEILL HAMILTON
Examiner	**Art Unit**
MATTHEW NELSON	3732

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS
148	563

INTERNATIONAL CLASSIFICATION					
CLAIMED					NON-CLAIMED
C	2	2	F	1 / 00 (2006.01.01)	

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				

(Assistant Examiner)	(Date)	**Total Claims Allowed:** 22
/MATTHEW NELSON/ Examiner.Art Unit 3732 (Primary Examiner)	3/5/2016 (Date)	O.G. Print Claim(s): 1 / O.G. Print Figure: 1a

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Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
14522013	LUEBKE, NEILL HAMILTON
Examiner	**Art Unit**
MATTHEW NELSON	3732

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	17	17												
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3	4	19	19												
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14	14														
15	15														
16	16														

(Assistant Examiner)	(Date)	**Total Claims Allowed:** 22	
/MATTHEW NELSON/ Examiner.Art Unit 3732 (Primary Examiner)	3/5/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1a

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14522013
Filing Date	2014-10-23
First Named Inventor	Neill Hamilton Luebke
Art Unit	3732
Examiner Name	Nelson, Matthew M.
Attorney Docket Number	115207.00014

U.S.PATENTS

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Examiner Initial*	Cite No	Patent Number	Kind Code1	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4850867		1989-07-25	Senia et al.	
	2	5843244		1998-12-01	Pelton et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14522013
	Filing Date	2014-10-23
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

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.	T5
	1	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-00632, U.S. Patent No. 8,727,773, Decision - Institution of Inter Partes Review, August 5, 2015	
	2	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-00632, U.S. Patent No. 8,727,773, Declaration of Neill H. Luebke, D.D.S., M.S., November 4, 2015	
	3	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-01476, U.S. Patent No. 8,727,773, Patent Owner's Preliminary Response to Petition for Inter Partes Review, July 30, 2015	
	4	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case IPR2015-01476, U.S. Patent No. 8,727,773, Decision Denying Institution of Inter Partes Review, October 26, 2015	
	5	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case PRG2015-00019, U.S. Patent No. 8,876,991, Patent Owner's Preliminary Response to Petition for Post-Grant Review, November 19, 2015	
	6	UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD, US Endodontics LLC v. Gold Standard Instruments LLC, Case PRG2015-00019, U.S. Patent No. 8,876,991, Decision - Institution of Post-Grant Review, January 29, 2016	
	7	GUHRING COATING SERVICES, High Performance Thin-Film Coatings for Cutting Tools & Wear Parts, Product Brochure, Copyright Guhring, Inc. 2003	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MATTHEW M NELSON/	Date Considered	03/05/2016

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

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Application Number	14522013
	Filing Date	2014-10-23
	First Named Inventor	Neill Hamilton Luebke
	Art Unit	3732
	Examiner Name	Nelson, Matthew M.
	Attorney Docket Number	115207.00014

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2016-03-01
Name/Print	Richard T. Roche	Registration Number	38,599

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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 record s.

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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PART B - FEE(S) TRANSMITTAL

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

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

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

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

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

	(Depositor's name)
	(Signature)
March 15, 2016	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/522,013	10/23/2014	Neill Hamilton Luebke	115207.00014	9570

TITLE OF INVENTION: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
Non-Prov.	Undiscounted	$960	$0	$0	$960	06/14/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
Matthew M. Nelson	3732	433-102000

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

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

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

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

(A) NAME OF ASSIGNEE: Gold Standard Instruments, LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Brookfield, Wisconsin

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

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

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- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 17-0055 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Richard T. Roche/ Date March 15, 2016

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

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

Electronic Patent Application Fee Transmittal

Application Number:	14522013
Filing Date:	23-Oct-2014
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Richard T. Roche/Sandra Szablewski
Attorney Docket Number:	115207.00014

Filed as Large Entity

Filing Fees for **Utility under 35 USC 111(a)**

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**960**

Electronic Acknowledgement Receipt

EFS ID:	25200637
Application Number:	14522013
International Application Number:	
Confirmation Number:	9570
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:	115207.00014
Receipt Date:	15-MAR-2016
Filing Date:	23-OCT-2014
Time Stamp:	15:08:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$960
RAM confirmation Number	1500
Deposit Account	170055
Authorized User	ROCHE, RICHARD T.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	luebke_issue_fee_transmittal.pdf	189030 b676491aba44aebb1fbcdfe83cf82f89d2767911	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30558 6697e6159434492ea2da729ec657efe152eb91a8	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	219588	

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.

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	14/522,013	LUEBKE, NEILL HAMILTON	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 9/28/2015	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

Patricia Volpe, OCRU
571-272-6825

4 TDs Approved

U.S. Patent and Trademark Office

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/522,013	04/19/2016	9314316	115207.00014	9570

26710 7590 03/30/2016

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

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

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

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

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

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

Neill Hamilton Luebke, Brookfield, WI;
Gold Standard Instruments, LLC, Brookfield, WI;

IR103 (Rev. 10/09)