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PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
115207.00002	11628933

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US2005/019947	7 June 2005 (07.06.05)	8 June 2004 (08.06.04)

TITLE OF INVENTION
DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

APPLICANT(S) FOR DO/EO/US
LUEBKE, Neill Hamilton

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☑ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☑ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☑ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☑ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☑ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☑ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☑ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.2 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

6009159.1

Rec'd PCT/PTO 07 DEC 2006

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
11/628933	PCT/US2005/019947	115207.00002

20. Other items or information:

Postcard Receipt.

The following fees have been submitted	CALCULATIONS	PTO USE ONLY
21. ☑ Basic national fee (37 CFR 1.492(a)) **$300**	$ 300.00	
22. ☑ Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... **$0** All other situations..... **$200**	$ 200.00	
23. ☑ Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... **$0** Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... **$100** International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... **$400** All other situations..... **$500**	$ 100.00	
TOTAL OF 21, 22 and 23 =	600.00	
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is **$250** for each additional 50 sheets of paper or fraction thereof.		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	
26 - 100 =	0 /50 =	0	x $250	$ 0

Surcharge of **$130.00** for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	20 - 20 =	0	x $ 50	$ 0	
Independent claims	3 - 3 =	0	x $200	$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $360	$	
			TOTAL OF ABOVE CALCULATIONS =	$ 600.00	
☑ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.					
			SUBTOTAL =	$ 300.00	
Processing fee of **$130.00** for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). +				$	
			TOTAL NATIONAL FEE =	$ 300.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$	
			TOTAL FEES ENCLOSED =	$ 300.00	
			Amount to be refunded:	$	
			Amount to be charged	$	

PTO-1390 (Rev. 07-2005)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

a. ☐ A check in the amount of $ _____ to cover the above fees is enclosed. 11628933

b. ☑ Please charge my Deposit Account No. 17-0055 in the amount of $ 300.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.

c. ☑ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 17-0055. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **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.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

QUARLES & BRADY LLP
411 E. Wisconsin Ave.
Milwaukee, WI 53202
(414) 277-5000
(414) 271-3552 (Fax)

Richard T. Roche
SIGNATURE

Richard T. Roche
NAME

38,599
REGISTRATION NUMBER

(09-04)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☑ Declaration Submitted With Initial Filing **OR** ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	115207.00002
First Named Inventor	LUEBKE, Neill Hamilton
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Art Unit	
Examiner Name	

I hereby declare that:

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

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

DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

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

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

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

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

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

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

5883562

(09-04)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☑ The address associated with Customer Number: 26710 OR ☐ Correspondence address below

Name: ROCHE, Richard T., QUARLES & BRADY LLP

Address: 411 E. Wisconsin Avenue

City	State	ZIP
Milwaukee	WI	53202

Country	Telephone	Fax
US	414-277-5805	414-271-3552

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

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Neill Hamilton	LUEBKE

Inventor's Signature: Neill Luebke. Date: 9-29-06

Residence: City	State	Country	Citizenship
Brookfield	WI	US	US

Mailing Address: 18010 Continental Drive

City	State	Zip	Country
Brookfield	WI	53045-1204	US

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname

Inventor's Signature | Date

Residence: City	State	Country	Citizenship

Mailing Address

City	State	Zip	Country

☐ Additional inventors or a legal representative are being named on the _____supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

PATENT APPLICATION SERIAL NO. _____

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

12/12/2006 GFREY1 00000050 170055 11628933

01 FC:2631 150.00 DA
02 FC:2633 100.00 DA
03 FC:2641 50.00 DA

PTO-1556
(5/87)

Docket No.: 115207.00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Neill H. Luebke
Filing date:	Filed Herewith
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Based on PCT International Application No.:	PCT/US2005/019947
PCT International Filing Date:	7 June 2005

PRELIMINARY AMENDMENT

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

Sir:

Please amend the above-identified patent application before examination as follows:

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

Remarks begin on page 6 of this paper.

Amendments To The Claims

1. (Original) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein 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.

2. (Original) The instrument of claim 1 wherein:

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

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

the temperature is from 400°C up to but not equal to the melting point of the titanium alloy.

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

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

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

the shank is heat-treated for 1 to 2 hours.

6. (Original) The instrument of claim 1 wherein:

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

7. (Original) The instrument of claim 1 wherein:

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

8. (Original) The instrument of claim 1 wherein:

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

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

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

the shank is heat-treated for 1 to 2 hours.

9. (Original) The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

the shank is heat-treated for 1 to 2 hours.

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

the cutting edge is formed by helical flutes in the shank.

11. (Original) The instrument of claim 1 wherein:

the shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

12. (Original) The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. (Original) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the shank is prepared by heat-treating the shank at a temperature from 475°C to 525°C in an atmosphere consisting essentially of argon gas.

14. (Original) The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. (Currently Amended) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 1 ~~any of claims 1-14~~.

16. (Original) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank consists essentially of a titanium alloy selected from alpha-titanium alloys, beta-titanium alloys, and alpha-beta-titanium alloys.

17. (Original) The instrument of claim 16 wherein:

the cutting edge is formed by helical flutes in the shank.

18. (Original) The instrument of claim 16 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

19. (Currently Amended) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 16 ~~any of claims 15-18~~.

20. (New) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 13.

REMARKS

Original PCT claim 15 was a multiple dependent claim that depended on claims 1-14. Claim 15 has been amended to depend only from claim 1 to remove the multiple dependency. New claim 20 is identical to original claim 15 with the exception that claim 20 depends only from claim 13.

Original PCT claim 19 was a multiple dependent claim that depended on claims 15-18. Claim 19 has been amended to depend only from claim 16 to remove the multiple dependency.

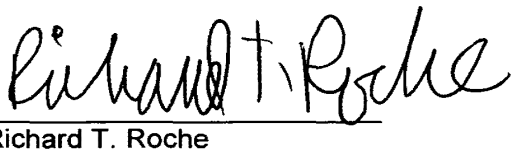
Please enter the amendments before fee calculation.

No fees are believed to be needed for this amendment. However, if fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: December 7, 2006

By: 

Richard T. Roche
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411 East Wisconsin Ave.
Milwaukee, WI 53202
(414) 277-5805

6009177

EXPRESS MAIL LABEL NO. EV 863511665 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	LUEBKE, Neill Hamilton
Serial No.:	Not Yet Assigned
I.A. Filing Date:	7 June 2005
Priority Date:	8 June 2004
PCT Appl. No.:	PCT/US2005/019947
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Docket:	115207.00002

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

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

The accompanying form PTO-1449, listing documents to be considered with respect to the subject patent application, is being submitted in compliance with 37 CFR §1.97 and §1.98.

This paper is submitted in accordance with 37 CFR §1.97(b) and a fee is not required for consideration of these documents.

Date: 12-7-06

Respectfully Submitted,

Richard T. Roche
Reg. No. 38,599
QUARLES & BRADY LLP
411 E. Wisconsin Avenue
Milwaukee, WI 53202-4497
Tel. No. (414) 277-5805
Fax No. (414) 271-3552

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PTO/SB/08a (07-06)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	Not Yet Assigned 11/612,933
Filing Date	7 December 2006
First Named Inventor	LUEBKE, Neill Hamilton
Art Unit	--
Examiner Name	--
Attorney Docket Number	115207.00002

U. S. PATENT DOCUMENTS

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

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

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	Not Yet Assigned
Filing Date	7 December 2006
First Named Inventor	LUEBKE, Neill Hamilton
Art Unit	--
Examiner Name	--
Attorney Docket Number	115207.00002

NON PATENT LITERATURE DOCUMENTS

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

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

6009181.1

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 115207.00002	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US05/19947	International filing date (*day/month/year*) 07 June 2005 (07.06.2005)	(Earliest) Priority Date (*day/month/year*) 08 June 2004 (08.06.2004)
Applicant LUEBKE, NEIL HAMILTON		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 9 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
   a. With regard to the **language**, the international search was carried out 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))
   b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1a
      ☐ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☒ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/19947

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61C 5/02
US CL : 433/102
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 433/102

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,431,863 B1 (Lal Sachdeva et al.) 13 August 2002 (13.08.2002), See whole document.	1-19
Y	US 6,422,865 B1 (Fischer) 23 July 2002 (23.07.2002). Column 4, lines 40-43.	1-19
Y	US 6,428,634 B1 (Besselink et al.) 6 August 2002 (06.06.2002). See whole document	4-5, 7-9-14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
14 October 2005 (14.10.2005)

Date of mailing of the international search report
10 NOV 2005

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Authorized officer
For Kevin P Shaver

Telephone No. (571) 272-4720

Form PCT/ISA/210 (second sheet) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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)

Date of mailing *(day/month/year)*	10 NOV 2005
Applicant's or agent's file reference 115207.00002	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US05/19947	07 June 2005 (07.06.2005)	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.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

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

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing (*day/month/year*)
Applicant's or agent's file reference 115207.00002	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US05/19947	International filing date (*day/month/year*) 07 June 2005 (07.06.2005)
Applicant LUEBKE, NEIL HAMILTON	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

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

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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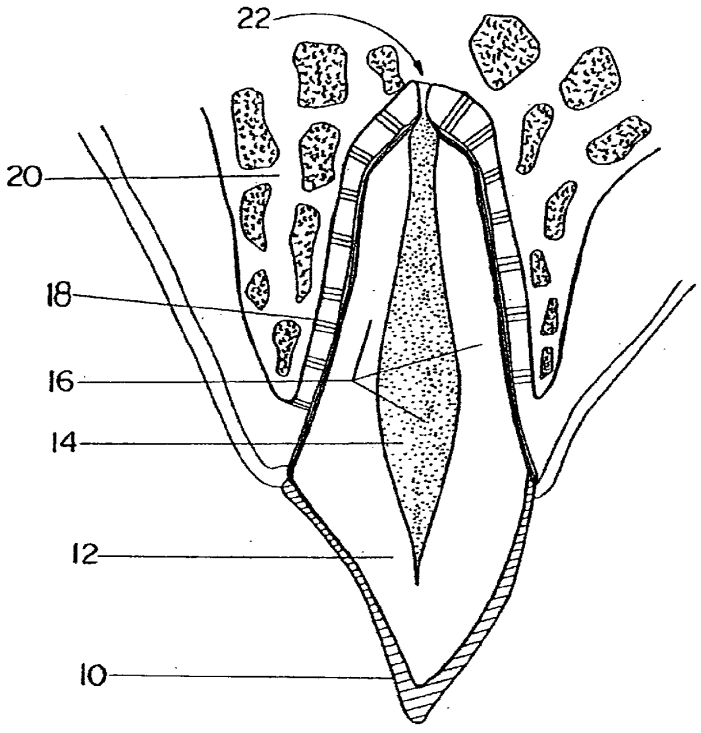
Published:
— *with international search report*

[Continued on next page]

(54) Title: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM



(57) Abstract: 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.

WO 2005/122942 A1

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Dental and Medical Instruments Comprising Titanium

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims priority from United States Provisional 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); Molybdenum Disulfide Coating (MoS_2) (see, e.g., U.S. Patent No. 5,037,516 or SAE Standard AMS2526); 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. 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 in each size, and the mean and standard deviation for each group (Control, TT, Ti-N) of ten files were calculated. The ten files in all but one size 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. 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 in each size, and the mean and standard deviation for each group (Control, TT, Ti-N) of ten files were calculated. The ten files in each size 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. 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 in each size, 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 in each size impart less torque when bent and appear to have higher flexibility 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. 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 in each size, and the mean and standard deviation for each group (Control, TT, Ti-N) of ten files were calculated. The ten files in each size 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 significantly 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. 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 in each size, and the mean and standard deviation for each group (Control, TT, Ti-N) of the six file sizes were calculated. The ten files in all but one size that were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes showed the best result with 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. An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein 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.

2. The instrument of claim 1 wherein:

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

3. The instrument of claim 1 wherein:

the temperature is from 400°C up to but not equal to the melting point of the titanium alloy.

4. The instrument of claim 1 wherein:

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

5. The instrument of claim 1 wherein:

the shank is heat-treated for 1 to 2 hours.

6. The instrument of claim 1 wherein:

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

7. The instrument of claim 1 wherein:

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

8. The instrument of claim 1 wherein:

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

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

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

the shank is heat-treated for 1 to 2 hours.

9. The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

the shank is heat-treated for 1 to 2 hours.

10. The instrument of claim 1 wherein:

the cutting edge is formed by helical flutes in the shank.

11. The instrument of claim 1 wherein:

the shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

12. The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the shank is prepared by heat-treating the shank at a temperature from 475°C to 525°C in an atmosphere consisting essentially of argon gas.

14. The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to any of claims 1-14.

16. An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank consists essentially of a titanium alloy selected from alpha-titanium alloys, beta-titanium alloys, and alpha-beta-titanium alloys.

17. The instrument of claim 16 wherein:

the cutting edge is formed by helical flutes in the shank.

18. The instrument of claim 16 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

19. A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to any of claims 15-18.

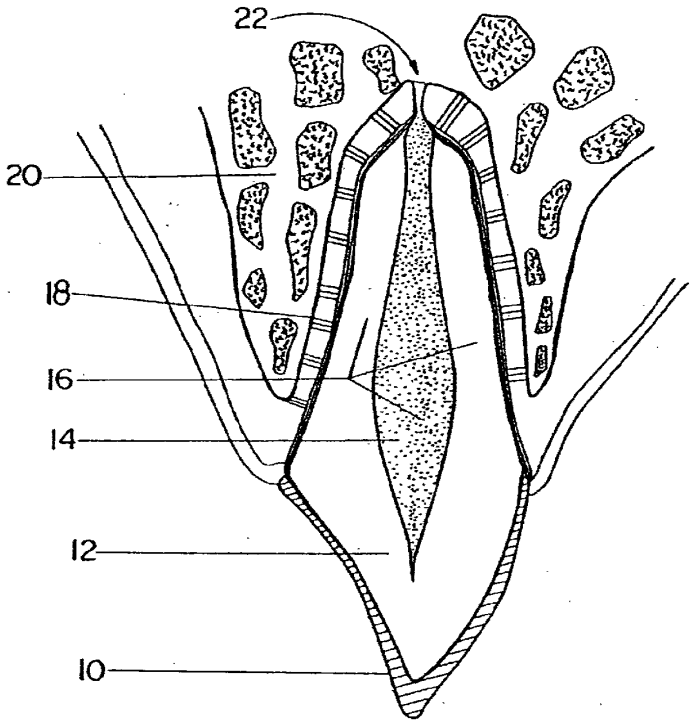
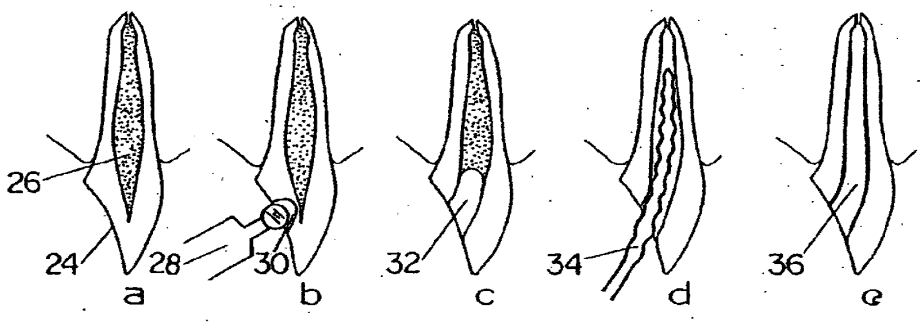


FIG. 1

FIG. 2



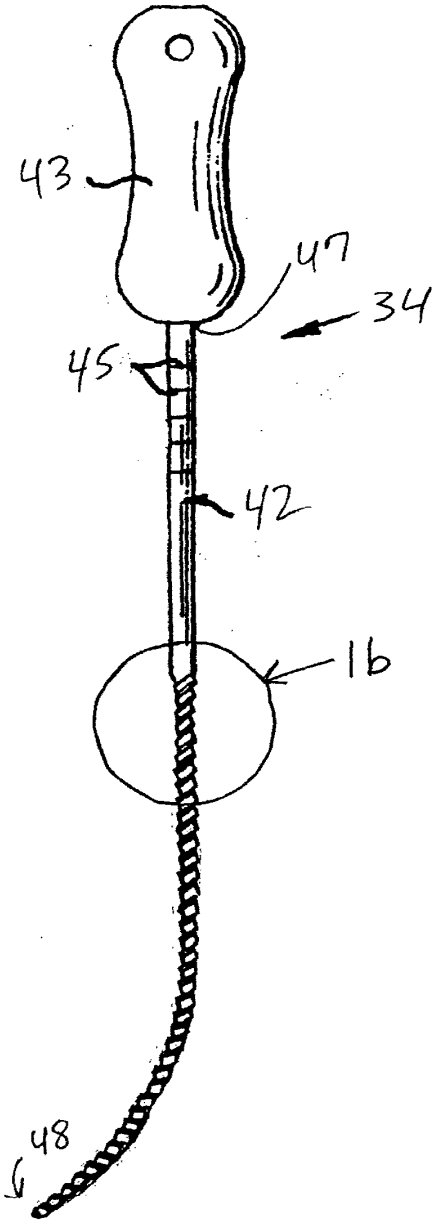


Fig. 1a

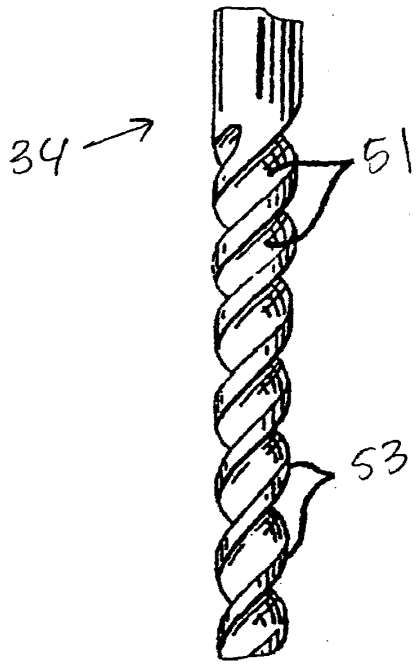


Fig. 1b

Figure 3

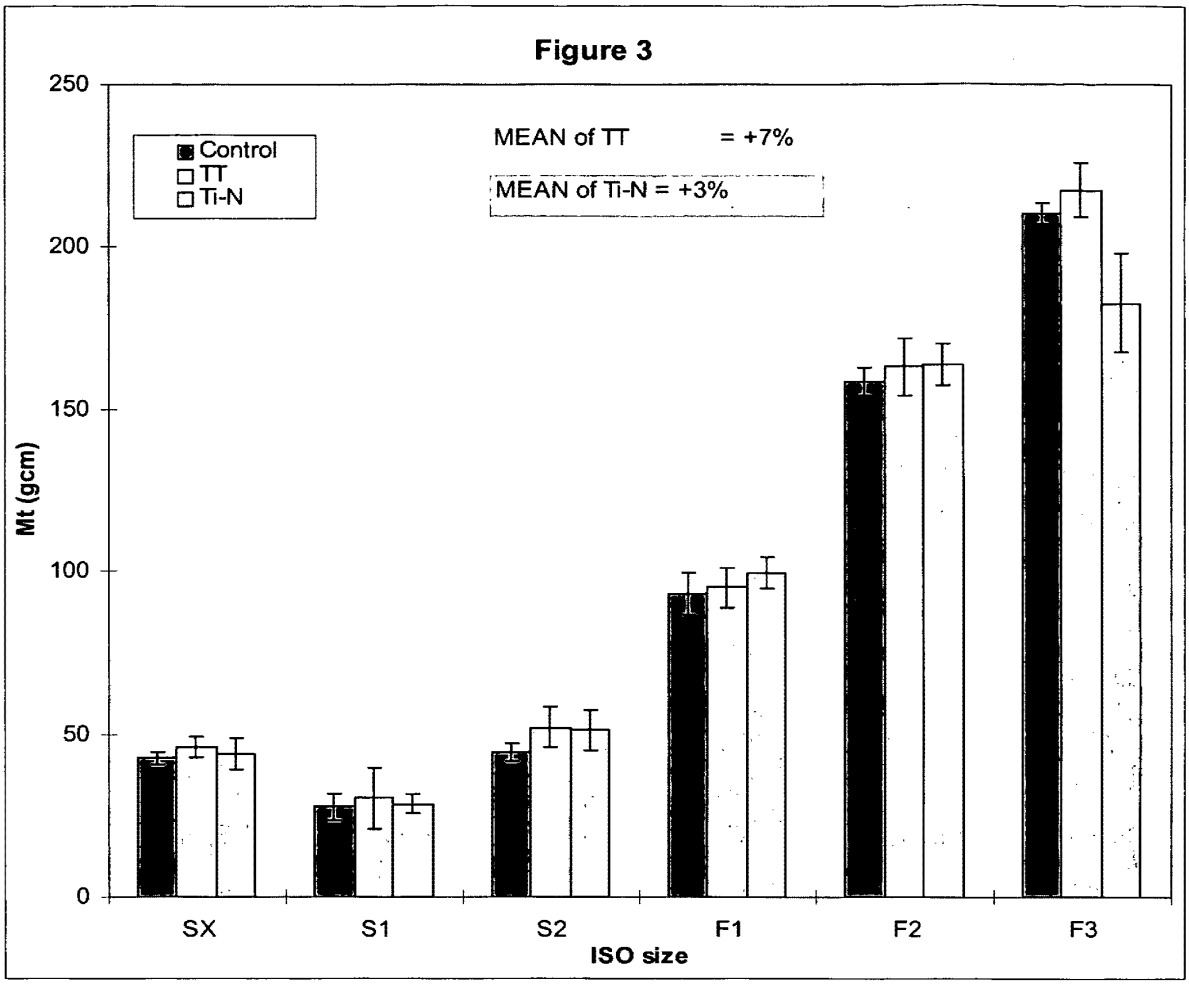


Figure 4

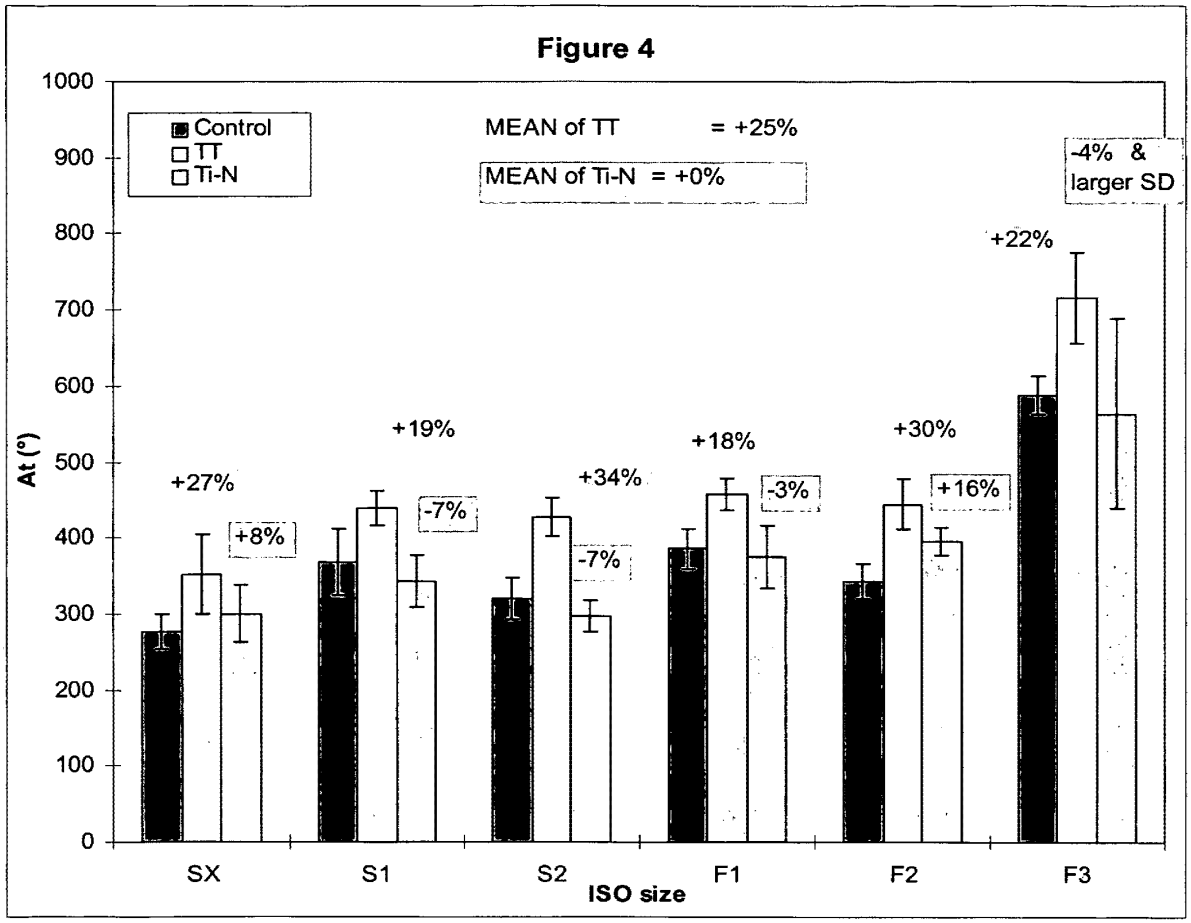


Figure 5

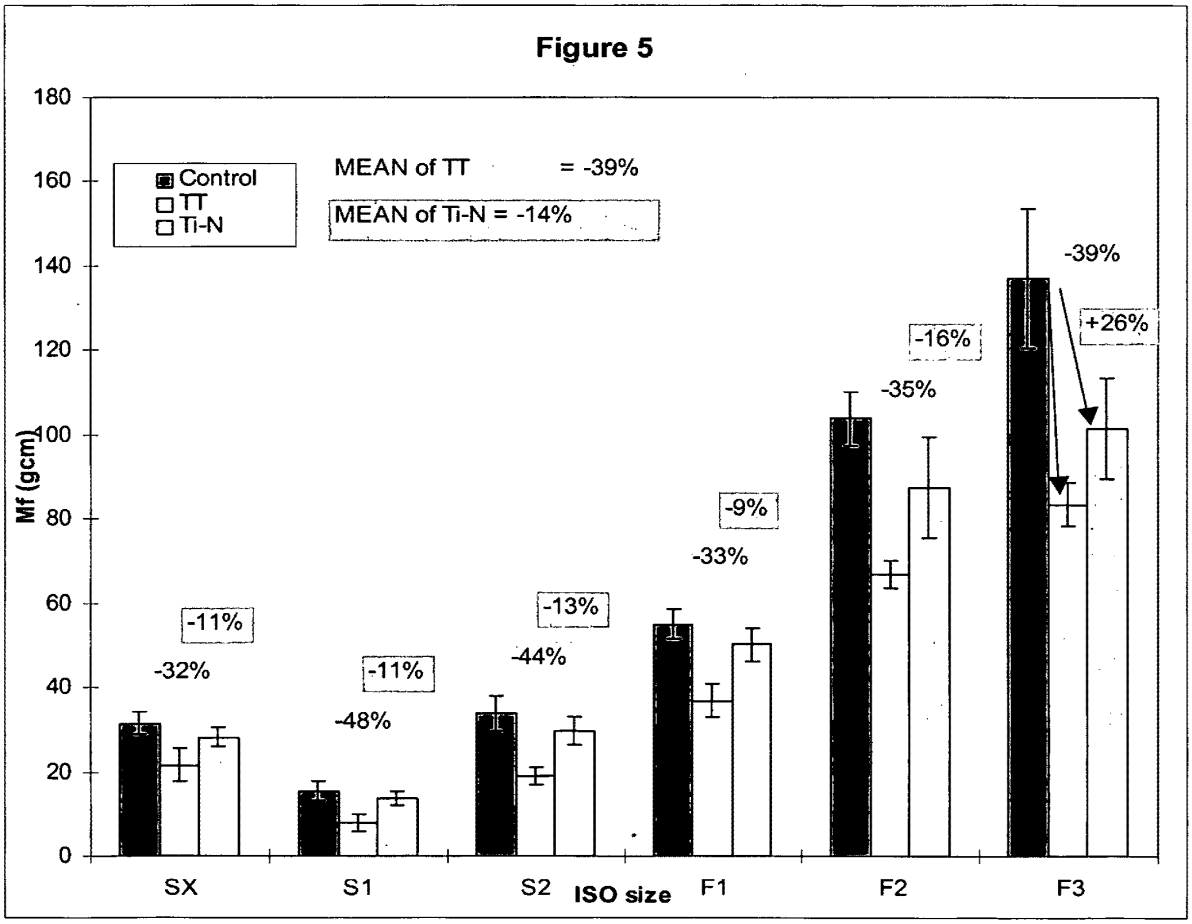
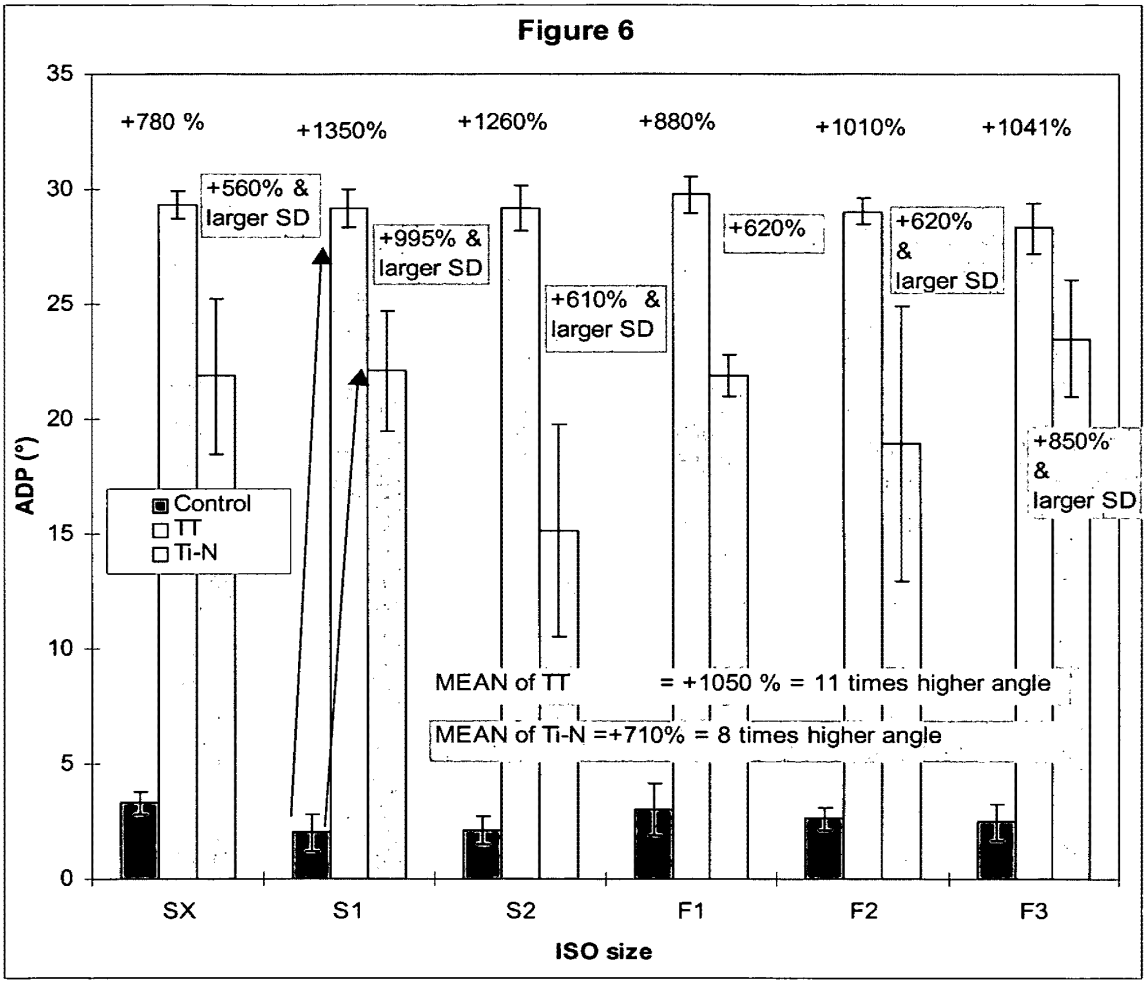
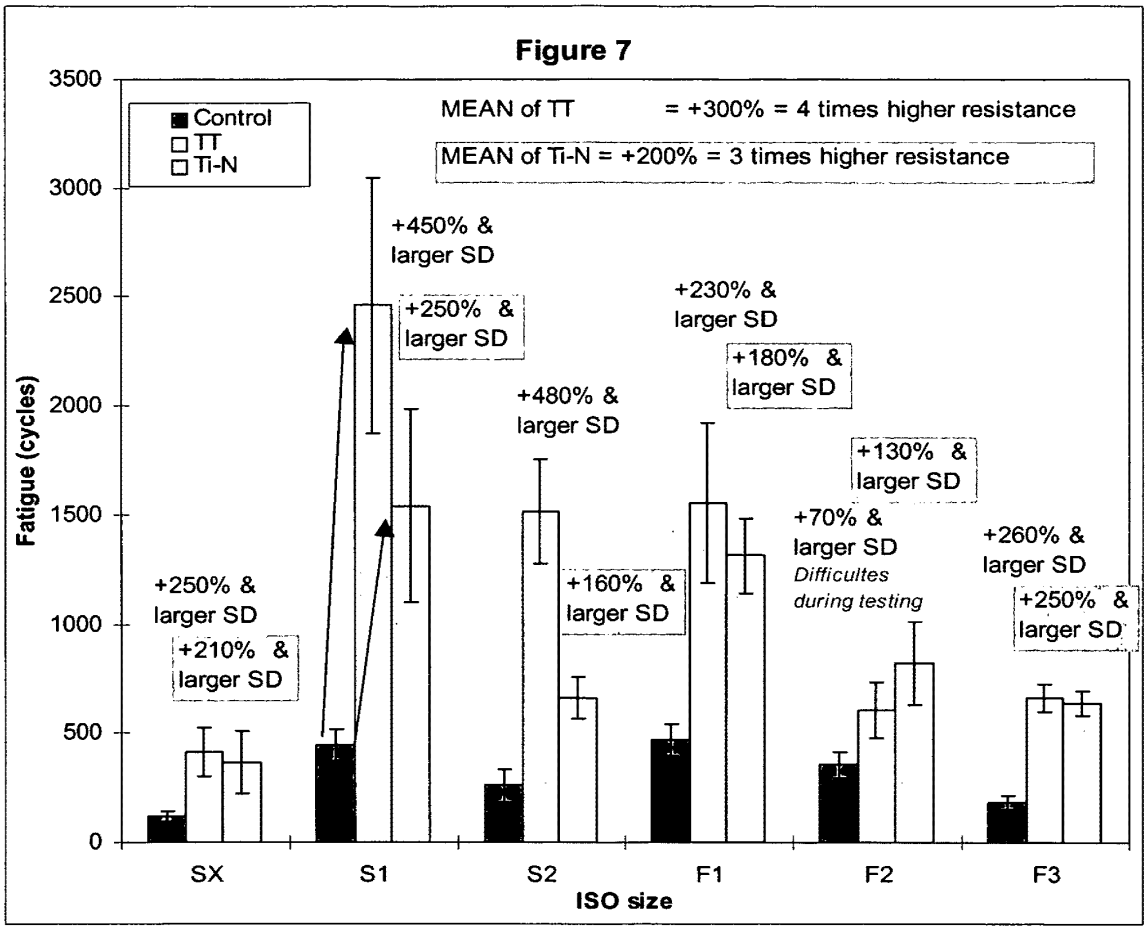


Figure 6





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FILING DATE: *June 08, 2004*
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Neill H.	Luebke	Brookfield, Wisconsin

Additional inventors are being named on the ___ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

Dental and Medical Instruments Comprising Titanium and Dental and Medical Instruments Having a Coating

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☑ Customer Number 000043629
OR *Type Customer Number here*

☐ Firm *or* Individual Name

Address

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ENCLOSED APPLICATION PARTS ***(check all that apply)***

☑ Specification *Number of Pages* 12
☑ Drawing(s) *Number of Sheets* 1
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☑ Other (specify) Return Postcard

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☑ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees
☑ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 17-0055
☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): $80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE Richard Roche

Date 6/8/04

TYPED or PRINTED NAME Richard T. Roche

REGISTRATION NO. *(if appropriate)* 38,599

Docket Number: 115207.00002

TELEPHONE 414-277-5805

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4

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Effective 10/01/2003. Patent fees are subject to annual revision.

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 80.00

Complete if Known	
Application Number	
Filing Date	Filed Herewith
First Named Inventor	Neill H. Luebke
Examiner Name	
Art Unit	
Attorney Docket No.	115207.00002

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Deposit Account Name: Quarles & Brady LLP

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1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	80

SUBTOTAL (1) ($) 80.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below		Fee Paid
Total Claims		-20* =		x	=	0.00
Independent Claims		-3** =		x	=	0.00
Multiple Dependent					=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0.00

***or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 0.00

SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	Richard T. Roche	*Registration No. (Attorney/Agent)*	38,599	*Telephone*	414-277-5805
Signature	Richard T. Roche			*Date*	6-8-2004

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This collection of information is required by 37 CFR 1.17 and 1.27. 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.**

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Dental and Medical Instruments Comprising Titanium and Dental and Medical Instruments Having a Coating

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] Not Applicable.

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 of the pulp canal (root canal).

[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 reamers and/or files 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., files) 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. However, 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 outside of the curve and will not cut on the inside 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.

[0009] 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. 5,464,362 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.

[0010] It has also been proposed to manufacture orthodontic appliances from beta-titanium. However, it is believed that this material has not been proposed for endodontic instruments. 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.

[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 endodontic instruments fabricated from beta-titanium. These instruments have improved sharpness, cutting ability, and instrument longevity compared to instruments fabricated from nickel-titanium. Also, beta-titanium is superior because it is harder and hence will hold an edge better and still maintains near the flexibility of nickel-titanium to negotiate curved canals. Thus, endodontic instruments fabricated from beta-titanium according to the invention limit the problems encountered when cleaning and enlarging a curved root canal.

[0013] In another aspect, the invention provides for coating and/or heat-treating instruments including coatings to maintain and/or improve their sharpness, cutting ability, and/or instrument longevity and heat treatment(s) that improve their sharpness, cutting ability, and/or instrument longevity. Thus, endodontic instruments fabricated with such coating and/or heat treatment according to the invention limit the problems encountered when cleaning and enlarging a curved root canal. In one embodiment, the instrument includes a nickel-titanium substrate, and a coating on the substrate wherein the coating comprises a material selected from the group consisting of titanium nitride, titanium carbonitride, titanium aluminum nitride, aluminum titanium nitride, and mixtures thereof.

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

DETAILED DESCRIPTION OF THE INVENTION

[0017] In one aspect, the present invention relates to medical and dental instruments fabricated from beta-titanium, an alloy of titanium that includes a stabilizing amount of a metal selected from the group consisting of molybdenum, columbium, tantalum, vanadium, zirconium, and niobium; a eutectoid beta stabilizer selected from the group consisting of chromium, cobalt, nickel, manganese or iron; and at least one metallic alpha stabilizer selected from the group consisting of aluminum and lanthanum. These instruments have improved sharpness, cutting ability, and instrument longevity than instruments fabricated from nickel-titanium. Beta-titanium is superior because it is harder and hence will hold an edge better and still maintains near the flexibility of nickel-titanium to negotiate curved canals. These 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.

[0018] 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 invention would use the metal alloy beta-titanium 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 from beta-titanium 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.

[0019] In another aspect, the present invention provides for coating and/or heat-treating instruments including coatings to maintain and/or improve their sharpness, cutting ability, and/or instrument longevity and heat treatment(s) that improve their sharpness, cutting ability, and/or instrument longevity. Such an instrument may be manufactured from nickel-titanium, beta-titanium (as described above), 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.

[0020] The coating processes may include 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.

[0021] 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/or 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, 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.

[0022] 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™.

[0023] 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.

[0024] 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 dental or medical instrument for use in creating or enlarging an opening, the instrument comprising:

an alloy of titanium that includes

a stabilizing amount of a metal selected from the group consisting of molybdenum, columbium, tantalum, vanadium, zirconium, and niobium;

a eutectoid beta stabilizer selected from the group consisting of chromium, cobalt, nickel, manganese or iron; and

at least one metallic alpha stabilizer selected from the group consisting of aluminum and lanthanum.

2. The instrument of claim 1 wherein the instrument is an endodontic instrument for use in performing root canal therapy on a tooth.

3. A dental or medical instrument for use in creating or enlarging an opening, the instrument comprising:

a substrate; and

a coating on the substrate, the coating comprising a material selected from the group consisting of titanium nitride, titanium carbonitride, titanium aluminum nitride, aluminum titanium nitride, and mixtures thereof.

4. The instrument of claim 3 wherein the substrate comprises a material is selected from nickel-titanium, beta-titanium, stainless steel and carbide steel.

5. The instrument of claim 4 wherein the instrument is an endodontic instrument for use in performing root canal therapy on a tooth.

6. A dental or medical instrument for use in creating or enlarging an opening, the instrument comprising:

a nickel-titanium substrate; and

a coating on the substrate, the coating comprising a material selected from the group consisting of titanium nitride, titanium carbonitride, titanium aluminum nitride, aluminum titanium nitride, and mixtures thereof.

7. The instrument of claim 6 wherein the coating comprises titanium nitride and titanium aluminum nitride.

8. The instrument of claim 6 wherein the instrument is an endodontic instrument for use in performing root canal therapy on a tooth.

9. A dental or medical instrument for use in creating or enlarging an opening, the instrument comprising:

a substrate; and

a coating on the substrate, the coating comprising a metal or metal alloy incorporating particulate matter.

10. The instrument of claim 9 wherein the substrate comprises a material selected from nickel-titanium, beta-titanium, stainless steel and carbide steel.

11. The instrument of claim 9 wherein the instrument is an endodontic instrument for use in performing root canal therapy on a tooth.

12. A method for creating or enlarging an opening in a patient undergoing a medical or dental procedure, the method comprising:

creating or enlarging the opening using an instrument comprising an alloy of titanium that includes

a stabilizing amount of a metal selected from the group consisting of molybdenum, columbium, tantalum, vanadium, zirconium, and niobium;

a eutectoid beta stabilizer selected from the group consisting of chromium, cobalt, nickel, manganese or iron; and

at least one metallic alpha stabilizer selected from the group consisting of aluminum and lanthanum.

13. The method of claim 12 wherein the procedure is root canal therapy.

14. A method for creating or enlarging an opening in a patient undergoing a medical or dental procedure, the method comprising:

creating or enlarging the opening using an instrument comprising

a substrate; and

a coating on the substrate, the coating comprising a material selected from the group consisting of titanium nitride, titanium carbonitride, titanium aluminum nitride, aluminum titanium nitride, and mixtures thereof.

15. The method of claim 14 wherein the procedure is root canal therapy.

16. A method for creating or enlarging an opening in a patient undergoing a medical or dental procedure, the method comprising:

creating or enlarging the opening using an instrument comprising

a nickel-titanium substrate; and

a coating on the substrate, the coating comprising a material selected from the group consisting of titanium nitride, titanium carbonitride, titanium aluminum nitride, aluminum titanium nitride, and mixtures thereof.

17. The method of claim 16 wherein the procedure is root canal therapy.

18. A method for creating or enlarging an opening in a patient undergoing a medical or dental procedure, the method comprising:

creating or enlarging the opening using an instrument comprising

a substrate; and

a coating on the substrate, the coating comprising a metal or metal alloy incorporating particulate matter.

19. The method of claim 18 wherein the procedure is root canal therapy.

ABSTRACT OF THE DISCLOSURE

Medical and dental instruments, such as drills, burs and files, and endodontic instruments, such as drills, burs and files, used by dentists are described.

5

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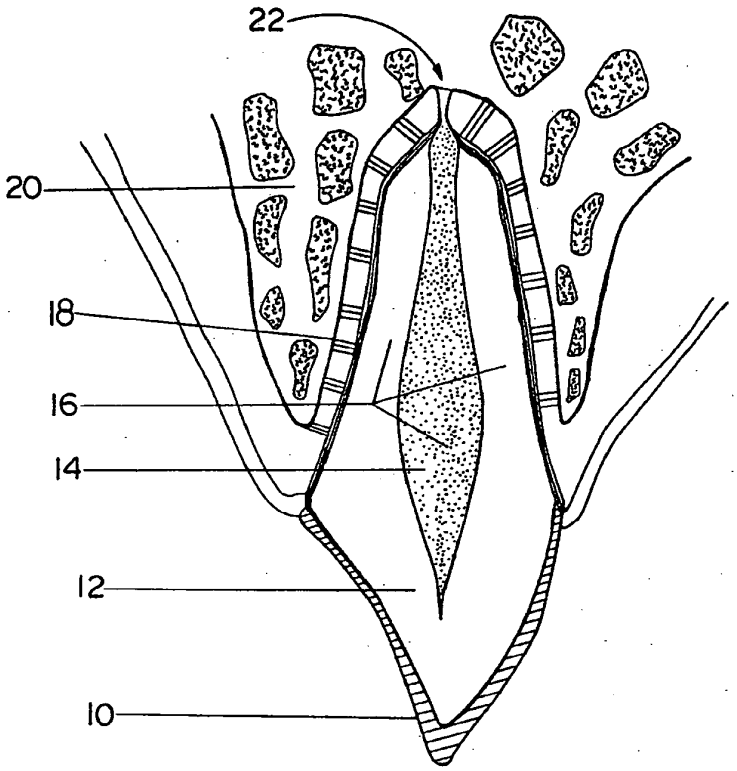
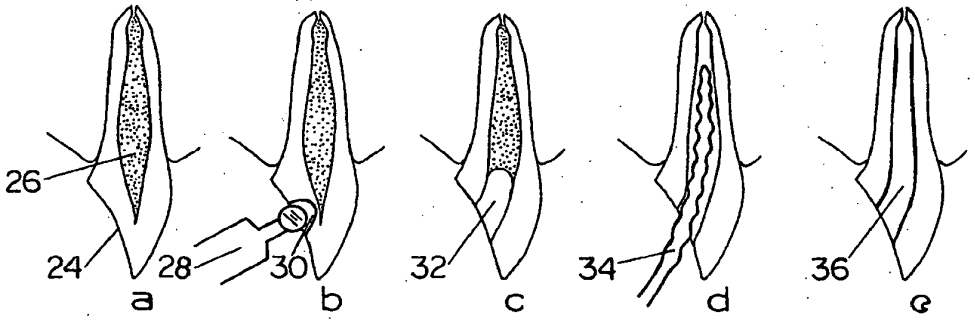


FIG. 1

FIG. 2



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APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002

CONFIRMATION NO. 9736

26710
QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
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MILWAUKEE, WI53202-4497

Date Mailed. 11/01/2007

NOTICE OF NEW OR REVISED PROJECTED PUBLICATION DATE

The above-identified application has a new or revised projected publication date. The current projected publication date for this application is 02/07/2008. If this is a new projected publication date (there was no previous projected publication date), the application has been cleared by Licensing & Review or a secrecy order has been rescinded and the application is now in the publication queue.

If this is a revised projected publication date (one that is different from a previously communicated projected publication date), the publication date has been revised due to processing delays in the USPTO or the abandonment and subsequent revival of an application. The application is anticipated to be published on a date that is more than six weeks different from the originally-projected publication date.

More detailed publication information is available through the private side of Patent Application Information Retrieval (PAIR) System. The direct link to access PAIR is currently http://pair.uspto.gov. Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Questions relating to this Notice should be directed to the Office of Patent Publication at 1-888-786-0101.

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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
11/628,933	Neill Hamilton Luebke	115207.00002

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INTERNATIONAL APPLICATION NO.	
PCT/US05/19947	
I.A. FILING DATE	PRIORITY DATE
06/07/2005	06/08/2004

CONFIRMATION NO. 9736
371 ACCEPTANCE LETTER

OC000000026531941

Date Mailed: 11/02/2007

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

12/07/2006	12/08/2006
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** *The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363).* Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Indication of Small Entity Status
- Copy of the International Application filed on 12/07/2006
- Copy of the International Search Report filed on 12/07/2006
- Preliminary Amendments filed on 12/07/2006
- Information Disclosure Statements filed on 12/07/2006
- Oath or Declaration filed on 12/07/2006
- U.S. Basic National Fees filed on 12/07/2006
- Priority Documents filed on 12/07/2006
- Specification filed on 12/07/2006
- Claims filed on 12/07/2006
- Abstracts filed on 12/07/2006
- Drawings filed on 12/07/2006

FORM PCT/DO/EO/903 (371 Acceptance Notice)

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

PAULETTE R KIDWELL

Telephone: (703) 308-9140 EXT 216

FORM PCT/DO/EO/903 (371 Acceptance Notice)

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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
11/628,933	12/07/2006	3732	300	115207.00002	20	3

CONFIRMATION NO. 9736

26710
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MILWAUKEE, WI 53202-4497

FILING RECEIPT

OC00000026531940

Date Mailed: 11/02/2007

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 write to the Office of Initial Patent Examination's Filing Receipt Corrections. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Neill Hamilton Luebke, Brookfield, WI;

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

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US05/19947 06/07/2005
which claims benefit of 60/578,091 06/08/2004

Foreign Applications

If Required, Foreign Filing License Granted: 10/30/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 11/628,933**

Projected Publication Date: 02/07/2008

Non-Publication Request: No

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

Title

Dental And Medical Instruments Comprising Titanium

Preliminary Class

433

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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NOT GRANTED

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11/658,933

PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 8, 2004

Application or Docket Number: 11 5207.0002

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)	SMALL ENTITY TYPE ☐	RATE	FEE	OR	OTHER THAN SMALL ENTITY	RATE	FEE
U.S. NATIONAL STAGE FEES									
BASIC FEE	SMALL ENT. = $ 150	LARGE ENT. = $ 300		BASIC FEE	150	OR		BASIC FEE	
EXAMINATION FEE	Satisfies PCT Article 33(1)-(4) = $ 50 / $ 100	All other situations = $ 100 / $ 200		EXAM. FEE	100			EXAM. FEE	
SEARCH FEE	U.S. is ISA = $ 50 / $ 100 ALL other countries = $ 200 / $ 400	ALL other situations = $ 250 / $ 500		SEARCH FEE	50			SEARCH FEE	
FEE FOR EXTRA SPEC. PGS.	26 minus 100 =	/ 50 =		X $ 125 =				X $ 250 =	
TOTAL CHARGEABLE CLAIMS	20 minus 20 =	*		X $ 25 =		OR		X $ 50 =	
INDEPENDENT CLAIMS	3 minus 3 =	*		X $ 100 =		OR		X $ 200 =	
MULTIPLE DEPENDENT CLAIM PRESENT		☐		+ $ 180 =		OR		+ $ 360 =	
* If the difference in column 1 is less than zero, enter "0" in column 2				TOTAL	300	OR		TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	ADDI-TIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDI-TIONAL FEE
Total	*	Minus	**	=	X $ 25 =		OR	X $ 50 =	
Independent	*	Minus	***	=	X $ 100 =		OR	X $ 200 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐					+ $ 180 =		OR	+ $ 360 =	
					TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE	ADDI-TIONAL FEE	OR	RATE	ADDI-TIONAL FEE
Total	*	Minus	**	=	X $ 25 =		OR	X $ 50 =	
Independent	*	Minus	***	=	X $ 100 =		OR	X $ 200 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐					+ $ 180 =		OR	+ $ 360 =	
					TOTAL ADDIT. FEE		OR	TOTAL ADDIT. 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.

, PCT National Stage Division

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

(FOR USE WITH FORM PTO-875)

SERIAL NO.	FILING DATE
11/628933	
APPLICANT(S)	

CLAIMS

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
1	1		1			
2		1		1		
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TOTAL IND.		↓	3	↓		↓
TOTAL DEP.		←	17	←		←
TOTAL CLAIMS			20			

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
51						
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TOTAL IND.		↓		↓		↓
TOTAL DEP.		←		←		←
TOTAL CLAIMS						

PTO - 1360 (REV. 11/04)

U.S. DEPARTMENT of COMMERCE
Patent and Trademark Office

DO/ EO WORKSHEET

[redacted], Patent Application Specialist/ National Stage Division

U.S. Appl. No. 11/629333 International Appl. No. PCT/ US05/19947

Application filed by : ☐ 20 months ☑ 30 months

WIPO PUBLICATION INFORMATION :

Publication No.: WO2005/122942 Publication Language : ☑ English ☐ German ☐ Japanese ☐ Chinese ☐ Korean ☐ French ☐ Spanish ☐ Russian ☐ Other : _____

Publication Date : 29 Dec 2005 Not Published : ☐ U.S. only designated ☐ EP request Published : ☐ EP request

INTERNATIONAL APPLICATION PAPERS IN THE APPLICATION FILE :

- ☑ International Application *(RECORD COPY)*
- ☐ Article 19 Amendments
- ☐ PCT/IPEA/409 IPER : ☐ EP ☐ JP ☐ SE ☐ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☐ KR ☐ ___
- ☐ Annexes to 409
- ☐ PCT/ISA/237 : ☐ EP ☐ JP ☐ SE ☐ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☐ KR ☐ ___
  - ☐ PCT/IPEA/409 or PCT/ISA/237 was NOT AVAILABLE at the time of paralegal review
- ☐ PCT/IB/306
- ☐ Request form PCT/RO/101
- ☑ PCT/ISA/210 - Search Report : ☐ EP ☐ JP ☐ SE ☐ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☐ KR ☐ ___ ☐ NONE
- ☐ Search Report References
- ☑ Priority Document (s) No. 1
  - ☐ N/A
  - ☐ Priority Document was NOT AVAILABLE at the time of paralegal review
- ☐ Other : _____

RECEIPTS FROM THE APPLICANT *(other than checked above) :*

- ☑ Basic National Fee *(or authorization to charge)*
- ☑ Description ☑ Claims ☑ Abstract
- ☑ Drawing Figure(s) - (# of drwgs. 7)
- ☐ Translation of Article 19 Amendments ☐ entered ☐ not entered :
  - ☐ not a page for page substitution
  - ☐ replaced by Article 34 Amendment
- ☐ Annexes to 409 ☐ entered ☐ not entered :
  - ☐ not a page for page substitution
  - ☐ no translation ☐ other : _____
- ☐ Application Data Sheet
- ☐ Power of Attorney
- ☐ Change of Address
- ☑ Preliminary Amendment(s) Filed on : 1. ☐ same as 371 request date 2. 12/07/06 3. _____
- ☑ Information Disclosure Statement(s) Filed on : 1. ☐ same as 371 request date 2. 12/07/06 3. _____
- ☐ Assignment Document (forwarded to Assignment Branch)
- ☐ Assignee Statement Under 37 CFR 3.73(b)
- ☐ Assignee PG Publication Notice
- ☐ Substitute Specification Filed on : 1. ☐ same as 371 request date 2. _____ 3. _____
- ☑ Verified Small Status Statement
- ☑ Oath/ Declaration (executed)
- ☐ Oath/ Declaration ☐ unsigned ☐ no citizenship ☐ other
- ☐ DNA Diskette ☐ Sequence Listing
- ☐ Other : _____

NOTES : ☐ I.A. used as Specification ☐ Other :

35 U.S.C. 371 - Receipt of Request (PTO-1390)	12/07/06
Date Acceptable Oath/ Declaration Received	
Date of Completion of requirements under 35 U.S.C. 371	
Date of Completion of DO/ EO 903 - Notification of Acceptance	10/2/07
Date of Completion of DO/ EO 905 - Notification of Missing Requirements	
Date of Completion of DO/ EO 909 - Notification of Abandonment	
Date of Completion of DO/ EO 916 - Notification of Defective Response	
Date of Completion of DO/ EO 922 - Notification to Comply w/ Requirements for Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures	
Date of Completion of DO/ EO 923	

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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002

CONFIRMATION NO. 9736

26710
QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI53202-4497

Title: Dental And Medical Instruments Comprising Titanium

Publication No. US-2008-0032260-A1
Publication Date: 02/07/2008

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.

Pre-Grant Publication Division, 703-605-4283

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 05/30/2008

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
4166	

MAIL DATE	DELIVERY MODE
05/30/2008	PAPER

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.

Office Action Summary	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	Matthew M. Nelson	4166	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *07 December 2006*.

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

3)☐ 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

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

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

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

Application Papers

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

10)☒ The drawing(s) filed on *07 December 2006* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☒ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07 December 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 16-17, 19 rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,431,863 to Sachdeva (Sachdeva).

Sachdeva teaches:

In Reference to Claim 16

An endodontic instrument (Fig. 1) for use in performing root canal therapy on a tooth, the instrument comprising: an elongate shank (working shaft 12) having a cutting edge (Fig. 2b) extending from a distal end of the shank along an axial length of the shank (Fig. 1), wherein the shank consists essentially of a titanium alloy selected from alpha- titanium alloys, beta-titanium alloys, and alpha-beta-titanium alloys (col. 3, line 30-39).

Sachdeva lists alloy constituents that may comprise the working shaft. These fall within the titanium alloy classifications of alpha, beta, and alpha-beta.

In Reference to Claim 17

The instrument of claim 16 (see rejection of claim 16 above) wherein: the cutting edge is formed by helical flutes in the shank (reamer tip 16b, Fig. 2b).

In Reference to Claim 19

A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy (col. 1, line 17-19), the method comprising: creating or enlarging the opening using an instrument according to claim 16 (see rejection of claim 16 above).

Claim Rejections - 35 USC § 103

3. 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.

4. Claims 1-3, 6-7, 10-12, 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of US Patent No. 6,422,865 to Fischer (Fischer).

In Reference to Claim 1

Sachdeva teaches:

An endodontic instrument (Fig. 1) for use in performing root canal therapy on a tooth, the instrument comprising: an elongate shank (working shaft 12) having a cutting edge (Fig. 2b) extending from a distal end of the shank along an axial length of the shank (Fig. 1), wherein the shank comprises a titanium alloy (col. 3, line 30-33), and wherein the shank is

prepared by heat-treating the shank at a temperature above 25°C[1] (col. 4, line 23; col. 4, line 60-64)

Sachdeva fails to disclose:

heat treating in an atmosphere consisting essentially of a gas unreactive with the shank.

Fischer teaches:

heat treating in an atmosphere consisting essentially of a gas unreactive with the shank in order to avoid discoloration (col. 4, line 40-42).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have the shank of Sachdeva heat-treated in an atmosphere consisting essentially of a gas unreactive with the shank according to Fischer in order to avoid discoloration as explicitly taught by Fischer.

In Reference to Claim 2

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above)

Sachdeva further in view of Fischer teaches:

wherein: the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon (Fischer: col. 4, line 40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have selected a gas from the group consisting of helium, neon,

[1] "wherein 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" is a product-by-process claim. MPEP 2113 states "Even though product-by-process claims are limited by and defined by the process,

argon, krypton, xenon, and radon of Fischer in the heat-treating of the shank of Sachdeva in order to avoid discoloration as explicitly taught by Fischer.

In Reference to Claim 3

Sachdeva in view of Fischer teaches:

> The instrument of claim 1 (see rejection of claim 1 above) wherein: the temperature is from 400°C up to but not equal to the melting point of the titanium alloy (Sachdeva: col. 4, line 59-65; Fig. 4, 5).

In Reference to Claim 6

Sachdeva in view of Fischer teaches:

> The instrument of claim 1 (see rejection of claim 1 above) wherein: the titanium alloy is selected from alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys, and nickel-titanium alloys (Sachdeva: col. 3, line 30-33).

Sachdeva lists alloy constituents that may comprise the working shaft. These fall within the titanium alloy classifications of alpha, beta, and alpha-beta.

In Reference to Claim 7

Sachdeva in view of Fischer teaches:

> The instrument of claim 1 (see rejection of claim 1 above) wherein: the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium (Sachdeva: col. 3, line 30-32; Table 1).

---

determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production." This applies to all subsequent product-by process claims.

When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim.

In Reference to Claim 10

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above) wherein: the cutting edge is formed by helical flutes in the shank (Sachdeva: reamer tip 16b; Fig. 2b).

In Reference to Claim 11

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above)

Sachdeva in view of Fischer fails to disclose:

wherein: the shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified 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).

In Reference to Claim 12

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above)

Sachdeva in view of Fischer fails to disclose:

wherein: the shank has a diameter of 0.5 to 1.6 millimeters.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the diameter of the shank in order to drill a hole with diameter of corresponding size, 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).

In Reference to Claim 15

Sachdeva in view of Fischer teaches:

A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising: creating or enlarging the opening (col. 1, line 17) using an instrument according to claim 1 (see rejection of claim 1 above).

5. Claims 13, 14, 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Fischer and US Patent No. 6,428,634 to Besselink (Besselink)

In Reference to Claim 13

Sachdeva teaches:

An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising: an elongate shank (working shaft 12) having helical flutes (Fig. 2b) defining a cutting edge extending from a distal end of the shank along an axial length of the shank (Fig. 1), wherein

the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium (col. 3, line 30; Table 1)

When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim.

Sachdeva fails to disclose:

wherein the shank is prepared by heat-treating the shank at a temperature from 475°C to 525°C (col. 4, line 65; Fig. 4, 5), and

in an atmosphere consisting essentially of argon gas.

Fischer teaches:

heat-treating in an atmosphere consisting essentially of argon gas in order to avoid discoloration (col. 4, line 40-42).

Besselink teaches:

wherein the shank is prepared by heat-treating the shank at a temperature from 475°C to 525°C (col. 4, line 65; Fig. 4, 5)

It would have been obvious to one having ordinary skill in the art at the time of the invention to have selected an atmosphere consisting essentially of argon gas of Fischer in the heat-treating of the shank of Sachdeva in order to avoid discoloration as explicitly taught by Fischer. It would have been further obvious to have selected a temperature from 475°C to 525°C of Besselink in the heat-treating of the shank of Sachdeva as modified by Fischer in order to produce a

textured crystal structure in the alloy as explicitly taught by Besselink (col. 2, line 43).

In Reference to Claim 14

Sachdeva in view of Fischer and Besselink teaches:

The instrument of claim 13 (see rejection of claim 13 above)

Sachdeva in view of Fischer and Besselink fails to disclose:

wherein: the shank has a diameter of 0.5 to 1.6 millimeters.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the diameter of the shank in order to drill a hole with diameter of corresponding size, 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).

In Reference to Claim 20

Sachdeva in view of Fischer and Besselink teaches:

A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy (Sachdeva: col. 1, line 17), the method comprising: creating or enlarging the opening using an instrument according to claim 13 (see rejection of claim 13 above).

6. Claims 4-5, 8-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Fischer as applied to claim 1 above and further in view of Besselink.

In Reference to Claim 4

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above)

Sachdeva in view of Fischer fails to disclose:

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

Besselink teaches:

heat-treating Ni-Ti alloys wherein: the temperature is from 475°C to 525°C (col. 2, lines 20-26; col. 4, line 32-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have chosen a temperature from 475°C to 525°C of Besselink in the heat-treating of the shank of Sachdeva in view of Fischer in order to produce a textured crystal structure in the alloy as explicitly taught by Besselink (col. 2, line 43).

In Reference to Claim 5

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above)

Sachdeva in view of Fischer fails to disclose:

wherein: the shank is heat-treated for 1 to 2 hours.

Besselink teaches:

wherein: the shank is heat-treated for a period of time that depends on the temperature that is chosen (col. 4, line 38-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the heat-treatment time based on the temperature and material chosen, 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).

In Reference to Claim 8

Sachdeva in view of Fischer teaches:

> The instrument of claim 1 (see rejection of claim 1 above) wherein: the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium (col. 4, line 65; Table 1),

When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim.

Sachdeva further in view of Fischer teaches (see rejection of claim 2 above):

> the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon (Fischer: col. 4, line 40),

Sachdeva in view of Fischer fails to disclose:

> the temperature is from 475°C to 525°C, and the shank is heat-treated for 1 to 2 hours.

Besselink teaches:

> heat-treating Ni-Ti alloys wherein the temperature is 475°C to 525°C (col. 2, lines 20-26; col. 4, line 32-40)

wherein: the shank is heat-treated for a period of time that depends on the temperature that is chosen. (col. 4, line 38-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have chosen a temperature from 475°C to 525°C of Besselink in the heat-treating of the shank of Sachdeva in view of Fischer in order to produce a textured crystal structure in the alloy as explicitly taught by Besselink (col. 2, line 43). It would have been further obvious to have modified the heat-treatment time based on the temperature and material chosen, 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).

In Reference to Claim 9

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above) wherein: the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium (col. 4, line 65; Table 1),

When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim.

Sachdeva in further view of Fischer teaches (see rejection of claim 2 above):

the gas is argon (Fischer: col. 4, line 40),

Sachdeva in view of Fischer fails to disclose:

temperature is 500°C, and the shank is heat-treated for 1 to 2 hours.

Besselink teaches:

heat-treating Ni-Ti alloys wherein the temperature is 500°C (col. 2, lines 20-26; col. 4, line 32-40)

wherein: the shank is heat-treated for a period of time that depends on the temperature that is chosen. (col. 4, line 38-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have chosen a temperature from 500°C of Besselink in the heat-treating of the shank of Sachdeva in view of Fischer in order to produce a textured crystal structure in the alloy as explicitly taught by Besselink (col. 2, line 43). It would have been further obvious to have modified the heat-treatment time based on the temperature and material chosen, 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).

7. Claim 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva.

Sachdeva teaches:

The instrument of claim 16 (see rejection of claim 16 above)

Sachdeva fails to disclose:

wherein: the shank has a diameter of 0.5 to 1.6 millimeters.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the diameter of the shank in order to drill a hole with diameter of corresponding size, 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).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 4,490,112 to Tanaka et al. discloses an orthodontic system and method utilizing a Ni-Ti alloy containing 50.5 atomic percent of nickel.

US PGPUB No. 2004/0121283 to Mason discloses a precision cast dental instrument utilizing an improved class of alloys. The common use of Ni-Ti alloys in endodontic instruments is mentioned as well.

US Patent No. 6,375,458 to Moorleghem et al. discloses medical instruments and devices and parts thereof using shape memory alloys. Methods of heat-treatment including length of time are discussed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew M. 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, the examiner's supervisor, Kenneth Bomberg can be reached on (571) 272-4922. The fax phone

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

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

MMN

/Kenneth Bomberg/
Supervisory Patent Examiner, Art Unit 4124

Notice of References Cited	Application/Control No. 11/628,933	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner Matthew M. Nelson	Art Unit 4166	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,375,458 B1	04-2002	Moorleghem et al.	433/2
*	B	US-2004/0121283 A1	06-2004	Mason, Robert M.	433/102
*	C	US-4,490,112	12-1984	Tanaka et al.	433/20
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

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.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	Matthew M Nelson	4166

✓	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	04/29/2008								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
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	14	✓								
	15	✓								
	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	Matthew M Nelson	4166

SEARCHED			
Class	Subclass	Date	Examiner
433	102, 224	4/29/2008	MMN
29	896.1	4/29/2008	MMN

SEARCH NOTES		
Search Notes	Date	Examiner
Search received from John Wilson for Class/Subclass 433/102,224 & 29/896.1	4/28/2008	MMN
See EAST search history	4/29/2008	MMN

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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

4/29/2008 3:39:49 PM
C:\Documents and Settings\mnelson3\My Documents\EAST\Workspaces\11628933 Dental Instruments Comprising Titanium.wsp

PTO/SB/08a (07-06)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	Not Yet Assigned 11/612,033
Filing Date	7 December 2006
First Named Inventor	LUEBKE, Neill Hamilton
Art Unit	--
Examiner Name	--
Attorney Docket Number	115207.00002

U. S. PATENT DOCUMENTS

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

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

Examiner Signature	/Matthew Nelson/	Date Considered	05/15/2008

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	Not Yet Assigned
Filing Date	7 December 2006
First Named Inventor	LUEBKE, Neill Hamilton
Art Unit	--
Examiner Name	--
Attorney Docket Number	115207.00002

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

Examiner Signature	/Matthew Nelson/	Date Considered	05/15/2008

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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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BIB DATA SHEET

CONFIRMATION NO. 9736

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/628,933	12/07/2006	433	4166	115207.00002

APPLICANTS
Neill Hamilton Luebke, Brookfield, WI;

**** CONTINUING DATA **************************
This application is a 371 of PCT/US05/19947 06/07/2005
which claims benefit of 60/578,091 06/08/2004

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

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
10/30/2007

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☑ Yes ☐ No	☑ Yes ☐ No	/MATTHEW M NELSON/ Examiner's Signature	☐ Initials	WI	7	20	3

ADDRESS

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

TITLE

Dental And Medical Instruments Comprising Titanium

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

BIB (Rev. 05/07).

Docket No.: 115207.00002

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

Date of Signature
and Transmission: August 29, 2008

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Art Unit:	4166
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 Office Action mailed May 30, 2008.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 6 of this paper.

Amendments To The Claims

1. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein 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,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy.

2. (Original) The instrument of claim 1 wherein:

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

3. (Cancelled)

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

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

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

the shank is heat-treated for 1 to 2 hours.

6. (Original) The instrument of claim 1 wherein:

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

7. (Original) The instrument of claim 1 wherein:

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

8. (Original) The instrument of claim 1 wherein:

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

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

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

the shank is heat-treated for 1 to 2 hours.

9. (Original) The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

the shank is heat-treated for 1 to 2 hours.

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

the cutting edge is formed by helical flutes in the shank.

11. (Original) The instrument of claim 1 wherein:

the shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

12. (Original) The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. (Original) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the shank is prepared by heat-treating the shank at a temperature from 475°C to 525°C in an atmosphere consisting essentially of argon gas.

14. (Original) The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 1.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 13.

REMARKS

Claim Amendments

Claim 1 has been amended to include the limitations of original claim 3. Claim 3 has been canceled accordingly.

Claims 16-19 have been canceled. Applicant reserves the right to pursue the subject matter of claims 16-19 in a continuation application.

Art Rejections

A.

Claims 16-17 and 19 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,431,863 to Sachdeva *et al.* ("Sachdeva").

This rejection is overcome due to the cancellation of claims 16-19.

B.

Claims 1-3, 6-7, 10-12 and 15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Sachdeva in view of U.S. Patent No. 6,422,865 to Fischer ("Fischer").

First, M.P.E.P. § 2144.05 III. notes that "Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range." Also, M.P.E.P. § 716.02(d) II. states that "[t]o establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960)."

Looking now at claim 1, the claimed invention requires that the shank be heat-treated at a temperature from 400°C up to but not equal to the melting point of the titanium alloy. Attached for Examiner consideration is an Inventor's Declaration describing comparative tests of two groups of heat treated files, that is, a first group

of files heat treated at 375°C for 1¼ hours and a second group of files heat treated at 500°C for 1¼ hours. The first group was heat treated at a temperature (375°C) outside of the claimed temperature range in amended claim 1 and the second group was heat treated at a temperature (500°C) within the claimed range in amended claim 1 (and also within the narrower temperature range of claims 4, 8, 9 and 13).

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.

Looking at Sachdeva, two heat treatment temperatures are described (350°C and 450°C), and the heat treatment was undertaken on a wire, not an elongate shank having a cutting edge as recited in claim 1. Nothing in Sachdeva suggests the criticality of the temperature range of amended claim 1 or that the claimed temperature range is critical when heat treating an elongate shank having a cutting edge.

Furthermore, M.P.E.P. § 2144.05 III. notes that "Applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing "(1) [t]hat the prior art taught away from the claimed invention... ." Column 4, lines 25-29 of Sachdeva state that "heat treating the working shaft tip 16 at a higher temperature than the treatment temperature of the mid-section will result

in greater hardness and stiffness at the tip of the instrument vis-a-vis the mid-section". Thus, Sachdeva teaches using higher temperatures for stiffness, and it follows that such a teaching suggests using lower temperatures when flexibility (less stiffness) is desired. Note how Sachdeva uses 350°C in the heat treatment described at column 4, lines 62-63.

In contrast, the Inventor's Declaration describes how higher temperatures lead to increased flexibility. Thus, the present inventor has taken a completely different path from the teachings of Sachdeva which indicate that higher temperatures decrease flexibility. It is well settled that the "totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness." M.P.E.P. § 2145 X. D. 3. citing *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986).

Therefore, to the extent that a *prima facie* case of obviousness could be established for original claim 1, it is believed that the Inventor's Declaration, the arguments above, and the amendments to claim 1 rebut any possible *prima facie* case of obviousness that could be established for amended claim 1 (and claims 2-12 and 15 that depend thereon) using Sachdeva and Fischer.

C.

Claims 13, 14 and 20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Sachdeva in view of Fischer and U.S. Patent No. 6,428,634 to Besselink *et al.* ("Besselink"). Claims 4-5 and 8-9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Sachdeva in view of Fischer and Besselink.

At column 4, lines 33-39 of Besselink, heat treatment temperatures of 300°C to 700°C are disclosed, and the heat treatment was undertaken on a wire, not an

elongate shank having a cutting edge as in independent claims 1 and 13. Nothing in Besselink suggests the criticality of the temperature range (475°C to 525°C) used in claims 4-5, 8-9, 13, 14 and 20, or that the claimed temperature range is critical when heat treating an elongate shank having a cutting edge.

Again, attention is directed to the attached Inventor's Declaration which 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 temperature range (475°C to 525°C) used in claims 4-5, 8-9, 13, 14 and 20 was critical to improving the beneficial properties of the endodontic instruments.

Therefore, to the extent that a *prima facie* case of obviousness could be established for claims 4-5, 8-9, 13, 14 and 20, it is believed that the Inventor's Declaration and the arguments above rebut any possible *prima facie* case of obviousness that could be established for claims 4-5, 8-9, 13, 14 and 20 using Sachdeva and Fischer and Besselink.

D.

Claim 18 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Sachdeva.

This rejection is overcome due to the cancellation of claims 16-19.

Conclusion

It is respectfully submitted that amended claim 1 (and claims 2-12 and 15 that

depend thereon) and original claim 13 (and claims 14 and 20 that depend thereon) are patentable over the cited art.

No fees are believed to be needed for this amendment. However, if fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: August 29, 2008

By: _____

Richard T. Roche
Registration No. 38,599
Quarles and Brady LLP
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6355354

Docket Number: 115207.00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke

Application No.: 11/628,933

Filing Date: December 7, 2006

Title: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

Art Unit: 4166

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 selected endodontic files from the same lot and same type of instrument. The files were nickel-titanium (NiTi) rotary instruments with a 2% taper.

3. Others working according to my directions heat treated a first group of these files at 375°C for 1¼ hours and heat treated a second group of these files at 500°C for 1¼ hours.

4. Others working according to my directions tested the heat treated files using the ADA/ANSI Standard #28 and ISO 3630-1 tests for torque, angular deflection and bending. I performed a cyclic fatigue test that has not yet been approved as a

standard test in either ISO or ADA/ANSI, but both working groups have been asking for a proposal for this test to be included as a standard.

5. When performing these tests on endodontic files, one looks for torque data that is similar because this indicates that the heat did not degrade the metal in the instrument. For better endodontic file performance, one looks for an increased number in angular deflection, a lower gm·cm number in the bend test, and a higher number in cyclic fatigue that demonstrates the property of passive flexibility.

6. The test results (n = 5) are shown in the Illustrations below.

Illustration 1

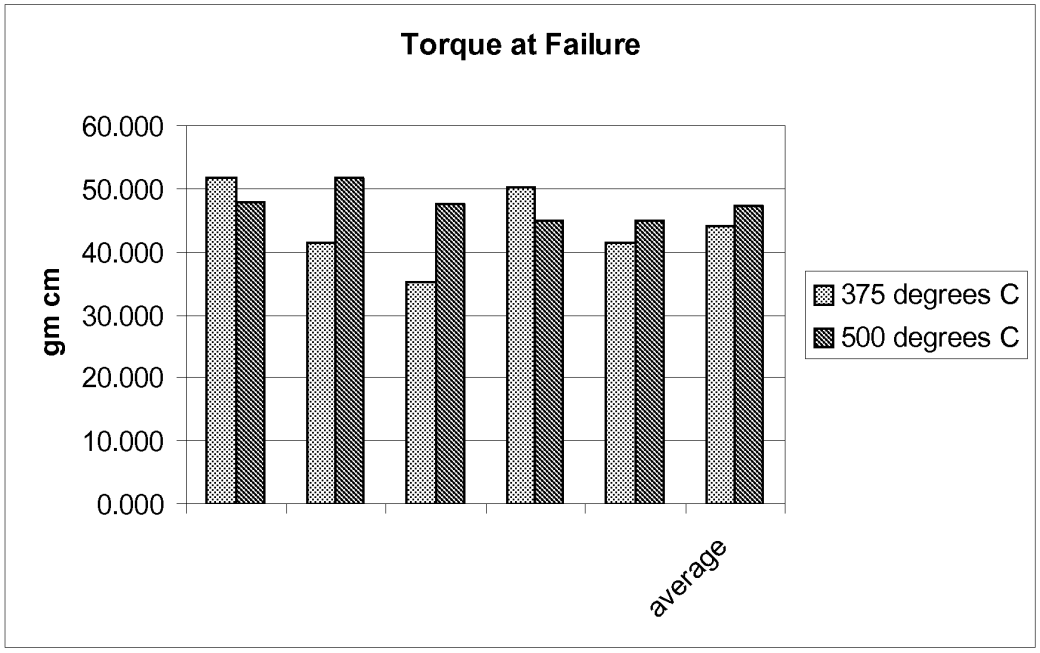


Illustration 2

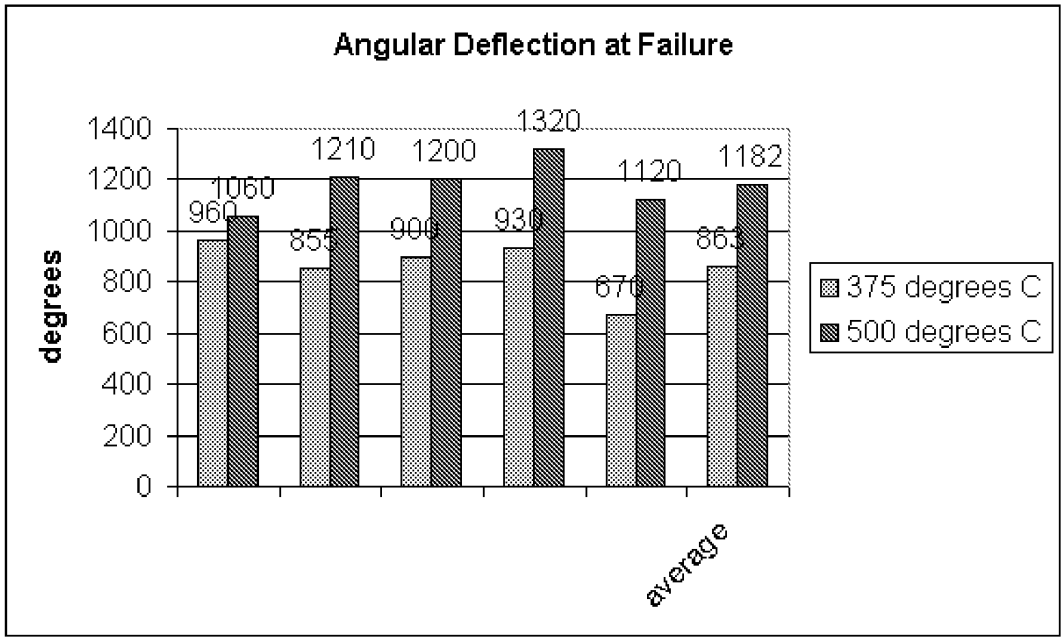


Illustration 3

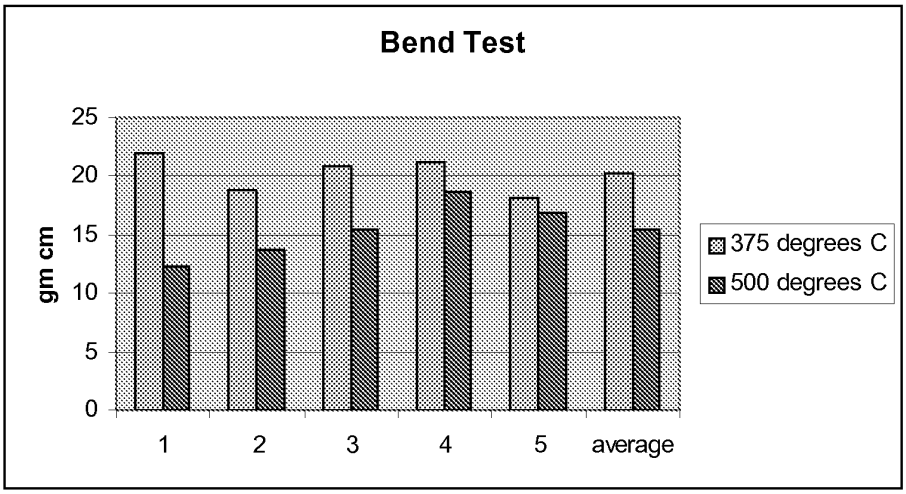
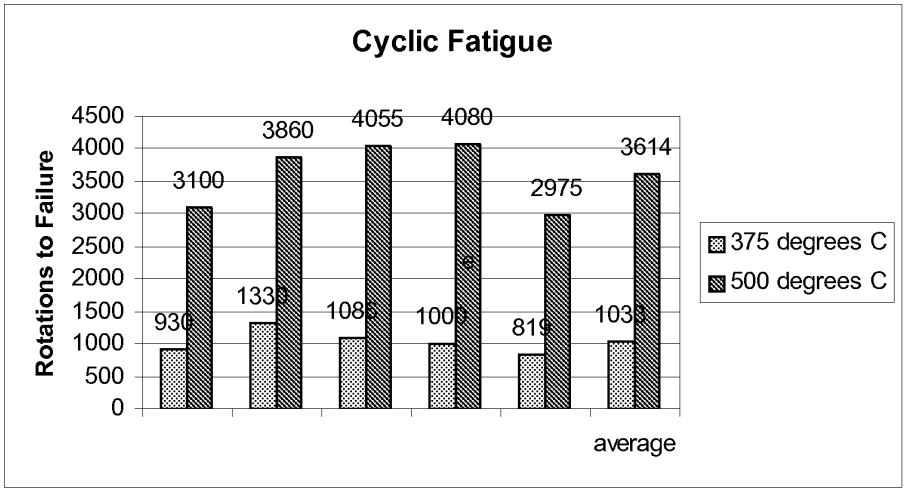


Illustration 4



7. In Illustration 1 above, the torque data is similar for the endodontic files which indicates that the heat did not degrade the metal in the files heat treated at 500°C. As noted in Item 5 above, the angular deflection is preferably larger in endodontic files and in these tests as graphed in Illustration 2, the angular deflection was significantly larger for the files heat treated at 500°C, on average 130% better than the files heat treated at 375°C. In the bend test data of Illustration 3, the smaller the gm cm number, the more flexible the file. This bend test data show that it is significant between the two temperatures, i.e., the files heat treated at 500°C have improved flexibility compared to the files heat treated at 375°C. The cyclic fatigue data of Illustration 4 demonstrate the remarkable property of passive flexibility in that the numbers for the files heat treated at 500°C are significantly larger than the files heat treated at 375°C.

8. 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: August 29, 2008

Neill H. Luebke

Dr. Neill H. Luebke

Electronic Acknowledgement Receipt

EFS ID:	3866551
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	29-AUG-2008
Filing Date:	07-DEC-2006
Time Stamp:	17:04:36
Application Type:	U.S. National Stage under 35 USC 371

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		amendment.pdf	263347 c0192ae44d03ae2df301c1fd9da9e688bccb88fc	yes	10

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment - After Non-Final Rejection		1	1	
	Claims		2	5	
	Applicant Arguments/Remarks Made in an Amendment		6	10	
Warnings:					
Information:					
2	Rule 130, 131 or 132 Affidavits	Luebke.pdf	85120 f64184574c1f800dbda86ee3d96dc64ce715bf97	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	348467		

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

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

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

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

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/628,933	12/07/2006	

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT	08/29/2008	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 15	Minus	** 20	= 0	X $25 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $105 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/PATSY ZIMMERMAN/

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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 10/24/2008

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

MAIL DATE	DELIVERY MODE
10/24/2008	PAPER

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.

Office Action Summary	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	Matthew M. Nelson	4166	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *29 August 2008*.

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

3)☐ 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

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *3 and 16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-15 and 20* is/are rejected.

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

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

Application Papers

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

10)☒ The drawing(s) filed on *07 December 2006* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed August 29, 2008 has been entered. Claims 1-2, 4-15, 20 remain pending in the application and claims 3, 16-19 have been cancelled.

Claim Objections

2. Claim 1 is objected to because of the following informalities: Claim 1 recites "the shank at a temperature in an atmosphere" which appears to mean "the shank in an atmosphere". Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. 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.

2. Claims 1-2, 6-7, 10-12, 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva (US 6,431,863) in view of Fischer (US 6,422,865).

In Reference to Claim 1

Sachdeva teaches:

> An endodontic instrument (Fig. 1) for use in performing root canal therapy on a tooth, the instrument comprising: an elongate shank (working shaft 12) having a cutting edge (Fig. 2b) extending from a distal end of the

shank along an axial length of the shank (Fig. 1), wherein the shank comprises a titanium alloy (col. 3, line 30-33), and wherein the shank is prepared by heat-treating the shank (col. 4, line 23; col. 4, line 60-64), wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy (Sachdeva: col. 4, line 59-65; Fig. 4, 5).

Sachdeva fails to disclose:

heat treating in an atmosphere consisting essentially of a gas unreactive with the shank.

Fischer teaches:

heat treating in an atmosphere consisting essentially of a gas unreactive with the shank in order to avoid discoloration (col. 4, line 40-42).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have the shank of Sachdeva heat-treated in an atmosphere consisting essentially of a gas unreactive with the shank according to Fischer in order to avoid discoloration as explicitly taught by Fischer.

In Reference to Claim 2

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above)

Sachdeva further in view of Fischer teaches:

wherein: the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon (Fischer: col. 4, line 40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have selected a gas from the group consisting of helium, neon, argon, krypton, xenon, and radon of Fischer in the heat-treating of the shank of Sachdeva in order to avoid discoloration as explicitly taught by Fischer.

In Reference to Claim 6

Sachdeva in view of Fischer teaches:

> The instrument of claim 1 (see rejection of claim 1 above) wherein: the titanium alloy is selected from alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys, and nickel-titanium alloys (Sachdeva: col. 3, line 30-33).

Sachdeva lists alloy constituents that may comprise the working shaft. These fall within the titanium alloy classifications of alpha, beta, and alpha-beta.

In Reference to Claim 7

Sachdeva in view of Fischer teaches:

> The instrument of claim 1 (see rejection of claim 1 above) wherein: the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium (Sachdeva: col. 3, line 30-32; Table 1).

When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim.

In Reference to Claim 10

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above) wherein: the cutting edge is formed by helical flutes in the shank (Sachdeva: reamer tip 16b; Fig. 2b).

In Reference to Claim 11

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above)

Sachdeva in view of Fischer fails to disclose:

wherein: the shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified 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).

In Reference to Claim 12

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above)

Sachdeva in view of Fischer fails to disclose:

wherein: the shank has a diameter of 0.5 to 1.6 millimeters.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the diameter of the shank in order to drill a hole with diameter of corresponding size, 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).

In Reference to Claim 15

Sachdeva in view of Fischer teaches:

> A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising: creating or enlarging the opening (col. 1, line 17) using an instrument according to claim 1 (see rejection of claim 1 above).

3. Claims 13, 14, 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Fischer and US Patent No. 6,428,634 to Besselink (Besselink)

In Reference to Claim 13

Sachdeva teaches:

> An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising: an elongate shank (working shaft 12) having helical flutes (Fig. 2b) defining a cutting edge extending from a distal end of the shank along an axial length of the shank (Fig. 1), wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium (col. 3, line 30; Table 1)

When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim.

Sachdeva fails to disclose:

wherein the shank is prepared by heat-treating the shank at a temperature from 475°C to 525°C (col. 4, line 65; Fig. 4, 5), and

in an atmosphere consisting essentially of argon gas.

Fischer teaches:

heat-treating in an atmosphere consisting essentially of argon gas in order to avoid discoloration (col. 4, line 40-42).

Besselink teaches:

wherein the shank is prepared by heat-treating the shank at a temperature from 475°C to 525°C (col. 4, line 65; Fig. 4, 5)

It would have been obvious to one having ordinary skill in the art at the time of the invention to have selected an atmosphere consisting essentially of argon gas of Fischer in the heat-treating of the shank of Sachdeva in order to avoid discoloration as explicitly taught by Fischer. It would have been further obvious to have selected a temperature from 475°C to 525°C of Besselink in the heat-treating of the shank of Sachdeva as modified by Fischer in order to produce a textured crystal structure in the alloy as explicitly taught by Besselink (col. 2, line 43).

In Reference to Claim 14

Sachdeva in view of Fischer and Besselink teaches:

The instrument of claim 13 (see rejection of claim 13 above)

Sachdeva in view of Fischer and Besselink fails to disclose:

wherein: the shank has a diameter of 0.5 to 1.6 millimeters.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the diameter of the shank in order to drill a hole with diameter of corresponding size, 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).

In Reference to Claim 20

Sachdeva in view of Fischer and Besselink teaches:

A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy (Sachdeva: col. 1, line 17), the method comprising: creating or enlarging the opening using an instrument according to claim 13 (see rejection of claim 13 above).

4. Claims 4-5, 8-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Fischer as applied to claim 1 above and further in view of Besselink.

In Reference to Claim 4

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above)

Sachdeva in view of Fischer fails to disclose:

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

Besselink teaches:

heat-treating Ni-Ti alloys wherein: the temperature is from 475°C to 525°C (col. 2, lines 20-26; col. 4, line 32-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have chosen a temperature from 475°C to 525°C of Besselink in the heat-treating of the shank of Sachdeva in view of Fischer in order to produce a textured crystal structure in the alloy as explicitly taught by Besselink (col. 2, line 43).

In Reference to Claim 5

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above)

Sachdeva in view of Fischer fails to disclose:

wherein: the shank is heat-treated for 1 to 2 hours.

Besselink teaches:

wherein: the shank is heat-treated for a period of time that depends on the temperature that is chosen (col. 4, line 38-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the heat-treatment time based on the temperature and material chosen, 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).

In Reference to Claim 8

Sachdeva in view of Fischer teaches:

The instrument of claim 1 (see rejection of claim 1 above) wherein: the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium (col. 4, line 65; Table 1),

When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim.

Sachdeva further in view of Fischer teaches (see rejection of claim 2 above):

the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, and radon (Fischer: col. 4, line 40),

Sachdeva in view of Fischer fails to disclose:

the temperature is from 475°C to 525°C, and the shank is heat-treated for 1 to 2 hours.

Besselink teaches:

heat-treating Ni-Ti alloys wherein the temperature is 475°C to 525°C (col. 2, lines 20-26; col. 4, line 32-40)

wherein: the shank is heat-treated for a period of time that depends on the temperature that is chosen. (col. 4, line 38-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have chosen a temperature from 475°C to 525°C of Besselink in the heat-treating of the shank of Sachdeva in view of Fischer in order to produce a textured crystal structure in the alloy as explicitly taught by Besselink (col. 2, line 43). It would have been further obvious to have modified the heat-treatment

time based on the temperature and material chosen, 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).

In Reference to Claim 9

Sachdeva in view of Fischer teaches:

> The instrument of claim 1 (see rejection of claim 1 above) wherein: the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium (col. 4, line 65; Table 1),

When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim.

Sachdeva in further view of Fischer teaches (see rejection of claim 2 above):

> the gas is argon (Fischer: col. 4, line 40),

Sachdeva in view of Fischer fails to disclose:

> temperature is 500°C, and the shank is heat-treated for 1 to 2 hours.

Besselink teaches:

> heat-treating Ni-Ti alloys wherein the temperature is 500°C (col. 2, lines 20-26; col. 4, line 32-40)
>
> wherein: the shank is heat-treated for a period of time that depends on the temperature that is chosen. (col. 4, line 38-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have chosen a temperature from 500°C of Besselink in the heat-

treating of the shank of Sachdeva in view of Fischer in order to produce a textured crystal structure in the alloy as explicitly taught by Besselink (col. 2, line 43). It would have been further obvious to have modified the heat-treatment time based on the temperature and material chosen, 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).

Response to Arguments

3. Applicant's arguments filed August 29, 2008 have been fully considered but they are not persuasive.

4. Applicant argues on pages 6-7, with the aid of Inventor's Declaration, that heat treatment within the claimed range was critical to improving the beneficial properties of the endodontic instruments. MPEP 2144.05 III notes that "applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." The inventor's declaration does not show unexpected results and that this particular range is critical. Rather, it shows the trend temperature has on flexibility and one of ordinary skill in the art would simply alter the temperature to achieve the desired degree of flexibility. Further on page 7, applicant argues that the heat treatment was undertaken on a wire and not an elongate shank having a cutting edge. Sachdeva states in regards to the wire tests that "it will be appreciated by persons skilled in the art that variable heat treatments of the working

shaft portion 12 of the endodontic instruments of the present invention can be advantageously utilized to achieve the desired properties" (col. 4, line 65 - col. 5, line 2).

5. Applicant argues on pages 7-8 that Sachdeva teaches away from the claimed invention. However, a reference only "teaches away" when it states that something cannot be done. See In re Gurley, 27 F.3d 551, 553, 31 USPQ2d 1130, 1130 (Fed. Cir. 1994).

6. Applicant argues on pages 8-9 that heat treatment was undertaken on a wire and not an elongate shank having a cutting edge. Similarly to Sachdeva, Besselink is concerned with articles made from such alloys and is generally referring to using a wire for testing purposes. Applicant further argues on page 9 that nothing in Besselink suggests the criticality of the temperature range, however Besselink states heat treatment at "more preferably more than about 400 C" and "more preferably less than about 500 C" (col. 4, lines 32-39) which overlaps the range and even includes the temperature tested in Inventor's Declaration.

Conclusion

7. **THIS ACTION IS MADE FINAL.** 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 mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew M. 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, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. 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.

/John J Wilson/
Primary Examiner
Art Unit 3732

/MMN/

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	Matthew M Nelson	4166

✓	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	04/29/2008	10/21/2008							
	1	✓	✓							
	2	✓	✓							
	3	✓	-							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	✓	✓							
	10	✓	✓							
	11	✓	✓							
	12	✓	✓							
	13	✓	✓							
	14	✓	✓							
	15	✓	✓							
	16	✓	-							
	17	✓	-							
	18	✓	-							
	19	✓	-							
	20	✓	✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	Matthew M Nelson	4166

SEARCHED

Class	Subclass	Date	Examiner
433	102, 224	4/29/2008	MMN
29	896.1	4/29/2008	MMN
433	102, 224	10/21/2008	MMN
29	896.1	10/21/2008	MMN

SEARCH NOTES

Search Notes	Date	Examiner
Search received from John Wilson for Class/Subclass 433/102,224 & 29/896.1	4/28/2008	MMN
See EAST search history	4/29/2008	MMN
Updated EAST search	10/21/2008	MMN

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	891	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
L3	67	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
L4	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
L5	30	L2 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
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

10/21/2008 1:00:58 PM
C:\Documents and Settings\mnelson3\My Documents\EAST\Workspaces\11628933 Dental Instruments Comprising Titanium.wsp

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BIB DATA SHEET

CONFIRMATION NO. 9736

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/628,933	12/07/2006	433	4166	115207.00002

APPLICANTS
Neill Hamilton Luebke, Brookfield, WI;

**** CONTINUING DATA **************************
This application is a 371 of PCT/US05/19947 06/07/2005
which claims benefit of 60/578,091 06/08/2004

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

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
10/30/2007

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /MATTHEW M NELSON/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		WI	7	20	3

ADDRESS

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411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497
UNITED STATES

TITLE

Dental And Medical Instruments Comprising Titanium

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

BIB (Rev. 05/07).

PTO/SB/30EFS (11-08)
Approved for use through 12/31/2008. 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	11628933	Filing Date	2006-12-07	Docket Number (if applicable)	115207.00002	Art Unit	4166
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
Declaration Under 37 C.F.R. 1.132

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 (11-08)
Approved for use through 12/31/2008. 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)	2008-12-23
Name	Richard T. Roche	Registration Number	38599

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

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

Docket No.: 115207.00002

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

Date: December 23, 2008

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Confirmation No.:	9736
Art Unit:	3732
Examiner:	Matthew M. Nelson

AMENDMENT ACCOMPANYING REQUEST FOR CONTINUED EXAMINATION

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

Sir:

This is in response to the Office Action mailed October 24, 2008.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 6 of this paper.

Amendments To The Claims

1. (Presently Presented) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein the shank is prepared by heat-treating the shank at a temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy.

2. (Original) The instrument of claim 1 wherein:

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

3. (Cancelled)

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

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

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

the shank is heat-treated for 1 to 2 hours.

6. (Original) The instrument of claim 1 wherein:

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

7. (Original) The instrument of claim 1 wherein:

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

8. (Original) The instrument of claim 1 wherein:

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

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

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

the shank is heat-treated for 1 to 2 hours.

9. (Original) The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

the shank is heat-treated for 1 to 2 hours.

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

the cutting edge is formed by helical flutes in the shank.

11. (Original) The instrument of claim 1 wherein:

the shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

12. (Original) The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. (Original) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the shank is prepared by heat-treating the shank at a temperature from 475°C to 525°C in an atmosphere consisting essentially of argon gas.

14. (Original) The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 1.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 13.

21. (New) The instrument of claim 1 wherein:

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

REMARKS

Claim Amendments

New claim 21 includes a lower temperature limit from claim 1 and an upper temperature limit from claim 4.

Claim Objections

Claim 1 was objected to because of informalities. However, the Applicant submits that the recitation of "at a temperature" is proper in claim 1 in that it provides proper antecedent basis for "the temperature" at line 8 of claim 1.

Claim Rejections - 35 USC § 103

Claims 1-2, 6-7, 10-12, and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva (US 6,431,863) in view of Fischer (US 6,422,865).

M.P.E.P. § 2144.05 III. notes that "Applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing "(1) [t]hat the prior art taught away from the claimed invention... ." Column 4, lines 25-29 of Sachdeva state that "heat treating the working shaft tip 16 at a higher temperature than the treatment temperature of the mid-section will result in greater hardness and stiffness at the tip of the instrument vis-a-vis the mid-section". Thus, Sachdeva teaches using higher temperatures for stiffness, and it follows that such a teaching suggests using lower temperatures when flexibility (less stiffness) is desired.

Looking at Sachdeva, two heat treatment temperatures are described (350°C and 450°C). When choosing between the two temperatures of Sachdeva, one seeking flexibility (less stiffness) would be led away from the higher temperature (450°C) to the lower temperature (350°C - which is clearly outside the scope of claim 1). With respect

to Fischer, heat treatment temperatures of 1600°F-1800°F (871°C-982°C) are taught at column 4, line 38-40 and therefore, Fischer does not make up for the deficiencies of Sachdeva. Thus, it is submitted that Sachdeva and Fischer teach away from the invention recited in claim 1.

At page 13 of the Office Action, it is stated that "a reference only 'teaches away' when it states that something cannot be done. See *In re Gurley* 27 F.2d 551, 553, 31 USPQ2d 1130, 1130 (Fed. Cir. 1994)." The Applicant's Representative reviewed *In re Gurley* and could not find this holding. In fact, *In re Gurley* states:

> "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." 27 F.2d at 553 (Underlining added.)

Referring back to Sachdeva, when choosing between the two temperatures of Sachdeva, one seeking flexibility (less stiffness) would be led away from the higher temperature (450°C) to the lower temperature (350°C - which is clearly outside the scope of claim 1). Thus, applying the test of *In re Gurley,* upon reading Sachdeva, one would be led in a direction divergent [to lower temperatures] from the path that was taken by the applicant [higher temperatures]. It is submitted that Sachdeva and Fischer teach away from the invention recited in claim 1.

Claims 13, 14, and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Fischer and US Patent No. 6,428,634 to Besselink (Besselink). Claims 4-5, and 8-9 were rejected under 35 U.S.C. 103(a) as

being unpatentable over Sachdeva in view of Fischer as applied to claim 1 above and further in view of Besselink.

The arguments above regarding the "teaching away" of Sachdeva and Fischer also apply to claims 4-5, 8-9, 13, 14, and 20. However, the Office Action also states that it "would have been further obvious to have selected a temperature from 475°C to 525°C of Besselink in the heat treating of the shank of Sachdeva as modified by Fischer in order to produce a textured crystal structure in the alloy as explicitly taught by Besselink (col. 2, line 43)."

Upon further review of col. 2, line 43 of Besselink, it can be seen that Besselink is referring to rolling and drawing techniques for producing a textured crystal structure. Therefore, nothing in Besselink teaches that a temperature from 475°C to 525°C should be selected "to produce a textured crystal structure in the alloy" as asserted in the Office Action. As explained above, when choosing between the two temperatures of Sachdeva, one seeking flexibility (less stiffness) would be led away from the higher temperature (450°C) to the lower temperature (350°C - which is clearly outside the scope of claim 1). Nothing in Besselink would stop one from following this teaching in Sachdeva.

In the previous response of August 29, 2008, Applicant submitted an Inventor's Declaration in order to rebut any *prima facie* case of obviousness that could be established using Sachdeva and Fischer and Besselink. Page 12 of the present Office Action states that "M.P.E.P. § 2144.05 III. notes that 'applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.'" The Office Action contends that the

Inventor's Declaration of August 29, 2008 "does not show unexpected results and that this particular range is critical".

Attached for Examiner consideration is a second Inventor's Declaration addressing the contention in the Office Action that the Inventor's Declaration of August 29, 2008 "does not show unexpected results and that this particular range is critical". First, the Inventor's Declaration explains that one reading U.S. Patent No. 6,431,863 to Sachdeva would expect less flexibility when heat treating at higher temperatures, and the Inventor's tests show increased flexibility. Therefore, the Inventor's test results would be unexpected to one reading U.S. Patent No. 6,431,863 to Sachdeva.

Second, the attached Inventor's Declaration points out that the average rotation to failure for files heat treated at 500°C was 3614 compared to 1033 for files heat treated at 375°C. This is a 250% increase. Thus, heat treating files within the temperature range of claim 1 (i.e., at 500°C) provides for much improved properties compared to heat treating files outside the claimed range (i.e., at 375°C).

Third, not only does the Inventor's data show that the temperature range is critical, the attached Inventor's Declaration includes a technical journal article of Zinelis *et al.*, entitled "The effect of thermal treatment on the resistance of nickel-titanium rotary files in cyclic fatigue", *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, Endodontology*, 2007;103:843-847. This article, which was published later than the filing date of the present application, supports the Inventor's assertion that the claimed temperature range for heat treatment is critical.

Therefore, to the extent that a *prima facie* case of obviousness could be established for claims 1-2, 6-7, 10-12, and 15 and 21, it is believed that the attached

Inventor's Declaration rebuts any arguments that the Inventor's Declaration of August 29, 2008 "does not show unexpected results and that this particular range is critical". It is submitted that the attached Inventor's Declaration and the arguments above rebut any possible *prima facie* case of obviousness that could be established for claims 1-2, 6-7, 10-12, and 15 and 21 using Sachdeva and Fischer and Besselink.

Conclusion

It is respectfully submitted that claim 1 (and claims 2-12 and 15 and 21 that depend thereon) and claim 13 (and claims 14 and 20 that depend thereon) are patentable over the cited art.

No fees are believed to be needed for this amendment. However, if fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: December 23, 2008

By: Richard T. Roche

Richard T. Roche
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6694651

Docket Number: 115207.00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Art Unit:	4166
Examiner:	Matthew M. Nelson

DECLARATION UNDER 37 C.F.R. § 1.132

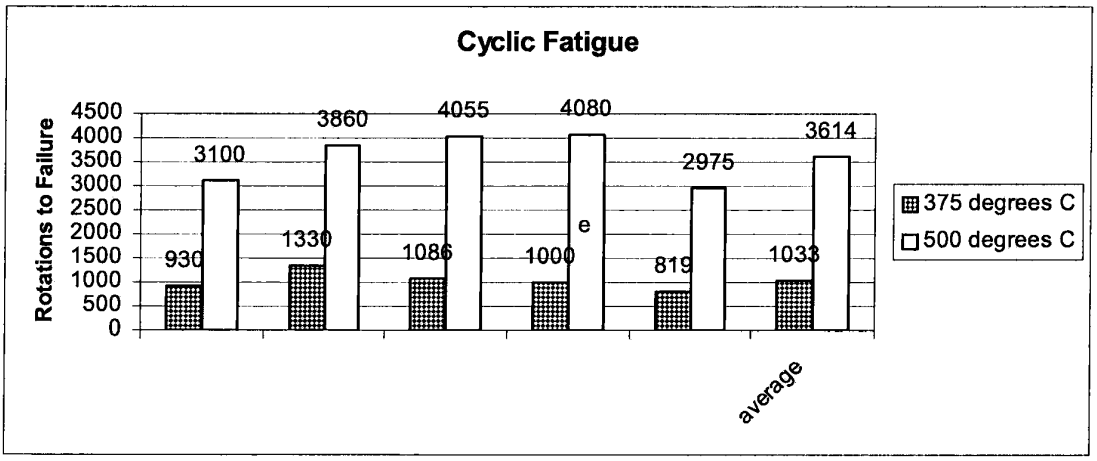
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

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

2. I have reviewed the Office Action of October 24, 2008 (hereinafter the "Office Action") in the above-identified patent application. I have noted that Item 4 on page 12 of the Office Action provides a response to arguments (hereinafter the "Response to Arguments") submitted with the response of August 29, 2008.

3. I have reproduced below the cyclic fatigue data of Illustration 4 submitted with my Inventor's Declaration of August 29, 2008.

Illustration 4



I stated in my Inventor's Declaration of August 29, 2008 that the "cyclic fatigue data of Illustration 4 demonstrate the remarkable property of passive flexibility in that the numbers for the files heat treated at 500°C are significantly larger than the files heat treated at 375°C."

4. The Response to Arguments contends that my Inventor's Declaration of August 29, 2008 "does not show unexpected results". In this regard, I have noted column 4, lines 23-29 of U.S. Patent No. 6,431,863 to Sachdeva that was cited in the Office Action. Lines 23-29 state: "In yet another alternative, the flexibility/stiffness of the instrument can be controlled by selected heat treatment of specific areas of the working shaft. For example, heat treating the working shaft tip 16 at a higher temperature than the treatment temperature of the mid-section will result in greater hardness and stiffness at the tip of the instrument vis-a-vis the mid-section." (Underlining added). This

indicates to me that one reading U.S. Patent No. 6,431,863 would expect less flexibility when heat treating at higher temperatures.

5. As detailed in Item 3 above, I detected an increase in passive flexibility when heat treating the files in the higher temperature (which is within my claimed temperature range). Thus, my tests show increased flexibility whereas U.S. Patent No. 6,431,863 indicates that less flexibility would result when heat treating at higher temperatures. Accordingly, I submit that my results would be unexpected to one reading U.S. Patent No. 6,431,863. Therefore, I respectfully disagree with the statement in the Response to Arguments that contends that my Inventor's Declaration of August 29, 2008 "does not show unexpected results".

6. The Response to Arguments further contends that my Inventor's Declaration of August 29, 2008 "does not show . . . that this particular range is critical". I disagree. Looking at Illustration 4 above, the average rotation to failure for files heat treated at 500°C was 3614 compared to 1033 for files heat treated at 375°C. This is a 250% increase. Heat treating files within my claimed range provides for much improved properties compared to heat treating files outside my claimed range.

7. As further evidence that my claimed range is critical, I attach a technical journal article of Zinelis *et al.*, entitled "The effect of thermal treatment on the resistance of nickel-titanium rotary files in cyclic fatigue", *Oral Surgery, Oral Medicine, Oral*

Pathology, Oral Radiology, Endodontology, 2007;103:843-847 ("Zinelis *et al.*"). This article published in June 2007 after the filing date of my application.

8. The later independent work of Zinelis *et al.* (none of whom I know) shows in Figure 3 at page 845 that there is a critical temperature range for the thermal treatment of nickel-titanium files in order to improve cyclic fatigue. Therefore, others in my field, working after my invention date, have confirmed that there is a critical range for heat treatment.

9. The Response to Arguments further contends that my Inventor's Declaration of August 29, 2008 merely "shows the trend temperature has on flexibility". I disagree. In Figure 3, Zinelis *et al.* show that there is no "trend" line with respect to temperature as the fatigue data peaks and then falls off based on temperature. There is no "trend" as asserted in the Office Action.

10. In summary, I submit that my claimed range is critical, and heat treatment within my claimed range achieves unexpected results.

11. 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: December 07, 2008

Dr. Neill H. Luebke

Vol. 103 No. 6 June 2007

Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology

ENDODONTOLOGY Editor: Larz S. W. Spångberg

The effect of thermal treatment on the resistance of nickel-titanium rotary files in cyclic fatigue

Spiros Zinelis, PhD,[a] Myrsini Darabara, BEng,[b] Toshiyuki Takase, BEng,[c] Kaoru Ogane, BEng,[c] and George D. Papadimitriou, PhD,[d] Athens, Greece
UNIVERSITY OF ATHENS

Objective. The purpose of this study was to determine the effect of various thermal treatments on the fatigue resistance of a nickel-titanium (NiTi) engine-driven endodontic file.
Study design. Fifteen groups of 5 files each of ISO 30 and taper .04 were tested in this study. The cutting tip (5 mm from the end) of files from 14 groups were heat treated for 30 minutes in temperatures 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, respectively, while 1 group was used as reference. The files were placed in a device that allowed the instruments to be tested for rotating bending fatigue inside an artificial root canal. The number of rotations to breakage was recorded for each file. The mean values of all groups were statistically analyzed using 1-way analysis of variance and Student Newman Keuls multiple comparison test at $\alpha = .05$.
Results. The 430°C and 440°C groups showed the highest values, with fatigue resistance decreasing for thermal treatment at lower and higher temperatures. This may be the result of metallurgical changes during annealing.
Conclusion. Within the limitations of the low sample size and the specific instrument size tested, it appears that the appropriate thermal treatment may significantly increase the fatigue resistance of the NiTi file tested. **(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2007;103:843-7)**

Nickel-titanium (NiTi) alloy has been used in endodontics for about 2 decades. It was introduced to facilitate instrumentation of curved root canals. Although NiTi files showed increased flexibility compared with stainless steel counterparts, the unexpected fracture during mechanical preparation of root canals still remains a problem.[1-3] It has been reported that rotary NiTi instruments are more prone to intracanal fracture compared with stainless steel hand instruments.[3] These unexpected fractures occur without any visible changes to the instruments, such as permanent defect or deformation.[1,2]

It is widely accepted that the fracture of engine-driven NiTi instruments is associated with the fatigue mechanism mainly due to cyclic loading, although some recent studies based on clinically failed instruments implied that fracture occurs due to a sudden overload rather than a progressive fatigue process.[3-6] In any case, the mechanical properties of NiTi alloys associated with fatigue resistance in the former mechanism or the fracture strength in the latter play an important role on the fracture susceptibility under clinical conditions.

However, the mechanical as well as the shape memory and superelastic properties of endodontic files are strongly dependent on the thermomechanical processing history of NiTi alloys through the manufacturing process.[7] Although the exact thermomechanical history of NiTi wires used for the production of endodontic

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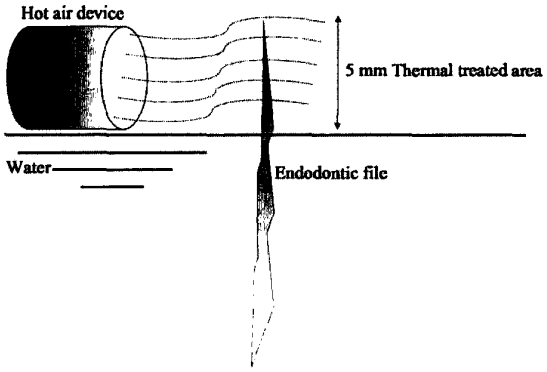

Fig. 1. Illustration of the thermal treatment process. The tip of the instrument is heat treated under a constant flow of hot air while the rest is immersed in a water bath.

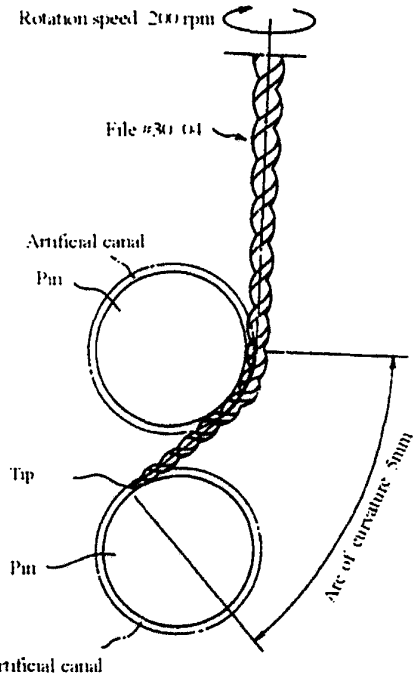

Fig. 2. Experimental setup for the evaluation of rotation to breakage of the nickel-titanium instruments.

files is proprietary, typical processing of superelastic NiTi-based wires includes vacuum casting of an ingot and hot forging, rolling, and drawing followed by a heat treatment. The NiTi alloys are usually heat treated between 450°C and 550°C, in air or inert atmosphere furnaces, to obtain superelastic or shape memory properties and to achieve the appropriate balance of mechanical properties for the application.[7-9]

Nickel-titanium wires are provided by the manufacturer in a cold-worked state (known also as *drawn* or *rolled*) in cases where further mechanical and/or thermal treatment might take place, because cold-worked microstructures demonstrate less ductility, facilitating the grinding process.[7] It is assumed that the same procedure is followed for the production of NiTi instruments, as they are produced exclusively by CAD/CAM manufacturing processes.[8] Therefore, it is expected that the endodontic instrument manufacturers are supplied the NiTi alloys in the cold-work state. The composition of alloy used to construct endodontic instruments is 56% wt Ni and 44% wt Ti, according to the information provided by one manufacturer (Dentsply, Maillefer Instruments SA, Ballaigues, Switzerland);[8] the same is true for other manufacturers of endodontic files, based on unpublished data by energy-dispersive x-ray microanalysis by our research group. For NiTi alloys with the aforementioned elemental composition, the fracture strength of 1723 MPa and 7% elongation after fracture in the cold-worked drawn state are changed to 1378 MPa and 15%, respectively, after heat treatment.[7]

Previous studies[10-14] have already proved that additional thermal treatments significantly modify the mechanical and superelastic properties of NiTi files, implying that the assumption that NiTi files are manufactured by fully cold-worked alloys is right. In this perspective, the aim of this study was to evaluate the effect of thermal treatment on the fatigue resistance of a commercially available engine-driven NiTi file.

MATERIAL AND METHODS

Fifteen sets of 5 endodontic NiTi files each (NRT, Mani Inc., Tochigi-Ken, Japan) of ISO 30 and taper .04 (Lot number 5040677600) were selected for this study. The tips (5 mm from the cutting tip) of files from 14 sets were heat treated for 30 minutes in temperatures 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, respectively. One set was used as a reference. The tip of each file was heat treated by a hot air device (Weldy hot air tool, Malcom Hot Air Systems, Andover, MA), whereas the rest of the file remained immersed in water as illustrated in Fig. 1. The processed pieces were cooled to room temperature. Then, the files were placed in a specific device that allowed the instruments to be tested in rotating-bending position inside a guide that had the form of an artificial root canal engraved on the surface of 2 hard-steels pins (Fig. 2). The instruments were rotated inside the artificial canal with a 5-mm bending arc of curvature at a constant speed of 200 rpm. The number of rotations to breakage was recorded for each file and the mean

Table I. Mean values and standard deviations of number of rotations to breakage of nickel-titanium files for all groups tested

Aging temperature	*Number of rotations to breakage**	*SNK grouping†*
430°C	4918 ± 453	A
440°C	4264 ± 487	AB
425°C	3571 ± 376	BC
410°C	3536 ± 412	BC
420°C	3325 ± 639	CD
400°C	3241 ± 672	CD
450°C	3183 ± 522	CD
375°C	2480 ± 471	DE
350°C	2093 ± 477	EF
475°C	1991 ± 433	EF
500°C	1318 ± 479	FG
300°C	1316 ± 294	FG
250°C	1147 ± 232	FG
Reference	936 ± 136	G
550°C	864 ± 201	G

*Results are sorted in decreasing order of mean values.
†Means with same SNK (Student Newman Keuls) grouping letter are not significantly different ($P > .05$).

values of all groups were statistically analyzed using 1-way analysis of variance and Student Newman Keuls multiple comparison test at $\alpha = .05$.

RESULTS

Table I shows the results of number of rotations to breakage for each group, sorted in decreasing order. According to the statistical analysis, the group at 430°C showed the highest number of rotations to breakage, with statistical significance differences with all groups except that of 440°C. Fractures of all specimens occurred within the deflected part of the file. Fig. 3 illustrates the alteration of rotation to breakage in relation to the annealing temperature. The reference group was set at room temperature. The number of rotations to breakage was found to increase from the reference group to the group of 430°C and 440°C and then to decrease again until the group of 550°C.

DISCUSSION

According to the results of this study, the fatigue resistance of files was found to steadily increase from the *as received state* to 440°C annealing temperature and then to decrease again up to 550°C. The explanation of this behavior is associated with the thermomechanical processing and the subsequent metallurgical alterations.

When metals and alloys are rolled or forged or drawn to wire such as in this case, they *work harden* or *strain harden.* Cold-worked alloys demonstrate increased hardness but with decreased ductility. This is attributed

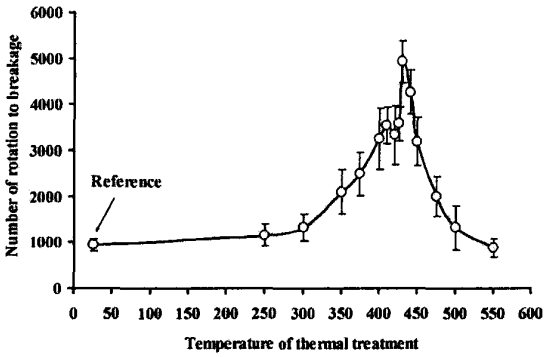

Fig. 3. The curve shows the alteration of number of rotations to breakage in relation to the annealing temperature, demonstrating the maximum value at 430°C.

to the fact that cold working significantly increases the dislocation (defects in crystal structure) density.[15] Although the presence of dislocations in a crystalline material such as alloy is essential for plastic deformation, the overgrowth of dislocation density induced by cold working has the inverse effect, decreasing the ductility of the alloys. This is appended to the fact that each dislocation produces a strain field, hindering the sliding of adjacent dislocations.[15] Annealing through thermal treatment gives the atoms enough thermal energy to rearrange themselves in the lattice under the driving force of this strain energy in a process known as *recovery.* After the rearrangement of dislocations, the total strain energy is significantly lowered and the internal stresses are released with subsequent changes in strength and ductility. The next process is recrystallization, which occurs in higher temperatures than recovery, whereas new grains nucleate and grow until the whole structure consists of undeformed grains.[15] After this process, the dislocation density returns to its initial value and the same happens for the strength and ductility.

The maximum fatigue resistance for the 440°C group might be explained by the fact that recovery of NiTi cold-worked alloys is commonly taking place[7] within the range of 450°C to 550°C. The progressive attenuation of dislocation density from the as received state to the 440°C annealing temperature state significantly decreases the brittleness,[7] enhancing the resistance to the crack propagation mechanism and thus the fatigue strength. However, the aforementioned approach cannot explain the decrease of fatigue resistance beyond 450°C, as the dislocation's density is steadily decreased through annealing at higher temperatures. A significant insight in the metallurgical alterations of cold-worked NiTi alloys is given by the work of Frick et al., 2005.[14]

The microstructure of cold-worked NiTi alloys consists of a large dislocation density as well as residual martensite in an austenitic matrix. During heat treating, the microstructure is changed by 2 antagonistic mechanisms: precipitate growth of Ni_3Ti_4 and dislocation annihilation. Precipitate growth of Ni_3Ti_4 is also effective at stopping dislocation sliding, as does a large dislocation density in cold-worked structures. Although ductility is progressively increased through attenuation of dislocation density, the precipitation process during annealing has the inverse effect by hindering dislocation motion. According to the results of this study, the temperature range of 430°C to 440°C is the optimum for the specific alloy, and for its thermomechanical treatment, in obtaining the maximum fatigue resistance. Of course, thermal treatment definitely has an effect on characteristic transformation temperatures (Af, As, Ms and Mf)[7] of this alloy, but the evaluation of this phenomenon is beyond the aim of this study.

The justification for heat treating only the tip of the files is also associated with the alterations of mechanical properties after thermal treatment. Intracanal fracture of endodontic instruments is commonly observed within the first one third of its length.[2,16] The increase in fatigue resistance through the aforementioned mechanism associated with the release of residual strain is followed by a significant decrease in hardness, affecting the cutting ability of these instruments. A previous study made on ProFile files showed that recrystallization is followed by a tremendous decrease in hardness—from 475 in the as received state to 258 Vickers Hardness (VHN)—a value approaching the hardness of fully annealed NiTi alloys (200 VHN)[17] used for nondental applications.[10] Therefore, the constraint of the thermal treatment effect only in the tip region increases the fatigue resistance at the fracture-sensitive area, retaining the maximum cutting ability to the rest of the file.

Of course, the results of this study are appended only to the tested files. However, previous studies[18] showed that commercially available endodontic files have hardness values (HV_{200}: ProFile = 450, Ergoflex K = 410, Hero642 = 376, Hyflex X-File = 371) close to the tested files in the as received condition (465 VHN), and much higher than those of the fully annealed state (200 VHN),[17] denoting that endodontic files are manufactured from cold-worked NiTi wires. This is also advocated by the fact that ProFile instruments of the same size and taper (number 30, taper .04) demonstrate comparable cycles to failure (812 ± 52)[19] when tested with the tested files in the reference group (rotations to breakage 936 ± 136). Of course, differences in hardness among the aforementioned materials are appended to variations to their thermomechanical history—which of course remains unknown for each product—whereas variations in cycles to failure may also be attributed to the geometric differences between ProFile and Mani NRT instruments. This means that heat treatment can be applied to all endodontic files to modify their mechanical properties.

The results of rotation to breakage are indicative of the mechanical properties of the alloy and definitely cannot be used as a safe limit to avoid fracture under clinical conditions. This is the reason for applying the technique for only 1 instrument size. In addition, the quantitative differences in fatigue resistance between thermal-treated reference groups cannot be extrapolated to other commercially available endodontic instruments due to differences in geometric features, as well as in the thermomechanical history of NiTi alloy.

Recent studies[3,5-6] based on clinically fractured NiTi instruments reported that fracture occurs due to a single overloading under torsion, tensile, or bending-loading conditions (the combination of all the aforementioned loading is also very possible), rather than a fatigue mechanism. Given that the fracture strength is significantly decreased after thermal treatment (from 1723 to 1378 MPa),[7] it is expected that the instrument will be more susceptible to fracture. However, the decrease in fracture strength is followed by an increase in ductility (from 7%-15%), enhancing the fracture toughness of the alloy. Generally, this means that the alloy might be more susceptible to the initiation of plastic deformation but more resistant to separation. In any case, this is only a speculation, and thus the behavior of thermal-treated NiTi instruments in this failure mechanism, together with the possible adverse effect on the cutting ability of endodontic instruments, requires further analysis to optimize the effect of thermal treatment on the efficacy of engine-driven NiTi instruments. Although the current results definitely show a trend for fatigue resistance, manufacturers should modify the parameters of the thermal treatment (i.e., temperature, time portion of instrument subjected to heat treatment) according to the thermomechanical history of NiTi alloy used, as well as the clinical demands to optimize the effect of thermal treatment on NiTi instruments.

Although the thermomechanical history of NiTi instruments still remains unknown, the results of this study show that the mechanical properties of such instruments can be effectively modified by thermal treatment. However, the application of heat treatment can significantly vary for different commercial products due to differences in their thermomechanical history. Therefore, thermal treatment can be used to increase the in vivo performance of NiTi instruments, modifying the mechanical properties that have crucial implication

on the cutting and failure mechanisms encountered under clinical conditions.

CONCLUSIONS

The results suggest that fatigue resistance of the tested NiTi instruments may be significantly enhanced by the appropriate heat treatment.

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Electronic Patent Application Fee Transmittal	
Application Number:	11628933
Filing Date:	07-Dec-2006
Title of Invention:	Dental And Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Richard T. Roche
Attorney Docket Number:	115207.00002
Filed as Small Entity	

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**405**

Electronic Acknowledgement Receipt	
EFS ID:	4514385
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	23-DEC-2008
Filing Date:	07-DEC-2006
Time Stamp:	17:13:25
Application Type:	U.S. National Stage under 35 USC 371

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Payment was successfully received in RAM	$405
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	Request for Continued Examination (RCE)	1	2
	Amendment Submitted/Entered with Filing of CPA/RCE	3	3
	Claims	4	7
	Applicant Arguments/Remarks Made in an Amendment	8	12
	Rule 130, 131 or 132 Affidavits	13	22

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/628,933	12/07/2006	

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT	12/23/2008	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/TONI HAKIM/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 02/27/2009

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

MAIL DATE	DELIVERY MODE
02/27/2009	PAPER

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.

Office Action Summary	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	Matthew M. Nelson	3732	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

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

3)☐ 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

4)☒ Claim(s) *1,2,5-15,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-15,20 and 21* is/are rejected.

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

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

Application Papers

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

10)☒ The drawing(s) filed on *07 December 2006* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 12/23/2008 is acknowledged. Claims 1-2, 4-15, 20 remain pending and claim 21 has been added. Claim objection is withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 4-10, 13, 15, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sachdeva et al. (US 6,431,863).

Sachdeva shows an endodontic instrument (Fig. 1) comprising an elongate shank (working shaft 12) having a cutting edge (Fig. 2b) extending from a distal end of the shank along an axial length of the shank (Fig. 1), wherein the shank comprises a titanium alloy (col. 3, line 30-33). With respect to claim 6, the titanium alloy is selected from alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys, and nickel-titanium alloys (col. 3, line 30-33). With respect to claim 7, 8, 9, 13, the titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium (col. 3, line 30-32; Table 1). When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim. With respect to claim 10, the cutting edge is formed by helical flutes in the shank (reamer tip 16b; Fig. 2b). The

method claims 15, 20 are rejected similarly to the above apparatus claims (col. 1, lines 17-19).

Please note that claims 1-2, 4-5, 8-9, 13, 21 are product-by-process claims, and therefore the process has not been given patentable weight. See MPEP 2113. Furthermore, with respect to the heat-treating temperatures, environments, and durations of claims 1-2, 4-5, 8-9, 13, 21, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP 2113, 2173.05(p).

Claim Rejections - 35 USC § 103

4. 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.

5. Claims 11-12, 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva.

Sachdeva discloses the device as previously described above, but fails to show wherein the shank has a diameter of 0.5 to 1.6 mm and has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the shank to have a diameter of 0.5 to 1.6 mm and so that it maintains a deformation of greater than 10 degrees after a 45 degree torque in order to drill a hole with diameter of corresponding size, 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).

Response to Arguments

6. Applicant's arguments with respect to claims 1-2, 4-15, 20-21 have been considered but are moot in view of the new ground(s) of rejection.

7. The declaration filed on 12/23/2008 is insufficient to overcome the art rejection because a declaration under 37 C.F.R. § 1.132 is to overcome 103 rejections and the current office action has new grounds of rejection under 102. In addition, most of the claims are considered product-by-process claims, where the process has not been given patentable weight, and the submitted declaration addresses only the process.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew M. 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, the examiner's supervisor, Cris Rodriguez can be reached on (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.

/MMN/

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

Notice of References Cited	Application/Control No. 11/628,933	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner Matthew M. Nelson	Art Unit 3732	Page 1 of 1

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-5,775,902 A	07-1998	Matsutani et al.	433/102
*	D	US-6,375,458 B1	04-2002	Moorleghem et al.	433/2
*	E	US-6,431,863 B1	08-2002	Sachdeva et al.	433/102
*	F	US-6,428,634 B1	08-2002	Besselink et al.	148/421
*	G	US-2004/0121283 A1	06-2004	Mason, Robert M.	433/102
*	H	US-6,422,865	07-2002	Fischer, Dan E.	433/81
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

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.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	Matthew M Nelson	4166

✓	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	04/29/2008	10/21/2008	02/24/2009						
	1	✓	✓	✓						
	2	✓	✓	✓						
	3	✓	-							
	4	✓	✓	✓						
	5	✓	✓	✓						
	6	✓	✓	✓						
	7	✓	✓	✓						
	8	✓	✓	✓						
	9	✓	✓	✓						
	10	✓	✓	✓						
	11	✓	✓	✓						
	12	✓	✓	✓						
	13	✓	✓	✓						
	14	✓	✓	✓						
	15	✓	✓	✓						
	16	✓	-							
	17	✓	-							
	18	✓	-							
	19	✓	-							
	20	✓	✓	✓						
	21			✓						

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	Matthew M Nelson	4166

SEARCHED			
Class	Subclass	Date	Examiner
433	102, 224	4/29/2008	MMN
29	896.1	4/29/2008	MMN
433	102, 224	10/21/2008	MMN
29	896.1	10/21/2008	MMN
433	102, 224	2/24/2009	MMN
29	896.1	2/24/2009	MMN

SEARCH NOTES		
Search Notes	Date	Examiner
Search received from John Wilson for Class/Subclass 433/102,224 & 29/896.1	4/28/2008	MMN
See EAST search history	4/29/2008	MMN
Updated EAST search	10/21/2008	MMN
Updated EAST search	2/24/2009	MMN

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	903	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/24 12:26
L3	71	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/24 12:26
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

2/24/2009 12:27:17 PM
C:\Documents and Settings\mnelson3\My Documents\EAST\Workspaces\11628933 Dental Instruments Comprising Titanium.wsp

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

Date: April 1, 2009

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Confirmation No.:	9736
Art Unit:	3732
Examiner:	Matthew M. Nelson
Docket No.:	115207.00002

RESPONSE TO NON FINAL OFFICE ACTION

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

Sir:

This is in response to the Non-Final Office Action mailed on February 27, 2009.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 6 of this paper.

Amendments To The Claims

1. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein the shank [[is]] has a microstructure prepared by heat-treating the entire shank at a temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy.

2. (Original) The instrument of claim 1 wherein:

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

3. (Cancelled)

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

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

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

the shank is heat-treated for 1 to 2 hours.

6. (Original) The instrument of claim 1 wherein:

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

7. (Original) The instrument of claim 1 wherein:

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

8. (Original) The instrument of claim 1 wherein:

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

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

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

the shank is heat-treated for 1 to 2 hours.

9. (Original) The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

the shank is heat-treated for 1 to 2 hours.

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

the cutting edge is formed by helical flutes in the shank.

11. (Original) The instrument of claim 1 wherein:

the shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

12. (Original) The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the shank [[is]] <u>has a microstructure</u> prepared by heat-treating the <u>entire</u> shank at a temperature from 475°C to 525°C in an atmosphere consisting essentially of argon gas.

14. (Original) The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 1.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 13.

21. (Previously Presented) The instrument of claim 1 wherein:

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

REMARKS

Claim Amendments

Claim 1 has been amended recite that the shank has a microstructure prepared by heat-treating the entire shank.

Claim 13 has been amended recite that the shank has a microstructure prepared by heat-treating the entire shank.

The basis for the claim limitation "entire shank" in amended claims 1 and 13 can be found in Example 1 where each ISO size file was heat-treated in a furnace.

The basis for the claim limitation "microstructure" in amended claims 1 and 13 can be found in Example 1 where each ISO size file was heat-treated in a furnace. While the word "microstructure" does not explicitly appear in Example 1, the Court of Appeals for the Federal Circuit outlined the written description requirement in *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (2000), as follows:

> "In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir.1996). Nonetheless, the disclosure must ... convey with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed.Cir.1991). Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. Waldemar Link GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558, 31 UPSQ2d 1855, 1857 (Fed.Cir.1994)."

The marked sentence at page 93, column 2 of attached Exhibit A shows that one skilled in the art would recognize that the heat treatment of an alloy including titanium produces a microstructure. Therefore, it is respectfully submitted that the Applicant has met the written description requirement as one skilled in the art would be able to immediately discern that the heat treatment in Example 1 produces a microstructure in the shank of

the endodontic instrument as now recited in claims 1 and 13. (See, also attached "Zinelis *et al.*, "The Effect of Thermal Treatment On the Resistance of Nickel-Titanium Rotary Files In Cyclic Fatigue", Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontology 2007 103, 6, page 846, first paragraph, which explains that heat treating controls microstructure in NiTi alloys; and attached Li, *et al.*, "Structure and thermomechanical behavior of NiTiPt shape memory alloy wires", Acta Biomaterialia, 30 July 2008, page 262 under "4. Discussion" which also explains that heat treating controls microstructure in NiTi alloys.)

Claim Rejections - 35 USC § 102 & 35 USC § 103

Claims 1-2, 4-10, 13, 15, 20 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,431,863 to Sachdeva *et al.* (Sachdeva). Claims 11-12 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva.

The Office Action states that "claims 1-2, 4-5, 8-9, 13, 21 are product-by-process claims, and therefore the process has not been given patentable weight. See MPEP 2113." The Applicant respectfully submits that all of the limitations in amended independent claims 1 and 13 must be considered when assessing the patentability of the invention.

First, amended independent claims 1 and 13 now recite that the shank has a microstructure prepared by heat-treating the entire shank. The attached technical articles demonstrate that the microstructure of an alloy is dictated by the heat treatment. Thus, the heat treating temperatures, environments and durations of claims 1-2, 4-5, 8-9, 13 and 21 provide the microstructure recited in amended independent claims 1 and

13. Thus, when comparing the present invention to Sachdeva, one cannot ignore the microstructure in the present invention and Sachdeva.

Looking at Sachdeva, column 4, lines 31-36, state that "it is believed that the desired flexibility/stiffness and hardness properties, as discussed below, can be achieved ... by performing selective heat treatments of the working shaft portion", and column 4, lines 59-63 of Sachdeva state that "FIG. 6 represents, in a graphic manner, the effect of selective heat treatment. The FIG. 6 data is for a Ni--Ti wire (50.6% Ni) of 0.018" diameter wherein a first section was heat treated (annealed) at 450°C., and a second portion was heat treated at 350°C".

Thus, Sachdeva is heat treating different portions of a wire at different temperatures. In contrast, the invention of amended independent claims 1 and 13 requires that the entire shank be heat treated in the same temperature range to create the microstructure in the shank.

Attention is again directed at the marked sentence at page 93, column 2 of attached Exhibit A. This reference notes that localized heat treatment (such as practiced in Sachdeva) yields a nonuniform microstructure. Therefore, there are structural differences between the present invention and Sachdeva. Specifically, the microstructure of Sachdeva will be nonuniform due to localized heat treatment whereas the present invention will have a more uniform microstructure as the entire shank is heat treated in the same temperature range.

Second, if it were concluded that the phrase "prepared by heat-treating the entire shank" is a process limitation, it is noted that the Court of Appeals for the Federal Circuit stated in *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570 (Fed. Cir. 1983)

"[t]hat a process limitation appears in a claim does not convert it to a product by process claim". Independent claims 1 and 13 now recite that the shank has a microstructure. This is a structural limitation. Therefore, the phrase "prepared by heat-treating the entire shank" is limiting the "microstructure" structural limitation. Accordingly, the use of the phrase "prepared by heat-treating the entire shank" does not convert the claims into product by process claims.

Third, in the event that the Office concludes that the claims are still product-by-process claims, the Applicant believes that the Office needs to consider all of the guidance in MPEP 2113. Specifically, the second paragraph of MPEP 2113 states:

> "The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)" (Underlining added.)

In the present invention, the process limitation (i.e., heat treating) will impart distinctive structural characteristics (i.e., the microstructure of the shank) to the final product (i.e., the endodontic instrument). Thus, MPEP 2113 requires that the heat treating limitation be considered when assessing the patentability of the endodontic instrument.

As noted above, the invention of amended independent claims 1 and 13 is distinguishable from Sachdeva in that the microstructure of Sachdeva will be nonuniform due to localized heat treatment whereas the present invention will have a more uniform microstructure as the entire shank is heat treated in the same temperature

range. Thus, when considering the structure implied by the process limitation of amended independent claims 1 and 13, these claims are patentable over Sachdeva.

Fourth, M.P.E.P. § 2144.05 III. notes that "Applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing "(1) [t]hat the prior art taught away from the claimed invention... ." Column 4, lines 25-29 of Sachdeva state that "heat treating the working shaft tip 16 at a higher temperature than the treatment temperature of the mid-section will result in greater hardness and stiffness at the tip of the instrument vis-a-vis the mid-section". Sachdeva teaches using two heat treatment temperatures (350°C and 450°C). When choosing between the two temperatures of Sachdeva, one seeking flexibility (less stiffness) would be led away from the higher temperature (450°C) to the lower temperature (350°C - which is clearly outside the scope of claim 1). Thus, it is submitted that Sachdeva teaches away from the invention recited in claim 1. In addition, both heat treatment temperatures in Sachdeva (350°C and 450°C) are outside the scope of claim 13.

Fifth, in the previous response of December 23, 2008, Applicant submitted a second Inventor's Declaration in order to rebut any *prima facie* case of obviousness that could be established. The second Inventor's Declaration explained that one reading U.S. Patent No. 6,431,863 to Sachdeva would expect less flexibility when heat treating at higher temperatures, and the Inventor's tests show increased flexibility. Therefore, the Inventor's test results would be unexpected to one reading U.S. Patent No. 6,431,863 to Sachdeva.

The second Inventor's Declaration also pointed out that the average rotation to failure for files heat treated at 500°C was 3614 compared to 1033 for files heat treated

at 375°C. This is a 250% increase. Thus, heat treating files within the temperature range of independent claims 1 and 13 (i.e., at 500°C) provides for much improved properties compared to heat treating files outside the claimed range (i.e., at 375°C).

The second Inventor's Declaration also included the attached technical journal article of Zinelis *et al.* This article, which was published later than the filing date of the present application, supports the Inventor's assertion that the claimed temperature range for heat treatment is critical.

Therefore, to the extent that a *prima facie* case of obviousness could be established for claims 1-2, 4-15 and 20-21 using Sachdeva, it is believed that the second Inventor's Declaration rebuts any possible *prima facie* case of obviousness that could be established for claims 1-2, 4-15 and 20-21 using Sachdeva.

Conclusion

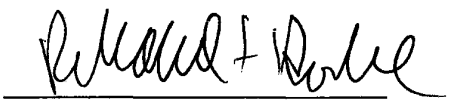
It is respectfully submitted that amended independent claim 1 (and claims 2, 4-12, 15 and 21 that depend thereon) and amended independent claim 13 (and claims 14 and 20 that depend thereon) are patentable over Sachdeva.

No fees are believed to be needed for this amendment. However, if fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: April 1, 2009

By: 

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7529707

Microstructural Gradients in the Superplastic Forming of i-6Al-4V

S. RHAIPU, M.L.H. WISE, and P.S. BATE

The effect of microstructural gradients, introduced by local induction heating, on the behavior of a Ti-6Al-4V sheet in superplastic forming has been investigated. Heat treatment led to a change in the morphology of the α phase present at the start of superplastic deformation, which caused an increase in initial flow stress. This has a significant effect on the strain distribution. Trials using two axially symmetric shapes showed that the effect of microstructural gradients can be adequately predicted—*via* numerical modeling—and controlled. The technique has the potential to control the thickness distribution in formed parts.

I. INTRODUCTION

SUPERPLASTIC forming of sheet is used commercially in a number of applications. It involves the use of moderate gas pressures at elevated temperatures to stretch-form the sheet into a die and relies on a combination of low flow stress and high tensile ductility in the material being formed. This phenomenon usually occurs at high temperatures and slow forming speeds. Two main factors contribute to the high tensile ductility. One is a resistance to the formation of internal cavities, which can lead to ductile fracture, and the other is a high sensitivity of the plastic flow stress to the strain rate. This second factor is the dominant feature of superplasticity.

The effect of strain rate on flow stress can be quantified as the rate-sensitivity index (m). This is given by

$$m = \frac{\partial \ln \sigma}{\partial \ln \dot{\varepsilon}} \qquad [1]$$

where σ is the flow stress and $\dot{\varepsilon}$ is the strain rate. In superplastic metals, m is typically in the range of 0.4 to 0.8, with temperatures greater than half the melting temperature and strain rates of the order of 10^{-4} to 10^{-3} s^{-1}. The mechanical consequence of a high-strain-rate sensitivity is that it counteracts strain localization: any local increase in strain rate will give an increase in stress. This was recognized by Backofen *et al.*[1] and Hedworth and Stowell.[2] The rate sensitivity contributes to the resistance to ductile fracture as well. Other aspects of material behavior should be considered. For example, most superplastic materials show strain hardening, although this is due to grain growth during deformation rather than conventional, low-temperature, dislocation accumulation mechanisms. This can make an important additional contribution to the resistance to strain localization.

The mechanical behavior is very sensitive to the microstructure of the material. A fine grain size, typically 1 to 10 μm, is involved, and this needs to be nominally stable at the elevated temperature involved. Grain growth is controlled by the Zener pinning mechanism,[3,4] either by a small volume fraction of particles significantly smaller than the desired grain size or by a high volume fraction of coarser particles, which effectively pin the vertices of the matrix grains. In both cases, the second phase also needs to be resistant to coarsening. Generally, superplastic behavior is assumed to require that the grains, including large particles where appropriate, be reasonably equiaxed.

Despite the high ductilities and strain uniformities exhibited in simple tensile tests, the strain distribution in actual formed parts will usually be highly nonuniform. This is a straightforward consequence of the shape involved and the effect of friction between the die and workpiece. This nonuniformity is exacerbated by the fact that more complicated shapes, with higher degrees of stretching involved, can be formed without workpiece fracture in superplastic forming than in conventional sheet pressing.

There are various possible ways of overcoming the nonuniformity of straining. The initial thickness of the sheet can be changed by, for example, chemical milling. It might be possible to introduce temperature gradients, although, because the process is rather slow, this would not be trivial. A further possibility is to introduce, in a controlled manner by localized heat treatment, a nonuniform initial microstructure. This "microstructural-gradients" technique leads to differences in mechanical behavior in different regions of the sheet and was investigated by Jiang and Bate,[5] using Zn-22 pct Al, with promising results. In that case, a very simple "thermal printing" method was feasible because low temperatures were involved. Currently, the most important alloy, commercially, for superplastic forming is Ti-6 pct Al-4 pct V. In this material, a noncontact heating method needs to be used, such as induction heating, and the work presented here used that method to introduce microstructural gradients in Ti-6Al-4V prior to superplastic forming.

S. RHAIPU, formerly Graduate Student with the IRC in Materials for High Performance Applications, the University of Birmingham, is Lecturer, Department of Industrial Engineering, Mahidol University, Salaya Nakornprathom 73170, Thailand. M.L.H. WISE, formerly Senior Lecturer with the IRC in Materials for High Performance Applications, is Senior Lecturer, School of Metallurgy and Materials, the University of Birmingham. P.S. BATE, formerly Senior Research Fellow with the IRC in Materials for High Performance Applications, is Reader, Manchester Materials Science Centre, The University of Manchester, Manchester, MI 7HS, England.

Manuscript submitted May 8, 2001.

Electronic Acknowledgement Receipt

EFS ID:	5079112
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	01-APR-2009
Filing Date:	07-DEC-2006
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Application Type:	U.S. National Stage under 35 USC 371

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		response.pdf	485387 d8ba2efb3fb861bbc91442bc25b2dd50942d041a	yes	12

	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	12
Warnings:			
Information:			
	Total Files Size (in bytes):	485387	

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/628,933	12/07/2006	

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT 04/01/2009

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/Fennell A. Pearlie/

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.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 08/10/2009

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EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

MAIL DATE	DELIVERY MODE
08/10/2009	PAPER

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.

Office Action Summary	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	Matthew M. Nelson	3732	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *01 April 2009*.

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

3)☐ 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

4)☒ Claim(s) *1,2,4-15,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-15,20 and 21* is/are rejected.

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

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

Application Papers

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

10)☐ 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 4/1/2009 is acknowledged. Claims 1-2, 4-15, 20-21 remain pending.

Claim Rejections - 35 USC § 112

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

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

3. Claims 1-2, 4-15, 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of "a microstructure" and "the entire shank" are not included in the disclosure as originally filed. For instance, the disclosure does not state that a microstructure is imparted in the shank as a result of the heat-treating. With regards to the entire shank, there is no statement that the entirety of the shank is in the furnace or that it is fully exposed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4-10, 13, 15, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sachdeva et al. (US 6,431,863).

Sachdeva shows an endodontic instrument (Fig. 1) comprising an elongate shank (working shaft 12) having a cutting edge (Fig. 2b) extending from a distal end of the shank along an axial length of the shank (Fig. 1), wherein the shank comprises a titanium alloy (col. 3, line 30-33) and has a microstructure (an alloy including titanium is heat treated and therefore there is a microstructure). With respect to claim 6, the titanium alloy is selected from alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys, and nickel-titanium alloys (col. 3, line 30-33). With respect to claim 7, 8, 9, 13, the titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium (col. 3, line 30-32; Table 1). When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim. With respect to claim 10, the cutting edge is formed by helical flutes in the shank (reamer tip 16b; Fig. 2b). The method claims 15, 20 are rejected similarly to the above apparatus claims (col. 1, lines 17-19).

Please note that claims 1-2, 4-5, 8-9, 13, 21 are product-by-process claims, and therefore the process has not been given patentable weight. See MPEP 2113. Furthermore, with respect to the heat-treating temperatures, environments, and durations of claims 1-2, 4-5, 8-9, 13, 21, “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the

product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP 2113, 2173.05(p).

Claim Rejections - 35 USC § 103

6. 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.

7. Claims 11-12, 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva.

Sachdeva discloses the device as previously described above, but fails to show wherein the shank has a diameter of 0.5 to 1.6 mm and has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the shank to have a diameter of 0.5 to 1.6 mm and so that it maintains a deformation of greater than 10 degrees after a 45 degree torque in order to drill a hole with diameter of corresponding size, 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).

Response to Arguments

8. Applicant's arguments filed 4/1/2009 have been fully considered but they are not persuasive.

9. Applicant argues that Sachdeva teaches heat treating different portions of a wire at different temperatures. The current claim language does not state that the entire shank is heat treated at a singular temperature or is heat treated in the exact same fashion along the length of the shank. Furthermore, the process has not been given patentable weight but rather the product.

10. Applicant argues that Sachdeva's microstructure is non-uniform whereas applicant's is uniform. This language is also not in the claims and Sachdeva satisfies the limitation that there is some form of microstructure.

11. Examiner agrees that including "microstructure" in the claim adds a structural limitation, however Sachdeva covers this additional limitation.

12. Applicant argues that the process imparts distinctive structural characteristics, specifically the microstructure of the shank. However, Sachdeva also has a microstructure as applicant admits, and therefore this structural characteristic is not distinctive.

13. Applicant argues that Sachdeva teaches away by only disclosing two temperatures and that a higher temperature will result in greater hardness and stiffness. First, the two temperatures Applicant is referring to are only part of one of the examples and are not limiting. Second, Applicant's Declaration, specifically the Zinelis et al.

reference, confirms the Sachdeva statement that a higher temperature could result in greater hardness and stiffness as seen in Fig. 3. It is seen that above about 450 degrees Celsius the flexibility decreases with increasing temperature.

Conclusion

14. 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 M. 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, the examiner's supervisor, Cris Rodriguez can be reached on (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.

/MMN/

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1092	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:13
L2	78	L1 AND (heat WITH treat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
L3	917	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
L4	32	L3 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
L5	917	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
L6	192	L5 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
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

EAST Search History (Interference)

<This search history is empty>

8/3/2009 1:37:40 PM
C:\Documents and Settings\mnelson3\My Documents\EAST\Workspaces\11628933 Dental Instruments Comprising Titanium.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	Matthew M Nelson	4166

✓	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	04/29/2008	10/21/2008	02/24/2009	08/03/2009					
	1	✓	✓	✓	✓					
	2	✓	✓	✓	✓					
	3	✓	-	-	-					
	4	✓	✓	✓	✓					
	5	✓	✓	✓	✓					
	6	✓	✓	✓	✓					
	7	✓	✓	✓	✓					
	8	✓	✓	✓	✓					
	9	✓	✓	✓	✓					
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	11	✓	✓	✓	✓					
	12	✓	✓	✓	✓					
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	14	✓	✓	✓	✓					
	15	✓	✓	✓	✓					
	16	✓	-	-	-					
	17	✓	-	-	-					
	18	✓	-	-	-					
	19	✓	-	-	-					
	20	✓	✓	✓	✓					
	21			✓	✓					

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	Matthew M Nelson	4166

SEARCHED

Class	Subclass	Date	Examiner
433	102, 224	4/29/2008	MMN
29	896.1	4/29/2008	MMN
433	102, 224	10/21/2008	MMN
29	896.1	10/21/2008	MMN
433	102, 224	2/24/2009	MMN
29	896.1	2/24/2009	MMN
433,29	Updated search	8/3/2009	MMN

SEARCH NOTES

Search Notes	Date	Examiner
Search received from John Wilson for Class/Subclass 433/102,224 & 29/896.1	4/28/2008	MMN
See EAST search history	4/29/2008	MMN
Updated EAST search	10/21/2008	MMN
Updated EAST search	2/24/2009	MMN
Updated EAST search history	8/3/2009	MMN

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

Docket No.: 115207.00002

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

Date: September 24, 2009

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Confirmation No.:	9736
Art Unit:	3732
Examiner:	Matthew M. Nelson

RESPONSE TO FINAL OFFICE ACTION

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

Sir:

This is in response to the Final Office Action mailed on August 10, 2009.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 6 of this paper.

Amendments To The Claims

1. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein the shank has a microstructure prepared by heat-treating the entire shank for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy.

2. (Original) The instrument of claim 1 wherein:

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

3. (Cancelled)

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

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

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

the shank is heat-treated for 1 to 2 hours.

6. (Original) The instrument of claim 1 wherein:

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

7. (Original) The instrument of claim 1 wherein:

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

8. (Original) The instrument of claim 1 wherein:

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

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

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

the shank is heat-treated for 1 to 2 hours.

9. (Original) The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

the shank is heat-treated for 1 to 2 hours.

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

the cutting edge is formed by helical flutes in the shank.

11. (Original) The instrument of claim 1 wherein:

the shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

12. (Original) The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the shank has a microstructure prepared by heat-treating the entire shank for a time period at a single temperature from 475°C to 525°C in an atmosphere consisting essentially of argon gas.

14. (Original) The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 1.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 13.

21. (Previously Presented) The instrument of claim 1 wherein:

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

REMARKS

Claims 1 and 13 have been amended to recite that the shank has a microstructure prepared by heat-treating the entire shank for a time period at a single temperature. Example 1 of the application states that "[t]en of each ISO size [file] were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes." Thus, support for the amendments to claims 1 and 13 can be found in Example 1 of the application.

Claim Rejections - 35 U.S.C. § 112

Claims 1-2, 4-15, and 20-21 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action states that the "claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of a 'microstructure' and 'the entire shank' are not included in the disclosure as originally filed."

As noted in the previous response of April 1, 2009, the basis for the claim limitation "entire shank" in claims 1 and 13 can be found in Example 1 where each ISO size file was heat-treated in a furnace. It was also noted that the basis for the claim limitation "microstructure" in claims 1 and 13 can be found in Example 1 where each ISO size file was heat-treated in a furnace. While the word "microstructure" does not explicitly appear in Example 1, the Court of Appeals for the Federal Circuit outlined the written description requirement in *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (2000), as follows:

> "In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir.1996). Nonetheless, the disclosure must ... convey with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed.Cir.1991). Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. Waldemar Link GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558, 31 UPSQ2d 1855, 1857 (Fed.Cir.1994)."

Thus, patent case law from the U.S. Court of Appeals for the Federal Circuit has explained that a patent application "disclosure must ... convey with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention. Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims."

Attached please find the Declaration of Frank N. Lentine, who has worked in the dental manufacturing industry for 40 years, including 28 years at Kerr Manufacturing Company, in various technical and management positions including Director, Research and Development. He is the named inventor on a number of patents and the author or co-author of numerous publications noted in the Declaration.

At Item 7 of the Declaration, Mr. Lentine states that he has read pending claims 1 and 13 and Item 3 from the Office Action of August 10, 2009. He states that he understands that the "limitation[s] at issue in the claims" are the terms "microstructure" and "entire shank". At Item 8 of the Declaration, Mr. Lentine also states that he has read Example 1 from the present application, and can discern that the heat treatment in Example 1 produces a "microstructure" and that the "entire shank" is being heat treated.

The attached Declaration makes it clear that one skilled in the art, reading Example 1, will discern the "microstructure" and "entire shank" limitations at issue in

claims 1 and 13. Therefore, under the guidance of the CAFC in *Purdue Pharma L.P. v. Faulding Inc.* quoted above, it is submitted that one skilled in the art would understand that the inventor was in possession of the invention of claims 1 and 13. It is respectfully requested that the claim rejections under 35 U.S.C. § 112 be withdrawn.

Claim Rejections - 35 USC § 102 & 35 USC § 103

Claims 1-2, 4-10, 13, 15, 20 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,431,863 to Sachdeva *et al.* (Sachdeva). Claims 11-12 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva.

Amended independent claims 1 and 13 now recite that the shank has a microstructure prepared by heat-treating the entire shank for a time period at a single temperature. Looking at Sachdeva, column 4, lines 31-36, state that "it is believed that the desired flexibility/stiffness and hardness properties, as discussed below, can be achieved ... by performing selective heat treatments of the working shaft portion", and column 4, lines 59-63 of Sachdeva state that "FIG. 6 represents, in a graphic manner, the effect of selective heat treatment. The FIG. 6 data is for a Ni--Ti wire (50.6% Ni) of 0.018" diameter wherein a first section was heat treated (annealed) at 450°C., and a second portion was heat treated at 350°C".

Thus, Sachdeva is heat treating different portions of a wire at different temperatures. In contrast, the invention of amended independent claims 1 and 13 requires that the shank has a microstructure prepared by heat-treating the entire shank for a time period at a single temperature.

In Item 9 of the Office Action, it was noted that the previous claim language did not state that the entire shank is heat treated at a singular temperature. This concern has been addressed by the amendments to claim 1 and 13.

Item 9 of the Office Action also states that the process has not been given patentable weight. The Applicant respectfully submits that all of the limitations in amended independent claims 1 and 13 must be considered when assessing the patentability of the invention. If it were concluded that the phrase "prepared by heat-treating the entire shank" is a process limitation, it is noted that the Court of Appeals for the Federal Circuit stated in *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570 (Fed. Cir. 1983) "[t]hat a process limitation appears in a claim does not convert it to a product by process claim". Independent claims 1 and 13 recite that the shank has a microstructure. This is a structural limitation. Therefore, the phrase "prepared by heat-treating the entire shank" is limiting the "microstructure" structural limitation. Accordingly, the use of the phrase "prepared by heat-treating the entire shank" does not convert the claims into product by process claims.

Without agreeing that the claims are product-by-process claims, the Applicant believes that the Office also needs to consider all of the guidance in MPEP 2113. Specifically, the second paragraph of MPEP 2113 states:

> "The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)" (Underlining added.)

In the present invention, the process limitation (i.e., heat treating for a time period at a single temperature) will impart distinctive structural characteristics (i.e., the microstructure of the shank) to the final product (i.e., the endodontic instrument). Thus, MPEP 2113 requires that the heat treating limitation be considered when assessing the patentability of the endodontic instrument.

In Item 11, the Office Action concedes that the term "microstructure" in the claims adds a structural limitation. However, in Items 10 and 12 of the Office Action, it is stated that Sachdeva has a microstructure and that the structural characteristics of the present invention are "not distinctive".

Looking at the attached Declaration of Mr. Lentine, Item 11 states "I believe that localized heat treatment (such as practiced in Sachdeva) yields a nonuniform microstructure. Therefore, there are microstructural differences between the Sachdeva wire and the invention of attached pending claims 1 and 13 of U.S. Patent Application No. 11/628,933." Therefore, it is respectfully submitted that the statement in Item 11 of the Office Action that the structural characteristics of the present invention are "not distinctive" is incorrect.

Referring back to the guidance in MPEP 2113 cited above, MPEP 2113 cites case law stating that "[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, ... where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." Item 11 of the attached Declaration of Mr. Lentine provides evidence that the process limitations of claims 1 and 13 "impart

distinctive structural characteristics" to the claimed invention. Therefore, it is submitted that amended independent claim 1 (and claims 2, 4-12, 15 and 21 that depend thereon) and amended independent claim 13 (and claims 14 and 20 that depend thereon) are patentable over Sachdeva.

Even if a prima facie case of obviousness could be established, M.P.E.P. § 2144.05 III. notes that "Applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing "(1) [t]hat the prior art taught away from the claimed invention... ." Column 4, lines 25-29 of Sachdeva state that "heat treating the working shaft tip 16 at a higher temperature than the treatment temperature of the mid-section will result in greater hardness and stiffness at the tip of the instrument vis-a-vis the mid-section". Sachdeva teaches using two heat treatment temperatures (350°C and 450°C). When choosing between the two temperatures of Sachdeva, one seeking flexibility (less stiffness) would be led away from the higher temperature (450°C) to the lower temperature (350°C - which is clearly outside the scope of claim 1). Thus, it is submitted that Sachdeva teaches away from the invention recited in claim 1. In addition, both heat treatment temperatures in Sachdeva (350°C and 450°C) are outside the scope of claim 13.

Item 13 of the Office Action notes that "the two temperatures Applicant is referring to are only part of one of the examples and are not limiting". However, on further review of Sachdeva, there is nothing to indicate any other specific temperatures or temperature ranges in Sachdeva. In other words, Sachdeva only lists 350°C and 450°C and does not state what these other "variable heat treatments" (see column 4, lines 66-67 of Sachdeva) are.

Item 13 of the Office Action also refers to the Zinelis et al. reference. However, Zinelis published in June 2007 (well after the filing date of the present application) and therefore cannot be used as prior art.

Conclusion

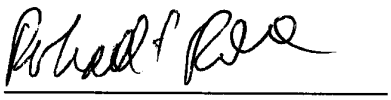
It is respectfully submitted that amended independent claim 1 (and claims 2, 4-12, 15 and 21 that depend thereon) and amended independent claim 13 (and claims 14 and 20 that depend thereon) are patentable over Sachdeva.

No fees are believed to be needed for this amendment. However, if fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: September 24, 2009

By: 

Richard T. Roche
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Quarles and Brady LLP
411 East Wisconsin Ave.
Milwaukee, WI 53202
(414) 277-5805

8780553

Docket No.: 115207.00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke

Application No.: 11/628,933

Filing Date: December 7, 2006

Title: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

Confirmation No.: 9736

Art Unit: 3732

Examiner: Matthew M. Nelson

DECLARATION UNDER 37 C.F.R. 1.132

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

Sir:

I, Frank N. Lentine, hereby declare as follows:

1. I have worked in the dental manufacturing industry for 40 years, including 28 years at Kerr Manufacturing Company, in various technical and management positions including Director, Research and Development. My career includes leadership positions in the development of dental product standards and specification working groups and subcommittees, including the International Organization of Standardization (ISO) and the American National Standards Institute/American Dental Association (ANSI/ADA). I am owner and president of Lentine Enterprises, Limited, Taylor, Michigan.

2. I am an Honorary Member of the American Association of Endodontics.

3. I have a B. S. in Mechanical Engineering from the University of Detroit.

4. I am a named inventor on the following U.S. Patents: 3,798,776, 3,871,589, 3,924,334, 4,173,219, 4,260,379, and 6,726,005.

5. I have authored or contributed to the following publications:

(a) Lentine, Frank N., A Study of Torsional and Angular Deflection of Endodontic Files and Reamers, J Endod 1979;5:181-92;

(b) American National Standard Institute/American Dental Association
(i) Specification No. 28 for Root canal Files and Reamers Significant contributor: 1976 Principal author June, 1988, Feb., 1996 (Addendum), 2002, 2007 Pending;
(ii) Specification No. 43 for Electrically powered dental amalgamators, Significant contributor: 1986, 1995
(iii) Specification No. 48 for Dental activator, disclosing and transillumination devices, Significant contributor: 1983, 1989
(iv) Specification No. 55 for Dispensers of alloy and mercury for dental amalgam, Significant contributor: 1985, 1992
(v) Specification No. 57 for Endodontic filling materials, Significant contributor: 1983, Principal author: 1993, 2000
(vi) Specification No. 58 for Root canal files, type H (Hedstrom) Principal author: 1981,1988, 1997, 2004
(vii) Specification No. 63 for Rasps and barbed broaches, Principal author: 1989, 1999, 2006
(viii) Specification No. 71 for Root canal filling condensers, pluggers and spreaders, Principal author: 1995, 2000, 2007 Pending
(ix) Specification No. 73 for Dental absorbent points, Principal author: 1993, 2001, 2007 Pending
(x) Specification No. 78 for Dental obturation points, Principal author: 1994, 2000, 2006
(xi) Specification No. 95 for Root canal enlargers, Principal author: 2000, 2003
(xii) Specification No. 101 for Endodontic instruments: General requirements, Principal author: 2001

(c) International Organization for Standardization (ISO)
(i) ISO 3630 Dental root canal instruments, Co-author: 1984
(ii) ISO 3630 -Part 1: Files, reamers, Principal author: 1992, 2006 in progress
(iii) ISO 3630 -Part 2: Root canal enlargers, Co-author: 1986, 2006 in progress

(iv) ISO 3630 -Part 3: Condensers, pluggers and spreaders, Principal author: 1994
(v) ISO 3630 -Part 4: General requirements, Principal author: 2000, 2006 in process
(vi) ISO 6876 Dental root canal sealers, Co-author: 1986, 2001
(vii) ISO 6877 Dental obturating points, Principal author: 1995, 2001, 2006
(viii) ISO 7551 Dental absorbent points, Principal author: 1996
(ix) ISO 7488 Mechanical amalgamators, Significant contributor: 1991
(x) ISO 8282 Dental mercury dispensers, Significant contributor: 1994
(xi) ISO 13897 Dental amalgam capsule, Significant contributor: 2003

6. I have been informed that patent case law from the U.S. Court of Appeals for the Federal Circuit has explained that a patent application "disclosure must ... convey with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention. Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims."

7. I have read attached pending claims 1 and 13 of U.S. Patent Application No. 11/628,933 and attached Item 3 from the Office Action of August 10, 2009. I understand that the "limitation[s] at issue in the claims" are the terms "microstructure" and "entire shank".

8. I have read attached Example 1 from U.S. Patent Application No. 11/628,933, and I can discern that the heat treatment in Example 1 produces a "microstructure" and that the "entire shank" is being heat treated.

9. I have reviewed attached U.S. Patent No. 6,431,863 to Sachdeva et al. (Sachdeva). Looking at Sachdeva, I have noted that column 4, lines 31-36, state that "it is believed that the desired flexibility/stiffness and hardness properties, as discussed below, can be achieved ... by performing selective heat treatments of the working shaft

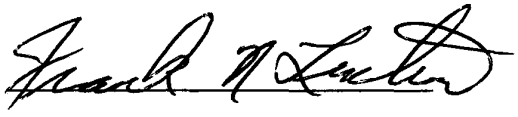
portion", and that column 4, lines 59-63 of Sachdeva state that "FIG. 6 represents, in a graphic manner, the effect of selective heat treatment. The FIG. 6 data is for a Ni–Ti wire (50.6% Ni) of 0.018" diameter wherein a first section was heat treated (annealed) at 450°C., and a second portion was heat treated at 350°C".

10. I understand that Sachdeva is heat treating different portions of a wire at different temperatures. In contrast, the invention of attached pending claims 1 and 13 of U.S. Patent Application No. 11/628,933 requires that the entire shank be heat treated in the same temperature range to create the microstructure in the shank.

11. I believe that localized heat treatment (such as practiced in Sachdeva) yields a nonuniform microstructure. Therefore, there are microstructural differences between the Sachdeva wire and the invention of attached pending claims 1 and 13 of U.S. Patent Application No. 11/628,933.

12. I declare that all statements are 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.

Respectfully submitted,

Dated: September 16, 2009 By: 

Frank N. Lentine

Pending claims 1 and 13 of U.S. Patent Application No. 11/628,933

1. (Previously Presented) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein the shank has a microstructure prepared by heat-treating the entire shank at a temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy.

13. (Previously Presented) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the shank has a microstructure prepared by heat-treating the entire shank at a temperature from 475°C to 525°C in an atmosphere consisting essentially of argon gas.

Item 3 from the Office Action of August 10, 2009

3. Claims 1-2, 4-15, 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of "a microstructure" and "the entire shank" are not included in the disclosure as originally filed. For instance, the disclosure does not state that a microstructure is imparted in the shank as a result of the heat-treating. With regards to the entire shank, there is no statement that the entirety of the shank is in the furnace or that it is fully exposed.

Example 1 from U.S. Patent Application No. 11/628,933

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 (Mt) 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. 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. Mt was determined for each of the thirty files in each size, and the mean and standard deviation for each group (Control, TT, Ti-N) of ten files were calculated. The ten files in all but one size that were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes showed the best result with the highest Mt.

US006431863B1

(12) **United States Patent**
Sachdeva et al.

(10) **Patent No.: US 6,431,863 B1**
(45) **Date of Patent: Aug. 13, 2002**

(54) **ENDODONTIC INSTRUMENTS HAVING IMPROVED PHYSICAL PROPERTIES**

(76) Inventors: **Rohit Chaman Lal Sachdeva**, 2605 Courtside La., Plano, TX (US) 75093; **Farrokh Farzin-Nia**, 141 W. Fairview Blvd., Inglewood, CA (US) 90302

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1017 days.

(21) Appl. No.: **08/942,732**

(22) Filed: **Oct. 2, 1997**

Related U.S. Application Data

(63) Continuation of application No. 08/453,969, filed on May 30, 1995, now abandoned.

(51) **Int. Cl.**[7] **A61C 5/02**
(52) **U.S. Cl.** **433/102**; 433/224
(58) **Field of Search** 433/102, 224

(56) **References Cited**

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4,600,391	A		7/1986	Jacob
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4,990,088	A	*	2/1991	Weissman 433/102
5,066,230	A		11/1991	Weissman
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5,389,226	A	*	2/1995	Scruggs et al. 205/50
5,464,362	A	*	11/1995	Heath et al. 433/102

OTHER PUBLICATIONS

H. Walia et al., "An Initial Investigation of the Bending and Torsional Properties of Nitinol Root Canal Files", Journal of Endodontics, vol. 14, No. 7, Jul. 1988, pp. 346–351.
Croopnick, G.A. et al., "A Low Environmental–Risk Replacement for Chromium and Electroless Nickel", Metal Finishing, pp. 13–16 (Apr. 1994).
The Kerr Endo Difference Brochure, Kerr Manufacturing Company, Romulus, Michigan 1991.

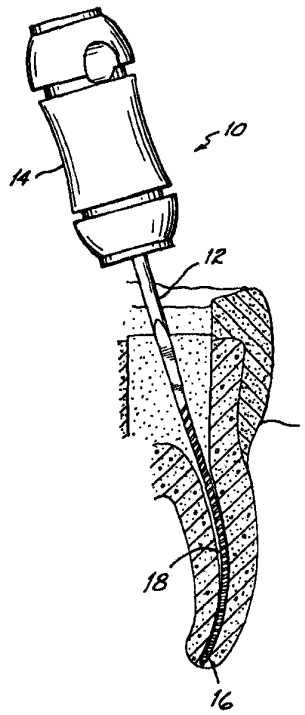
* cited by examiner

Primary Examiner—Ren Yan
(74) *Attorney, Agent, or Firm*—Wood, Herron & Evans, L.L.P.

(57) **ABSTRACT**

Endodontic instruments, including files, reamers, and broaches, wherein the working shaft portion has flexibility/stiffness properties and hardness properties that may vary along its length. These variations in physical properties can be accomplished by utilization of specific materials having a prescribed amorphous phase content, by application of specific coatings or surface treatments, or by selective or differential heat treatment.

3 Claims, 2 Drawing Sheets



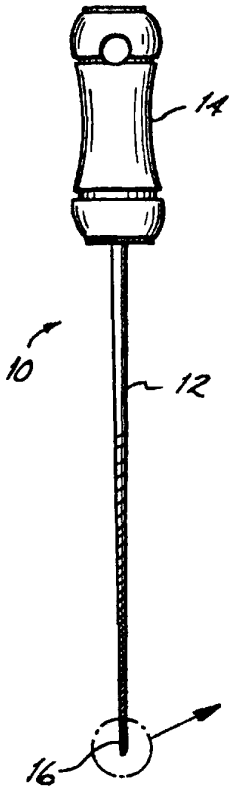


FIG. 1

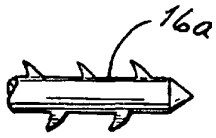


FIG. 2A

FIG. 2B

FIG. 2C

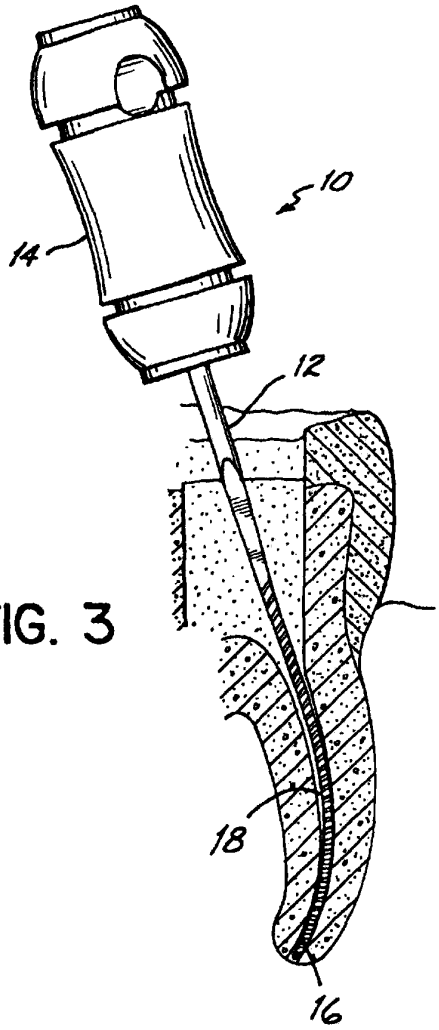


FIG. 3

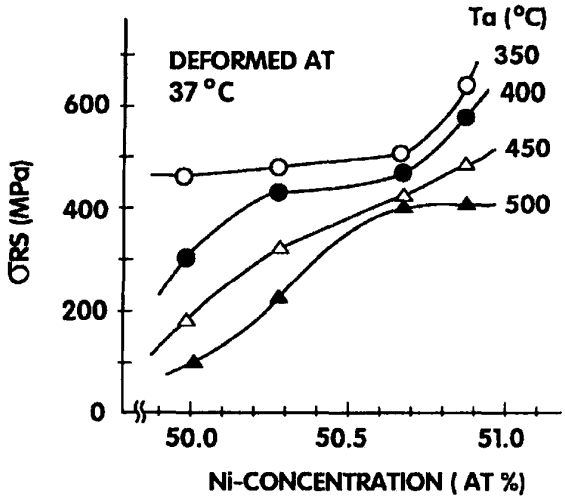


FIG. 4

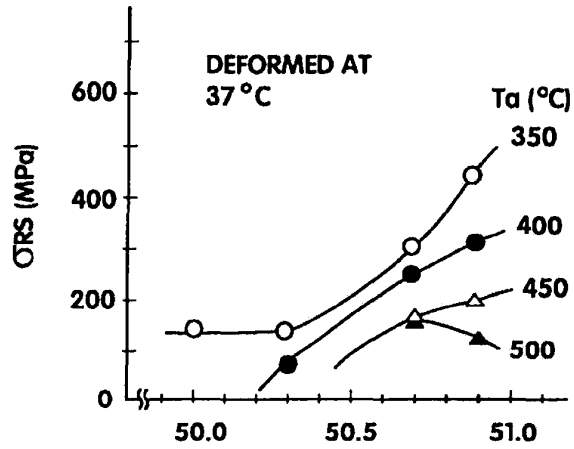


FIG.5

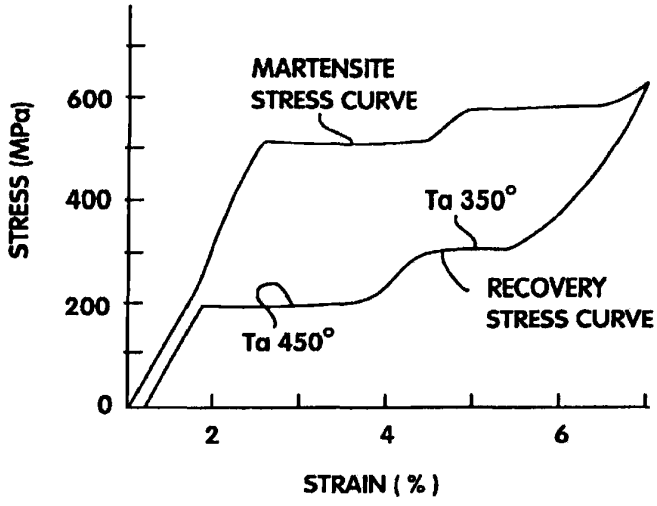


FIG. 6

ENDODONTIC INSTRUMENTS HAVING IMPROVED PHYSICAL PROPERTIES

RELATED APPLICATION

This application is a continuation of application Ser. No. 08/453.969 filed on May 30, 1995, entitled ENDODONTIC INSTRUMENTS HAVING IMPROVED PHYSICAL PROPERTIES now abandoned.

FIELD OF THE INVENTION

The invention relates to endodontic instruments, and more particularly to such instruments having improved physical properties in the nature of combined flexibility and hardness.

BACKGROUND OF THE INVENTION

Endodontic instruments, particularly files, reamers and broaches, are used for both cleaning and shaping root canals during endodontic procedures. There are a variety of factors which dictate the required physical characteristics of such instruments. These include the desired stiffness and/or flexibility of the instrument, as well as the sharpness of its cutting edges (which relates to the hardness as well as the structure of the material) coupled with certain dimensional and design limitations for the different root canals.

In the past, endodontic instruments have been made from carbon steels and stainless steels due to the propensity of these materials for maintaining adequate cutting edges, as well as the relatively high stiffness thereof. For example, carbon steel and stainless steel endodontic instruments are available from Kerr Corporation, Romulus, Michigan. Endodontic instruments constructed of such materials have certain drawbacks, however, including flexibility limitations which do not allow the instrument to readily conform to the shape of a curved root canal. This inflexibility can cause excessive, unwanted erosion of the root canal.

Recently, there have been some attempts in the endodontic instrument field to address these problems. More particularly, titanium based alloys and Ni/Ti materials have been introduced for use in the manufacture of endodontic instruments. For example, Seigneurin U.S. Pat. No. 5,125, 838 relates to endodontic canal instruments made of titanium or titanium alloys. The use of materials such as titanium or Ni/Ti have certain advantages in the flexibility of the material. However, endodontic instruments of such materials may have as a drawback the lack of necessary stiffness, particularly in small sized (diameter) instruments, sufficient to provide guidance in the root canals. Furthermore, the sharpness of the cutting edges in such instruments is compromised due to the lower hardness of the material.

What is needed is an instrument which combines the desired stiffness and sharp edge-maintaining characteristics along with desired enhanced flexibility so as to alleviate canal erosion.

SUMMARY OF THE INVENTION

In its broadest aspects, the present invention is directed to endodontic instruments which include a working shaft portion wherein the shaft portion has a modulus of elasticity that provides enhanced flexibility along its length and yet is stiff enough to provide the necessary guidance for the instrument. Furthermore, the working shaft has sufficient hardness so the cutting edges maintain their sharpness. The shaft may have varying flexibility and hardness properties along its length; however, the variation in flexibility (modulus) is not to be due solely to any variation in dimensions of the working shaft; e.g., the variation in flexibility is not due solely to a greater diameter at one location relative to another location on the working shaft.

In one aspect, the invention contemplates that at least the working shaft portion of the endodontic instrument, which may be a file, reamer or broach, or other endodontic instrument, is comprised of a titanium-based alloy, or other alloy possessing desirable physical characteristics. Suitable alloys contemplated are Ni—Ti based alloys; Ni—Ti alloys that include Nb or Fe as an additional alloying element; and alloys selected from the group consisting of Ti, Zr, Mo, Co, and Cr-based alloys. All of the above are suitable materials for the endodontic instruments of the present invention so long as the alloy is at least partially amorphous. Preferably, the alloy is structurally greater than about 10% amorphous. By selecting and utilizing an appropriate partially amorphous alloy from the noted group, the endodontic instrument is provided with the desired flexibility/stiffness and hardness properties for the particular endodontic procedure.

In an alternative aspect of the invention, the desired flexibility/stiffness and hardness properties are achieved by providing a coating or surface treatment on at least a portion of an exposed surface of the working shaft. The shaft itself may be a titanium-based alloy, or one of the other types of alloys noted above, and the coating or surface treatment may be continuous or discontinuous over the working shaft. Variations in flexibility and hardness along the length of the working shaft can be achieved utilizing discontinuous or intermittent coatings/surface treatments, or by variations in coating thickness. By utilizing continuous coatings of amorphous materials, such as Amplate, available from ATI of Laguna Niguel, Calif., the stiffness of the tip is improved while minimizing erosion of the cutting edges. Discontinuous TiN or TiAlN coatings can improve the hardness at the cutting edges while selectively increasing the stiffness of the instrument along its length.

In yet another aspect of the invention, the desired flexibility/stiffness and hardness properties can be achieved by selective or preferential heat treatment of the working shaft. Particularly in the embodiment wherein the working shaft portion is comprised of Ni—Ti alloy, selective heat treatment can be used to achieve the desired physical properties. Additionally, adjustments to the proportions of Ni and Ti as well as to the cold work ratio, can be advantageously used to achieve desired physical properties.

Utilizing any one of the above techniques, the flexibility and hardness of the working shaft portion can be varied along the length thereof, or specific hardness and/or flexibility properties can be imparted at specific locations along its length. For example, it is generally desired to have a stiffer tip in an endodontic instrument so as to provide improved cutting ability at the tip and to facilitate directing the instrument into the canal. Whereas the middle section of the working shaft portion of the instrument may need to be less stiff so as to improve steerability of the instrument through the canal, thereby minimizing erosion of the canal walls. This minimizing of canal wall erosion is achieved due to the fact that as the instrument is inserted through the canal, the lower modulus of elasticity of the material at the flexed or bent portion (e.g., the middle section) produces smaller forces against the canal walls, thereby minimizing erosion thereof.

These and other features and advantages of the present invention will become apparent to persons skilled in the art upon review of the detailed description of the invention, taken in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side elevation of an endodontic instrument according to the invention;

FIGS. **2A–2C** are enlarged, partially broken away sections of the area of FIG. **1** encircled at **2**;

FIG. **3** is an endodontic instrument of FIG. **1** in use;

FIG. **4** is a graphical representation of the variation in critical stress for inducing martensite (σ_{MS}) as a function of Ni concentration;

FIG. **5** is a graphical representation of the variation in critical stress for reverse transformation (σ_{RS}) as a function of Ni concentration; and

FIG. **6** is a stress-strain curve that shows the effects of differential heat treatment.

DETAILED DESCRIPTION OF THE INVENTION

With reference to the Figures, there is shown in FIG. **1** an endodontic instrument **10** according to the present invention, which includes a working shaft portion **12** and a handle portion **14**. FIGS. **2A–2C** simply depict enlargements of the tip portion encircled in FIG. **1**. More particularly, FIG. **2A** shows a barbed broach tip **16***a*; FIG. **2B** shows a typical reamer tip **16***b*; and FIG. **2C** shows a typical file tip **16***c*. FIG. **3** shows endodontic instrument **10** wherein the working shaft portion **12** has been inserted into a root canal **18** and is flexed to conform to the curvature of the canal.

In a first embodiment, the invention contemplates an endodontic instrument **10** wherein at least the working shaft portion comprises one of the following: (1) a nickel-titanium-based alloy; (2) a nickel-titanium-based alloy including Nb or Fe as an additional alloying element that is present in an amount exceeding about 0.5%, and as much as 1% or more; (3) alloys selected from the group consisting of Ti, Zr, Mo, V, Nb, Co and Cr-based alloys; and (4) other Ti-based alloys which include 10–15% of one or more of the elements in item (3), and up to 5% Al. The modulus of elasticity of the alloys recited in item (4) is expected to be in the range of about 4–17 million psi. In the case of alloys of the type recited in item (3), the alloy must be at least partially amorphous in structure; preferably greater than about 10% amorphous. More specifically, the desired modulus of elasticity and flexibility of the working shaft portion can elasticity and flexibility of the working shaft portion can be achieved by controlling the relative proportion of amorphous structure in the alloy. It is also contemplated that different portions of the working shaft may have different flexibility/stiffness properties and this may be controlled by adjusting the amorphous content of the alloy to different levels at different locations in the working shaft portion **12**. That is, the tip **16** may have less amorphous structure than the mid-portion of the working shaft. In that case, the tip would exhibit greater stiffness and hardness than the mid-portion of the working shaft **12**.

In an alternative embodiment, the flexibility/stiffness and hardness properties which are desired are achieved by providing a coating or surface treatment, as described below, on at least a portion of an exposed surface of the working shaft. Preferably, the working shaft is a titanium-based alloy. In one specific embodiment, the metal substrate of the working shaft is coated with a continuous metallic layer that is at least partially amorphous. The coating may be applied by an electroplating process such as described in an article by G. A. Croopnick et al. entitled "A Low Environmental-Risk Replacement For Chromium And Electroless Nickel", *Metal Finishing*, pps. 13–16, April, 1994, which is incorporated herein by reference in its entirety. Other processes by which, for example, Ni—W composition can be plated on substrates while forming an amorphous structure, are described in U.S. Pat. No. 5,389,226, the entirety of which is incorporated herein by reference.

Alternatively, the working shaft may be coated with a ceramic material such as TiN, TiC, Al_2O_3, TiO_2, and other known ceramics. Selection of the coating material and its application will control the ultimate flexibility of the working shaft, as well as its hardness. Additional means for achieving the desired flexibility/stiffness and hardness properties include other coating techniques such as plating, sputtering, plasma deposition, and surface treatment techniques including ion beam implantation, and any other method which allows accurate control of the thickness and/or location of the coating. One specific example is the implantation of nitrogen ions to achieve the desired variation in flexibility of the working shaft. It will be appreciated that discontinuous coatings may serve to appropriately modify the flexibility/stiffness and/or hardness of the working portion at the desired location.

In yet another alternative, the flexibility/stiffness of the instrument can be controlled by selected heat treatment of specific areas of the working shaft. For example, heat treating the working shaft tip **16** at a higher temperature than the treatment temperature of the mid-section will result in greater hardness and stiffness at the tip of the instrument vis-a-vis the mid-section.

More particularly, in accordance with the present invention, it is believed that the desired flexibility/stiffness and hardness properties, as discussed below, can be achieved by adjusting the composition of the alloy material, by performing selective heat treatments of the working shaft portion, or by changing the cold work ratio, or any combination of the above. As shown in Table **1** below, and reflected generally in FIGS. **4** and **5**, adjusting the Ni content in a Ni—Ti alloy and adjusting the anneal temperature (T_a) of that alloy will change the critical stress for inducing martensite (σ_{MS}) (see FIG. **4**), and the critical stress for reverse transformation (σ_{RS}) (see FIG. **5**). All data are for a NiTi wire of 0.018" diameter, having the noted composition and annealed at the noted temperature. Also, the stress values in Table 1 were obtained upon deformation at 25° C., whereas the stress values shown in FIGS. **4** and **5** were obtained upon deformation at 37° C.

TABLE 1

Annealed at 400° C., deformed at 25° C.

NiTi Alloy Ni %	σ_{MS} Martensite	σ_{RS} Reverse Transformation
50.9	500 MPA	200 MPA
50.7	400 MPA	100 MPA
50.3	325 MPA	75 MPA
50.0	200 MPA	50 MPA

FIG. **6** represents, in a graphic manner, the effect of selective heat treatment. The FIG. **6** data is for a Ni—Ti wire (50.6% Ni) of 0.018" diameter wherein a first section was heat treated (annealed) at 450° C., and a second portion was heat treated at 350° C. The variation in stress plateaus for inducing martensite and for reverse transformation are apparent at the noted anneal temperatures. Thus it will be appreciated by persons skilled in the art that variable heat treatments of the working shaft portion **12** of the endodontic

instruments of the present invention can be advantageously utilized to achieve the desired properties.

Generally speaking, it is desired that the endodontic instruments according to the present invention have a hardness in the range of 20–60 R_c (Rockwell hardness scale) and flexibility/stiffness (as represented by the modulus of elasticity) in the range of 4 million to 17 million psi.

Having now described the invention with respect to specific features and embodiments, persons having ordinary skill in the art will readily ascertain that various changes and modifications may be made without departing from the scope of the invention, as defined in the appended claims.

What is claimed is:

1. An endodontic instrument including a working shaft portion wherein said working shaft portion has varying stiffness/flexibility properties along at least a portion of its length, said variation in stiffness/flexibility not being due solely to any variation in dimensions or cross-sectional shape of said working shaft, further comprising a coating on at least a portion of an exposed surface of said working shaft portion, said coating resulting in said variation in stiffness/flexibility, and wherein said coating has a thickness gradient along the length of said working shaft portion.

2. An endodontic instrument including a working shaft portion wherein said working shaft portion has varying stiffness/flexibility properties along at least a portion of its length, said variation in stiffness/flexibility not being due solely to any variation in dimensions or cross-sectional shape of said working shaft wherein said variation in stiffness/flexibility is due to selective heat treatment of portions of said working shaft portion.

3. An endodontic instrument including a working shaft portion comprising a NiTi-based alloy, said working shaft portion having stiffness/flexibility properties that vary along at least a portion of its length, said variation in stiffness/flexibility not being due solely to any variation in dimensions or cross-sectional shape of said working shaft, wherein said alloy further includes Nb or Fe in an amount exceeding about 0.5%, and wherein said variation in stiffness/flexibility is due to selective heat treatment of portions of said working shaft.

* * * * *

Electronic Acknowledgement Receipt

EFS ID:	6141141
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	24-SEP-2009
Filing Date:	07-DEC-2006
Time Stamp:	17:10:08
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		response.pdf	410037 312cdb1703797eed229e2c1d754987fe50972960	yes	12

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment After Final		1	1	
	Claims		2	5	
	Applicant Arguments/Remarks Made in an Amendment		6	12	
Warnings:					
Information:					
2	Rule 130, 131 or 132 Affidavits	Declaration.PDF	634961 395c59f3e1a430d3f79e7d999a2ec942f5a16b7d	no	13
Warnings:					
Information:					
		Total Files Size (in bytes):	1044998		

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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.

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/628,933	12/07/2006	

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT 09/24/2009

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/DAWN BREWER/

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.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 10/13/2009

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
10/13/2009	ELECTRONIC

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

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

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

pat-dept@quarles.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 11/628,933	**Applicant(s)** LUEBKE, NEILL HAMILTON	
	Examiner Matthew M. Nelson	**Art Unit** 3732	

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

THE REPLY FILED 24 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. 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. 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.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. 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) 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 amendment(s) 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.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,2,4-15,20 and 21*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a 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 a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

/Matthew M Nelson/
Examiner, Art Unit 3732

Continuation of 3. NOTE: The new issues raised include heat-treating the entire shank for a time period at a single temperature.

Continuation of 10. NOTE: The affidavit appears to show that the entire shank is heat treated, however it is still unclear that the microstructure claimed is a direct result of this as the term does not appear in the cited paragraph. Additionally, the arguments rely upon the amendments filed, which have not been entered for the reasons given above.

Continuation of 11. does NOT place the application in condition for allowance because: The applicants arguments are not persuasive, as they rely upon the amendments filed, which have not been entered for the reasons given above.

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

Application Number	11/628,933	Filing Date	2006-12-07	Docket Number (if applicable)	115207.00002	Art Unit	3732
First Named Inventor	Neill Hamilton Luebke			Examiner Name	Matthew M. Nelson		

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

SUBMISSION REQUIRED UNDER 37 CFR 1.114

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

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

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

☒ Other After final amendment filed on September 24, 2009

☐ Enclosed

☐ Amendment/Reply

☐ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

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

☐ Other _____

FEES

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

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

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

Signature of Registered U.S. Patent Practitioner			
Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2009-10-16
Name	Richard T. Roche	Registration Number	38599

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

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

Electronic Patent Application Fee Transmittal

Application Number:	11628933
Filing Date:	07-Dec-2006
Title of Invention:	Dental And Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Richard T. Roche
Attorney Docket Number:	115207.00002

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**405**

Electronic Acknowledgement Receipt

EFS ID:	6274415
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	16-OCT-2009
Filing Date:	07-DEC-2006
Time Stamp:	10:53:37
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$405
RAM confirmation Number	7002
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. 1.492 (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	Request for Continued Examination (RCE)	rce.PDF	76509 8979e6e0f258f2d5431e14a4cec91ad1b2ed5cba	no	2
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	30255 7c0a4021543daf8719ae8cfb8a78086d65a50460	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	106764		

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/628,933	12/07/2006	

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT 10/16/2009

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/RUTH M. LLOYD/

10/14/09

Docket No.: 115207.00002

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

Date: September 24, 2009

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Confirmation No.:	9736
Art Unit:	3732
Examiner:	Matthew M. Nelson

Entered with RCE 10/16/09 RL 10/21/09

RESPONSE TO FINAL OFFICE ACTION

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

Sir:

This is in response to the Final Office Action mailed on August 10, 2009.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 6 of this paper.

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.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 01/11/2010

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
01/11/2010	ELECTRONIC

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

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

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

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	Matthew M. Nelson	3732	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *16 October 2009*.

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

3)☐ 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

4)☒ Claim(s) *1,2,4-15,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-15,20 and 21* is/are rejected.

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

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

Application Papers

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

10)☐ 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 10/16/2009 is acknowledged. Claims 1-2, 4-15, 20-21 remain pending.

Claim Rejections - 35 USC § 112

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

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

3. Claims 1-2, 4-15, 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of "a microstructure" and "the entire shank" are not included in the disclosure as originally filed. For instance, the disclosure does not state that a microstructure is imparted in the shank as a result of the heat-treating. With regards to the entire shank, there is no statement that the entirety of the shank is in the furnace or that it is fully exposed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4-10, 13, 15, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sachdeva et al. (US 6,431,863).

Sachdeva shows an endodontic instrument (Fig. 1) comprising an elongate shank (working shaft 12) having a cutting edge (Fig. 2b) extending from a distal end of the shank along an axial length of the shank (Fig. 1), wherein the shank comprises a titanium alloy (col. 3, line 30-33) and has a microstructure (an alloy including titanium is heat treated and therefore there is a microstructure). With respect to claim 6, the titanium alloy is selected from alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys, and nickel-titanium alloys (col. 3, line 30-33). With respect to claim 7, 8, 9, 13, the titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium (col. 3, line 30-32; Table 1). When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim. With respect to claim 10, the cutting edge is formed by helical flutes in the shank (reamer tip 16b; Fig. 2b). The method claims 15, 20 are rejected similarly to the above apparatus claims (col. 1, lines 17-19).

Please note that claims 1-2, 4-5, 8-9, 13, 21 are product-by-process claims, and therefore the process has not been given patentable weight. See MPEP 2113. Furthermore, with respect to the heat-treating temperatures, environments, and durations of claims 1-2, 4-5, 8-9, 13, 21, “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the

product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP 2113, 2173.05(p). Alternatively, Sachdeva teaches the shank having a microstructure (same temperature range and alloy as claim language means a similar microstructure is produced) prepared by heat-treating the entire shank for a time period at a single temperature (col. 1, line 59 – col. 2, line 4; the shaft *may* have variation in flexibility but different heat treatments along the length are not required in the broadest embodiment of Sachdeva).

Claim Rejections - 35 USC § 103

6. 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.

7. Claims 11-12, 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva.

Sachdeva discloses the device as previously described above, but fails to show wherein the shank has a diameter of 0.5 to 1.6 mm and has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the shank to have a diameter of 0.5 to 1.6 mm and so that it maintains a deformation of greater than 10 degrees after a 45 degree torque in order to drill a hole with diameter of corresponding size, 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).

Response to Amendment

8. The declaration under 37 CFR 1.132 filed 9/24/2009 is insufficient to overcome the rejection of claims 1-2, 4-15, 20-21 based upon 112, 102(b), and 103(a) as set forth in the last Office action because: Examiner still does not see where the microstructure being prepared by heat-treating the entire shank is supported since there is no description of how the shank was exposed and heat-treated. One could just as easily argue that only the working portion of the shank would be exposed to heat-treatment.

Response to Arguments

9. Applicant's arguments filed 10/16/2009 have been fully considered but they are not persuasive.

10. Applicant argues with the aid of the Declaration that “microstructure” and “entire shank” are supported by the disclosure as originally filed. Examiner still does not see where the microstructure being prepared by heat-treating the entire shank is supported since there is no description of how the shank was exposed and heat-treated.

11. Applicant argues that Sachdeva's microstructure is non-uniform whereas applicant's is uniform. This language is not in the claims and Sachdeva satisfies the limitation that there is some form of microstructure. Sachdeva also deals with similar alloys, temperatures, and heat-treatment process, so the resulting microstructure would be similar. Therefore, Examiner agrees that including "microstructure" in the claim adds a structural limitation, however Sachdeva covers this additional limitation.

12. Applicants arguments with respect to Sachdeva only being directed to selective heat treatment at several temperatures has been addressed in the above rejection.

13. Applicant argues that the process imparts distinctive structural characteristics, specifically the microstructure of the shank. However, Sachdeva also has a microstructure as applicant admits, and therefore this structural characteristic is not distinctive.

14. Applicant argues that Sachdeva teaches away by only disclosing two temperatures and that a higher temperature will result in greater hardness and stiffness. First, the two temperatures Applicant is referring to are only part of one of the examples and are not limiting. See Fig. 4-5 for example. Second, Applicant's Declaration, specifically the Zinelis et al. reference, confirms the Sachdeva statement that a higher temperature could result in greater hardness and stiffness as seen in Fig. 3. It is seen that above about 450 degrees Celsius the flexibility decreases with increasing temperature. Zinelis is not being used as prior art, but was rather used to help clarify to the Applicant what was meant by the disclosure of Sachdeva.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew M. 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, the examiner's supervisor, Cris Rodriguez can be reached on (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.

/MMN/

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1099	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:33
L2	18	L1 AND microstructure	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:34
L3	200	L1 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:35
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

EAST Search History (Interference)

< This search history is empty>

12/31/2009 12:35:21 PM
C:\Documents and Settings\mnelson3\My Documents\EAST\Workspaces\11628933 Dental Instruments Comprising Titanium.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	Matthew M Nelson	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	04/29/2008	10/21/2008	02/24/2009	08/03/2009	12/31/2009				
	1	✓	✓	✓	✓	✓				
	2	✓	✓	✓	✓	✓				
	3	✓	-	-	-	-				
	4	✓	✓	✓	✓	✓				
	5	✓	✓	✓	✓	✓				
	6	✓	✓	✓	✓	✓				
	7	✓	✓	✓	✓	✓				
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	9	✓	✓	✓	✓	✓				
	10	✓	✓	✓	✓	✓				
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	13	✓	✓	✓	✓	✓				
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	18	✓	-	-	-	-				
	19	✓	-	-	-	-				
	20	✓	✓	✓	✓	✓				
	21			✓	✓	✓				

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	Matthew M Nelson	3732

SEARCHED

Class	Subclass	Date	Examiner
433	102, 224	4/29/2008	MMN
29	896.1	4/29/2008	MMN
433	102, 224	10/21/2008	MMN
29	896.1	10/21/2008	MMN
433	102, 224	2/24/2009	MMN
29	896.1	2/24/2009	MMN
433,29	Updated search	8/3/2009	MMN
433, 29	Updated search	12/31/2009	MMN

SEARCH NOTES

Search Notes	Date	Examiner
Search received from John Wilson for Class/Subclass 433/102,224 & 29/896.1	4/28/2008	MMN
See EAST search history	4/29/2008	MMN
Updated EAST search	10/21/2008	MMN
Updated EAST search	2/24/2009	MMN
Updated EAST search history	8/3/2009	MMN
Updated EAST search history	12/31/2009	MMN

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

PTO/SB/130 (07-09)
Approved for use through 07/31/2012. OMB 0651- 0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PETITION TO MAKE SPECIAL BASED ON AGE FOR ADVANCEMENT OF EXAMINATION UNDER 37 CFR 1.102(c)(1)

Application Information

Application Number	11628933	Confirmation Number	9736	Filing Date	2006-12-07
Attorney Docket Number (optional)	115207.00002	Art Unit	3732	Examiner	Matthew Nelson
First Named Inventor	Neill H. Luebke				
Title of Invention	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM				

Attention: Office of Petitions

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

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

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

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

Given Name	Middle Name	Family Name	Suffix
Neill	Hamilton	Luebke	

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

Select (1) or (2) :

○ (1) I am an inventor in this application and I am 65 years of age, or more.

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

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2010-02-08
Name	Richard T. Roche	Registration Number	38599

PTO/SB/130 (07-09)
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

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 Fr eedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about indivi duals.

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.

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Application of
Neill Hamilton Luebke

Application No. 11628933
Filed: December 7,2006

Attorney Docket No. 115207.00002

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

This is a decision on the electronic petition under 37 CFR 1.102 (c)(1), filed 08-FEB-2010 to make the above-identified application special based on applicant's age as set forth in MPEP § 708.02, Section IV.

The petition is **GRANTED**.

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

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	6971574
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	08-FEB-2010
Filing Date:	07-DEC-2006
Time Stamp:	17:36:50
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Petition automatically granted by EFS	petitionagesb130.pdf	904538 d86d3c726906193eba65a7b9ae950d5b90afd690	no	2
Warnings:					
Information:					

Total Files Size (in bytes):	904538

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

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

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

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

Docket No.: 115207.00002

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

Date: February 15, 2010

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Confirmation No.:	9736
Art Unit:	3732
Examiner:	Matthew M. Nelson

RESPONSE TO NON FINAL OFFICE ACTION

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

Sir:

This is in response to the Non-Final Office Action mailed on January 11, 2010.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 8 of this paper.

Amendments To The Claims

1. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being in accordance with ISO Standard 3630-1,

wherein the shank comprises a titanium alloy, and

wherein the instrument is ~~shank has a microstructure~~ prepared by heat-treating the instrument ~~entire shank~~ for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy.

2. (Original) The instrument of claim 1 wherein:

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

3. (Cancelled)

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

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

5. (Currently Amended) The instrument of claim 1 wherein:

the instrument ~~shank~~ is heat-treated for 1 to 2 hours.

6. (Original) The instrument of claim 1 wherein:

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

7. (Original) The instrument of claim 1 wherein:

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

8. (Currently Amended) The instrument of claim 1 wherein:

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

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

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

the instrument ~~shank~~ is heat-treated for 1 to 2 hours.

9. (Currently Amended) The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

the instrument ~~shank~~ is heat-treated for 1 to 2 hours.

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

the cutting edge is formed by helical flutes in the shank.

11. (Currently Amended) The instrument of claim 1 wherein:

the heat-treated instrument ~~shank~~ has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

12. (Original) The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being in accordance with ISO Standard 3630-1,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the instrument is ~~shank has a microstructure~~ prepared by heat-treating the instrument ~~entire shank~~ at a temperature from 475°C to 525°C in an atmosphere consisting essentially of a ~~argon~~ gas unreactive with the shank.

14. (Original) The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 1.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 13.

21. (Previously Presented) The instrument of claim 1 wherein:

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

22. (New) The instrument of claim 13 wherein:

the heat-treated instrument has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

23. (New) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

wherein the heat-treated instrument has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

24. (New) The instrument of claim 23 wherein:

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

25. (New) The instrument of claim 23 wherein:

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

REMARKS

Examiner Interview

Applicant and Applicant's Representative thank Examiner Nelson and Examiner Rodriguez for the courtesy of a telephonic interview on February 5, 2010.

Claim Amendments

Claims 1 and 13 have been amended to recite that the instrument is in accordance with ISO Standard 3630-1 and that the instrument is heat treated as described in Example 4, page 12, lines 16-20 and 26-28 of the specification. Claims 1 and 13 have also been amended to delete the terms "entire shank" and "microstructure". Claim 13 has also been amended to recite that the gas is unreactive with the shank as in claim 1.

Claims 5, 8 and 9 have been amended to maintain antecedent basis in view of the amendments to claim 1.

Claim 11 has been amended to make it clear that the heat treated instrument undergoes permanent deformation as described at page 5, lines 1-6 and at Example 4 and at page 13, lines 1-3 of the specification.

New claim 22 depends from claim 13 and has a basis in claim 11.

New claim 23 includes the elements and limitations of previous claim 1 without the terms "entire shank" and "microstructure" and also includes the limitations of amended claim 11.

New claim 24 has a basis in claim 21.

New claim 25 has a basis in claim 4.

Claim Rejections 35 USC § 112

Claims 1-2, 4-15, 20-21 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Applicant believes that the Declaration submitted 09-24-2009 makes it clear that one skilled in the art would understand that the inventor was in possession of the invention of previous claims 1 and 13. Therefore, the Applicant respectfully disagrees with this rejection. However, claims 1 and 13 have been amended to delete the terms "entire" and "microstructure" in order to overcome this rejection.

Claim Rejections - 35 USC § 102 & 35 USC § 103

Claims 1-2, 4-10, 13, 15, 20 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,431,863 to Sachdeva *et al*. (Sachdeva). Claims 11-12 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva.

Looking first at amended independent claims 1 and 13, the invention of these claims now requires an instrument in accordance with ISO Standard 3630-1. This structural limitation is not taught or suggested in Sachdeva. It is well settled that "unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." *Net Moneyin v. Verisign*, 545 F.3d 1359, 1371 (Fed. Cir. 2008). Accordingly, it is submitted that the amendments to independent claims 1 and 13 overcome the rejection under 35 U.S.C. 102(b).

Next, the Office Action of January 11, 2010 states that

> "claims 1-2, 4-5, 8-9, 13, 21 are product-by-process claims, and therefore the process has not been given patentable weight. … The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)."

However, this reasoning from *In re Thorpe* is not without limits. In particular, when the process steps confer a structure or characteristic of the product which distinguishes it from products made by other processes, the process steps should be considered. *In re Garnero*, 412 F.2d 276, 279 (CCPA 1979).

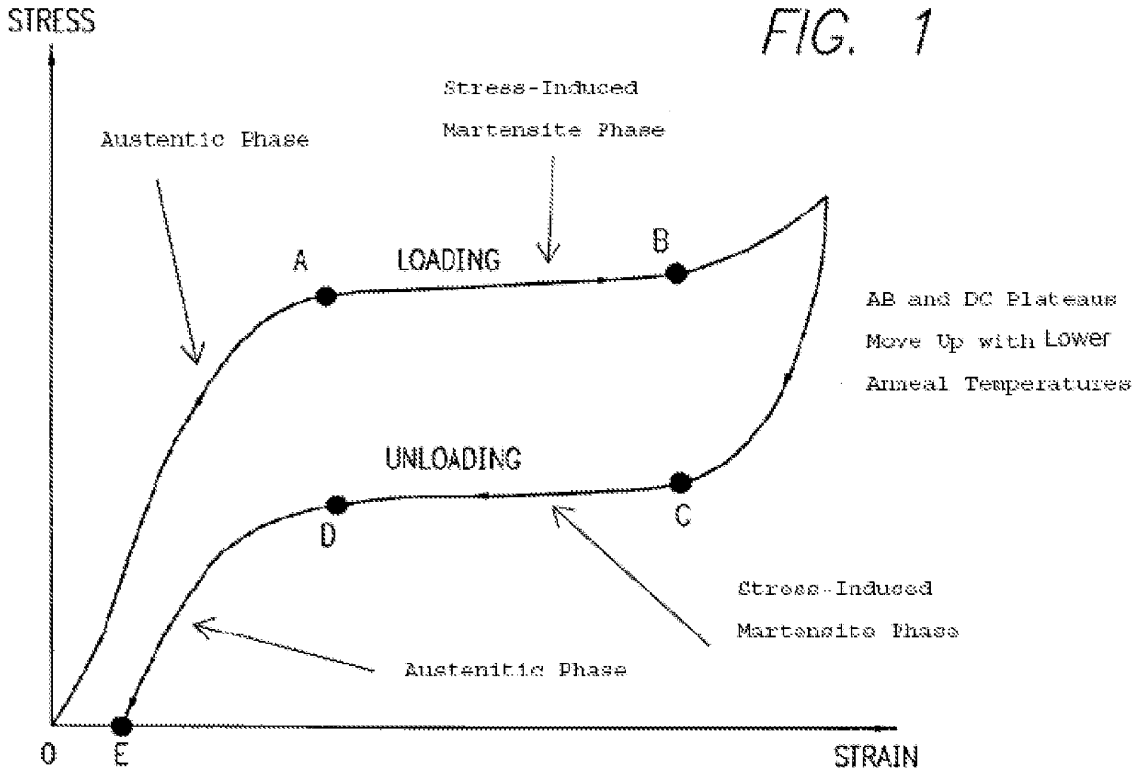
In fact, the Board Of Patent Appeals and Interferences ("Board") has used this reasoning in the past year. For example, in *Ex parte Gist*, the Board stated "[t]he patentability of a product is based on the product itself unless the process steps confer a structure or characteristic which distinguishes it from products made by other processes." *Ex parte Gist*, Appeal 2008-6122, Technology Center 3700, March 30, 2009, page 9, (underlining added). See, also, *Ex parte Agrawal*, Appeal 2009-1014, Technology Center 3700, March 23, 2009, page 10, where it states "[t]he patentability of a product in a product-by-process claim is based on the patentability of the product itself even though the process by which the product is processed may differ from the prior art. But, the process steps should be considered if the steps confer a structure or characteristic of the product which distinguishes it from products made by other processes" (underlining added).

Therefore, the Applicant wishes to provide evidence that the process limitation in claim 1 (i.e., the instrument is prepared by heat-treating the instrument for a time period at a single temperature … wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy") and the process limitation in claim 13 ("the

instrument is prepared by heat-treating the instrument at a temperature from 475°C to 525°C") confer a distinguishing characteristic over the product of Sachdeva.

Attached for Examiner consideration is an Information Disclosure Statement in which U.S. Patent No. 7,175,655 to Molaci ("Molaci") is listed. Looking at column 5, line 43 to column 6, line 23 and the marked version of Figure 1 of Molaci below, a strain-stress curve for a superelastic material is shown. "Superelasticity or pseudoelasticity refers to the ability of a material to undergo extremely large elastic deformation" (see column 1, lines 27-28 of Molaci).

FIG. 1



As explained at column 5, line 64 to column 6, line 23 of Molaci, the curve depicted in FIG. 1 above represents the temperature range where superelasticity occurs. As the

material is stressed, the curve represented by line OA shows where the material is completely austenitic. The transformation from austenite to stress-induced martensite occurs at point A indicated in FIG. 1 above. The austenite converts to stress-induced martensite in the nickel-titanium alloy, as represented by line segment AB. Further application of stress beyond point B creates elastic deformation in the stress-induced martensite. The slope of the curve depicted in FIG. 1 reverses from beyond point B, dropping down to point C, as a result of the release of stress. At approximately point C the initial conversion of stress-induced martensite back to austenite begins. At a certain stress level, as represented by line segment CD, the material converts entirely from the stress-induced martensitic phase to the austenitic phase.

In summary, Figure 1 of Molaci explained above shows a stress-strain curve for a superelastic material with one anneal temperature. As the anneal temperature decreases, the stress plateaus (AB, DC) increase.

Turning now to Sachdeva which was cited against the present claims, the objective of Sachdeva is to control the flexibility/stiffness of the instrument "by selected heat treatment of specific areas of the working shaft. For example, heat treating the working shaft tip 16 at a higher temperature than the treatment temperature of the mid-section will result in greater hardness and stiffness at the tip of the instrument vis-a-vis the mid-section" (see column 4, lines 23-29 of Sachdeva. Sachdeva further explains this concept at column 4, lines 59-65 which state "FIG. 6 represents, in a graphic manner, the effect of selective heat treatment. The FIG. 6 data is for a Ni--Ti wire (50.6% Ni) of 0.018" diameter wherein a first section was heat treated (annealed) at 450°°C., and a second portion was heat treated at 350°C. The variation in stress

plateaus for inducing martensite and for reverse transformation are apparent at the noted anneal temperatures."

Figure 1 of Molaci above evidences the shape of a stress-strain curve for a superelastic material, and using Figure 1 of Molaci as background, it is apparent that the Figure 6 of Sachdeva shows the shape of a stress-strain curve of a superelastic material with two anneal temperatures.

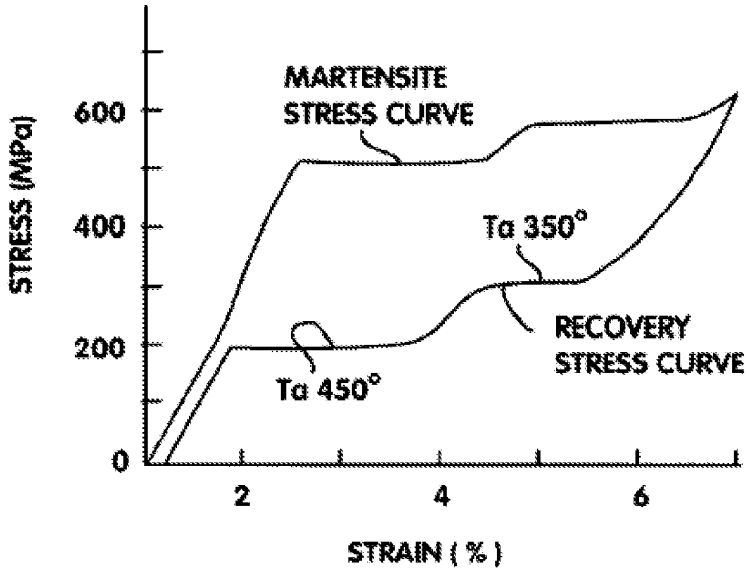


FIG. 6

Note how Sachdeva labels the two stress plateaus Tα 450° and Tα 350° on the unloading curve in Figure 6. Thus, the product of Sachdeva includes a superelastic material with two stress plateaus.

The Applicant submits that the Figures from Molaci and Sachdeva provide ample evidence that the process limitation in claim 1 (i.e., the instrument is prepared by heat-treating the instrument for a time period at a single temperature … wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy") confers a distinguishing characteristic over the product of Sachdeva. In this regard, an

instrument heated at a single temperature as in claim 1 would not exhibit the two stress plateaus Tα 450° and Tα 350° on the unloading curve in Figure 6 of Sachdeva. Furthermore, to the extent that Sachdeva suggests using two other temperatures, the product of Sachdeva would still have the characteristic of two stress plateaus. Accordingly, it is submitted that claim 1 includes a process limitation (i.e., heat-treating the instrument for a time period at a single temperature) that confers a distinguishing characteristic over the product of Sachdeva.

Turning now to independent claim 13 of the present application, the process limitation in claim 13 ("the instrument is prepared by heat-treating the instrument at a temperature from 475°C to 525°C") also confers a distinguishing characteristic over the product of Sachdeva. Specifically, Sachdeva anneals at 450°C and 350°C as shown on the unloading curve in Figure 6 of Sachdeva. Sachdeva does not use a temperature from 475°C to 525°C as recited in claim 13. As explained above, the anneal temperature controls the location of the stress plateaus for inducing martensite in the Sachdeva material. Therefore, the product of Sachdeva would have different stress plateaus in the stress-strain curve as Sachdeva uses different temperatures compared to claim 13.

Referring now to new claim 23, the claimed invention requires an instrument that "has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion". As discussed in the interview on February 5, 2010, this provides another structural limitation for the claimed invention. This structural limitation further distinguishes the product of Sachdeva.

As noted above, Molaci explains that "superelasticity or pseudoelasticity refers to the ability of a material to undergo extremely large elastic deformation" (see column 1, lines 27-28 of Molaci). The above analysis also demonstrates that the Sachdeva material is superelastic. Therefore, the Sachdeva material will undergo an extremely large elastic deformation.

In contrast, the invention of claim 23 "has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion" (underling added). This limitation in new claim 23 further distinguishes the claimed invention from the product of Sachdeva (which will undergo extremely large elastic deformation). This feature of the invention is also recited in claims 11 and 22.

In order to more fully demonstrate that the present invention will undergo permanent deformation (unlike Sachdeva), the attached Inventor's Declaration shows a test in which the inventor heat treated an instrument in accordance with independent claims 1, 13 and 23 and thereafter deformed the shank after heat treating. The deformation was permanent. In contrast, the non-heat treated instrument that was deformed returned to its original shape (no permanent deformation) like the product of Sachdeva.

In summary, it is submitted that amended independent claim 1 (and claims 2, 4-12, 15 and 21 that depend thereon) and amended independent claim 13 (and claims 14, 20, and 22 that depend thereon) and new independent claim 23 (and claims 24-25 that depend thereon) are patentable over Sachdeva.

Conclusion

Claims 1-2, 4-15, and 20-25 are believed to be in condition for allowance. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

Having already paid for twenty total claims and three independent claims, no fees are believed to be needed for this amendment. However, if fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: February 15, 2010

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

9550570

Electronic Acknowledgement Receipt

EFS ID:	7011296
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	15-FEB-2010
Filing Date:	07-DEC-2006
Time Stamp:	15:35:55
Application Type:	U.S. National Stage under 35 USC 371

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	Rule 130, 131 or 132 Affidavits	luebke_declaration.pdf	325056 38724d969902d9c3707e82311213b7bafd54bead	no	5

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Filed (SB/08)	luebke_ids.pdf	31447 54d6614dadecf73f0d3c961176e23b8d3e0d9972	no	3
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3		luebke_response.pdf	128233 3457f1e3905a89595049b6e883b0b87f936e4178	yes	16

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	16

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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.

Docket Number: 115207.00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Art Unit:	4166
Examiner:	Matthew M. Nelson

DECLARATION UNDER 37 C.F.R. § 1.132

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

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

2. As a control standard, I obtained an instrument in accordance with ISO Standard 3630-1 made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium and including an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. The control (non-heat treated) instrument had a natural straight orientation before pressure was applied. See the top photo in attached Applicant's Exhibit 1. Pressure was applied to the control instrument with a cotton pliers until the control instrument had a bend of approximately 90 degrees. See the middle photo in Applicant's Exhibit 1. After the bending pressure was released, the control instrument returned to the original natural straight orientation. See the bottom photo in Applicant's Exhibit 1.

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

4. It is believed that the control instrument detailed in Item 2 above exhibited superelastic behavior as in the product of U.S. Patent No. 6,431,863 to Sachdeva *et al.* (Sachdeva) that was cited in the Office Action mailed on January 11, 2010.

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

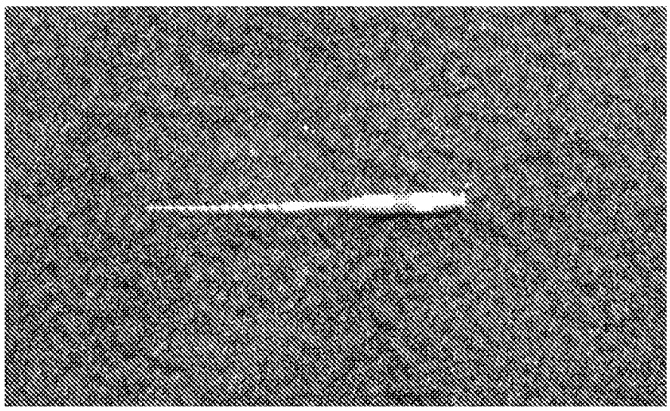
6. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like made are punishable by fine or imprisonment, or both, under Section 1001

of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Dated: February 15, 2010

Dr. Neill H. Luebke

Applicant's Exhibit 1
Standard Nickel Titanium Endodontic File

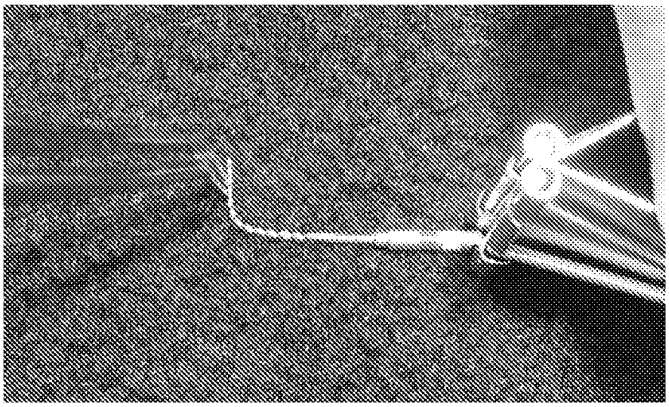


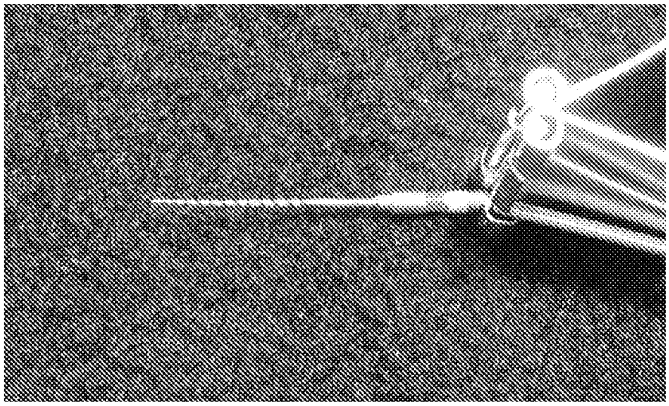
File Size 25 with 04 taper

Natural straight orientation before pressure is applied

File Size 25 with 04 taper

with pressure applied

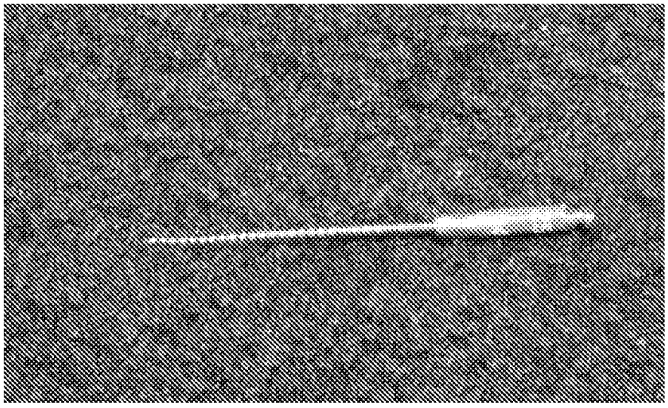




File Size 25 with 04 taper

with pressure released, file returns to natural straight orientation

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



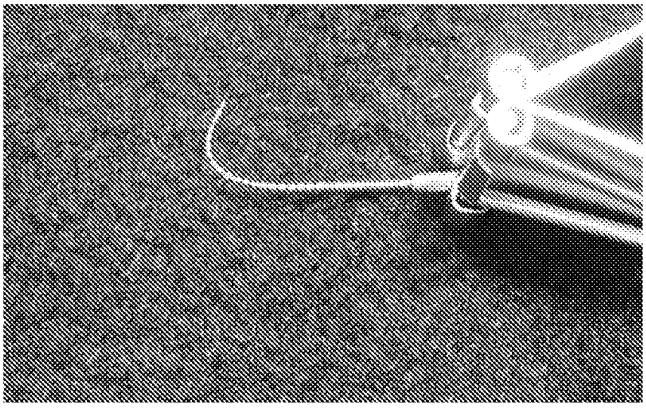
File Size 25 with 04 taper

Natural straight state before pressure is applied

File Size 25 with 04 taper

Curved state after bending pressure applied and after pressure released.

It does not return to original state



PTO/SB/08a (03-09)
Approved for use through 03/31/2009. 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	11628933
Filing Date	2006-12-07
First Named Inventor	Neill H. Luebke
Art Unit	3732
Examiner Name	Matthew M. Nelson
Attorney Docket Number	115207.00002

U.S.PATENTS

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

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11628933
	Filing Date	2006-12-07
	First Named Inventor	Neill H. Luebke
	Art Unit	3732
	Examiner Name	Matthew M. Nelson
	Attorney Docket Number	115207.00002

	1		☐

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

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	11628933
	Filing Date	2006-12-07
	First Named Inventor	Neill H. Luebke
	Art Unit	3732
	Examiner Name	Matthew M. Nelson
	Attorney Docket Number	115207.00002

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.

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

☒ None

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)	2010-02-15
Name/Print	Richard T. Roche	Registration Number	38599

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.**

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

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/628,933	12/07/2006	

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT 02/15/2010

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/Mamye Wagstaff/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 02/18/2010

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
02/18/2010	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

Interview Summary	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	Matthew M. Nelson	3732	

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

(1) *Matthew M. Nelson*. (3)*Richard Roche*.

(2) *Cris Rodriguez*. (4)*Neill and Fran Luebke*.

Date of Interview: *05 February 2010*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

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

Claim(s) discussed: *1 and 11*.

Identification of prior art discussed: *Sachdeva 6,431,863*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Discussed the 112 issues and proposed amendment to overcome those issues. Reviewed superelastic properties and the distinguishing features of the present invention over the prior art of Sachdeva. Clarified how the claims were being treated with respect to them being product-by-process and discussed the inclusion of claim 11 into an independent claim in order to provide more structure to the claim*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Matthew M Nelson/ Examiner, Art Unit 3732	

Summary of Record of Interview Requirements

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

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

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

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

———

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

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

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

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

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

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

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

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

Examiner to Check for Accuracy

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 03/26/2010

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
03/26/2010	ELECTRONIC

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

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

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

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	Matthew M. Nelson	3732	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *15 February 2010*.

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

3)☐ 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

4)☒ Claim(s) *1,2,4-15 and 20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-15 and 20-25* is/are rejected.

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

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

Application Papers

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

10)☐ 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/15/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 2/15/2010 is acknowledged. New claims 22-25 have been added and claims 1-2, 4-15, 20-21 remain pending.

Claim Rejections - 35 USC § 103

2. 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.

3. Claims 1-2, 4-15, 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva et al. (US 6,431,863) in view of Wong et al. (US 6,206,695).

4. Sachdeva shows an endodontic instrument (Fig. 1) comprising an elongate shank (working shaft 12) having a cutting edge (Fig. 2b) extending from a distal end of the shank along an axial length of the shank (Fig. 1), wherein the shank comprises a titanium alloy (col. 3, line 30-33), the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank (col. 1, line 59 – col. 2, line 4; the shaft *may* have variation in flexibility but different heat treatments along the length are not required in the broadest embodiment of Sachdeva), wherein the temperature is from 400 degrees Celsius up to but not equal to the melting point of the titanium alloy, 400 to 525, or 475 to 525 (several temperatures above 400 including 500 are shown in Fig. 4-5

for instance). With respect to claim 6, the titanium alloy is selected from alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys, and nickel-titanium alloys (col. 3, line 30-33). With respect to claim 7, 8, 9, 13, the titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium (col. 3, line 30-32; Table 1). When converted to weight percent, the range of nickel percentage, and therefore titanium percentage, as provided by Sachdeva overlaps the weight percent of nickel and titanium provided in the claim. With respect to claim 10, the cutting edge is formed by helical flutes in the shank (reamer tip 16b; Fig. 2b). The method claims 15, 20 and apparatus claims 23-25 are rejected similarly to the above apparatus claims (col. 1, lines 17-19).

5. Please note that claims 1-2, 4-5, 8-9, 13, 21, 23-25 are product-by-process claims, and therefore the process has not been given patentable weight where they do not confer a structure or characteristic which distinguishes it from the prior art. See MPEP 2113. Furthermore, with respect to the heat-treating temperatures, environments, and durations of claims 1-2, 4-5, 8-9, 13, 21, 23-25, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP 2113, 2173.05(p).

6. However, Sachdeva fails to show wherein the shank has a diameter of 0.5 to 1.6 mm and has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion, and the instrument is in accordance with ISO Standard 3630-1.

7. Wong teaches a dental cutting instrument in accordance with ISO Standard 3630-1 and therefore shanks with diameters of 0.5 to 1.6 mm (col. 1, line 65 – col. 2, line 21; Table 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva's instrument by incorporating the ISO Standards of Wong in order to provide sizes and an internationally recognized standard that is recognizable by and commonly used by dentists.

8. It would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva/Wong's deformation of 10 degrees after a 45 degree torque in order to provide desired flexibility since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05 II). The resulting flexibility and modulus of elasticity are recognized as results effective variables by Sachdeva in col. 3, line 30-56 and col. 4, line 23-30.

Response to Amendment

9. The declaration under 37 CFR 1.132 filed 2/15/2010 is insufficient to overcome the rejection of claims 1-2, 4-15, 20-25 based upon 102(b) and 103(a) as set forth in the last Office action because: Applicant has compared the physical properties of their invention (heat treated shank) and a non-heat treated shank. Sachdeva is considered

to be the non-heat treated shank in the comparison by the Applicant, however Sachdeva explicitly teaches heat treating of the shank in a similar fashion to the present invention in col. 4, lines 23-30.

Response to Arguments

10. Applicant's arguments filed 2/15/2010 have been fully considered but they are not persuasive.

11. Applicants arguments with respect to Sachdeva only being directed to selective heat treatment at several temperatures (two stress plateaus) has been addressed in the above rejection (specifically paragraph 4 of this action).

12. Applicant argues Sachdeva does not show an anneal temperature of 475 to 525, however 500 is shown in Fig. 4-5 for instance.

13. Applicant argues Sachdeva does not show an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion with the aid of an Inventor's Declaration. See response to declaration above. Also, Sachdeva teaches the same material and anneal conditions as the present invention, so it would display similar physical properties such as the amount of permanent deformation. This is also considered a results effective variable as rejected above.

Conclusion

14. 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 M. 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, the examiner's supervisor, Cris Rodriguez can be reached on (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.

/MMN/

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

Notice of References Cited	Application/Control No. 11/628,933	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner Matthew M. Nelson	Art Unit 3732	Page 1 of 1

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-5,775,902 A	07-1998	Matsutani et al.	433/102
*	D	US-6,206,695 B1	03-2001	Wong et al.	433/102
*	E	US-6,375,458 B1	04-2002	Moorleghem et al.	433/2
*	F	US-6,431,863 B1	08-2002	Sachdeva et al.	433/102
*	G	US-6,428,634 B1	08-2002	Besselink et al.	148/421
*	H	US-2004/0121283 A1	06-2004	Mason, Robert M.	433/102
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	Matthew M Nelson	3732

SEARCHED

Class	Subclass	Date	Examiner
433	102, 224	4/29/2008	MMN
29	896.1	4/29/2008	MMN
433	102, 224	10/21/2008	MMN
29	896.1	10/21/2008	MMN
433	102, 224	2/24/2009	MMN
29	896.1	2/24/2009	MMN
433,29	Updated search	8/3/2009	MMN
433, 29	Updated search	12/31/2009	MMN
433, 29	Updated	3/22/2010	MMN

SEARCH NOTES

Search Notes	Date	Examiner
Search received from John Wilson for Class/Subclass 433/102,224 & 29/896.1	4/28/2008	MMN
See EAST search history	4/29/2008	MMN
Updated EAST search	10/21/2008	MMN
Updated EAST search	2/24/2009	MMN
Updated EAST search history	8/3/2009	MMN
Updated EAST search history	12/31/2009	MMN
Updated EAST search	3/22/2010	MMN

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	Matthew M Nelson	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	04/29/2008	10/21/2008	02/24/2009	08/03/2009	12/31/2009	03/22/2010			
	1	✓	✓	✓	✓	✓	✓			
	2	✓	✓	✓	✓	✓	✓			
	3	✓	-	-	-	-	-			
	4	✓	✓	✓	✓	✓	✓			
	5	✓	✓	✓	✓	✓	✓			
	6	✓	✓	✓	✓	✓	✓			
	7	✓	✓	✓	✓	✓	✓			
	8	✓	✓	✓	✓	✓	✓			
	9	✓	✓	✓	✓	✓	✓			
	10	✓	✓	✓	✓	✓	✓			
	11	✓	✓	✓	✓	✓	✓			
	12	✓	✓	✓	✓	✓	✓			
	13	✓	✓	✓	✓	✓	✓			
	14	✓	✓	✓	✓	✓	✓			
	15	✓	✓	✓	✓	✓	✓			
	16	✓	-	-	-	-	-			
	17	✓	-	-	-	-	-			
	18	✓	-	-	-	-	-			
	19	✓	-	-	-	-	-			
	20	✓	✓	✓	✓	✓	✓			
	21			✓	✓	✓	✓			
	22						✓			
	23						✓			
	24						✓			
	25						✓			

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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

EAST Search History (Interference)

< This search history is empty>

3/22/2010 1:00:52 PM
C:\ Documents and Settings\ mnelson3\ My Documents\ EAST\ Workspaces\ 11628933 Dental Instruments Comprising Titanium.wsp

PTO/SB/08a (03-09)
Approved for use through 03/31/2009. 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	11628933
	Filing Date	2006-12-07
	First Named Inventor	Neill H. Luebke
	Art Unit	3732
	Examiner Name	Matthew M. Nelson
	Attorney Docket Number	115207.00002

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7175655	B1	2007-02-13	Molaci	
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U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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

Receipt date: 02/15/2010	Application Number	11628933
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2006-12-07
	First Named Inventor	Neill H. Luebke
	Art Unit	3732
	Examiner Name	Matthew M. Nelson
	Attorney Docket Number	115207.00002

	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/Matthew Nelson/	Date Considered	03/22/2010

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

Date: June 23, 2010

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Confirmation No.:	9736
Art Unit:	3732
Examiner:	Matthew M. Nelson

RESPONSE TO FINAL OFFICE ACTION

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

Sir:

This is in response to the Non-Final Office Action mailed on March 26, 2010.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 8 of this paper.

Amendments To The Claims

1. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being in accordance with ISO Standard 3630-1,

wherein the shank comprises a titanium alloy, and

wherein the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

wherein the heat-treated instrument has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

2. (Original) The instrument of claim 1 wherein:

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

3. (Cancelled)

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

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

5. (Previously Presented) The instrument of claim 1 wherein:

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

6. (Original) The instrument of claim 1 wherein:

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

7. (Original) The instrument of claim 1 wherein:

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

8. (Previously Presented) The instrument of claim 1 wherein:

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

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

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

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

9. (Previously Presented) The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

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

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

the cutting edge is formed by helical flutes in the shank.

11. (Cancelled)

12. (Original) The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. (Previously Presented) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being in accordance with ISO Standard 3630-1,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the instrument is prepared by heat-treating the instrument at a temperature from 475°C to 525°C in an atmosphere consisting essentially of a gas unreactive with the shank, and

wherein the heat-treated instrument has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

14. (Original) The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 1.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 13.

21. (Previously Presented) The instrument of claim 1 wherein:

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

22. (Cancelled)

23. (Previously Presented) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

wherein the heat-treated instrument has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

24. (Previously Presented) The instrument of claim 23 wherein:

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

25. (Previously Presented) The instrument of claim 23 wherein:

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

REMARKS

Claim Amendments

Claim 1 has been amended to include all of the elements and limitations of previous claim 11. Previous claim 11 has been cancelled.

Claim 13 has been amended to include all of the elements and limitations of previous claim 22. Previous claim 22 has been cancelled.

Claim Rejections - 35 USC § 103(a)

Claims 1-2, 4-15, and 20-25 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,431,863 to Sachdeva *et al*. (Sachdeva) in view of U.S. Patent No. 6,431,863 to Wong *et al*. ("Wong").

The Office Action states that

> "claims 1-2, 4-5, 8-9, 13, 21, 23-25 are product-by-process claims, and therefore the process has not been given patentable weight. … The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)."

However, this reasoning from *In re Thorpe* is not without limits. In particular, when the process steps confer a structure or characteristic of the product which distinguishes it from products made by other processes, the process steps should be considered. *In re Garnero*, 412 F.2d 276, 279 (CCPA 1979).

In fact, the Board Of Patent Appeals and Interferences ("Board") has used this reasoning in the past year. For example, in *Ex parte Gist*, the Board stated "[t]he patentability of a product is based on the product itself unless the process steps confer a structure or characteristic which distinguishes it from products made by other

processes." *Ex parte Gist*, Appeal 2008-6122, Technology Center 3700, March 30, 2009, page 9, (underlining added). See, also, *Ex parte Agrawal*, Appeal 2009-1014, Technology Center 3700, March 23, 2009, page 10, where it states "[t]he patentability of a product in a product-by-process claim is based on the patentability of the product itself even though the process by which the product is processed may differ from the prior art. But, the process steps should be considered if the steps confer a structure or characteristic of the product which distinguishes it from products made by other processes" (underlining added).

Therefore, the Applicant wishes to provide further evidence that the process limitation in claim 1 (i.e., the instrument is prepared by heat-treating the instrument for a time period at a single temperature … wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy") and the process limitation in claim 13 ("the instrument is prepared by heat-treating the instrument at a temperature from 475°C to 525°C") and the process limitation in claim 23 ("the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank, wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy) confer a distinguishing characteristic over the product of Sachdeva.

Item 6 of the Office Action concedes that "Sachdeva fails to show wherein the shank has … an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion…". However, Item 8 of the Office Action then argues that

> It would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva/Wong's deformation of 10 degrees after a 45 degree torque in order to provide desired flexibility since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955) (MPEP 2144.05 11). The resulting flexibility and modulus of elasticity are recognized as results effective variables by Sachdeva in col. 3, line 30-56 and col. 4, line 23-30.

Independent claims 1, 13 and 23 now all require that " the heat-treated instrument has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion". It is respectfully submitted that the materials of Sachdeva do not undergo permanent deformation as recited in independent claims 1, 13 and 23.

First, Applicant attaches as Exhibit A a definition of Flexibility and Elasticity in order to show how one in the dental field would understand these terms. Note from this excerpt from the U.S. Army course that "[f]lexibility is the characteristic of a metal, which allows it to deform temporarily" and the term "elasticity of a metal is used when it returns to its original shape when the load or force is removed". (Underlining added.) Stated in a different way, flexibility and elasticity do not connote permanent deformation (as recited in independent claims 1, 13 and 23).

Superelastic alloys belong to the larger family of shape memory alloys. When mechanically loaded, a superelastic alloy deforms reversibly to very high strains - up to 10% - by the creation of a stress-induced phase. When the load is removed, the new phase becomes unstable and the material regains its original shape. Unlike shape-memory alloys, no change in temperature is needed for the alloy to recover its initial shape.

Nickel Titanium is an example of an alloy exhibiting superelasticity. Superelastic devices take advantage of their large, reversible deformation and include antennas,

eyeglass frames, and biomedical stents. Pseudoelasticity, sometimes called superelasticity, is an elastic (reversible) response to an applied stress, caused by a phase transformation between the austenitic and martensitic phases of a crystal. It is exhibited in Shape memory alloys. Pseudoelasticity is from the reversible motion of domain boundaries during the phase transformation, rather than just bond stretching or the introduction of defects in the crystal lattice (thus it is not true superelasticity but rather pseudoelasticity). Even if the domain boundaries do become pinned, they may be reversed through heating. Thus, a pseudoelastic material may return to its previous shape (hence, shape memory) after the removal of even relatively high applied strains. One special case of pseudoelasticity is called the Bain Correspondence. This involves the austenite/martensite phase transformation between a face centered crystal lattice and a body centered tetragonal crystal structure.

Second, attention is directed at Figure 6 of Sachdeva below,

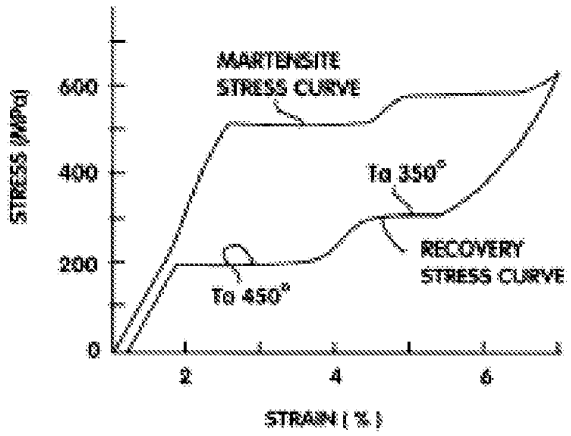


FIG. 6

Note in Figure 6 of Sachdeva how the Sachdeva wire material has a "recovery" curve. This means that the Sachdeva wire material is deforming temporarily or returning to its original shape as in the definitions of flexibility and elasticity in Applicant's Exhibit A.

Sachdeva does not undergo plastic deformation as recited in independent claims 1, 13 and 23. In contrast, the heat-treated file as recited in independent claims 1, 13 and 23 has lost recovery and remains bent which is referenced as the angle greater than 10 degrees of permanent deformation in claims 1, 13 and 23.

In order to even further demonstrate that the dental materials of Sachdeva do not undergo plastic deformation, attention is directed the comparison below of Figure 6 of Sachdeva (top) and Figure 1 of U.S. Patent No. 7,175,655 to Molaci (bottom). Molaci was previously submitted in an Information Disclosure Statement and was considered by the Patent Office. The Sachdeva and Molaci curves as shown together on the next page are nearly identical except for the extra plateau in Figure 6 of Sachdeva.

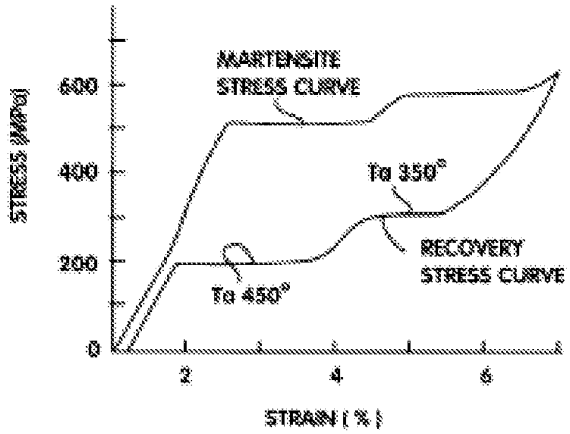


FIG. 6

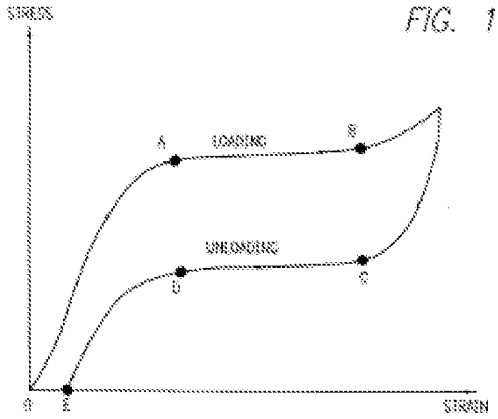


FIG. 1

The language at column 5, line 43 to column 6, line 23 of Molaci describes the strain-stress curve for a superelastic material shown in Figure 1 of Molaci. In particular, it is noted that at column 6, lines 8-11 of Molaci that a "continuous application of stress leads to elastic deformation, represented by an upward slope, then plastic deformation, which is not shown in FIG. 1, in the stress-induced martensite". (Underlining added.) Thus, the Sachdeva wire material, as demonstrated by Figure 6 of Sachdeva and by the specification and (nearly identical) Figure 1 of Molaci, only shows elastic deformation,

that is, the material "returns to its original shape" as in the definitions of flexibility and elasticity in Applicant's Exhibit A.

In summary, one skilled in the art when reviewing Figure 6 of Sachdeva in view of the specification and Figure 1 of Molaci would understand that the Sachdeva wire material would not undergo an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion as recited in independent claims 1, 13 and 23. Furthermore, Wong does not make up for this deficiency in Sachdeva.

It is well settled that in order to establish a prima facie case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Taken together, Sachdeva and Wong fail to teach or suggest an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion as recited in independent claims 1, 13 and 23. Accordingly it is respectfully submitted that amended independent claim 1 (and claims 2, 4-10, 12, 15 and 21 that depend thereon) and amended independent claim 13 (and claims 14 and 20 that depend thereon) and independent claim 23 (and claims 24 and 25 that depend thereon) are patentable over Sachdeva and Wong.

The Office Action contends in Item 6 that it would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva/Wong's deformation of 10 degrees after a 45 degree torque in order to provide desired flexibility because the flexibility and modulus of elasticity are recognized as results effective variables by Sachdeva in col. 3, line 30-56 and col. 4, line 23-30. The Applicant respectfully disagrees. Column 3, lines 30-56 of Sachdeva describe controlling elasticity and flexibility by adjusting the amorphous content. Column 4, lines 23-25 of

Sachdeva describe controlling the flexibility and stiffness by "selected heat treatment of specific areas of the working shaft". Column 4, lines 25-29 of Sachdeva postulate what heat-treating will do to the wire but offers no supporting data or evidence for these assertions. As explained above, flexibility and elasticity relate to materials that deform temporarily and return to shape. The Sachdeva wire material is elastic. Where in Sachdeva does it mention that permanent deformation can be controlled? Nothing in Sachdeva indicates any " result effective variable" that controls permanent (plastic) deformation.

Furthermore, column 4, lines 41-44 indicate that Sachdeva is heating a wire. Applicant attaches Exhibit B which is the cover page of U.S. Patent No. 5,527,205 to Heath ("Heath"). The Abstract of Heath describes that endodontic instruments such as Sachdeva are made by grinding a wire. One skilled in the art would know that if you heated a wire as in Figure 4 and 5 of Sachdeva (see, also, column 4, lines 41-43 of Sachdeva describing the use of a “NiTi wire of 0.018" diameter”) then you could not make an endodontic instrument because of the low force it takes to create shear (MPa). The wire becomes a "noodle" and would not hold up to grinding as described in the Heath patent. The claimed invention includes post treatment of an endodontic file and no other prior art addresses the post treatment of an instrument.

It is well settled that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification, *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Any attempted modification of Sachdeva to include the permanent deformation as recited in independent claims 1, 13 and 23 would render the

device of Sachdeva inoperable for its intended purpose. In other words, if Sachdeva's wire needs to be ground to create an instrument, why would one create a wire that can undergo permanent deformation that makes grinding impossible?

In addition, Item 7 of the Office Action states that "Wong teaches a dental cutting instrument in accordance with IS0 Standard 3630-1 and therefore … it would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva's instrument by incorporating the ISO Standards of Wong". Looking at Wong, it can be seen that Wong is actually teaching an alternative to ISO. For example, column 7, lines 47-50 of Wong state that it "is one object of this invention to provide a system by which an intermediate file can be identified by providing a combination of standard ISO colors on non-standard intermediate size files" (Underlining added.) See also, claim 1 of Wong which recites "a second handle portion having a color other than a standard ISO color". (Underlining added.)

ISO has never discussed nor adopted a split handle color for size and taper. Some thought has been given to split colors for "half sizes" but not to include taper. In ISO 3630-1 there are standard, non-standard, taper sized, shape sized, non-tapered, non-uniform tapered size and flexible instrument designations. While the color coding remains the same, the handle of the instrument is reserved for the size and the shank of the instrument for the taper OR a numbering system of "xxx" for size and "yy" for a taper designation. As manufactured today, no manufacturer utilizes the handle (plastic or rotary) for taper.

The CAFC has held that "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be … led in a direction divergent

from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). The Applicant submits that Wong teaches away from using an instrument in accordance with ISO Standard 3630-1 as recited in independent claims 1, 13 and 23.

It is also noted that independent claims 1, 13 and 23 require heat-treating an instrument in accordance with ISO Standard 3630-1. Wong mentions at column 1, lines 50-53 that ISO files include cutting edges. However, column 4, lines 41-44 of Sachdeva indicate that Figure 4 and 5 of Sachdeva is heating a wire. This is further evidence that Sachdeva is not heat-treating an instrument in accordance with ISO Standard 3630-1 as recited in independent claims 1, 13 and 23.

Item 9 of the Office Action objected to the declaration under 37 C.F.R. 1.132 filed 2/15/2010. The Applicant wishes to point put that the Inventor's Declaration was submitted to contrast an instrument that undergoes permanent deformation as recited in independent claims 1, 13 and 23 with a superelastic wire material as cited in Sachdeva.

In summary, it is submitted that amended independent claim 1 (and claims 2, 4-10, 12, 15 and 21 that depend thereon) and amended independent claim 13 (and claims 14 and 22 that depend thereon) and independent claim 23 (and claims 24-25 that depend thereon) are patentable over Sachdeva and Wong.

Conclusion

Claims 1-2, 4-10, 12-15, 20 and 22-25 are believed to be in condition for allowance. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

No fees are believed to be needed for this amendment. However, if fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: June 23, 2010

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

10681832

Electronic Acknowledgement Receipt

EFS ID:	7876966
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	23-JUN-2010
Filing Date:	07-DEC-2006
Time Stamp:	15:43:16
Application Type:	U.S. National Stage under 35 USC 371

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	Applicant Arguments/Remarks Made in an Amendment	luebke_2_exhibit_a.pdf	100334 be577463f08de4c4aa0a195a2b993fbfbf0bdbc8	no	2

Warnings:	
Information:	

2	Applicant Arguments/Remarks Made in an Amendment	luebke_2_exhibit_b.pdf	52592 031cd6d7bc5a32c5c8ba1bce7b1035e68806dbc5	no	1
Warnings:					
Information:					
3		luebke_2_response.pdf	107896 6e6734a1804abc0904206fcd920c6fe4041afd6e	yes	18

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment After Final	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	18

Warnings:	
Information:	
Total Files Size (in bytes):	260822

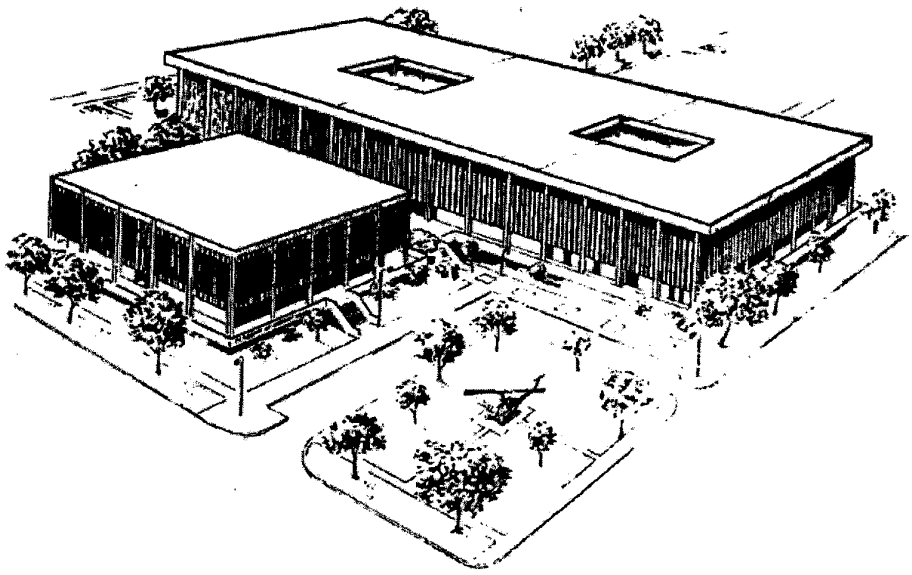
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<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.

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



Dental Materials

SUBCOURSE MD0502 EDITION 100

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

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

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

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

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

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

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

1-4. METALLURGICAL TERMS

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

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

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

US005527205A

United States Patent [19]

Heath et al.

[11] Patent Number: 5,527,205

[45] Date of Patent: Jun. 18, 1996

Applicant's Exhibit B

[54] **METHOD OF FABRICATING AN ENDODONTIC INSTRUMENT**

[75] Inventors: **Derek E. Heath; Jerry A. Mooneyhan**, both of Johnson City, Tenn.

[73] Assignee: **Tulsa Dental Products, L.L.C.**, Tulsa, Okla.

[21] Appl. No.: **76,367**

[22] Filed: **Jun. 14, 1993**

Related U.S. Application Data

[63] Continuation of Ser. No. 787,945, Nov. 5, 1991, abandoned.

[51] **Int. Cl.**[6] **B24B 19/04**

[52] **U.S. Cl.** **451/48**; 451/48

[58] **Field of Search** ..... 51/288, 326, 327, 51/95 LH, 74 R, 92 ND, 289 R, 103 TF

[56] **References Cited**

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4,611,509	9/1986	Matsutani	51/288
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OTHER PUBLICATIONS

Journal of Endodontics, "An Initial Investigation of the Bending and Torsional Properties of Nitinol Root Canal Files", Jul. 1988, vol. 14, No. 7, pp. 346–351.

Wire Journal International, "Superelastic Ni–Ti Wire", Mar. 1991, pp. 45–50.

RMI Company, Niles, Ohio, "RMI Titanium", 27 pages.

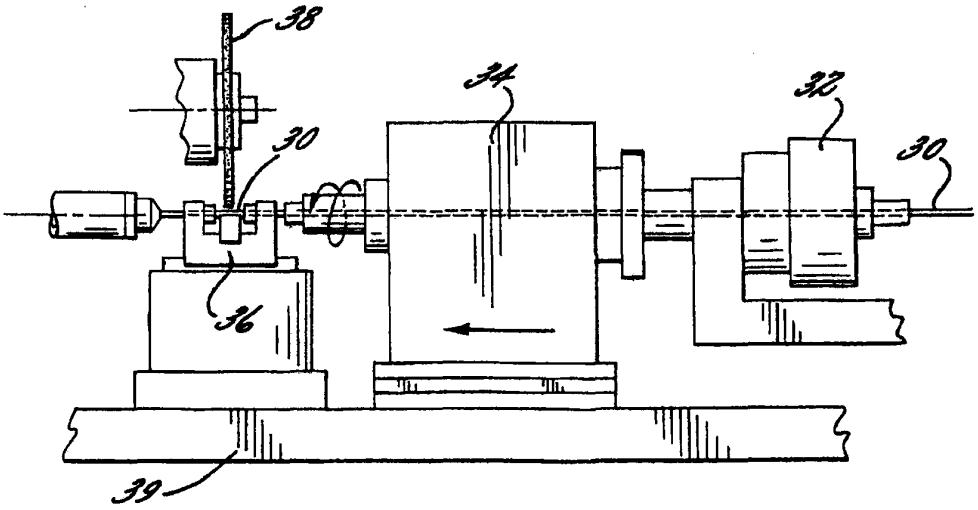
Primary Examiner—Robert A. Rose

Attorney, Agent, or Firm—Bell, Seltzer, Park & Gibson

[57] **ABSTRACT**

A method of fabricating an endodontic instrument by a machining operation is disclosed, and wherein a wire-like rod composed of a titanium alloy is advanced past a rotating grinding wheel at a relatively slow feed rate, with a sufficient depth of cut to remove all of the material on a given surface without over grinding a previously ground surface, and with the grinding wheel rotating at a relatively slow surface speed. The disclosed method is able to efficiently produce endodontic instruments having a high degree of flexibility, high resistance to torsional breakage, and with sharp cutting edges along the working length.

10 Claims, 3 Drawing Sheets



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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/628,933	12/07/2006	

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT 06/23/2010

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 18	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/NINA RATANAVONG/

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.

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 07/14/2010

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
07/14/2010	ELECTRONIC

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

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

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

pat-dept@quarles.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 11/628,933	**Applicant(s)** LUEBKE, NEILL HAMILTON	
	Examiner Matthew M. Nelson	**Art Unit** 3732	

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

THE REPLY FILED 23 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. 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. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* 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.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. 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) 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 amendment(s) 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.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,2,4-15 and 20-25*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☒ The affidavit or other evidence filed after the date of filing a 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 a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

/Matthew M Nelson/
Examiner, Art Unit 3732

Continuation of 3. NOTE: The scope of the claims have changed with the amendment. The method and aparatus claims were previously not specific to a heat-treated instrument having an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues that no plastic deformation is shown in Sachdeva, however Fig. 6 clearly shows some amount of plastic deformation. If it was only elastic deformation, both the beginning and end of the graph would share the same line, however there are two parallel lines that end at different amounts of strain and therefore plastic deformation is exhibited. By adjusting the flexibility or elasticity of the material, the point at which permanent deformation is reached would also be altered.
Applicant argues that Sachdeva only discloses wires, however Sachdeva is directed at a heat-treated endodontic instrument as detailed in at least col. 2, line 7.
Applicant argues that Wong teaches away from using an instrument in accordance with ISO Standard 3630-1, however the cited portion of Wong is actually referring to the background of the invention and the desirability of ISO Standards and therefore cannot be said to teach away.
In regards to the product by process steps, Sachdeva shows similar material composition and procedure as the claimed language, as previously rejected, and therefore would lead to a similar product.

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

Date: June 23, 2010 /Richard T. Roche/
Richard T. Roche, Reg. No. 38,599

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Confirmation No.:	9736
Art Unit:	3732
Examiner:	Matthew M. Nelson

RESPONSE TO FINAL OFFICE ACTION

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

Sir:

This is in response to the Non-Final Office Action mailed on March 26, 2010.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 8 of this paper.

DO NOT ENTER: /M.N./

07/07/2010

PTO/SB/30EFS (03-09)
Approved for use through 04/30/2009. 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	11/628,933	Filing Date	2006-12-07	Docket Number (if applicable)	115207.00002	Art Unit	3732
First Named Inventor	Neill Hamilton Luebke			Examiner Name	Matthew M. Nelson		

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

SUBMISSION REQUIRED UNDER 37 CFR 1.114

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

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

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

☒ Enclosed

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

MISCELLANEOUS

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

☐ Other _____

FEES

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

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

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (03-09)
Approved for use through 04/30/2009. 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)	2010-09-02
Name	Richard T. Roche	Registration Number	38599

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

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

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.

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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.

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

Date: September 2, 2010

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

IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Confirmation No.:	9736
Art Unit:	3732
Examiner:	Matthew M. Nelson

AMENDMENT ACCOMPANYING RCE

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

Sir:

This is in response to the Final Office Action mailed on March 26, 2010.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 8 of this paper.

Amendments To The Claims

1. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being in accordance with ISO Standard 3630-1,

wherein the shank comprises a titanium alloy, and

wherein the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

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

2. (Original) The instrument of claim 1 wherein:

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

3. (Cancelled)

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

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

5. (Previously Presented) The instrument of claim 1 wherein:

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

6. (Original) The instrument of claim 1 wherein:

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

7. (Original) The instrument of claim 1 wherein:

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

8. (Previously Presented) The instrument of claim 1 wherein:

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

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

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

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

9. (Previously Presented) The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

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

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

the cutting edge is formed by helical flutes in the shank.

11. (Cancelled)

12. (Original) The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being in accordance with ISO Standard 3630-1,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the instrument is prepared by heat-treating the instrument at a temperature from 475°C to 525°C in an atmosphere consisting essentially of a gas unreactive with the shank, and

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

14. (Original) The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 1.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 13.

21. (Previously Presented) The instrument of claim 1 wherein:

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

22. (Cancelled)

23. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

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

24. (Previously Presented) The instrument of claim 23 wherein:

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

25. (Previously Presented) The instrument of claim 23 wherein:

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

REMARKS

Claim Amendments

Claim 1 has been amended to include all of the elements and limitations of previous claim 11. Previous claim 11 has been cancelled. Claim 1 also now recites that the deformation is tested in accordance with ISO Standard 3630-1 as described at page 12, lines 16-20 of the specification.

Claim 13 has been amended to include all of the elements and limitations of previous claim 22. Previous claim 22 has been cancelled. Claim 13 also now recites that the deformation is tested in accordance with ISO Standard 3630-1 as described at page 12, lines 16-20 of the specification.

Claim 23 has been amended to recite that the deformation is tested in accordance with ISO Standard 3630-1 as described at page 12, lines 16-20 of the specification.

Claim Rejections - 35 USC § 103(a)

Claims 1-2, 4-15, and 20-25 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,431,863 to Sachdeva *et al.* (Sachdeva) in view of U.S. Patent No. 6,206,695 to Wong *et al.* ("Wong").

The Office Action states that

> "claims 1-2, 4-5, 8-9, 13, 21, 23-25 are product-by-process claims, and therefore the process has not been given patentable weight. ... The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)."

However, this reasoning from *In re Thorpe* is not without limits. In particular, when the process steps confer a structure or characteristic of the product, which distinguishes it from products made by other processes, the process steps should be considered. *In re Garnero*, 412 F.2d 276, 279 (CCPA 1979).

In fact, the Board Of Patent Appeals and Interferences ("Board") has used this reasoning in the past year. For example, in *Ex parte Gist*, the Board stated "[t]he patentability of a product is based on the product itself unless the process steps confer a structure or characteristic which distinguishes it from products made by other processes." *Ex parte Gist*, Appeal 2008-6122, Technology Center 3700, March 30, 2009, page 9, (underlining added). See, also, *Ex parte Agrawal*, Appeal 2009-1014, Technology Center 3700, March 23, 2009, page 10, where it states "[t]he patentability of a product in a product-by-process claim is based on the patentability of the product itself even though the process by which the product is processed may differ from the prior art. But, the process steps should be considered if the steps confer a structure or characteristic of the product which distinguishes it from products made by other processes" (underlining added).

Therefore, the Applicant wishes to provide further evidence that the process limitation in claim 1 (i.e., the instrument is prepared by heat-treating the instrument for a time period at a single temperature ... wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy") and the process limitation in claim 13 ("the instrument is prepared by heat-treating the instrument at a temperature from 475°C to 525°C") and the process limitation in claim 23 ("the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere

consisting essentially of a gas unreactive with the shank, wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy) confer a distinguishing characteristic over the products of Sachdeva. The Advisory Action of July 14 alleges that the process steps of Sachdeva "would lead to a similar product". In rebuttal, the Applicant submits herewith evidence showing that the products of Sachdeva and the claimed invention are distinguished by structure and the products are different. *See*, *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983).

Attached for consideration is a Declaration of David W. Berzins. In the Declaration, Dr. Berzins concludes that the nickel-titanium wire contained in U.S. Patent No. 6,431,863 to Sachdeva et al. and the endodontic instruments provided by Applicant Luebke differ in terms of what phases (austenite or martensite) are stable at temperatures relevant to their intended purpose (dentistry) and what induces the phase transformation (stress or temperature). Note in Item 7 of the Declaration how the Luebke files analyzed by Dr. Berzins are commensurate in scope with amended independent claims 1, 13 and 23. Item 9 of the Declaration states that the endodontic instruments of Dr. Luebke deform to an appreciable extent and remain deformed. (underlining added)

The Declaration points out that the superelastic nickel-titanium wire of Sachdeva undergoes "0.4% permanent deformation" after release of stress. This is well below the value recited in amended independent claims 1, 13 and 23. Furthermore, the testing procedure recited in amended independent claims 1, 13 and 23 (ISO Standard 3630-1) uses room temperature testing and the Declaration provides an analysis at this temperature. Note in Item 10 the far different Force vs. Deflection curves produced by a

superelastic product as in Sachdeva and a shape memory product such as the invention of amended independent claims 1, 13 and 23.

Item 6 of the Office Action concedes that "Sachdeva fails to show wherein the shank has ... an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion...". However, Item 8 of the Office Action then argues that

> It would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva/Wong's deformation of 10 degrees after a 45 degree torque in order to provide desired flexibility since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955) (MPEP 2144.05 11). The resulting flexibility and modulus of elasticity are recognized as results effective variables by Sachdeva in col. 3, line 30-56 and col. 4, line 23-30.

The Office Action contends in Item 8 that it would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva/Wong's deformation of 10 degrees after a 45 degree torque in order to provide desired flexibility because the flexibility and modulus of elasticity are recognized as results effective variables by Sachdeva in col. 3, line 30-56 and col. 4, line 23-30. The Applicant respectfully disagrees. Column 3, lines 30-56 of Sachdeva describe controlling elasticity and flexibility by adjusting the amorphous content. Column 4, lines 23-30 of Sachdeva postulate controlling the flexibility and stiffness by "selected heat treatment of specific areas of the working shaft" but offers no supporting data or evidence for these assertions. In addition, one essential component of the heat treating is missing and that is the length of time for the heat treatment. If one only heats the specific area to the prescribed anneal temperature (Tσ) then it would be obvious to one having ordinary skill in the art that the structure or the characteristic of the nickel-titanium wire would not change. Sachdeva's flexibility and stiffness data are found in Figures 4, 5 and 6. For

Figures 4 and 5, the data is based on Column 4 lines 41-43 which state "all data are for a NiTi wire of 0.018" diameter". In Column 4, lines 61-64, "(t)he Figure 6 data is (sic) for a Ni-Ti wire (50.6% Ni) of 0.018" diameter". Figure 6 can not be replicated unless one presumes an arbitrary time parameter for the heat treatment. As explained above, flexibility and elasticity relate to materials that deform temporarily and return to shape. The Sachdeva nickel-titanium wire material remains elastic, in fact, superelastic because one must assume the heat treatment only heats the wire to the anneal temperature (Tσ) with no duration of time.

Independent claims 1, 13 and 23 now all require that "the heat-treated instrument has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion tested in accordance with ISO Standard 3630-1". It is respectfully submitted that the materials (superelastic nickel-titanium wire) of Sachdeva do not undergo deformation as recited in independent claims 1, 13 and 23. In this regard, the Declaration points out that the nickel-titanium wire product shown in Figure 6 of Sachdeva undergoes "0.4% permanent deformation" after release of stress. Furthermore, Wong does not make up for this deficiency in Sachdeva with respect to the deformation. Where in Sachdeva does it mention that permanent deformation can be controlled? Nothing in Sachdeva indicates any "result effective variable" that controls permanent deformation but rather has elastic deformation that is controlled by a stress phase transformation and not a temperature phase transformation. In contrast, the Declaration states that the endodontic instruments of Dr. Luebke deform and remain deformed until there is a temperature phase transformation.

Furthermore, column 4, lines 41-43 indicate that Sachdeva is heating a nickel-titanium wire. Applicant attaches Exhibit B, which is the cover page of U.S. Patent No. 5,527,205 to Heath ("Heath"). The Abstract of Heath describes the manufacturing process by which nickel-titanium endodontic instruments are made by grinding a wire. The Office Action in Item 8 states "It would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva/Wong's deformation of 10 degrees after a 45 degree torque in order to provide desired flexibility since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art." However, if one heated a nickel-titanium wire such as Sachdeva shows in Figure 4 and 5 (see, also, column 4, lines 41-43 of Sachdeva describing the use of a "NiTi wire of 0.018" diameter") to create a nickel-titanium wire that could undergo a "deformation of 10 degrees after a 45 degree torque" as noted in Item 8 of the Office Action, the structure would be altered to the extent that one skilled in the art could not make an endodontic instrument because the grinding forces would deflect and deform the wire instead of cutting/removing material as intended. The wire would become a "noodle" and would not "remove all of the material on a given surface without over grinding a previously ground surface" as described in the Heath patent because the wire would deform away from the grinding wheel. In contrast to Item 8 of the Office Action, Sachdeva's wires remain superelastic as shown in the Figures and would be able to be ground to make endodontic instruments. However, if a wire has the property to undergo "deformation of 10 degrees after a 45 degree torque" that the heat treatment of independent claims 1, 13 and 23 impart to the wire, then the wire would not be able to be ground because the wire would deflect and deform away from the grinding wheel.

And therein lies the difference between the Sachdeva patent and amended independent claims 1, 13 and 23 of the present application.

In addition, the Sachdeva patent contains neither test data nor evidence of fabricating an instrument but only test data for superelastic nickel-titanium wires that is incomplete and would be impossible to replicate unless one makes some assumptions concerning the time parameter for the "selective heat treatments of the working shaft". Wong does not utilize a wire nor discuss deformation with his instrument modifications. The claimed invention embodies the post treatment by both time and temperature of a manufactured endodontic instrument and no other prior art addresses the post treatment of a manufactured instrument.

It is well settled that in order to establish a prima facie case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Taken together, Sachdeva and Wong fail to teach or suggest an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion as recited in independent claims 1, 13 and 23. Accordingly, it is respectfully submitted that amended independent claim 1 (and claims 2, 4-10, 12, 15 and 21 that depend thereon) and amended independent claim 13 (and claims 14 and 20 that depend thereon) and independent claim 23 (and claims 24 and 25 that depend thereon) are patentable over Sachdeva and Wong.

It is well settled that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification, *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Any attempted modification of Sachdeva's nickel-titanium

wire to include the permanent deformation of 10° as recited in independent claims 1, 13 and 23 would render manufacturing an instrument inoperable for its intended purpose. In other words, Sachdeva's nickel-titanium wire needs to be ground to create an instrument. Why would Sachdeva create a heat-treated wire that could undergo 10° of permanent deformation that would make instrument fabrication impossible?

Item 10 in the Declaration reasserts what was shown in previous responses. In order to even further demonstrate that the nickel-titanium wire of Sachdeva does not undergo significant permanent deformation, attention is directed to the comparison below of Figure 6 of Sachdeva (top), Figure 1 of U.S. Patent No. 7,175,655 to Molaci (bottom) and the Figure in Item 10 of the Declaration. Molaci was previously submitted in an Information Disclosure Statement and was considered by the Patent Office. The Sachdeva and Molaci curves as shown together on the next page are nearly identical including some minor permanent deformation except for the "extra" plateau in Figure 6 of Sachdeva.

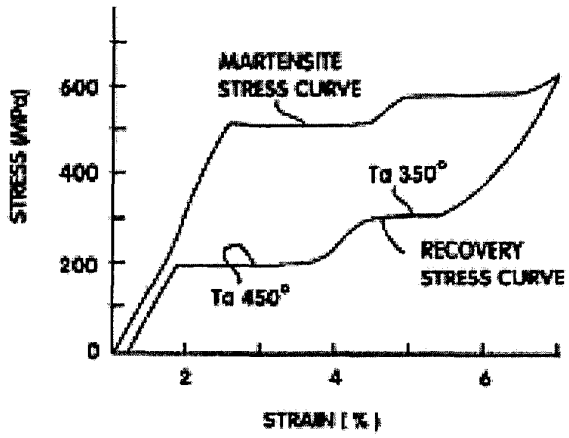

FIG. 6

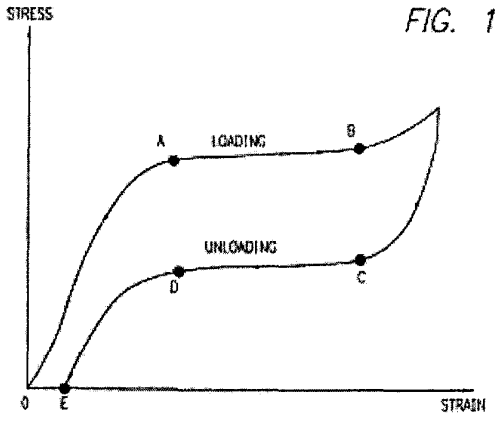

FIG. 1

The language at column 5, line 43 to column 6, line 23 of Molaci describes the strain-stress curve for a superelastic material shown in Figure 1 of Molaci. In particular, it is noted that at column 6, lines 8-11 of Molaci that a "continuous application of stress leads to elastic deformation, represented by an upward slope, then plastic deformation, which is not shown in FIG. 1, in the stress-induced martensite". (underlining added.) Thus, the Sachdeva nickel-titanium wire, as demonstrated by Figure 6 of Sachdeva and

by the specification and (nearly identical) Figure 1 of Molaci, shows elastic deformation, that is, the material "returns to its original shape" as in the definitions of flexibility and elasticity and only minor permanent deformation (0.4%). The Figure 6 curve is nearly identical to Figure 1 of Molaci and the superelastic curve of Item 10 of the Declaration. In the case of Figure 1 and Item 10 of the attached Declaration both of those samples had no heat treatment. (underlining added)

In addition, Item 7 of the Office Action states that "Wong teaches a dental cutting instrument in accordance with IS0 Standard 3630-1 and therefore ... it would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva's instrument by incorporating the ISO Standards of Wong". Looking at Wong, it can be seen that Wong is actually teaching an alternative to ISO 3630-1. For example, column 7, lines 47-50 of Wong state that it "is one object of this invention to provide a system by which an intermediate file can be identified by providing a combination of standard ISO colors on non-standard intermediate size files" (underlining added.) See also, claim 1 of Wong, which recites "a second handle portion having a color other than a standard ISO color". (underlining added.)

ISO has never discussed nor adopted a split handle color for size and taper. Some thought has been given to split colors for "half sizes" but not to include taper. In ISO 3630-1 there are standard, non-standard, taper sized, shape sized, non-tapered, non-uniform tapered size and flexible instrument designations. While the color coding remains the same, the color of the handle of the instrument is reserved for the size and the shank of the instrument for the taper OR a numbering system of "xxx" for size and

"yy" for a taper designation. As manufactured today, no manufacturer utilizes a handle color (plastic or rotary) for taper.

The CAFC has held that "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be ... led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). The Applicant submits that Wong teaches away from using an instrument in accordance with ISO Standard 3630-1 as recited in independent claims 1, 13 and 23.

It is also noted that independent claims 1, 13 and 23 require heat-treating an instrument in accordance with ISO Standard 3630-1. Wong mentions at column 1, lines 50-53 that ISO files include cutting edges. However, column 4, lines 41-43 of Sachdeva indicate that Figure 4 and 5 of Sachdeva is heating a "NiTi" wire. This is further evidence that Sachdeva is not heat-treating an instrument in accordance with ISO Standard 3630-1 as recited in independent claims 1, 13 and 23.

Item 9 of the Office Action objected to the declaration under 37 C.F.R. 1.132 filed 2/15/2010. The Applicant wishes to point out that the Inventor's Declaration was submitted to contrast an instrument that undergoes permanent deformation as recited in independent claims 1, 13 and 23 with a superelastic nickel-titanium wire material as cited in Sachdeva.

In summary, it is submitted that amended independent claim 1 (and claims 2, 4-10, 12, 15 and 21 that depend thereon) and amended independent claim 13 (and claims 14 and 22 that depend thereon) and independent claim 23 (and claims 24-25 that depend thereon) are patentable over Sachdeva and Wong.

Conclusion

Claims 1-2, 4-10, 12-15, 20 and 22-25 are believed to be in condition for allowance. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

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

Respectfully submitted,

Neill H. Luebke

Dated: September 2, 2010

By: Richard T. Roche

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11204005

US005527205A

United States Patent [19]

Heath et al.

[11] Patent Number: 5,527,205

[45] Date of Patent: Jun. 18, 1996

Applicant's Exhibit B

[54] **METHOD OF FABRICATING AN ENDODONTIC INSTRUMENT**

[75] Inventors: **Derek E. Heath; Jerry A. Mooneyhan**, both of Johnson City, Tenn.

[73] Assignee: **Tulsa Dental Products, L.L.C.**, Tulsa, Okla.

[21] Appl. No.: **76,367**

[22] Filed: **Jun. 14, 1993**

Related U.S. Application Data

[63] Continuation of Ser. No. 787,945, Nov. 5, 1991, abandoned.

[51] **Int. Cl.**[6] **B24B 19/04**

[52] **U.S. Cl.** **451/48**; 451/48

[58] **Field of Search** ..... 51/288, 326, 327, 51/95 LH, 74 R, 92 ND, 289 R, 103 TF

[56] **References Cited**

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Wire Journal International, "Superelastic Ni–Ti Wire", Mar. 1991, pp. 45–50.

RMI Company, Niles, Ohio, "RMI Titanium", 27 pages.

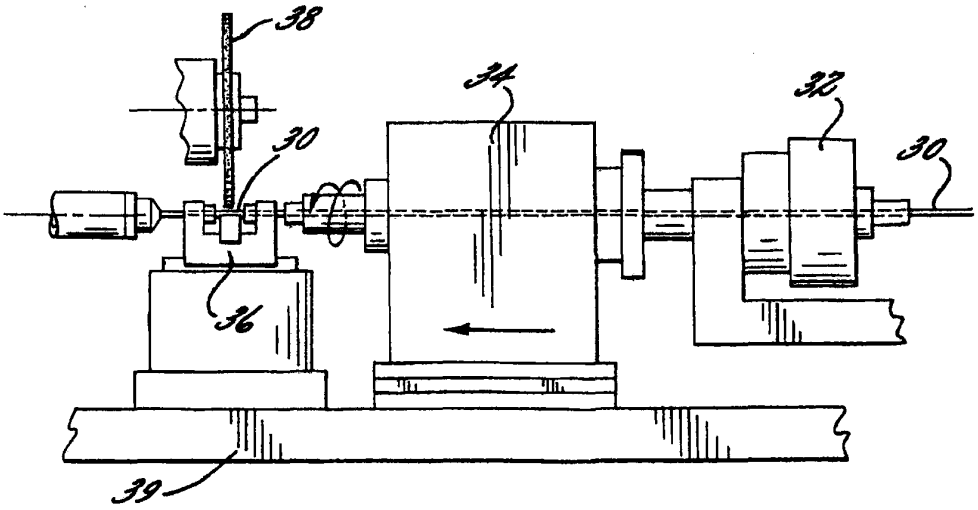
Primary Examiner—Robert A. Rose

Attorney, Agent, or Firm—Bell, Seltzer, Park & Gibson

[57] **ABSTRACT**

A method of fabricating an endodontic instrument by a machining operation is disclosed, and wherein a wire-like rod composed of a titanium alloy is advanced past a rotating grinding wheel at a relatively slow feed rate, with a sufficient depth of cut to remove all of the material on a given surface without over grinding a previously ground surface, and with the grinding wheel rotating at a relatively slow surface speed. The disclosed method is able to efficiently produce endodontic instruments having a high degree of flexibility, high resistance to torsional breakage, and with sharp cutting edges along the working length.

10 Claims, 3 Drawing Sheets



Docket No.: 115207.00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke

Application No.: 11/628,933

Filing Date: December 7, 2006

Title: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

Confirmation No.: 9736

Art Unit: 3732

Examiner: Matthew M. Nelson

DECLARATION UNDER 37 C.F.R. 1.132

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

Sir:

I, David W. Berzins, hereby declare as follows:

1. I am a tenured associate professor in the Marquette University School of Dentistry, Milwaukee, Wisconsin, USA.

2. I have a BS in Materials Science & Engineering from Case Western Reserve University and a PhD in Biomedical Engineering from Tulane University.

3. My research interests include nickel-titanium alloys.

4. I have co-authored the following publications related to nickel-titanium alloys:

(a) "Phase transformation changes in thermocycled nickel-titanium orthodontic wires", *Dental Materials*, vol. 26, no. 7, pp. 666–674, 2010; and

(b) "Influence of stress and phase on corrosion of a superelastic nickel-titanium orthodontic wire", *American Journal of Orthodontics and Dentofacial Orthopedics*, vol. 135, no. 6, pp. 764–770, 2009; and

(c) "Corrosion behavior of shape memory, superelastic, and nonsuperelastic nickel-titanium-based orthodontic wires at various temperatures", *Dental Materials*, vol. 24, no. 2, pp. 221–227, 2008; and

(d) "Thermal analysis of as-received and clinically retrieved copper-nickel-titanium orthodontic archwires", *Angle Orthodontist*, vol. 77, no. 3, pp. 499–503, 2007.

5. I have reviewed U.S. Patent No. 6,431,863 to Sachdeva *et al.*

6. I have reviewed U.S. Patent Application Publication No. 2008/0032260 which I understand is the publication of the above-referenced patent application to Dr. Neill H. Luebke.

7. Dr. Neill H. Luebke provided me with dental files. I was informed that these files were made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium. I was informed that these files are ISO size files and include an elongated shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. I was informed that these ISO size files were heat-treated in a furnace in an non-reactive atmosphere at 500°C for 75 minutes.

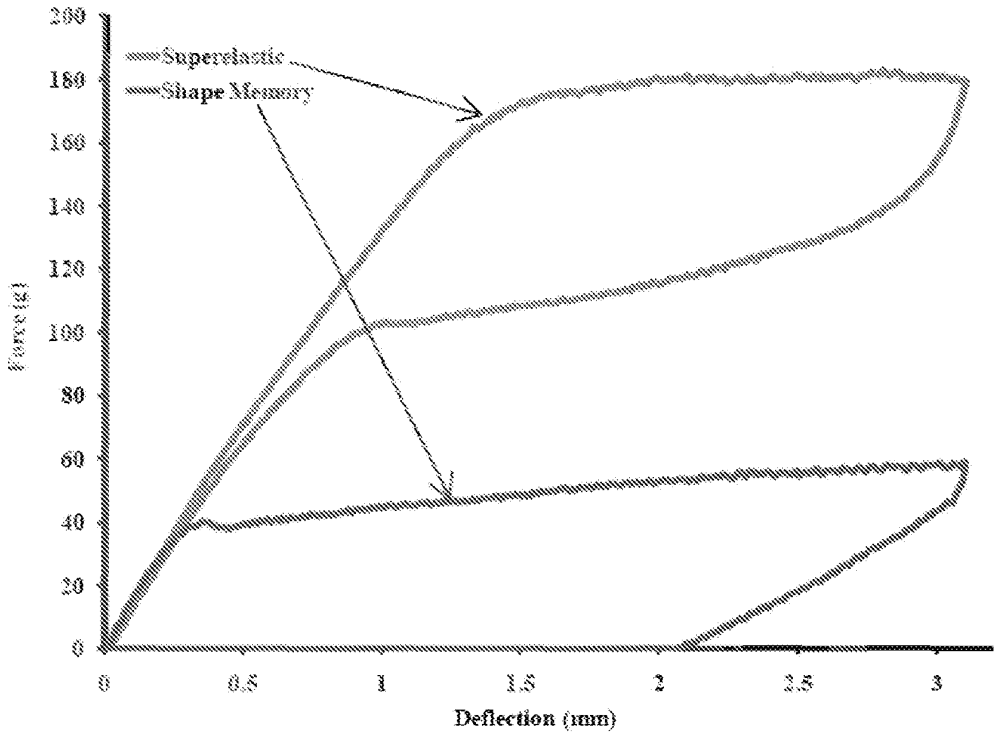
8. After review of U.S. Patent No. 6,431,863 to Sachdeva *et al.*, it is my belief that the nickel-titanium wire in U.S. Patent No. 6,431,863 is heat-treated at varied temperatures for unspecified times in such a way as to alter its critical stress for inducing martensite (σ_{MS}) and then the reverse transformation (σ_{RS}). Thus, the nickel-titanium wire in U.S. Patent No. 6,431,863 exists in the austenite phase and converts to martensite via application of stress. This is at both 25°C (as listed in Table 1 of U.S.

Patent No. 6,431,863) and at 37°C (as depicted in Figures 4 and 5 of U.S. Patent No. 6,431,863). Essentially, the nickel-titanium wire in U.S. Patent No. 6,431,863 is behaving as superelastic nickel-titanium undergoing a stress-induced phase transformation from austenite to martensite and returning back to austenite with the release of stress. As such, the elastic recovery (100% - permanent deformation) of the example in Figure 6 of U.S. Patent No. 6,431,863 is approximately 99.6% (100% - 0.4% permanent deformation).

9. As a result of the treatment of the endodontic instruments from Dr. Neill H. Luebke (i.e., ISO size files were heat-treated in a furnace in an non-reactive atmosphere at 500°C for 75 minutes), the Luebke files behave via a different mechanism. At room temperature (20-25°C), the endodontic instruments are primarily martensite in crystal structure. This was confirmed from differential scanning calorimetry (DSC) analysis which has shown the instruments to have austenite finish temperatures (A_f) greater than room temperature and thus greater than those in U.S. Patent No. 6,431,863. With application of stress, the endodontic instruments deform to an appreciable extent and remain deformed. Little to no stress-induced phase transformation occurs. Essentially, these endodontic instruments behave as shape-memory nickel-titanium with elastic recovery only afforded by a temperature-induced phase transformation from martensite to austenite.

10. For comparison, below are three-point bending curves of nickel-titanium wire behaving in a superelastic manner (stress-induced phase transformation from austenite to martensite, and reversed) and a shape-memory wire tested below its austenite finish temperature. The superelastic has nearly 100% recovery whereas the

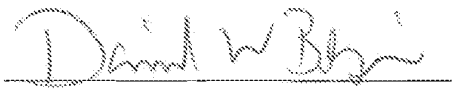
shape-memory wire shows deformation which is only recoverable with heating above its austenite finish temperature. The curves are analogous to the nickel-titanium wire contained in U.S. Patent No. 6,431,863 and the instruments in U.S. Patent Application Publication No. 2008/0032260, respectively. The superelastic bending curve is similar to the stress-strain curve in Figure 6 of U.S. Patent No. 6,431,863 without the steps which were achieved by selective heat treatment of different segments/portions of the wire.



11. In conclusion, the nickel-titanium wire contained in U.S. Patent No. 6,431,863 to Sachdeva *et al.* and the endodontic instruments provided to me by Dr. Luebke differ in terms of what phases are present at temperatures relevant to dentistry (austenite or martensite) and what induces the phase transformation (stress or temperature).

12. I declare that all statements are 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.

Respectfully submitted,

Dated: September 02, 2010 By: 

David W. Berzins

Electronic Patent Application Fee Transmittal

Application Number:	11628933
Filing Date:	07-Dec-2006
Title of Invention:	Dental And Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Richard T. Roche
Attorney Docket Number:	115207.00002

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with $0 paid	2253	1	555	555

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**960**

Electronic Acknowledgement Receipt

EFS ID:	8349736
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	02-SEP-2010
Filing Date:	07-DEC-2006
Time Stamp:	19:00:44
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$960
RAM confirmation Number	5036
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	Request for Continued Examination (RCE)	RCE-9-2-10.pdf	772826 e9804515cee4ac42e10b34ca94cf9c252eb17ac2	no	3
Warnings:					
Information:					
2		RCE-Amd-9-2-10.pdf	704969 3d1ac278e6944fcefcf07e65ba3c9780a5d129d4	yes	20

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment Submitted/Entered with Filing of CPA/RCE	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	20

Warnings:					
Information:					
3	Rule 130, 131 or 132 Affidavits	BerzinsDecl.pdf	661372 e478e3e530fa891df918fa4662aa91ac43ef7d6f	no	5
Warnings:					
Information:					
4	Fee Worksheet (PTO-875)	fee-info.pdf	32237 20d309453a90ccca659eb4f77afd3678123f4126	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2171404		

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

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

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

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

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/628,933	12/07/2006	

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT 09/02/2010

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 18	Minus	** 20	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***3	=	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

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/DEANNA L. RORIE/

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 10/29/2010

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3776	

NOTIFICATION DATE	DELIVERY MODE
10/29/2010	ELECTRONIC

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

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

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

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	Matthew M. Nelson	3776	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *02 September 2010*.

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

3)☐ 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

4)☒ Claim(s) *1,2,4-10,12-15,20,21 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10,12-15,20,21 and 23-25* is/are rejected.

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

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

Application Papers

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

10)☐ 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and Declaration filed on 9/2/2010 are acknowledged. Claims 1-2, 4-10, 12-15, 20-21 remain pending.

DETAILED ACTION

Claim Rejections - 35 USC § 103

2. 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.

3. Claims 1-2, 3-6, 10, 12, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani et al. (US 7,137,815) in view of Wong et al. (US 6,206,695).

4. Matsutani shows an endodontic instrument comprising an elongate shank (4) having a cutting edge (4b) extending from a distal end of the shank along an axial length of the shank, the shank comprises a titanium alloy (col. 4, lines 21-24), and the instrument has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion (col. 4, lines 31-44). With respect to claim 6, a nickel-titanium alloy (col. 4, lines 21-24). With respect to claim 10, the cutting edge is formed by helical flutes in the shank (4a). With respect to claim 12, the shank may have a diameter of 0.5 to 1.6 mm (col. 7, line 57). With respect to claim 15, creating or enlarging an opening using the above instrument (col. 3, lines 50-60).

5. Please note that claims 1-2, 4-5, 8-9, 13, 21, 23-25 are product-by-process claims, and therefore the process has not been given patentable weight where they do not confer a structure or characteristic which distinguishes it from the prior art. See MPEP 2113. Furthermore, with respect to the heat-treating temperatures, environments, and durations of claims 1-2, 4-5, 8-9, 13, 21, 23-25, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP 2113, 2173.05(p).

6. However, Matsutani fails to show the endodontic instrument being in accordance with ISO Standard 3630-1.

7. Wong teaches in the background of the invention endodontic tools manufactured pursuant to ISO Standard 3630 (col. 2, lines 5-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Matsutani's instrument by utilizing the ISO Standard as taught by Wong in order to provide sizes and an internationally recognized standard that is recognizable by and commonly used by dentists.

8. Claims 7-9, 13-14, 20-21, 23-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani in view of Wong and further in view of Heath et al. (US 5,653,590).

9. Matsutani/Wong discloses the device as previously described above, but fails to show the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.

10. Heath teaches endodontic instruments comprised of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium (col. 3, lines 50-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Matsutani/Wong's instrument by having the weight percentages as taught by Heath in order to take advantage of known weight percentages in the art for unique mechanical memory, non-magnetic properties, corrosion resistance, and a relatively low density.

Response to Arguments

11. Applicant's arguments with respect to claims 1-2, 4-10, 12-15, 20-21, 23-25 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

12. The declaration under 37 CFR 1.132 filed 9/2/2010 is insufficient to overcome the rejection of claims 1-2, 4-15, 20-25 based upon 35 U.S.C. 103 as set forth in the last Office action because: As in paragraph 7 of the declaration for instance, it appears that

this is an opinion based on gathered data rather than somebody doing the actual testing. Also, the declaration does not appear to be commensurate in scope with the claims other than claim 8. The claimed heating temperatures and length of time the files are exposed are not the same as those in the declaration. Further data encompassing the broader ranges and lengths of time of the claims would be required.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew M. 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, the examiner's supervisor, Cris Rodriguez can be reached on (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.

/MMN/

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

Notice of References Cited	Application/Control No. 11/628,933	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner Matthew M. Nelson	Art Unit 3776	Page 1 of 1

U.S. PATENT DOCUMENTS

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

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.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	Matthew M Nelson	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	04/29/2008	10/21/2008	02/24/2009	08/03/2009	12/31/2009	03/22/2010	10/20/2010		
	1	✓	✓	✓	✓	✓	✓	✓		
	2	✓	✓	✓	✓	✓	✓	✓		
	3	✓	-	-	-	-	-	-		
	4	✓	✓	✓	✓	✓	✓	✓		
	5	✓	✓	✓	✓	✓	✓	✓		
	6	✓	✓	✓	✓	✓	✓	✓		
	7	✓	✓	✓	✓	✓	✓	✓		
	8	✓	✓	✓	✓	✓	✓	✓		
	9	✓	✓	✓	✓	✓	✓	✓		
	10	✓	✓	✓	✓	✓	✓	✓		
	11	✓	✓	✓	✓	✓	✓	-		
	12	✓	✓	✓	✓	✓	✓	✓		
	13	✓	✓	✓	✓	✓	✓	✓		
	14	✓	✓	✓	✓	✓	✓	✓		
	15	✓	✓	✓	✓	✓	✓	✓		
	16	✓	-	-	-	-	-	-		
	17	✓	-	-	-	-	-	-		
	18	✓	-	-	-	-	-	-		
	19	✓	-	-	-	-	-	-		
	20	✓	✓	✓	✓	✓	✓	✓		
	21			✓	✓	✓	✓	✓		
	22						✓	-		
	23						✓	✓		
	24						✓	✓		
	25						✓	✓		

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	Matthew M Nelson	3732

SEARCHED

Class	Subclass	Date	Examiner
433	102, 224	4/29/2008	MMN
29	896.1	4/29/2008	MMN
433	102, 224	10/21/2008	MMN
29	896.1	10/21/2008	MMN
433	102, 224	2/24/2009	MMN
29	896.1	2/24/2009	MMN
433,29	Updated search	8/3/2009	MMN
433, 29	Updated search	12/31/2009	MMN
433, 29	Updated	3/22/2010	MMN
433, 29	Updated	10/20/2010	MN

SEARCH NOTES

Search Notes	Date	Examiner
Search received from John Wilson for Class/Subclass 433/102,224 & 29/896.1	4/28/2008	MMN
See EAST search history	4/29/2008	MMN
Updated EAST search	10/21/2008	MMN
Updated EAST search	2/24/2009	MMN
Updated EAST search history	8/3/2009	MMN
Updated EAST search history	12/31/2009	MMN
Updated EAST search	3/22/2010	MMN
Updated EAST search	10/20/2010	MN

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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

EAST Search History (Interference)

<This search history is empty>

10/20/2010 9:31:37 AM
C:\Documents and Settings\mnelson3\My Documents\EAST\Workspaces\11628933 Dental Instruments Comprising Titanium.wsp

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

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	11628933
Filing Date	2006-12-07
First Named Inventor	Neill H. Luebke
Art Unit	3732
Examiner Name	Matthew M. Nelson
Attorney Docket Number	115207.00002

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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FOREIGN PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

MKE\12865326

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

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	11628933
Filing Date	2006-12-07
First Named Inventor	Neill H. Luebke
Art Unit	3732
Examiner Name	Matthew M. Nelson
Attorney Docket Number	115207.00002

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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Electronic Patent Application Fee Transmittal

Application Number:	11628933
Filing Date:	07-Dec-2006
Title of Invention:	Dental And Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Richard T. Roche/Kristi Kasuboski
Attorney Docket Number:	115207.00002

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with $0 paid	2253	1	555	555

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**555**

Electronic Acknowledgement Receipt

EFS ID:	9987137
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	29-APR-2011
Filing Date:	07-DEC-2006
Time Stamp:	14:42:48
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$555
RAM confirmation Number	1069
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		Amendment_NF.pdf	120270 87f17098c6e88a5a900dc91c3d757104ebaf44ba	yes	13
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	7	
	Applicant Arguments/Remarks Made in an Amendment		8	13	
Warnings:					
Information:					
2	Rule 130, 131 or 132 Affidavits	Declaration_final.pdf	629320 3a8d9d7fa41bc036061a55402866d93790b8a917	no	7
Warnings:					
Information:					
3	Extension of Time	Extension_final.pdf	49679 50c6e573dd6b13b34e73d93852c65b8a054c4aa9	no	1
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Filed (SB/08)	IDS_final.PDF	686270 bb83f42905624b0fbc08315a8a344b32202ccabe	no	2
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5	Fee Worksheet (PTO-875)	fee-info.pdf	30200 0e07901d6c34c15e1ee93cd677ac8ef300722dc0	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1515739		

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.

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

Date: April 29, 2011

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

IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Confirmation No.:	9736
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 October 29, 2010.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 8 of this paper.

Amendments To The Claims

1. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being a size in accordance with ISO Standard 3630-1,

wherein the shank comprises a titanium alloy, and

wherein the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

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

2. (Original) The instrument of claim 1 wherein:

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

3. (Cancelled)

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

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

5. (Previously Presented) The instrument of claim 1 wherein:

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

6. (Original) The instrument of claim 1 wherein:

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

7. (Original) The instrument of claim 1 wherein:

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

8. (Previously Presented) The instrument of claim 1 wherein:

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

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

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

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

9. (Previously Presented) The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

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

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

the cutting edge is formed by helical flutes in the shank.

11. (Cancelled)

12. (Original) The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being a size in accordance with ISO Standard 3630-1,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the instrument is prepared by heat-treating the instrument at a temperature from 475°C to 525°C in an atmosphere consisting essentially of a gas unreactive with the shank, and

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

14. (Original) The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 1.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 13.

21. (Previously Presented) The instrument of claim 1 wherein:

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

22. (Cancelled)

23. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein the instrument has a size in accordance with ISO Standard 3630-1, and

wherein the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

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

24. (Previously Presented) The instrument of claim 23 wherein:

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

25. (Previously Presented) The instrument of claim 23 wherein:

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

REMARKS

Claim Amendments

Claim 1, 13 and 23 have been amended to recite that the instrument has a size in accordance with ISO Standard 3630-1 as described at paragraph [0036] of the specification.

Claim Rejections - 35 USC § 103(a)

Claims 1-2, 3-6, 10, 12 and 15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,137,815 to Matsutani *et al*. ("Matsutani") in view of U.S. Patent No. 6,206,695 to Wong *et al*. ("Wong"). Claims 7-9, 13-14, 20-21 and 23-25 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani in view of Wong and further in view of U.S. Patent No. 5,653,590 to Heath *et al*. ("Heath").

The Office Action states that

> "claims 1-2, 4-5, 8-9, 13, 21, 23-25 are product-by-process claims, and therefore the process has not been given patentable weight. … The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)."

However, this reasoning from *In re Thorpe* is not without limits. In particular, when the process steps confer a structure or characteristic of the product, which distinguishes it from products made by other processes, the process steps should be considered. *In re Garnero*, 412 F.2d 276, 279 (CCPA 1979).

In fact, the Board Of Patent Appeals and Interferences ("Board") has used this reasoning recently. For example, in *Ex parte Gist*, the Board stated "[t]he patentability

of a product is based on the product itself unless the process steps confer a structure or characteristic which distinguishes it from products made by other processes." *Ex parte Gist*, Appeal 2008-6122, Technology Center 3700, March 30, 2009, page 9, (underlining added). See, also, *Ex parte Agrawal*, Appeal 2009-1014, Technology Center 3700, March 23, 2009, page 10, where it states "[t]he patentability of a product in a product-by-process claim is based on the patentability of the product itself even though the process by which the product is processed may differ from the prior art. But, the process steps should be considered if the steps confer a structure or characteristic of the product which distinguishes it from products made by other processes" (underlining added).

Looking first at Matsutani, 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 11-16 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.

Independent claims 1, 13 and 23 of the present application all require heat-treating an instrument of a size in accordance with ISO Standard 3630-1. Below is an excerpt from ISO Standard 3630-1 which shows a standard size instrument having a working part l_3 (which must be 16 millimeters minimum in the endodontic instrument).

5.2 Standard sized (Type 1) instruments

5.2.1 Length

The length of the working part, l_3, shall be a minimum of 16 mm unless otherwise specified by the manufacturer. The lengths of the working part, when specified, and of the operative part, l_4, shall be within 0,5 mm of the specified lengths.

Test in accordance with 7.3.

Dimensions in millimetres

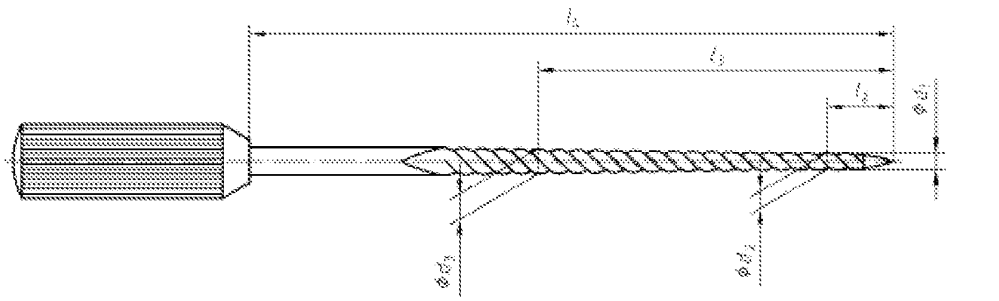


Figure 1 — Type 1: Standard-sized instrument: taper = 2 % — Dimensions, locations

The process steps of claims 1, 13 and 23, in which an instrument of a size in accordance with ISO Standard 3630-1 is heat-treated, can provide an instrument with uniform mechanical properties. In contrast, 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. As a result, the Matsutani root canal treatment tool has different mechanical properties at different regions of the tool. Thus, the process steps of claims 1, 13 and 23 of the present application confer a structure or characteristic of the product, which distinguishes it from products made by the Matsutani process. *In re Garnero*, 412 F.2d 276, 279 (CCPA 1979).

In addition, the Applicant wishes to provide further evidence that the process limitation in claim 1 (i.e., the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank … wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy") and the process limitation in claim 13 ("the instrument is prepared by heat-treating the instrument at a temperature from 475°C to 525°C in an atmosphere consisting essentially of a gas unreactive with the shank ") and the process limitation in claim 23 ("the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank, wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy) confer a distinguishing characteristic over the products of Matsutani. In rebuttal, the Applicant submits herewith evidence showing that the products of Matsutani and the claimed invention are distinguished by structure and the products are different. *See*, *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983).

Attached for consideration is a Declaration of David W. Berzins. In the Declaration, SEM photomicrographs show that a heat-treatment in air as in Matsutani yields a superelastic file (see Item 7 of the Declaration) and will create oxide debris on

the surface of the file (see Item 10 of the Declaration). This oxide can "affect the surface integrity of the file as well as its properties and transformations" (see Item 9 of the Declaration). Independent claims 1, 13 and 23 recite heat-treating the instrument in an atmosphere consisting essentially of a gas unreactive with the shank. Item 8 of the Declaration shows that this yields a shape memory file. Also, oxide will not form on the instrument of the claimed invention due to the unreactive gas. Accordingly, the products of Matsutani and the claimed invention are distinguished by structure and the products are different. *See*, *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983).

It is well settled that in order to establish a prima facie case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Taken together, Sachdeva and Wong and Heath fail to teach or suggest heat-treating an instrument of a size in accordance with ISO Standard 3630-1 as recited in independent claims 1, 13 and 23. Accordingly, it is respectfully submitted that independent claim 1 (and claims 2, 4-10, 12, 15 and 21 that depend thereon) and independent claim 13 (and claims 14 and 20 that depend thereon) and independent claim 23 (and claims 24 and 25 that depend thereon) are patentable over Matsutani and Wong and Heath.

Furthermore, the CAFC has held that "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be … led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Looking at column 5, lines 34-42 of Matsutani, it is stated that

> "If the length of the shape memory portion 6 is smaller than 2 mm, durability is not substantially different as compared with a reamer having a superelastic characteristic along the whole length of the work portion. Moreover, if the length of the shape memory portion 6 is larger than 3/4 of the work portion, at the time of inserting the tip 3 into the root canal and rotating it, a problem may occur in that the position of a rotational axis is not fixed, but is made eccentric to make it difficult to cut the root canal well."

Thus, Matsutani would lead one away from making an instrument with a shape memory portion larger than 3/4 of the work portion as this could be a "problem". However, the Applicant has proceeded in a divergent path and heat-treats an instrument of a size in accordance with ISO Standard 3630-1 as recited in independent claims 1, 13 and 23. See also *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986) (proceeding contrary to accepted wisdom in the art is strong evidence of nonobviousness).

Conclusion

Claims 1-2, 4-10, 12-15, 20 and 22-25 are believed to be in condition for allowance. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

The extension fee is submitted herewith. If additional fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: April 29, 2011

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

13184508

Docket No.: 115207.00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	9736
Art Unit:	3732
Examiner:	Matthew M. Nelson

DECLARATION UNDER 37 C.F.R. 1.132

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

Sir:

I, David W. Berzins, hereby declare as follows:

1. I am a tenured associate professor in the Marquette University School of Dentistry, Milwaukee, Wisconsin, USA.

2. I have a BS in Materials Science & Engineering from Case Western Reserve University and a PhD in Biomedical Engineering from Tulane University.

3. My research interests include nickel-titanium alloys.

4. I have co-authored the following publications related to nickel-titanium alloys:

(a) "Phase transformation changes in thermocycled nickel-titanium orthodontic wires", *Dental Materials*, vol. 26, no. 7, pp. 666–674, 2010; and

(b) "Influence of stress and phase on corrosion of a superelastic nickel-titanium orthodontic wire", *American Journal of Orthodontics and Dentofacial Orthopedics*, vol. 135, no. 6, pp. 764–770, 2009; and

(c) "Corrosion behavior of shape memory, superelastic, and nonsuperelastic nickel-titanium-based orthodontic wires at various temperatures", *Dental Materials*, vol. 24, no. 2, pp. 221–227, 2008; and

(d) "Thermal analysis of as-received and clinically retrieved copper-nickel-titanium orthodontic archwires", *Angle Orthodontist*, vol. 77, no. 3, pp. 499–503, 2007.

5. I stated in my last declaration dated September 2, 2010 that the data and diagrams from U.S. Patent No. 6,431,863 Sachdeva *et al.* demonstrated a superelastic file while the Luebke application data of the present application demonstrated a shape memory file.

6. I have reviewed U.S. Patent No. 7,137,815 to Matsutani *et al.* In order to determine the properties of a file processed via the Matsutani patent, I used "(B) Partial heating method by a furnace (see FIG. **4**B)" (column 6 lines 61-67 of Matsutani) as a guide. I utilized a temperature of 500°C and treated stock Ni-Ti endodontic files for 15 or 75 minutes. To accomplish this, I placed the files in a porcelain furnace. The oven had atmospheric air in the furnace. After this process, the files were analyzed with differential scanning calorimetry to determine if they had austenite finish temperatures (A_f) indicative of being shape memory or superelastic.

7. The austenite finish temperatures of the files heated in a porcelain oven at 500°C for 15 minutes and 75 minutes were 24.5 and 25.2°C, respectively. Compared to the stock NiTi file that was not treated (with an A_f of 18.2°C), the heat treatment in air was able to increase the A_f temperature. However, it is still within the temperature

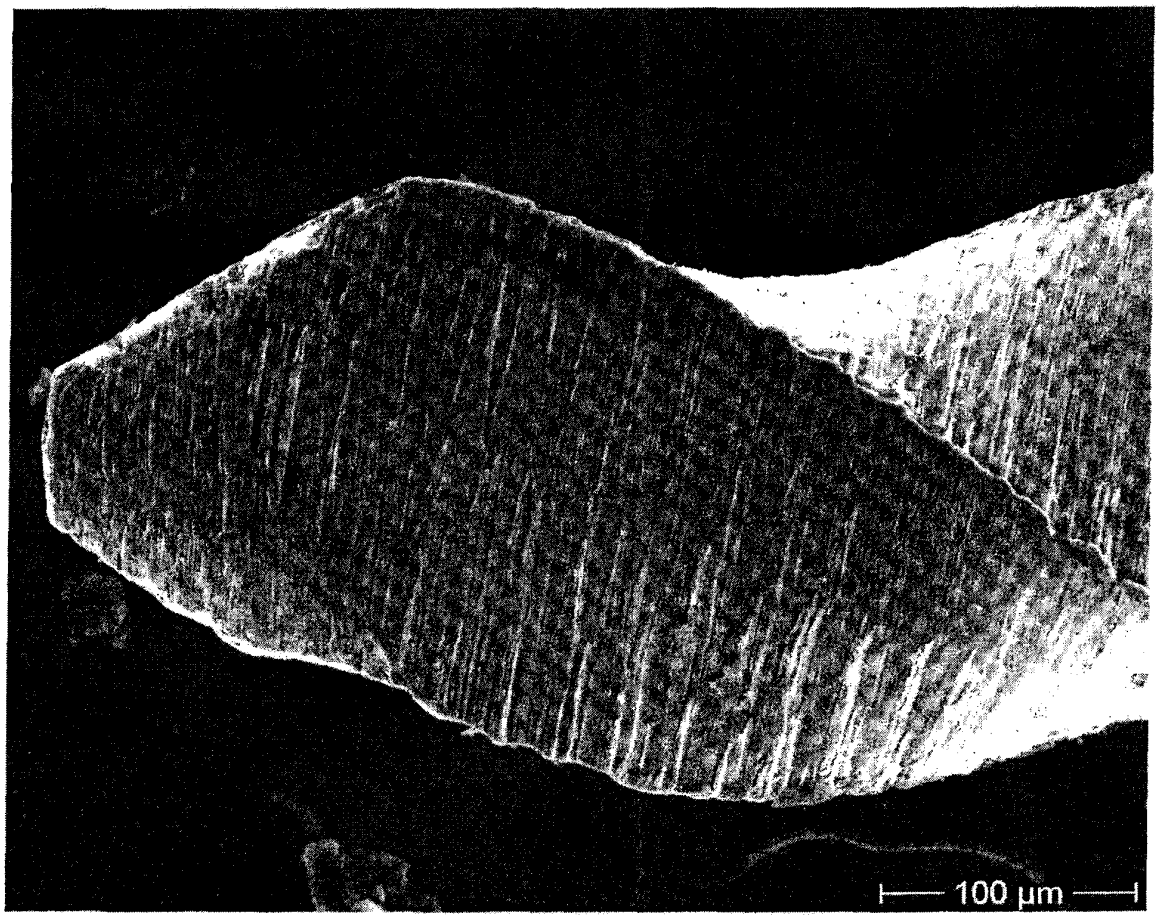
range at which I would characterize it as superelastic. At room temperature, both treated files will be 100% or nearly 100% austenite, allowing for the stress-induced phase transformation at room temperature and oral temperature.

8. Files were provided to me by Dr. Neill Luebke and processed according to his patent application. I was informed that these files were made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium. I was informed that these files are ISO size files and include an elongated shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. I was informed that these ISO size files were heat-treated in a furnace in an non-reactive atmosphere at 500°C for 75 minutes. These files were also analyzed with DSC and have displayed A_f temperatures of 37.5 +/- 0.9°C (Berzins DW. Differential Scanning Calorimetry Analysis of Contemporary Nickel-Titanium Endodontic Files, abstracted and presented at the 89th General Session of the International and American Associations for Dental Research in San Diego, CA on March 18, 2011; Journal of Dental Research Vol 90A:Abstract #1710), which is more consistent with a shape-memory file. Furthermore, simple bending of the files showed the Matsutani patent processed files to behave similar to most contemporary superelastic files (they were able to be bent and returned to their original shape with the release of stress). The Luebke files retained some of the bend, but were able to be straightened when the temperature was raised above its A_f temperature.

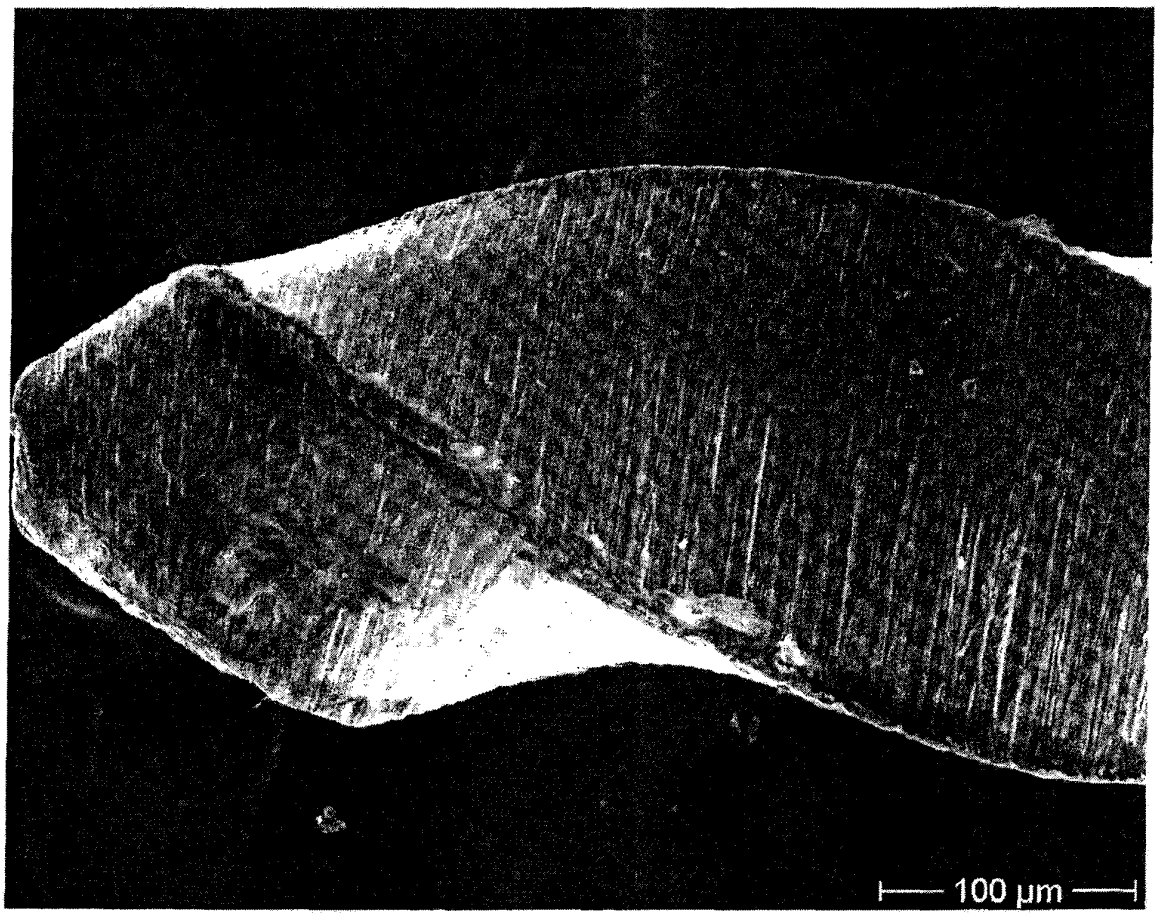
9. An issue associated with the processing of the files as in the Matsutani patent is that titanium is very reactive in air as it readily forms thick oxides when exposed to air at elevated temperatures. Just at room temperature, pure titanium will form an oxide layer, primarily composed of TiO_2, which is several nanometers thick (Lautenschlager and Monaghan. Titanium and titanium alloys as dental materials. Int Dent J. 1993 Jun;43(3):245-53). This protects Ti-based alloys from extensive corrosion. However, at elevated temperatures, the oxide layer grows in thickness, and this may affect the surface integrity of the file as well as its properties and transformations. The Luebke patent calls for heating the files in an inert atmosphere. This will limit oxide growth on the file surface. Furthermore, differences in the oxide layer on NiTi exist depending upon oxygen levels in the surrounding environment (Chan et al. Oxidation of a NiTi alloy surface. Surface and Interface Analysis 1990;15:349-355).

10. SEM photomicrographs were taken of the stock file and the files described above that were processed according to the Matsutani heat treatments. The tip of the file exposed to 500°C exposed to air for 75 minutes had apparent oxide debris on its surface whereas the stock file was relatively smooth. Below are scanning electron microscope (SEM) micrographs of the tips of the stock file and file heat treated at 500°C exposed to air.

NiTi File untreated, SEM (300 X)



NiTi File treated at 500° C for 75 minutes, SEM (300 X)



11. I declare that all statements are 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.

Respectfully submitted,

Dated: April 28, 2011 By: David W Berzins

David W. Berzins

PTO/SB/22 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE
Under the paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless if displays a valid OMB control number.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2009** (*Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).*)	Docket Number (Optional) 115207.00002
Application Number 11/628,933	Filed
For Dental and Medical Instruments Comprising Titanium	
Art Unit 4166	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	
☐	One month (37 CFR 1.17(a)(1))	$130	$65	$
☐	Two months (37 CFR 1.17(a)(2))	$490	$245	$
☑	Three months (37 CFR 1.17(a)(3))	$1110	$555	$555
☐	Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐	Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

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

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

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

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

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 170055 . I have enclosed a duplicate copy of this sheet.

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/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

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

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

/Richard T. Roche/	4/29/11
Signature	Date
Richard T. Roche	414-277-5805
Typed or printed name	Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 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.

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/628,933	12/07/2006	

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT 04/29/2011

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 15	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/WILLIAM PHILLIPS/

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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 06/03/2011

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3776	

NOTIFICATION DATE	DELIVERY MODE
06/03/2011	ELECTRONIC

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

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

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

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	MATTHEW NELSON	3776	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *29 April 2011*.

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

3)☐ 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

4)☒ Claim(s) *1,2,4-10,12-15,20,21 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10,12-15,20,21 and 23-25* is/are rejected.

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

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

Application Papers

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

10)☐ 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/29/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 4/29/2011 is acknowledged.

Claim Rejections - 35 USC § 103

2. 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.

3. Claims 1-2, 4-6, 10, 12, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani et al. (US 7,137,815) in view of Wong et al. (US 6,206,695) and further in view of Ueda et al. (US 2002/0191878).

4. Matsutani shows an endodontic instrument comprising an elongate shank (4) having a cutting edge (4b) extending from a distal end of the shank along an axial length of the shank, the shank comprises a titanium alloy (col. 4, lines 21-24), and the instrument has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion (col. 4, lines 31-44). With respect to claim 6, a nickel-titanium alloy (col. 4, lines 21-24). With respect to claim 10, the cutting edge is formed by helical flutes in the shank (4a). With respect to claim 12, the shank may have a diameter of 0.5 to 1.6 mm (col. 7, line 57). With respect to claim 15, creating or enlarging an opening using the above instrument (col. 3, lines 50-60).

5. Please note that claims 1-2, 4-5, 8-9, 13, 21, 23-25 contain product-by-process limitations, and therefore the process has not been given patentable weight where they

do not confer a structure or characteristic which distinguishes it from the prior art. See MPEP 2113. Specifically with respect to the heat-treating temperatures and durations of claims 1-2, 4-5, 8-9, 13, 21, 23-25, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP 2113, 2173.05(p).

6. However, Matsutani fails to show the endodontic instrument being in accordance with ISO Standard 3630-1.

7. Wong teaches in the background of the invention endodontic tools manufactured pursuant to ISO Standard 3630 (col. 2, lines 5-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Matsutani's instrument by utilizing the ISO Standard as taught by Wong in order to provide sizes and an internationally recognized standard that is recognizable by and commonly used by dentists. However, Matsutani/Wong fails to show the heat treatment being conducted in an atmosphere consisting essentially of a gas unreactive with the shank.

8. Ueda teaches heat treating a titanium alloy wherein the heat treatment being conducted in an atmosphere consisting essentially of a gas unreactive with the shank such as argon in claims 2 and 8 ([0039] for instance). Therefore, it would have been

obvious to one having ordinary skill in the art at the time of invention to modify Matsutani/Wong's instrument by including the heat treating in an atmosphere consisting essentially of a gas unreactive with the shank as taught by Ueda in order to prevent the titanium alloy from oxidizing as is known in the art.

9. Claims 7-9, 13-14, 20-21, 23-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani in view of Wong and Ueda and further in view of Heath et al. (US 5,653,590).

10. Matsutani/Wong/Ueda discloses the device as previously described above, but fails to show the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.

11. Heath teaches endodontic instruments comprised of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium (col. 3, lines 50-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Matsutani/Wong/Ueda's instrument by having the weight percentages as taught by Heath in order to take advantage of known weight percentages in the art for unique mechanical memory, non-magnetic properties, corrosion resistance, and a relatively low density.

Response to Arguments

12. Applicant's arguments filed 1-2, 4-10, 12-15, 20-21, 23-25 have been fully considered but they are not persuasive.

13. Applicant appears to be arguing that since Matsutani only heat treats a portion of the shank, it teaches away from and does not read on the independent claims. However, there is no language in the claims, nor support in the specification, for the entire shank being heat treated. Therefore the claims do not distinguish themselves over Matsutani based on what portion of the shank is heat treated.

14. A new reference has been incorporated to teach the desire of conducting the heat treatment in an atmosphere consisting essentially of a gas unreactive with the shank.

Response to Amendment

15. The declaration under 37 CFR 1.132 filed 4/29/2011 is sufficient to overcome the rejection of claims 1-2, 4-10, 12-15, 20-21, 23-25 based upon 103(a) in regards to the atmosphere consisting essentially of a gas unreactive with the shank inferring structural limitations.

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, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. 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.

/MMN/

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

Notice of References Cited	Application/Control No. 11/628,933	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON	
	Examiner MATTHEW NELSON	Art Unit 3776	Page 1 of 1

U.S. PATENT DOCUMENTS

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

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	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.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	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
L3	0	L2 AND gas	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
L4	2	L2 AND atmosphere	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
L5	982	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:32
L6	8	L5 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
L7	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

L8	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
L9	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
L10	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
L11	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
L12	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
L13	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

L15	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
L18	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
L19	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
L21	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
L22	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
L23	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

L24	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
L25	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
L26	2	"6783438".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:33
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

EAST Search History (Interference)

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5/12/2011 10:35:55 AM
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PTO/SB/08a (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	11628933
Filing Date	2006-12-07
First Named Inventor	Neill H. Luebke
Art Unit	3732
Examiner Name	Matthew M. Nelson
Attorney Docket Number	115207.00002

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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FOREIGN PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

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

MKE\12865326

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

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	11628933
Filing Date	2006-12-07
First Named Inventor	Neill H. Luebke
Art Unit	3732
Examiner Name	Matthew M. Nelson
Attorney Docket Number	115207.00002

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]

Examiner Signature	/Matthew Nelson/	Date Considered	05/12/2011

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

MKE\12865326

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

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	Matthew M Nelson	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	04/29/2008	10/21/2008	02/24/2009	08/03/2009	12/31/2009	03/22/2010	10/20/2010	05/12/2011	
	1	✓	✓	✓	✓	✓	✓	✓	✓	
	2	✓	✓	✓	✓	✓	✓	✓	✓	
	3	✓	-	-	-	-	-	-	-	
	4	✓	✓	✓	✓	✓	✓	✓	✓	
	5	✓	✓	✓	✓	✓	✓	✓	✓	
	6	✓	✓	✓	✓	✓	✓	✓	✓	
	7	✓	✓	✓	✓	✓	✓	✓	✓	
	8	✓	✓	✓	✓	✓	✓	✓	✓	
	9	✓	✓	✓	✓	✓	✓	✓	✓	
	10	✓	✓	✓	✓	✓	✓	✓	✓	
	11	✓	✓	✓	✓	✓	✓	-	-	
	12	✓	✓	✓	✓	✓	✓	✓	✓	
	13	✓	✓	✓	✓	✓	✓	✓	✓	
	14	✓	✓	✓	✓	✓	✓	✓	✓	
	15	✓	✓	✓	✓	✓	✓	✓	✓	
	16	✓	-	-	-	-	-	-	-	
	17	✓	-	-	-	-	-	-	-	
	18	✓	-	-	-	-	-	-	-	
	19	✓	-	-	-	-	-	-	-	
	20	✓	✓	✓	✓	✓	✓	✓	✓	
	21			✓	✓	✓	✓	✓	✓	
	22						✓	-	-	
	23						✓	✓	✓	
	24						✓	✓	✓	
	25						✓	✓	✓	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	Matthew M Nelson	3732

SEARCHED

Class	Subclass	Date	Examiner
433	102, 224	4/29/2008	MMN
29	896.1	4/29/2008	MMN
433	102, 224	10/21/2008	MMN
29	896.1	10/21/2008	MMN
433	102, 224	2/24/2009	MMN
29	896.1	2/24/2009	MMN
433,29	Updated search	8/3/2009	MMN
433, 29	Updated search	12/31/2009	MMN
433, 29	Updated	3/22/2010	MMN
433, 29	Updated	10/20/2010	MN
433, 29	Updated	5/23/2011	MN

SEARCH NOTES

Search Notes	Date	Examiner
Search received from John Wilson for Class/Subclass 433/102,224 & 29/896.1	4/28/2008	MMN
See EAST search history	4/29/2008	MMN
Updated EAST search	10/21/2008	MMN
Updated EAST search	2/24/2009	MMN
Updated EAST search history	8/3/2009	MMN
Updated EAST search history	12/31/2009	MMN
Updated EAST search	3/22/2010	MMN
Updated EAST search	10/20/2010	MN
Updated EAST search	5/23/2011	MN
Search request to Jermie Cozart for class 29	5/23/2011	MN

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

Doc Code: M865 or FAI.REQ.INTV

PTOL-413A (10-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 11/628,933 First Named Applicant: Neill H. Luebke
Examiner: Matthew Nelson Art Unit: 3732 Status of Application: Non-Final Rejection

Tentative Participants:
(1) Examiner Matthew Nelson (2) Neill H. Luebke, Inventor
(3) Richard Roche (38599) (4) Examiner Todd E. Manahan

Date of Interview: 8-4-2011 **Time:** 2 PM (AM/PM)

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

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

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) 35 USC 103	1	US 7,137,815	[ ]	[ ]	[ ]
(2) 35 USC 103	1	US 2002/019878	[ ]	[ ]	[ ]
(3) 35 USC 103	1	US 6,206,695	[ ]	[ ]	[ ]
(4) Item 12 of Office Action			[ ]	[ ]	[ ]

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

An interview was conducted on the above-identified application on _____.
NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).
This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

Applicant/Applicant's Representative Signature — Examiner/SPE Signature

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

38,599
Registration Number, if applicable

U.S. Patent Application No. 11/628,933
DO NOT ENTER

Agenda for Telephonic Interview

(1) U.S. Patent No. 7,137,815 to Matsutani et al.

(2) U.S. Patent Application Publication No. 2002/0191878 to Ueda et al.

(3) U.S. Patent No. 6,206,695 to Wong et al,

(4) Item 15 of Office Action of 6-3-2011

(5) Attached Proposed Amendment and Example 4 of the Specification

PAGE 3/5 * RCVD AT 8/3/2011 12:40:17 PM [Eastern Daylight Time] * SVR:W-PTOFAX-001/2 * DNIS:2738300 * CSID: * DURATION (mm-ss):01-35

U.S. Patent Application No. 11/628,933
DO NOT ENTER

1. (Previously Presented) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being a size in accordance with ISO Standard 3630-1,

wherein the shank comprises a titanium alloy, and

wherein the instrument is prepared by heat-treating the instrument for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

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

U.S. Patent Application No. 11/628,933
DO NOT ENTER

1. (Proposal Only) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being a size in accordance with ISO Standard 3630-1,

wherein the shank comprises a titanium alloy, and

wherein the instrument is prepared by heat-treating the entire shank ~~instrument~~ for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

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

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414/277-5591

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Milwaukee and Madison, Wisconsin
Phoenix and Tucson, Arizona
Chicago, Illinois
Naples and Tampa, Florida

FAX TRANSMITTAL COVER SHEET

To: **571-273-8300**
Company:
Fax number: 571-273-8300
Phone number:

From: **Kasuboski, Kristi L.**
Phone number: 414-277-5708
Senders direct fax:

Number of Pages (including cover sheet): 5
Date & Time Faxed: 8/3/2011 11:40:23 AM

Message:
Attn: Examiner Matthew Nelson

PAGE 1/5 * RCVD AT 8/3/2011 12:40:17 PM [Eastern Daylight Time] * SVR:W-PTOFAX-001/2 * DNIS:2738300 * CSID: * DURATION (mm-ss):01-35

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 08/11/2011

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3776	

NOTIFICATION DATE	DELIVERY MODE
08/11/2011	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

Interview Summary	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	MATTHEW NELSON	3776	

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

(1) *MATTHEW NELSON*. (3) *NEILL LUEBKE*.

(2) *RICHARD ROACH*. (4) *FRAN LUEBKE*.

Date of Interview: *04 August 2011*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

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

Claim(s) discussed: *1*.

Identification of prior art discussed: *Matsutani, Wong, Ueda*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Matthew M Nelson/ Examiner, Art Unit 3776	

Summary of Record of Interview Requirements

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

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

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

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

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

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

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

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

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

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

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

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

Examiner to Check for Accuracy

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

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussed differentiation of treating the shank to just treating the working portion and how this may be shown by the specification without explicitly stating "entire" shank. Discussed submission of an affidavit/effidence showing the structural criticality of treating at specific temperatures, times, and environments and whythis would not be covered by Matsutani or desired in Matsutani. Suggested incorporating these distinguishing features into the claim language. Further discussed why Wong does not teach away from an ISO 3630 standard and that Ueda may only be particular to the treatment of alpha/beta titanium and not nickel titanium.

.

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

Date: August 29, 2011

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

IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Confirmation No.:	9736
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, 2011.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 8 of this paper.

Amendments To The Claims

1. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being a size in accordance with ISO Standard 3630-1,

wherein the shank comprises a titanium alloy, and

wherein the instrument is prepared by heat-treating the entire shank ~~instrument~~ for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

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

2. (Original) The instrument of claim 1 wherein:

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

3. (Cancelled)

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

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

5. (Previously Presented) The instrument of claim 1 wherein:

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

6. (Original) The instrument of claim 1 wherein:

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

7. (Original) The instrument of claim 1 wherein:

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

8. (Previously Presented) The instrument of claim 1 wherein:

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

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

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

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

9. (Previously Presented) The instrument of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

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

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

the cutting edge is formed by helical flutes in the shank.

11. (Cancelled)

12. (Original) The instrument of claim 1 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

13. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being a size in accordance with ISO Standard 3630-1,

wherein the shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and

wherein the instrument is prepared by heat-treating the entire shank ~~instrument~~ at a temperature from 475°C to 525°C in an atmosphere consisting essentially of a gas unreactive with the shank, and

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

14. (Original) The instrument of claim 13 wherein:

the shank has a diameter of 0.5 to 1.6 millimeters.

15. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 1.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Previously Presented) A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to claim 13.

21. (Previously Presented) The instrument of claim 1 wherein:

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

22. (Cancelled)

23. (Currently Amended) An endodontic instrument for use in performing root canal therapy on a tooth, the instrument comprising:

an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank,

wherein the shank comprises a titanium alloy, and

wherein the instrument has a size in accordance with ISO Standard 3630-1, and

wherein the instrument is prepared by heat-treating the entire shank ~~instrument~~ for a time period at a single temperature in an atmosphere consisting essentially of a gas unreactive with the shank,

wherein the temperature is from 400°C up to but not equal to the melting point of the titanium alloy, and

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

24. (Previously Presented) The instrument of claim 23 wherein:

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

25. (Previously Presented) The instrument of claim 23 wherein:

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

REMARKS

Examiner Interview

Applicant and Applicant's representative wish to express appreciation to Examiner Nelson for the courtesy of a telephone interview on August 4, 2011. Among other things, Examiner suggested the submittal of Declarations under 37 C.F.R. 1.132 directed to: (i) the issues of the support in the Examples for a claim limitation regarding heat treatment of the entire shank, and (ii) the criticality of the temperatures in independent claims 1, 13 and 23.

Claim Amendments

Independent claims 1, 13 and 23 have been amended to recite that the "entire shank" is heat treated. The basis for this claim limitation "entire shank" can be found in Example 4 of the present application where each ISO size file was heat-treated in a furnace having an argon atmosphere. The Court of Appeals for the Federal Circuit outlined the written description requirement in *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (2000), as follows:

> "In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir.1996). Nonetheless, the disclosure must ... convey with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed.Cir.1991). Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. Waldemar Link GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558, 31 UPSQ2d 1855, 1857 (Fed.Cir.1994)."

Attached is a Declaration under 37 C.F.R. 1.132 for Office consideration. The Declaration notes that argon (which was used in Example 4 of the present application) is considered to be hazardous by OSHA. Therefore, when using argon gas in a heat

treating process as in Example 4 of the present application, a metal heat treating company will use the argon gas in a sealed closed system to provide containment of the argon gas. Item 6 of the Declaration states "[t]he use of an argon atmosphere as described in Example 4 requires that the entire file be heat treated in the furnace in order to keep the argon contained in a closed system".

Stated a different way, one skilled in the art, when reading the original disclosure of Example 4 of the present application, would immediately discern that the entire shank has to be heat treated in the furnace using a closed system due to the use of argon (which "can cause rapid suffocation" according to the MSDS attached to the Declaration). Therefore, Example 4 of the present application "convey[s] with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention" of amended independent claims 1, 13 and 23 (see *Purdue Pharma L.P.* above). In other words, one skilled in the art would discern that the "entire shank" as recited in amended independent claims 1, 13 and 23 is being heat treated in Example 4.

Claim Rejections - 35 USC § 103

Claims 1-2, 3-6, 10, 12 and 15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,137,815 to Matsutani *et al*. ("Matsutani") in view of U.S. Patent No. 6,206,695 to Wong *et al*. ("Wong") and further in view of U.S. Patent Application Publication No. 2002/0191878 to Ueda *et al*. ("Ueda"). Claims 7-9, 13-14, 20-21 and 23-25 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani, Wong and Ueda and further in view of U.S. Patent No. 5,653,590 to Heath *et al*. ("Heath").

Item 13 of the Office Action stated "Applicant appears to be arguing that since Matsutani only heat treats a portion of the shank, it teaches away from and does not read on the independent claims. However, there is no language in the claims, nor support in the specification, for the entire shank being heat treated. Therefore the claims do not distinguish themselves over Matsutani based on what portion of the shank is heat treated." Applicant has taken these helpful suggestions into consideration in this amendment.

First, independent claims 1, 13 and 23 have been amended as shown above to recite that the "entire shank" is heat treated. Second, the attached Declaration under 37 C.F.R. 1.132 from one skilled in the metal heat treating art provides evidence that Example 4 of the present application "convey[s] with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention" of amended independent claims 1, 13 and 23 in which the entire shank is heat treated. In this regard, it is noted that not heat treating the entire shank in a closed furnace as in Example 4 could lead to operator suffocation.

In view of these amendments to independent claims 1, 13 and 23, Applicant wishes to address Matsutani. Looking at Matsutani, 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 11-16 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.

The limitations of amended claims 1, 13 and 23, in which the entire shank is heat treated, can provide an instrument with uniform mechanical properties. In contrast, 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. As a result, the Matsutani root canal treatment tool has different mechanical properties at different regions of the tool.

Wong was cited as mentioning ISO Standard 3630. Wong does not teach heat treating an entire shank comprising a titanium alloy. Thus, Wong does not make up for the deficiencies of Matsutani with respect to amended independent claims 1, 13 and 23.

Ueda was cited as teaching the use of a gas unreactive with the shank. Ueda does not teach heat treating an entire shank comprising a titanium alloy. Thus, Ueda does not make up for the deficiencies of Matsutani with respect to amended independent claims 1, 13 and 23.

Heath was cited as teaching a titanium alloy with 54-57% nickel and 43-46% titanium. Heath does not teach heat treating an entire shank comprising a titanium

alloy. Thus, Heath does not make up for the deficiencies of Matsutani with respect to amended independent claims 1, 13 and 23.

It is well settled that in order to establish a prima facie case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Taken together, Matsutani and Wong and Ueda and Heath fail to teach or suggest heat treating an entire shank as recited in amended independent claims 1, 13 and 23. Accordingly, it is respectfully submitted that independent claim 1 (and claims 2, 4-10, 12, 15 and 21 that depend thereon) and independent claim 13 (and claims 14 and 20 that depend thereon) and independent claim 23 (and claims 24 and 25 that depend thereon) are patentable over Matsutani and Wong and Ueda and Heath.

In addition, claims 7-9 (which depend from claim 1) and independent claim 13 each require a nickel-titanium alloy and the use of an unreactive gas. Ueda is particular to the heat treatment of alpha/beta titanium in argon, and not nickel titanium. Therefore, nothing in Ueda would suggest the use of argon for the treatment of a nickel-titanium alloy. For these additional reasons, claims 7-9 (which depend from claim 1) and independent claim 13 are patentable over Matsutani and Wong and Ueda and Heath.

Furthermore, the CAFC has held that "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be … led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Looking at column 5, lines 34-42 of Matsutani, it is stated that

> "If the length of the shape memory portion 6 is smaller than 2 mm, durability is not substantially different as compared with a reamer having a superelastic characteristic along the whole length of the work portion. Moreover, if the length of the shape memory portion 6 is larger than 3/4 of the work portion, at the time of inserting the tip 3 into the root canal and rotating it, a problem may occur in that the position of a rotational axis is not fixed, but is made eccentric to make it difficult to cut the root canal well."

Thus, Matsutani would lead one away from making an instrument with a shape memory portion larger than 3/4 of the work portion as this could be a "problem". However, the Applicant has proceeded in a divergent path and heat-treats the entire shank as recited in independent claims 1, 13 and 23. See also *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986) (proceeding contrary to accepted wisdom in the art is strong evidence of nonobviousness).

Furthermore , the Office Action states that

> "claims 1-2, 4-5, 8-9, 13, 21, 23-25 contain product-by-process limitations, and therefore the process has not been given patentable weight where they do not confer a structure or characteristic which distinguishes it from the prior art. See MPEP 2113. Specifically with respect to the heat-treating temperatures and durations of claims 1-2, 4-5, 8-9, 13, 21, 23-25, 'even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP 2113, 2173.05(p)."

However, this reasoning from *In re Thorpe* is not without limits. In particular, when the process steps confer a structure or characteristic of the product, which distinguishes it from products made by other processes, the process steps should be considered. *In re Garnero*, 412 F.2d 276, 279 (CCPA 1979).

In fact, the Board Of Patent Appeals and Interferences ("Board") has used this reasoning recently. For example, in *Ex parte Gist*, the Board stated "[t]he patentability

of a product is based on the product itself unless the process steps confer a structure or characteristic which distinguishes it from products made by other processes." *Ex parte Gist*, Appeal 2008-6122, Technology Center 3700, March 30, 2009, page 9, (underlining added). See, also, *Ex parte Agrawal*, Appeal 2009-1014, Technology Center 3700, March 23, 2009, page 10, where it states "[t]he patentability of a product in a product-by-process claim is based on the patentability of the product itself even though the process by which the product is processed may differ from the prior art. But, the process steps should be considered if the steps confer a structure or characteristic of the product which distinguishes it from products made by other processes" (underlining added).

In the Rule 132 affidavit from Dr. David Berzins filed in the present application on 9-2-2010, differential scanning calorimetry (DSC) performed on Applicant's instruments showed that the printout was unique. In this regard, Item 9 of the affidavit from Dr. David Berzins filed 9-2-2010 stated that "[a]s a result of the treatment of the endodontic instruments from Dr. Neill H. Luebke (i.e., ISO size files were heat-treated in a furnace in an non-reactive atmosphere at 500°C for 75 minutes), the Luebke files behave via a different mechanism. At room temperature (20-25°C), the endodontic instruments are primarily martensite in crystal structure. This was confirmed from differential scanning calorimetry (DSC) analysis which has shown the instruments to have austenite finish temperatures (At) greater than room temperature and thus greater than those in U.S. Patent No. 6,431,863. With application of stress, the endodontic instruments deform to an appreciable extent and remain deformed. Little to no stress-induced phase

transformation occurs. Essentially, these endodontic instruments behave as shape memory nickel-titanium with elastic recovery only afforded by a temperature-induced phase transformation from martensite to austenite." Attached Phukaoluan, A. *et al.*, entitled "Effect of Ni-content on mechanical and transformation behavior of NiTi shape memory alloys for orthodontics applications" a paper presented at the first TSME international conference on mechanical engineering, 20-22 October, 2010 (Exhibit C) independently confirms the characteristic result that Dr. Berzins obtained and reported in the Rule 132 affidavit from 9-2-2010. With this evidence, it is shown that the characteristics of the product distinguish it from other products and also confers a structure unique to all other endodontic files.

As suggested in the Examiner interview on August 4, 2011, Applicant also provides Declaration evidence of the criticality of the process temperatures in independent claims 1, 13 and 23. M.P.E.P. § 2144.05 III. notes that "Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range." *See, In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) ("The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . [and] in such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." (citations omitted)).

Attached for convenience as Exhibit A is a copy the Inventor's Declaration that was submitted August 29, 2008 in the present application. Looking at independent claims 1, 13 and 23, the claimed invention requires that the entire shank be heat-treated

at a temperature from 400°C up to but not equal to the melting point of the titanium alloy. The Inventor's Declaration describes comparative tests of two groups of heat treated files, that is, a first group of files heat-treated at 375°C for 1¼ hours and a second group of files heat-treated at 500°C for 1¼ hours. The first group was heat treated at a temperature (375°C) outside of the claimed temperature range in independent claims 1, 13 and 23 and the second group was heat treated at a temperature (500°C) within the claimed range in independent claims 1, 13 and 23 (and also within the narrower temperature range of dependent claims 4, 8, 9, 13, 21, 24 and 25).

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.

Looking at Matsutani, no heat treatment temperatures are described, and the heat treatment was undertaken on only the tip of the file, not an entire shank as recited in independent claims 1, 13 and 23. Nothing in Matsutani suggests the criticality of the temperature range of independent claims 1, 13 and 23 or that the claimed temperature range is critical when heat treating an entire shank.

Additionally, the Rule 132 affidavit from 12-23-2008 in paragraphs 7, 8 and 9 cited Zinelis *et al*., entitled "The effect of thermal treatment on the resistance of nickel-titanium rotary files in cyclic fatigue", Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, Endodontology, 2007;103:843-847 (Exhibit B) as further evidence that the claimed range is critical. The later independent work of Zinelis *et al.* shows in Figure 3 at page 845 that there is a critical temperature range for the thermal treatment of nickel-titanium files in order to improve cyclic fatigue. Therefore, others in the Inventor's field, working after the filing date of the present application, have confirmed that there is a critical range for heat treatment.

Another citation is Phukaoluan, A. *et al.*, (cited above) which states that "[f]or the alloy heat treated at 600 degrees C, influences of reduction ratio can not be observed, since this temperature (600° C) is higher than the alloy recrystallization temperature which is about 500-600° C." The Zinelis and Phukaoluan references were all published after the filing date of the present application by authors that the present inventor does not know.

Therefore, evidence in Inventor's Declaration, and the Zinelis and Phukaoluan references (which were all published after the filing date of the present application) confirm that the particular temperature range of independent claims 1, 13 and 23 is critical. The Applicant respectfully submits that any *prima facie* case of obviousness based on Matsutani has been rebutted by the above showing of the criticality of the claimed temperature range of independent claims 1, 13 and 23.

Conclusion

Claims 1-2, 4-10, 12-15, 20 and 23-25 are believed to be in condition for

allowance. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

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

Respectfully submitted,

Neill H. Luebke

Dated: August 29, 2011

By: /Richard T. Roche/

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Milwaukee, WI 53202
(414) 277-5805

14164244

EXHIBIT A

Docket Number: 115207.00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke

Application No.: 11/628,933

Filing Date: December 7, 2006

Title: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

Art Unit: 4166

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 selected endodontic files from the same lot and same type of instrument. The files were nickel-titanium (NiTi) rotary instruments with a 2% taper.

3. Others working according to my directions heat treated a first group of these files at 375°C for 1¼ hours and heat treated a second group of these files at 500°C for 1¼ hours.

4. Others working according to my directions tested the heat treated files using the ADA/ANSI Standard #28 and ISO 3630-1 tests for torque, angular deflection and bending. I performed a cyclic fatigue test that has not yet been approved as a

standard test in either ISO or ADA/ANSI, but both working groups have been asking for a proposal for this test to be included as a standard.

5. When performing these tests on endodontic files, one looks for torque data that is similar because this indicates that the heat did not degrade the metal in the instrument. For better endodontic file performance, one looks for an increased number in angular deflection, a lower gm·cm number in the bend test, and a higher number in cyclic fatigue that demonstrates the property of passive flexibility.

6. The test results (n = 5) are shown in the Illustrations below.

Illustration 1

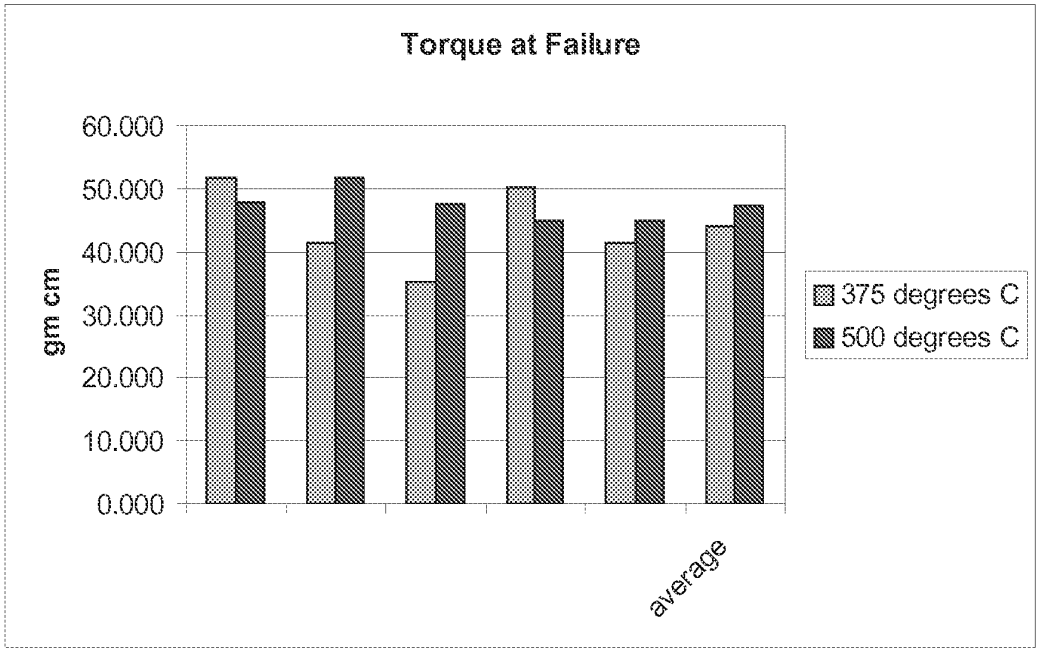


Illustration 2

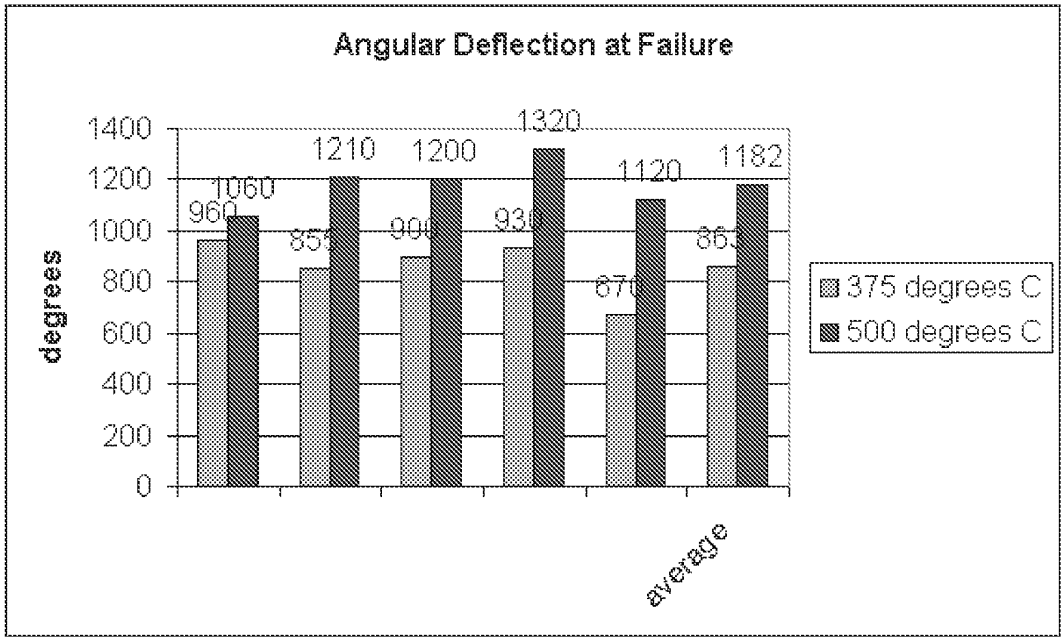


Illustration 3

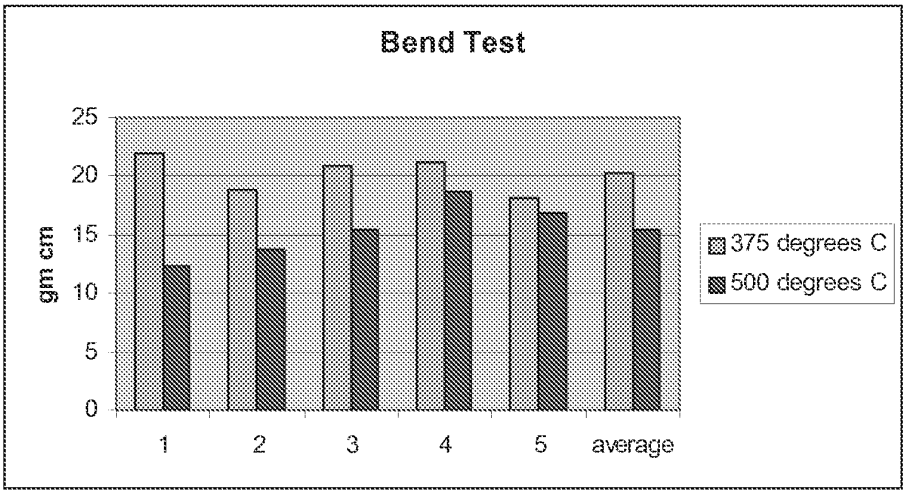
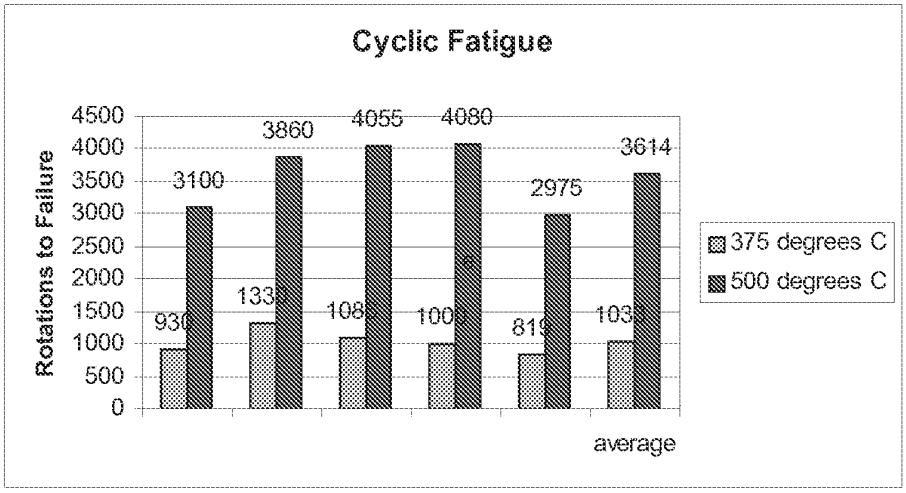


Illustration 4



7. In Illustration 1 above, the torque data is similar for the endodontic files which indicates that the heat did not degrade the metal in the files heat treated at 500°C. As noted in Item 5 above, the angular deflection is preferably larger in endodontic files and in these tests as graphed in Illustration 2, the angular deflection was significantly larger for the files heat treated at 500°C, on average 130% better than the files heat treated at 375°C. In the bend test data of Illustration 3, the smaller the gm cm number, the more flexible the file. This bend test data show that it is significant between the two temperatures, i.e., the files heat treated at 500°C have improved flexibility compared to the files heat treated at 375°C. The cyclic fatigue data of Illustration 4 demonstrate the remarkable property of passive flexibility in that the numbers for the files heat treated at 500°C are significantly larger than the files heat treated at 375°C.

8. 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: August 29, 2008

Neill H. Luebke

Dr. Neill H. Luebke

Vol. 103 No. 6 June 2007

Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology

ENDODONTOLOGY Editor: Larz S. W. Spångberg

The effect of thermal treatment on the resistance of nickel-titanium rotary files in cyclic fatigue

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UNIVERSITY OF ATHENS

Objective. The purpose of this study was to determine the effect of various thermal treatments on the fatigue resistance of a nickel-titanium (NiTi) engine-driven endodontic file.
Study design. Fifteen groups of 5 files each of ISO 30 and taper .04 were tested in this study. The cutting tip (5 mm from the end) of files from 14 groups were heat treated for 30 minutes in temperatures 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, respectively, while 1 group was used as reference. The files were placed in a device that allowed the instruments to be tested for rotating bending fatigue inside an artificial root canal. The number of rotations to breakage was recorded for each file. The mean values of all groups were statistically analyzed using 1-way analysis of variance and Student Newman Keuls multiple comparison test at $\alpha = .05$.
Results. The 430°C and 440°C groups showed the highest values, with fatigue resistance decreasing for thermal treatment at lower and higher temperatures. This may be the result of metallurgical changes during annealing.
Conclusion. Within the limitations of the low sample size and the specific instrument size tested, it appears that the appropriate thermal treatment may significantly increase the fatigue resistance of the NiTi file tested. **(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2007;103:843-7)**

Nickel-titanium (NiTi) alloy has been used in endodontics for about 2 decades. It was introduced to facilitate instrumentation of curved root canals. Although NiTi files showed increased flexibility compared with stainless steel counterparts, the unexpected fracture during mechanical preparation of root canals still remains a problem.[1-3] It has been reported that rotary NiTi instruments are more prone to intracanal fracture compared with stainless steel hand instruments.[3] These unexpected fractures occur without any visible changes to the instruments, such as permanent defect or deformation.[1,2]

It is widely accepted that the fracture of engine-driven NiTi instruments is associated with the fatigue mechanism mainly due to cyclic loading, although some recent studies based on clinically failed instruments implied that fracture occurs due to a sudden overload rather than a progressive fatigue process.[3-6] In any case, the mechanical properties of NiTi alloys associated with fatigue resistance in the former mechanism or the fracture strength in the latter play an important role on the fracture susceptibility under clinical conditions.

However, the mechanical as well as the shape memory and superelastic properties of endodontic files are strongly dependent on the thermomechanical processing history of NiTi alloys through the manufacturing process.[7] Although the exact thermomechanical history of NiTi wires used for the production of endodontic

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Received for publication Jun 2, 2006; returned for revision Nov 27, 2006; accepted for publication Dec 21, 2006.
1079-2104/$ - see front matter

doi:10.1016/j.tripleo.2006.12.026

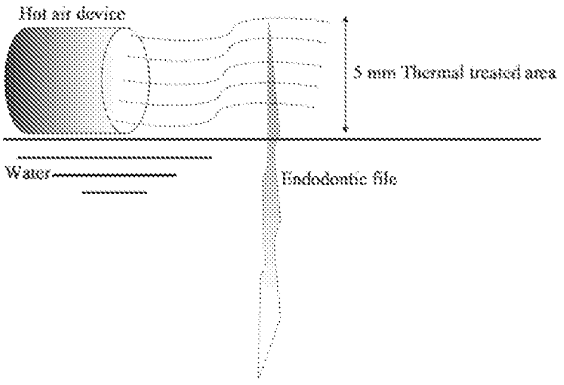

Fig. 1. Illustration of the thermal treatment process. The tip of the instrument is heat treated under a constant flow of hot air while the rest is immersed in a water bath.

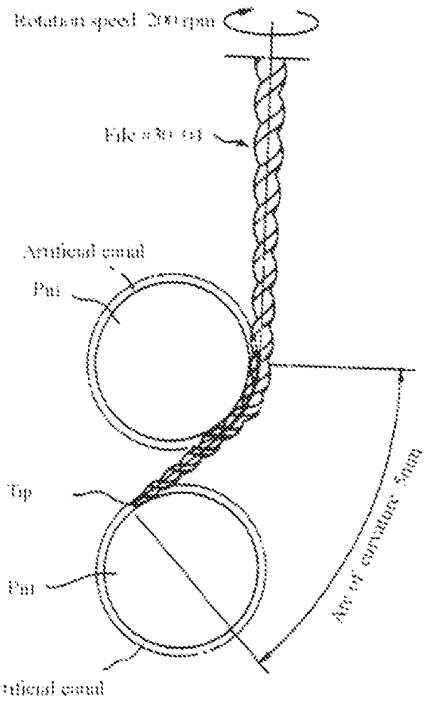

Fig. 2. Experimental setup for the evaluation of rotation to breakage of the nickel-titanium instruments.

files is proprietary, typical processing of superelastic NiTi-based wires includes vacuum casting of an ingot and hot forging, rolling, and drawing followed by a heat treatment. The NiTi alloys are usually heat treated between 450°C and 550°C, in air or inert atmosphere furnaces, to obtain superelastic or shape memory properties and to achieve the appropriate balance of mechanical properties for the application.[7-9]

Nickel-titanium wires are provided by the manufacturer in a cold-worked state (known also as *drawn* or *rolled*) in cases where further mechanical and/or thermal treatment might take place, because cold-worked microstructures demonstrate less ductility, facilitating the grinding process.[7] It is assumed that the same procedure is followed for the production of NiTi instruments, as they are produced exclusively by CAD/CAM manufacturing processes.[8] Therefore, it is expected that the endodontic instrument manufacturers are supplied the NiTi alloys in the cold-work state. The composition of alloy used to construct endodontic instruments is 56% wt Ni and 44% wt Ti, according to the information provided by one manufacturer (Dentsply, Maillefer Instruments SA, Ballaigues, Switzerland);[8] the same is true for other manufacturers of endodontic files, based on unpublished data by energy-dispersive x-ray microanalysis by our research group. For NiTi alloys with the aforementioned elemental composition, the fracture strength of 1723 MPa and 7% elongation after fracture in the cold-worked drawn state are changed to 1378 MPa and 15%, respectively, after heat treatment.[7]

Previous studies[10-14] have already proved that additional thermal treatments significantly modify the mechanical and superelastic properties of NiTi files, implying that the assumption that NiTi files are manufactured by fully cold-worked alloys is right. In this perspective, the aim of this study was to evaluate the effect of thermal treatment on the fatigue resistance of a commercially available engine-driven NiTi file.

MATERIAL AND METHODS

Fifteen sets of 5 endodontic NiTi files each (NRT, Mani Inc., Tochigi-Ken, Japan) of ISO 30 and taper .04 (Lot number 5040677600) were selected for this study. The tips (5 mm from the cutting tip) of files from 14 sets were heat treated for 30 minutes in temperatures 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, respectively. One set was used as a reference. The tip of each file was heat treated by a hot air device (Weldy hot air tool, Malcom Hot Air Systems, Andover, MA), whereas the rest of the file remained immersed in water as illustrated in Fig. 1. The processed pieces were cooled to room temperature. Then, the files were placed in a specific device that allowed the instruments to be tested in rotating-bending position inside a guide that had the form of an artificial root canal engraved on the surface of 2 hard-steels pins (Fig. 2). The instruments were rotated inside the artificial canal with a 5-mm bending arc of curvature at a constant speed of 200 rpm. The number of rotations to breakage was recorded for each file and the mean

Table I. Mean values and standard deviations of number of rotations to breakage of nickel-titanium files for all groups tested

Aging temperature	Number of rotations to breakage*	SNK grouping†
430°C	4918 ± 453	A
440°C	4264 ± 487	AB
425°C	3571 ± 376	BC
410°C	3536 ± 412	BC
420°C	3325 ± 639	CD
400°C	3241 ± 672	CD
450°C	3183 ± 522	CD
375°C	2480 ± 471	DE
350°C	2093 ± 477	EF
475°C	1991 ± 433	EF
500°C	1318 ± 479	FG
300°C	1316 ± 294	FG
250°C	1147 ± 232	FG
Reference	936 ± 136	G
550°C	864 ± 201	G

*Results are sorted in decreasing order of mean values.
†Means with same SNK (Student Newman Keuls) grouping letter are not significantly different ($P > .05$).

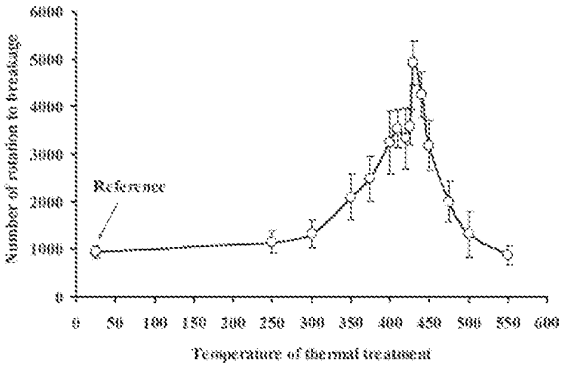

Fig. 3. The curve shows the alteration of number of rotations to breakage in relation to the annealing temperature, demonstrating the maximum value at 430°C.

values of all groups were statistically analyzed using 1-way analysis of variance and Student Newman Keuls multiple comparison test at $\alpha = .05$.

RESULTS

Table I shows the results of number of rotations to breakage for each group, sorted in decreasing order. According to the statistical analysis, the group at 430°C showed the highest number of rotations to breakage, with statistical significance differences with all groups except that of 440°C. Fractures of all specimens occurred within the deflected part of the file. Fig. 3 illustrates the alteration of rotation to breakage in relation to the annealing temperature. The reference group was set at room temperature. The number of rotations to breakage was found to increase from the reference group to the group of 430°C and 440°C and then to decrease again until the group of 550°C.

DISCUSSION

According to the results of this study, the fatigue resistance of files was found to steadily increase from the *as received state* to 440°C annealing temperature and then to decrease again up to 550°C. The explanation of this behavior is associated with the thermomechanical processing and the subsequent metallurgical alterations.

When metals and alloys are rolled or forged or drawn to wire such as in this case, they *work harden* or *strain harden*. Cold-worked alloys demonstrate increased hardness but with decreased ductility. This is attributed to the fact that cold working significantly increases the dislocation (defects in crystal structure) density.[15] Although the presence of dislocations in a crystalline material such as alloy is essential for plastic deformation, the overgrowth of dislocation density induced by cold working has the inverse effect, decreasing the ductility of the alloys. This is appended to the fact that each dislocation produces a strain field, hindering the sliding of adjacent dislocations.[15] Annealing through thermal treatment gives the atoms enough thermal energy to rearrange themselves in the lattice under the driving force of this strain energy in a process known as *recovery*. After the rearrangement of dislocations, the total strain energy is significantly lowered and the internal stresses are released with subsequent changes in strength and ductility. The next process is recrystallization, which occurs in higher temperatures than recovery, whereas new grains nucleate and grow until the whole structure consists of undeformed grains.[15] After this process, the dislocation density returns to its initial value and the same happens for the strength and ductility.

The maximum fatigue resistance for the 440°C group might be explained by the fact that recovery of NiTi cold-worked alloys is commonly taking place[7] within the range of 450°C to 550°C. The progressive attenuation of dislocation density from the as received state to the 440°C annealing temperature state significantly decreases the brittleness,[7] enhancing the resistance to the crack propagation mechanism and thus the fatigue strength. However, the aforementioned approach cannot explain the decrease of fatigue resistance beyond 450°C, as the dislocation's density is steadily decreased through annealing at higher temperatures. A significant insight in the metallurgical alterations of cold-worked NiTi alloys is given by the work of Frick et al., 2005.[14]

The microstructure of cold-worked NiTi alloys consists of a large dislocation density as well as residual martensite in an austenitic matrix. During heat treating, the microstructure is changed by 2 antagonistic mechanisms: precipitate growth of Ni_3Ti_4 and dislocation annihilation. Precipitate growth of Ni_3Ti_4 is also effective at stopping dislocation sliding, as does a large dislocation density in cold-worked structures. Although ductility is progressively increased through attenuation of dislocation density, the precipitation process during annealing has the inverse effect by hindering dislocation motion. According to the results of this study, the temperature range of 430°C to 440°C is the optimum for the specific alloy, and for its thermomechanical treatment, in obtaining the maximum fatigue resistance. Of course, thermal treatment definitely has an effect on characteristic transformation temperatures (Af, As, Ms and Mf)[7] of this alloy, but the evaluation of this phenomenon is beyond the aim of this study.

The justification for heat treating only the tip of the files is also associated with the alterations of mechanical properties after thermal treatment. Intracanal fracture of endodontic instruments is commonly observed within the first one third of its length.[2,16] The increase in fatigue resistance through the aforementioned mechanism associated with the release of residual strain is followed by a significant decrease in hardness, affecting the cutting ability of these instruments. A previous study made on ProFile files showed that recrystallization is followed by a tremendous decrease in hardness—from 475 in the as received state to 258 Vickers Hardness (VHN)—a value approaching the hardness of fully annealed NiTi alloys (200 VHN)[17] used for nondental applications.[10] Therefore, the constraint of the thermal treatment effect only in the tip region increases the fatigue resistance at the fracture-sensitive area, retaining the maximum cutting ability to the rest of the file.

Of course, the results of this study are appended only to the tested files. However, previous studies[18] showed that commercially available endodontic files have hardness values (HV_{200}: ProFile = 450, Ergoflex K = 410, Hero642 = 376, Hyflex X-File = 371) close to the tested files in the as received condition (465 VHN), and much higher than those of the fully annealed state (200 VHN),[17] denoting that endodontic files are manufactured from cold-worked NiTi wires. This is also advocated by the fact that ProFile instruments of the same size and taper (number 30, taper .04) demonstrate comparable cycles to failure (812 ± 52)[19] when tested with the tested files in the reference group (rotations to breakage 936 ± 136). Of course, differences in hardness among the aforementioned materials are appended to variations to their thermomechanical history—which of course remains unknown for each product—whereas variations in cycles to failure may also be attributed to the geometric differences between ProFile and Mani NRT instruments. This means that heat treatment can be applied to all endodontic files to modify their mechanical properties.

The results of rotation to breakage are indicative of the mechanical properties of the alloy and definitely cannot be used as a safe limit to avoid fracture under clinical conditions. This is the reason for applying the technique for only 1 instrument size. In addition, the quantitative differences in fatigue resistance between thermal-treated reference groups cannot be extrapolated to other commercially available endodontic instruments due to differences in geometric features, as well as in the thermomechanical history of NiTi alloy.

Recent studies[3,5-6] based on clinically fractured NiTi instruments reported that fracture occurs due to a single overloading under torsion, tensile, or bending-loading conditions (the combination of all the aforementioned loading is also very possible), rather than a fatigue mechanism. Given that the fracture strength is significantly decreased after thermal treatment (from 1723 to 1378 MPa),[7] it is expected that the instrument will be more susceptible to fracture. However, the decrease in fracture strength is followed by an increase in ductility (from 7%-15%), enhancing the fracture toughness of the alloy. Generally, this means that the alloy might be more susceptible to the initiation of plastic deformation but more resistant to separation. In any case, this is only a speculation, and thus the behavior of thermal-treated NiTi instruments in this failure mechanism, together with the possible adverse effect on the cutting ability of endodontic instruments, requires further analysis to optimize the effect of thermal treatment on the efficacy of engine-driven NiTi instruments. Although the current results definitely show a trend for fatigue resistance, manufacturers should modify the parameters of the thermal treatment (i.e., temperature, time portion of instrument subjected to heat treatment) according to the thermomechanical history of NiTi alloy used, as well as the clinical demands to optimize the effect of thermal treatment on NiTi instruments.

Although the thermomechanical history of NiTi instruments still remains unknown, the results of this study show that the mechanical properties of such instruments can be effectively modified by thermal treatment. However, the application of heat treatment can significantly vary for different commercial products due to differences in their thermomechanical history. Therefore, thermal treatment can be used to increase the in vivo performance of NiTi instruments, modifying the mechanical properties that have crucial implication

on the cutting and failure mechanisms encountered under clinical conditions.

CONCLUSIONS

The results suggest that fatigue resistance of the tested NiTi instruments may be significantly enhanced by the appropriate heat treatment.

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Effect of Ni-Content on Mechanical and Transformation Behavior of NiTi Shape Memory Alloys for Orthodontics Applications

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Abstract

This study aims to investigate the effect of Ni-content on mechanical properties and transformation behavior of NiTi shape memory alloys for utilizing as orthodontic wires. NiTi binary alloys with Ni-content ranging from 50 to 51 at% were prepared. The specimens were cold-rolled with percentage reduction of 10, 20 and 30%, respectively. Then they were heat treated at 400°C and 600°C for 3,600s, respectively. The results show that transformation temperatures strongly depend on Ni-content, i.e., transformation temperatures rapidly decrease with the increase of Ni-content. Moreover transformation temperature decreases with the increase of cold-rolling reduction ratio. However, the higher is the reduction ratio, the superelastic properties become more evidently. Further heat treatment temperature 400°C provides specimens with better properties compared to those of 600°C. The results obtained can be use to determine optimum alloy composition of NiTi alloy to be used as orthodontic wires.

Keywords: orthodontic wires, Ni-content, Reduction ratio

1. Introduction

NiTi was introduced to be used in clinical orthodontic for leveling phase in 1971[1]. The physical properties of nickel-titanium alloy have several advantages over precious metals and stainless steel. NiTi alloys have extraordinary properties: shape memory effect and superelasticity with excellent corrosion resistance, as well as good mechanical properties and biocompatibility. NiTi alloy are wildly used in clinical orthodontics since their superelasticity property gives continuous and light forces transmitted to the dentition over a long activation period, resulting in a desirable biological response [2-4]. The relative alloy composition of martensite and austenite is a

function of mechanical stress and ambient temperature. Some key characteristics of superelastic nickel-titanium may show exceptional temperature sensitivity [5-7]. Small chemical composition variations can produce significant modifications of such behavior, which can be analyzed considering variation of the start of martensitic transformation (Ms) temperature [8-9]. The properties of NiTi can be modified to a great extent by judicious choice of composition, cold work and heat treatment. This study will be a preliminary work to fabricate of NiTi alloy samples.

The purpose of this study is to evaluate the chemical composition, mechanical properties and phase transformation behavior of the fabricated near equiatomic NiTi alloy samples. The influence of degrees of cold-rolling and heat treatment temperatures will be discussed in order to further develop NiTi alloy used in orthodontics.

2. Experimental procedure

2.1 Materials

The raw materials used commercial grade with high purity; nickel 99.9% and titanium 99.8%. The targeted composition for each sample is equiatomic NiTi alloy (50-51 at.% Ni). Firstly, nickel and titanium were cleaned in the acid ($HF:HNO_3:H_2O$, 5:4:1) and then rinsed by acetone to remove surface grease and oxide before melting.

2.2 Melting method

A conventional Vacuum Arc Re-melting technique in argon atmosphere was employed. After charging the constituent element in crucible Fig.1(a), the furnace was purged with argon at pressure of 0.3-0.5 bar. Melting of the raw elements was performed with arc rotation torch created by tungsten electrode Fig.1(b). The ingot was turned over and re-melted five times to ensure chemical homogeneity. The examples of melted ingot is show in Fig.1(c). All melted ingots were then homogenized at 800°C for 3600s Fig.1(d).

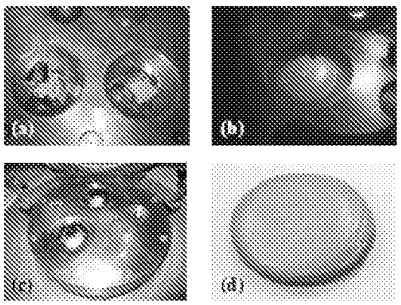

Fig. 1 Sequence of the VAR process: (a) pilling up raw materials, (b) rotating torch, (c) melted ingot on a copper crucible, (d) melted ingot after homogenized.

2.3 Characterization

Ingots were sliced into small plates (1.5 mm. in thickness) using a CNC wire cutting machine and then cold-rolled at determined reduction ratio, i.e., 10%, 20% and 30 %, respectively. The lubricant used for the rolling is ISO cut 570A in combination with sodium strearate soap. After removing oxide layers and surface contaminants on the specimen surfaces by mechanical polishing, they were annealed at 400°C and 600°C in heat treatment furnace for 3,600s. The specimens were then cut into specific by a CNC wire cutting machine. Specimens used for investigation phase-transformation behavior were test by using. Differential Scanning Calorimeter (DSC). During

the test temperature was varied in the range of -50°C to 100°C with cooling and heating rate of 10°C/min. The hardness of the specimens was determined by Vickers Microhardness tester with a Vickers diamond tip at room temperature under a maximum load of 500 g_f. To examine load-deflection characteristics of melted NiTi specimens, a three-point bending tests using the Instron Universal Testing Machine (load cell 100N) were performed. The span for bending test was 10 mm. Specimens were loaded to till a maximum deflection of 1.5 mm and deflection rate is 5 mm/min. The influences of Ni-content for NiTi on the mechanical properties and transformation behavior of the alloys were then discussed.

3. Results and Discussion

3.1 Transformation temperature behavior

The transformation temperatures of NiTi. Austenetic finish (Af) and Martensitic start (Ms) are critical factors of their transformation behavior. The results of Af and Ms values obtained are shown in Table 1. Actually, we intended to make a superelastic NiTi alloy having transitional temperature lower than oral temperature. It is generally known this can be achieved by increasing Ni content over 50 at.%. From Table 1, the NiTi having nominal composition of $Ni_{50.4}Ti_{49.6}$ at.% and $Ni_{50.6}Ti_{49.4}$ at.% provides Austenite finished temperature (A_f) set as 42.5°C and 32°C, which are closed to oral temperature.

Table 1 Transformation temperature of the specimens obtained by DSC

Nominal Composition (at.%)	Transformation temperature (°C)			
	Ms	Mf	As	Af
$Ni_{50}Ti_{50}$	51.5	20	50.5	79
$Ni_{50.2}Ti_{49.8}$	27	7	42	62.5
$Ni_{50.4}Ti_{49.6}$	12	-12	16.5	42.5
$Ni_{50.6}Ti_{49.4}$	4.5	-31	-8	32
$Ni_{51}Ti_{49}$	-37	-	-41	-4

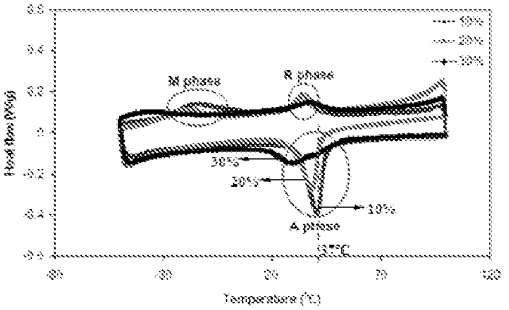

Fig. 2 Thermographs of $Ni_{50.4}Ti_{49.6}$ at.% with 10%, 20% and 30% reductions followed by heat-treatment at 400°C for 3,600s

Fig. 2 shows the results of DSC for $Ni_{50.4}Ti_{49.6}$ at.% with 10, 20 and 30% reductions followed by 400°C heat treatment for 3,600s. It can be found from the result that the peak on cooling curve reveals the R-phase transformation or the intermediate phase occurs. This R-phase transformation often occurs when the alloys are work-hardened, which also can occur in nickel-rich NiTi alloys. Further $Ni_{50.4}Ti_{49.6}$ at.% does not reveals superelasticity properties at the oral temperature because its A_f is higher than 37°C.

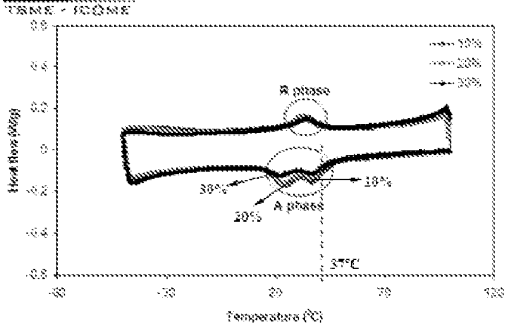

Fig. 3 Thermographs of $Ni_{50.6}Ti_{49.4}$ at.% with 10%, 20% and 30% reductions followed by heat-treatment at 400°C for 3,600s

Fig. 3 shows the DSC result for $Ni_{50.6}Ti_{49.4}$ at.% with 10, 20 and 30% reductions followed by 400°C heat treatment for 3,600s. The alloy has Af temperature very closed to oral temperature as shown previously. From Fig. 2, the higher of the percent reduction is the lower and shorter of transformation temperature of both heating and cooling paths are obtained. This can be implied that percent reduction has an impact on phase transformation, and can be explained that transformation was suppressed by internal stress due to cold work. In other words, the internal structure of the work-hardened material is composed of multiple dislocations that hinder the phase transformation. Some works reported that cold-worked NiTi alloys had wide transformation temperature range and the peak height was small. The broadening of the peak was enhanced by increasing the amount of cold-working reduction percent [10].

For the alloy heat treated at 600°C, influence of reduction ratio can not be observed, since this temperature (600°C) is higher than the alloy recrystalization temperature which is about 500-600°C [11]. This result confirms that the dislocation obstructing the phase transformation. Moreover, the Af temperature of the alloys obtained from all conditions are summarized and shown in Table 2.

Table 2 Transformation temperature of the specimens with heat-treatment at 400°C for 3,600s obtained by DSC

Nominal Composition (at.%)	% Reduction	Transformation temperature (°C)	
		Af	Rs
$Ti_{49.6}Ni_{50.4}$	10	49.8	48.8
	20	47	41.3
	30	45.7	39.1
$Ti_{49.4}Ni_{50.6}$	10	47	40
	20	40	39
	30	37	39

3.2 Vickers hardness test.

The micro-indentation hardness is measured at the cross-sectional areas of each alloy specimen. Fig. 4 and Fig. 5 shows the relation between the hardness value (HV) and the cold-rolled reduction ratio, for heat treatment temperature of 400 and 600°C, respectively.

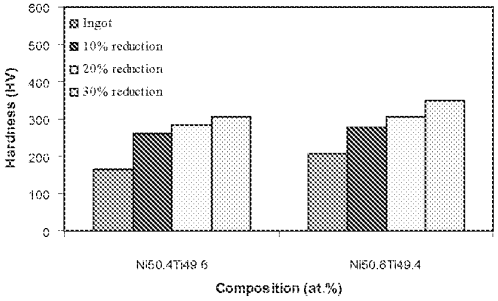

Fig. 4 Hardness values of NiTi with 10%, 20% and 30% reductions followed by heat-treatment at 400°C for 3,600s

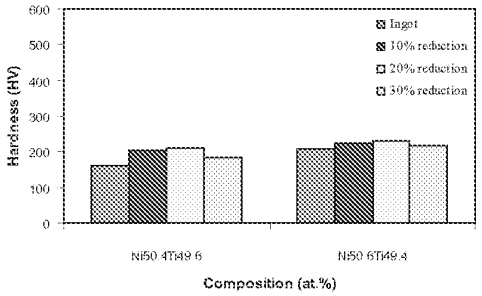

Fig. 5 Hardness values of NiTi with 10%, 20% and 30% reductions followed by heat-treatment at 600°C for 3,600s

From Fig. 5, at 600°C heat treatment temperature, which is higher than alloy recrystalization temperature, dislocations are eliminated, hence there is no difference between the hardness value of the specimens undergone rolling at different reduction ratio.

3.3 Three-point bending test.

Three-point bending tests of the specimens are conducted at oral temperature or at 37°C. The results are shown in Fig. 5 and Fig. 6 for the specimen with different. Composition for the $Ni_{50.6}Ti_{49.4}$ at.% with 10%, 20% and 30% reductions followed by heat treatment at 400°C for 3600s (Fig. 6), the completely reverse stress-strain curve is obtained only for the reduction ratio of 30%. From Fig. 7 for $Ni_{50.4}Ti_{49.6}$ at.% alloy, the completely reverse transformation cannot be obtained from any conditions.

This can be explained by the transformation temperature (Af) of the alloy. Since there is only $Ni_{50.6}Ti_{49.4}$ at.% undergone rolling 30% having Af lower than 37°C, it becomes only one condition that gives superior superelastic behavior without permanent strain left after unloading.

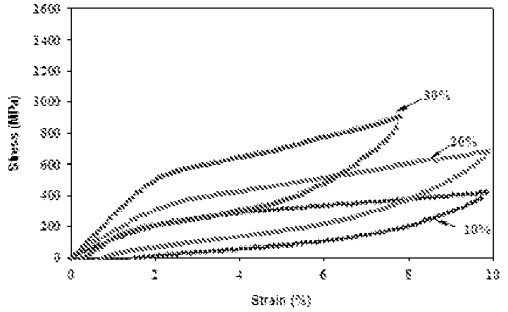

Fig. 6 Stress-strain curves for $Ni_{50.6}Ti_{49.4}$ at.% with 10%, 20% and 30% reductions follow by heat-treatment at 400°C for 3,600s (tested at 37°C)

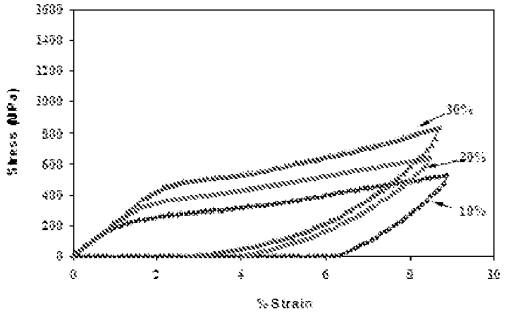

Fig. 7 Stress-strain curves for $Ni_{50.4}Ti_{49.6}$ at.% with 10%, 20% and 30% reductions follow by heat-treatment at 400°C for 3,600s (tested at 37°C)

4. Conclusions

In order to fabricate the NiTi shape memory alloy used in orthodontics, three principle factors, i.e., alloy composition, work hardening and heat treatment temperature, affecting the transformation behavior and mechanical properties of NiTi should be effectively determined. The cold work reduction higher than 30% tends to improve the superelastic property of the alloys. The heat treatment temperature higher than 600°C

remove all dislocation resulted in unsatisfied properties of the alloys. The fraction of Ni at 50.6% in the alloy provides the best mechanical properties as well as superelastic behavior to be used as orthodontic wires.

5. Acknowledgement

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Docket No.: 115207.00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	11/628,933
Filing Date:	December 7, 2006
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	9736
Art Unit:	3732
Examiner:	Matthew M. Nelson

DECLARATION UNDER 37 C.F.R. 1.132

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

Sir:

I, Robert Struebing, hereby declare as follows:

1. I am a production manager at the Sturtevant Plant of Bodycote Thermal Processing, Inc., ("Bodycote"). Bodycote is one of the world's largest providers of thermal processing services, with over 170 facilities in 27 countries. Further information on Bodycote is available at www.bodycote.com.

2. I am experienced in the vacuum heat treating of metals, including the use of argon gas in heat treating.

3. I have reviewed the attached "Praxair Material Safety Data Sheet" and confirm that OSHA regulations require special procedures when using argon gas in a heat treating process as argon "is considered hazardous" as stated on the MSDS.

4. When using argon gas in a heat treating process, a heat treating company will use the argon gas in a sealed closed system to provide containment of the argon gas.

5. I have read attached Example 4 from U.S. Patent Application No. 11/628,933, and I have noted the language "Ten of each ISO size were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes."

6. The use of an argon atmosphere as described in Example 4 requires that the entire file be heat treated in the furnace in order to keep the argon contained in a closed system.

7. I declare that all statements are 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.

Respectfully submitted,

Bodycote Thermal Processing, Inc.

Dated: August 23, 2011 By:

Robert Struebing

Production Manager

Example 4 from U.S. Patent Application No. 11/628,933

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. 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 in each size, and the mean and standard deviation for each group (Control, TT, Ti-N) of ten files were calculated. The ten files in each size 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 significantly maintain the acquired (test deformed) shape rather than the shape memory exhibited in the untreated control (nickel-titanium instruments).

Praxair Material Safety Data Sheet

1. Chemical Product and Company Identification

Product Name: Argon, compressed (MSDS No. P-4563-I)	**Trade Names:** Argon
Chemical Name: Argon	**Synonyms:** Shielding gas, argon 40
Chemical Family: Rare gas	**Product Grades:** 4.8 Oxygen Free, 4.8 Zero, 4.8 Inductively Coupled Plasma, 5.5 Trace Analytical, 6.0 Research, Industrial Gas

Telephone: **Emergencies:** 1-800-645-4633* **Company Name:** Praxair, Inc.
CHEMTREC: 1-800-424-9300* 39 Old Ridgebury Road
Routine: 1-800-PRAXAIR Danbury, CT 06810-5113

**Call emergency numbers 24 hours a day only for spills, leaks, fire, exposure, or accidents involving this product. For routine information, contact your supplier, Praxair sales representative, or call 1-800-PRAXAIR (1-800-772-9247).*

2. Hazards Identification

EMERGENCY OVERVIEW

CAUTION! High-pressure gas.
Can cause rapid suffocation.
May cause dizziness and drowsiness.
Self-contained breathing apparatus and protective clothing may be required by rescue workers.
Under ambient conditions, this is a colorless, odorless, tasteless gas with no odor.

OSHA REGULATORY STATUS: This material is considered hazardous by the OSHA Hazard Communications Standard (29 CFR 1910.1200).

POTENTIAL HEALTH EFFECTS:

Effects of a Single (Acute) Overexposure

Inhalation. Asphyxiant. Effects are due to lack of oxygen. Moderate concentrations may cause headache, drowsiness, dizziness, excitation, excess salivation, vomiting, and unconsciousness. Lack of oxygen can kill.

Skin Contact. No harm expected.

Swallowing. An unlikely route of exposure. This product is a gas at normal temperature and pressure.

Eye Contact. No harm expected.

Effects of Repeated (Chronic) Overexposure. No harm expected.

A vertical line in the left margin indicates revised or new material.

Electronic Acknowledgement Receipt

EFS ID:	10831968
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	29-AUG-2011
Filing Date:	07-DEC-2006
Time Stamp:	14:03:16
Application Type:	U.S. National Stage under 35 USC 371

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		115207_00002_Amendment.pdf	4151318 2c7b0d553e63adea6658a0d849c715ab240b18fa	yes	34

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	7	
	Applicant Arguments/Remarks Made in an Amendment		8	34	
Warnings:					
Information:					
2	Rule 130, 131 or 132 Affidavits	115207_00002_Declaration.pdf	2300374 7ba10386a9d520bcb497f525886487a4758606b1	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	6451692		

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

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

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

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

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/628,933	Filing Date 12/07/2006	☐ To be Mailed

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
	08/29/2011	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 18	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/FELICIA R. FARMER/

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

26710 7590 09/23/2011

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

EXAMINER	
NELSON, MATTHEW M	
ART UNIT	PAPER NUMBER
3776	

DATE MAILED: 09/23/2011

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

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
nonprovisional	YES	$755	$300	$0	$1055	12/23/2011

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 SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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

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

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

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

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

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

26710 7590 09/23/2011

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

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.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

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
nonprovisional	YES	$755	$300	$0	$1055	12/23/2011

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

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

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

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

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

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

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

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

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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

❑ 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 _____ Date _____

Typed or printed name _____ Registration No. _____

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

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

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.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

26710 7590 09/23/2011

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

EXAMINER	
NELSON, MATTHEW M	

ART UNIT	PAPER NUMBER
3776	

DATE MAILED: 09/23/2011

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

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

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No.	Applicant(s)	
	11/628,933	LUEBKE, NEILL HAMILTON	
	Examiner	Art Unit	
	MATTHEW NELSON	3776	

-- 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 *8/29/2011*.

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 *1,2,4-10,12-15,20,21 and 23-25*.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of 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. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ 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).

7. ☐ 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. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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

DETAILED ACTION

1. Amendment filed on 8/29/2011 is acknowledged.

Response to Amendment

2. The declaration under 37 CFR 1.132 filed 8/26/2011 in addition to the amendments to the independent claims is sufficient to overcome the previous rejections.

Allowable Subject Matter

3. Claims 1-2, 4-10, 12-15, 20-21, 23-25 are allowed.

4. The following is an examiner's statement of reasons for allowance: A titanium alloy endodontic instrument, and method of using, having a shank with cutting edges formed by heat treating the entire shank at a temperature from 400 degrees Celsius up to but not equal to the melting point of the titanium alloy in an atmosphere consisting essentially of a gas unreactive with the shank (this temperature range and environment has been shown to be critical in providing distinguishing shape memory qualities along the entire length of the shank from the prior art, which teaches heat treatment at temperatures outside this range, treatment only to the tips of devices, and without the described atmosphere) 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.

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

Conclusion

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

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

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

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

/MMN/

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	Matthew M Nelson	3732

SEARCHED

Class	Subclass	Date	Examiner
433	102, 224	4/29/2008	MMN
29	896.1	4/29/2008	MMN
433	102, 224	10/21/2008	MMN
29	896.1	10/21/2008	MMN
433	102, 224	2/24/2009	MMN
29	896.1	2/24/2009	MMN
433,29	Updated search	8/3/2009	MMN
433, 29	Updated search	12/31/2009	MMN
433, 29	Updated	3/22/2010	MMN
433, 29	Updated	10/20/2010	MN
433, 29	Updated	5/23/2011	MN
433	102, 224	9/14/2011	MN
29	896.1, 896.11	9/14/2011	MN
148	402,421,426,669	9/14/2011	MN

SEARCH NOTES

Search Notes	Date	Examiner
Search received from John Wilson for Class/Subclass 433/102,224 & 29/896.1	4/28/2008	MMN
See EAST search history	4/29/2008	MMN
Updated EAST search	10/21/2008	MMN
Updated EAST search	2/24/2009	MMN
Updated EAST search history	8/3/2009	MMN
Updated EAST search history	12/31/2009	MMN
Updated EAST search	3/22/2010	MMN
Updated EAST search	10/20/2010	MN
Updated EAST search	5/23/2011	MN
Search request to Jermie Cozart for class 29	5/23/2011	MN
Search request to Jermie Cozart for 29	9/7/2011	MN
Search request to George Wyszomierski for 148	9/7/2011	MN
Updated EAST search	9/14/2011	MN

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
433	102	9/14/2011	MN

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	Matthew M Nelson	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	04/29/2008	10/21/2008	02/24/2009	08/03/2009	12/31/2009	03/22/2010	10/20/2010	05/12/2011	09/14/2011
	1	✓	✓	✓	✓	✓	✓	✓	✓	=
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	3	✓	-	-	-	-	-	-	-	-
	4	✓	✓	✓	✓	✓	✓	✓	✓	=
	5	✓	✓	✓	✓	✓	✓	✓	✓	=
	6	✓	✓	✓	✓	✓	✓	✓	✓	=
	7	✓	✓	✓	✓	✓	✓	✓	✓	=
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	21			✓	✓	✓	✓	✓	✓	=
	22						✓	-	-	-
	23						✓	✓	✓	=
	24						✓	✓	✓	=
	25						✓	✓	✓	=

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2946	433/102,224.ccls. 29/896.1,896.11.ccls. 148/402,421,426,669.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/14 11:46
L2	11	L1 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	2011/09/14 11:46
L3	121	L1 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	2011/09/14 11:46
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

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	3	(433/102).CCLS.	UPAD	OR	OFF	2011/09/14 11:47

9/14/2011 11:58:30 AM
C:\ Documents and Settings\ mnelson3\ My Documents\ EAST\ Workspaces\ 11628933 Dental Instruments Comprising Titanium.wsp

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BIB DATA SHEET

CONFIRMATION NO. 9736

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/628,933	12/07/2006	433	3776	115207.00002

APPLICANTS
Neill Hamilton Luebke, Brookfield, WI;

**** CONTINUING DATA ***************************
This application is a 371 of PCT/US05/19947 06/07/2005
which claims benefit of 60/578,091 06/08/2004 /MMN/

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

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY ** /MMN/
10/30/2007

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /MATTHEW M NELSON/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		WI	7	20	3

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411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497
UNITED STATES

TITLE

Dental And Medical Instruments Comprising Titanium

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

BIB (Rev. 05/07).

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11628933	LUEBKE, NEILL HAMILTON
	Examiner	**Art Unit**
	MATTHEW NELSON	3776

ORIGINAL		INTERNATIONAL CLASSIFICATION									
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED				
433	102	A	6	1	C	5 / 02 (2006.0)					

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				

☐ 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
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2	2	18	25												
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14	15														
15	20														
16	23														

/MATTHEW NELSON/ Examiner.Art Unit 3776	9/14/2011	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/TODD MANAHAN/ Supervisory Patent Examiner.Art Unit 3776	09/17/2011	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1a

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
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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.
11/628,933	12/07/2006	Neill Hamilton Luebke	115207.00002	9736

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
nonprovisional	YES	$755	$300	$0	$1055	12/23/2011

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

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

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

1 Quarles & Brady LLP
2
3

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

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

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

Gold Standard Instruments, LLC Brookfield, WI

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

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

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (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 September 29, 2011

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	11628933
Filing Date:	07-Dec-2006
Title of Invention:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Filer:	Richard T. Roche
Attorney Docket Number:	115207.00002

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	2501	1	870	870
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1170**

Electronic Acknowledgement Receipt	
EFS ID:	11074758
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	29-SEP-2011
Filing Date:	07-DEC-2006
Time Stamp:	11:43:40
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1170
RAM confirmation Number	9455
Deposit Account	170055
Authorized User	

File Listing:

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

1	Issue Fee Payment (PTO-85B)	Luebke_00002_Issue_fee.pdf	1775538 b7a5002c4351a55a0770fdda83751260e4a846bc	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31739 6857a4fa7dfff475f2187d736cffb59e181a2536	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1807277		

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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.

Receipt date: 04/29/2011

PTO/SB/08a (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	11628933
Filing Date	2006-12-07
First Named Inventor	Neill H. Luebke
Art Unit	3732
Examiner Name	Matthew M. Nelson
Attorney Docket Number	115207.00002

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~~ 8/2004	Aloise et al.	
		US-20040171333	09/02/2004	Aloise et al.	
		US-20060014480	01/13/2006	Aloise et al.	
		US-			
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		US-			
		US-			

Change(s) applied to document, /M.A.H/ 10/11/2011

FOREIGN PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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

MKE\12865326

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/628,933	11/22/2011	8062033	115207.00002	9736

26710 7590 11/02/2011

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

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;

IR103 (Rev. 10/09)

I hereby certify that, on the date shown below, this correspondence is being transmitted via the U.S. Patent and Trademark Office's Patent Electronic Filing System (EFS).
Date of Signature
And Deposit: November 20, 2013 /Richard T. Roche/
Richard T. Roche, Reg. No. 38,599

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

US Patent No.: 8,062,033
Issued: November 22, 2011
Title: Dental and Medical Instruments Comprising Titanium
Applicants: Neill H. Luebke
Serial No.: 11/628,933
Filed: December 7, 2006
Docket: 115207.00002

Request for Certificate of Correction

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

Dear Sir:

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

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

Respectfully submitted,

Neill H. Luebke

Date: November 20, 2013 By: /Richard T. Roche/
Richard T. Roche
Reg. No. 38,599
Quarles & Brady, LLP
411 East Wisconsin Avenue
Suite 2350
Milwaukee, WI 53202
Tel. (414) 277-5805

QB\16708669.1

PTO/SB/44 (09-07)
Approved for use through 08/31/2010. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,062,033

APPLICATION NO.: 11/628,933

ISSUE DATE : November 22, 2011

INVENTOR(S) : Neill H. Luebke

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

Column 9, line 42 "root can" should read --root canal--

Column 11, line 9 "ahoy" should read --alloy--

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

16708735

Electronic Acknowledgement Receipt

EFS ID:	17450374
Application Number:	11628933
International Application Number:	
Confirmation Number:	9736
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:	115207.00002
Receipt Date:	20-NOV-2013
Filing Date:	07-DEC-2006
Time Stamp:	10:20:31
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	Luebke-00002-Certificate-Correction.PDF	139230 a87da95faae0683cf43bddbcc66d277e3683427f	no	2

Warnings:	
Information:	

Total Files Size (in bytes):	139230

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

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,062,033 B2
APPLICATION NO. : 11/628933
DATED : November 22, 2011
INVENTOR(S) : Neill H. Luebke

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

In the Claims

Column 9, line 42 “root can” should read --root canal--

Column 11, line 9 “ahoy” should read --alloy--

Signed and Sealed this
Thirty-first Day of December, 2013

Margaret A. Focarino

Margaret A. Focarino
Commissioner for Patents of the United States Patent and Trademark Office