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UTILITY	Attorney Docket No.	115207.00009
PATENT APPLICATION TRANSMITTAL	First Inventor	Neill H. Luebke
	Title	Dental and Medical Instruments Comprising Titanium
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6. Application	on Data Sheet. See 37 CFR 1.76	13. Preliminary An	nendment				
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Docket No.: 115207.00009

# **Dental and Medical Instruments Comprising Titanium**

#### CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 13/336,579 filed December 23, 2011, which is a continuation of U.S. Patent Application No. 12/977,625 filed December 23, 2010, now U.S. Patent No. 8,083,873, which is a divisional application of U.S. Patent Application No. 11/628,933, now U.S. Patent No. 8,062,033, filed December 7, 2006 which is a 371 of PCT/US05/19947 filed June 7, 2005 which claims priority from United States Patent Application No. 60/578,091 filed June 8, 2004.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable.

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#### **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.

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[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.

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[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 alphatitanium 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.

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**[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<sub>t</sub>) reported in gorm 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<sub>t</sub>) 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).

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[0021] Figure 5 is a graph showing the results of a study of maximum torque at 45° of flexion (Mf) reported in gorm 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.

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[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, betatitanium 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-5AI-2.5Sn alpha alloy; Ti-5AI-2.5Sn-ELI (low O<sub>2</sub>) alpha alloy; Ti-3AI-2.5V alpha alloy; Ti-5AI-5Zr-5Sn alpha alloy; Ti-6AI-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-8AI-1Mo-1V near alpha alloy; Ti-6AI-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 alphabeta alloy; Ti-5AI-2Sn-2Zr-4Mo-4Cr alpha-beta alloy; Ti-6AI-2Sn-4Zr-6Mo alpha-beta alloy; Ti-4Al-4Mn alpha-beta alloy; Ti-6Al-2Sn-2Zr-2Mo-2Cr-0.25Si alpha-beta alloy; Ti-4AI-3Mo-1V alpha-beta alloy; Ti-6AI-2Sn-4Zr-6Mo alpha-beta alloy; Ti-11Sn-5Zr-2AI-1Mo alpha-beta alloy; Ti-6AI-4V alpha-beta alloy; Ti-6AI-4V-ELI (low O<sub>2</sub>) alphabeta alloy; Ti-6AI-6V-2Sn-0.75Cu alpha-beta alloy; Ti-7AI-4Mo alpha-beta alloy; Ti-6AI-2Sn-4Zr-2Mo alpha-beta alloy; Ti-5AI-1.5Fe-1.5Cr-1.5Mo alpha-beta alloy; Ti-8Mn alpha-beta alloy; Ti-8Mo-8V-2Fe-3AI beta alloy; Ti-11.5Mo-6Zr-4.5Sn beta alloy;

Ti-3AI-8V-6Cr-4Mo-4Zr beta alloy; and Ti-3AI-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.

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[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, alphabeta-titanium alloys for use in this embodiment of the invention are: Ti-5AI-2.5Sn alpha alloy; Ti-5AI-2.5Sn-ELI (low O<sub>2</sub>) alpha alloy; Ti-3AI-2.5V alpha alloy; Ti-5AI-5Zr-5Sn alpha alloy; Ti-6AI-2Cb-1Ta-0.8Mo alpha alloy; Ti-5AI-5Sn-2Zr-2Mo-0.25Si near alpha alloy; Ti-6AI-2Nb-1Ta-1Mo near alpha alloy; Ti-8AI-1Mo-1V near alpha alloy; Ti-6AI-2Sn-4Zr-2Mo near alpha alloy; Ti-6AI-2Sn-1.5Zr-1Mo-0.35Bi-0.1Si near alpha alloy; Ti-2.25-AI-11Sn-5Zr-1Mo-0.2Si near alpha alloy; Ti-3AI-2.5V alpha-beta alloy; Ti-10V-2Fe-3AI alpha-beta alloy; Ti-5AI-2Sn-2Zr-4Mo-4Cr alpha-beta alloy; Ti-6AI-2Sn-4Zr-6Mo alpha-beta alloy; Ti-4AI - 4Mn alpha-beta alloy; Ti-6AI-2Sn-2Zr-2Mo-2Cr-0.25Si alpha-beta alloy; Ti-4AI-3Mo-1V alpha-beta alloy; Ti-6AI-2Sn-4Zr-6Mo

alpha-beta alloy; Ti-11Sn-5Zr-2Al-1Mo alpha-beta alloy; Ti-6Al-4V alpha-beta alloy; Ti-6AI-4V-ELI (low O₂) alpha-beta alloy: Ti-6AI-6V-2Sn-0.75Cu alpha-beta alloy: Ti-7AI-4Mo alpha-beta alloy; Ti-6AI-2Sn-4Zr-2Mo alpha-beta alloy; Ti-5AI-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-3AI-8V-6Cr-4Mo-4Zr beta alloy; and Ti-3AI-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 nickeltitanium. 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, betatitanium 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.

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[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.

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

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

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[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.

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# 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<sub>t</sub>) reported in gocm performed in accordance with "ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification No. 28, Endodontic files and reamers". The results are shown in Figure 3. The files were made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, and included an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. Ten of each ISO size were untreated (Control) files. Ten of each ISO size were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes and then slowly cooled. These are labeled "TT" in Figure 3. Ten of each ISO size were coated with titanium nitride using physical vapor deposition with an inherent heat-treatment. These are labeled "Ti-N" in Figure 3. Mt was determined for each of the thirty files, and the mean and standard deviation for each group (Control, TT, Ti-N) of ten files were calculated. The ten files that were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes showed the best result with the highest M<sub>t</sub>.

25 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 (At) reported in degrees of deflection performed in accordance with "ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification No. 28, Endodontic files and reamers".

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

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### Example 3

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

higher high flexibility, have higher resistance to torsion breakage than untreated (control) files.

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# Example 4

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

# Example 5

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

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

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

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

# **CLAIMS**

What is claimed is:

- 1. A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:
- (a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a titanium alloy, and
- (b) heat-treating the entire shank at a temperature from 400°C up to but not equal to the melting point of the titanium alloy,

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

- 2. The method of claim 1 wherein: the temperature is from 475°C to 525°C.
- 3. The method of claim 1 wherein: the shank is heat-treated for 1 to 2 hours.
- 4. The method of claim 1 wherein:

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

- The method of claim 1 wherein:
   the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.
  - 6. The method of claim 1 wherein: step (b) is performed in any atmosphere.

## 7. The method of claim 6 wherein:

the atmosphere may be unreactive, ambient or any other acceptable heat treatment process.

#### 8. The method of claim 6 wherein:

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

the atmosphere may be unreactive, ambient or any other acceptable heat treatment process,

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

#### 9. The method of claim 6 wherein:

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

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

## 10. The method of claim 1 wherein:

the instrument shank is in accordance with ISO Standard 3630-1.

## 11. The method of claim 1 wherein:

the instrument shank has a diameter of 0.5 to 1.6 millimeters.

#### 12. The method of claim 1 wherein:

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

#### 13. The method of claim 12 wherein:

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

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

- 15. A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:
- (a) providing an elongate shank having 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, the shank consisting essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium; and
- (b) heat-treating the entire instrument shank at a temperature from 475°C to 525°C.

wherein the heat-treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion tested in accordance with ISO Standard 3630-1.

- 16. The method of claim 15 wherein: the shank is heat-treated for 1 to 2 hours.
- 17. The method of claim 15 wherein: the instrument shank is heat-treated in step (b) at a single temperature.
- 18. The method of claim 15 wherein:

step (b) is performed in an atmosphere may be unreactive, ambient or any other acceptable heat treatment process.

# ABSTRACT OF THE DISCLOSURE

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

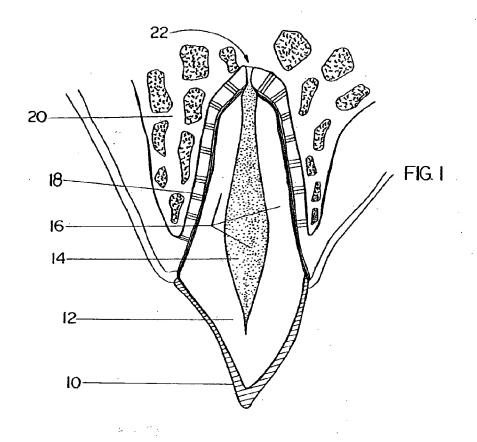
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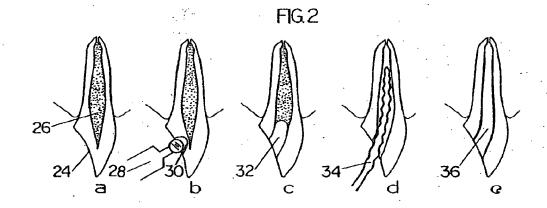
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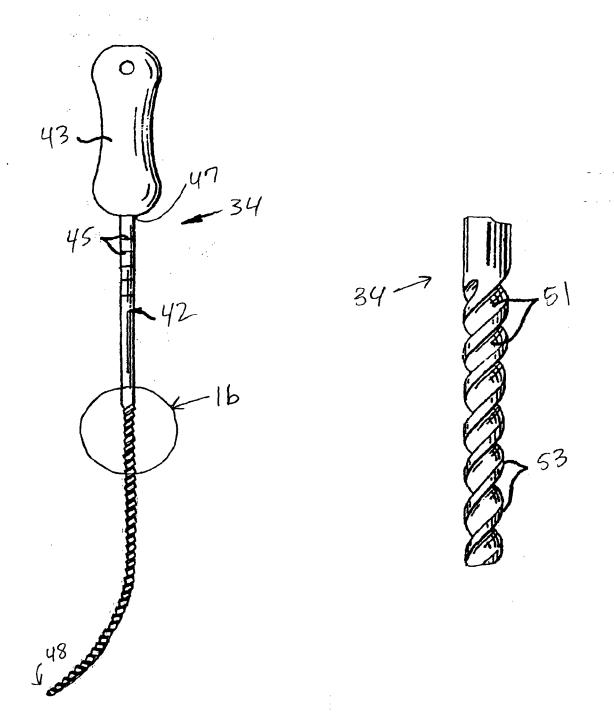
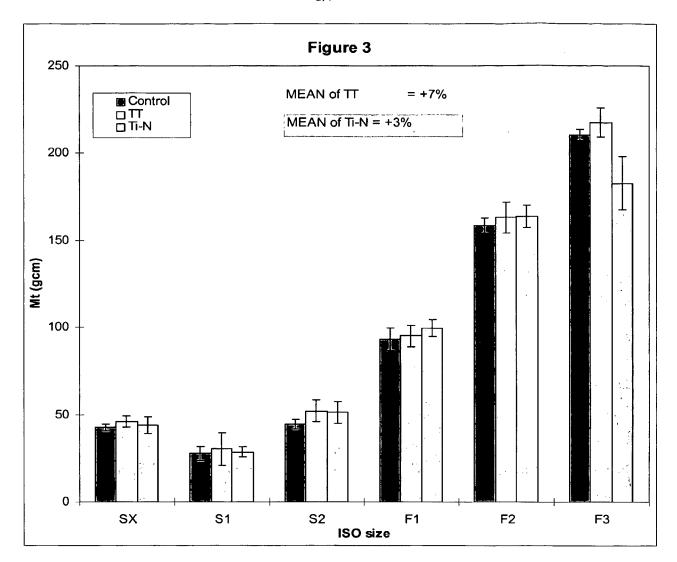
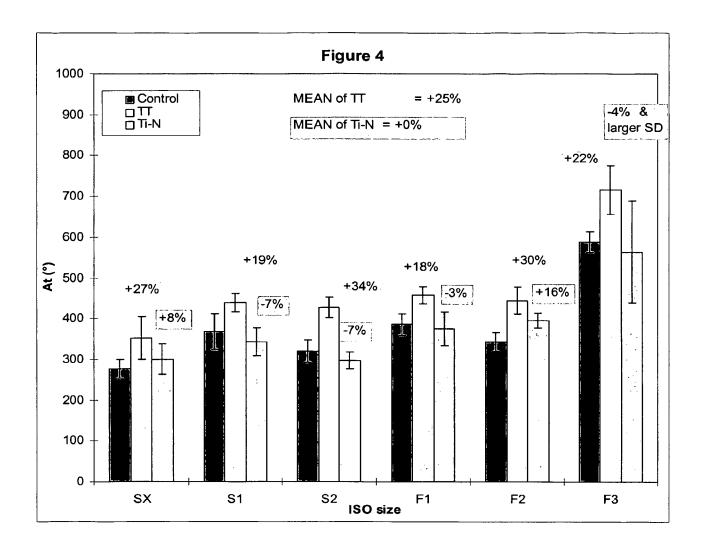
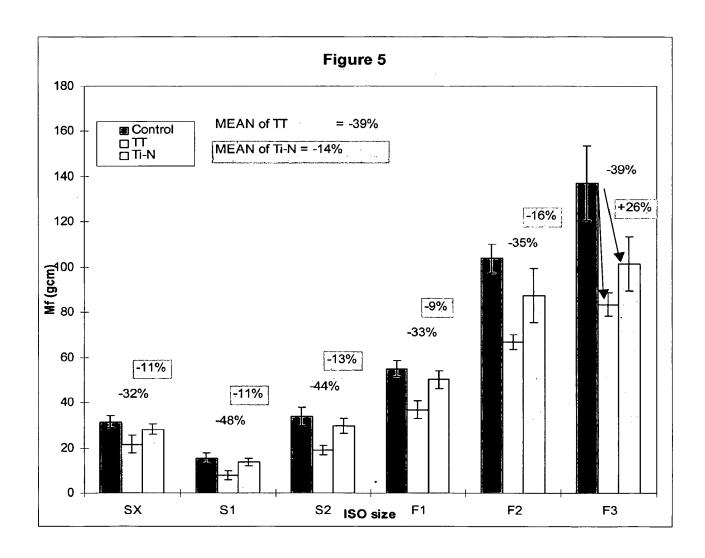


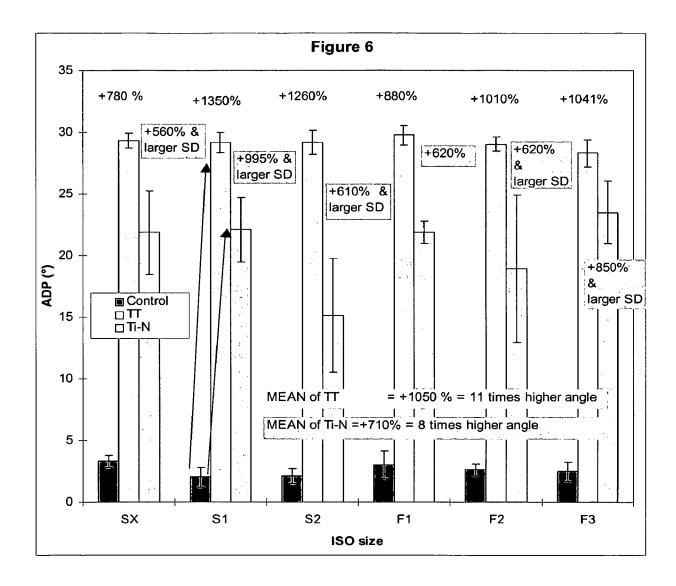
Fig. 1a

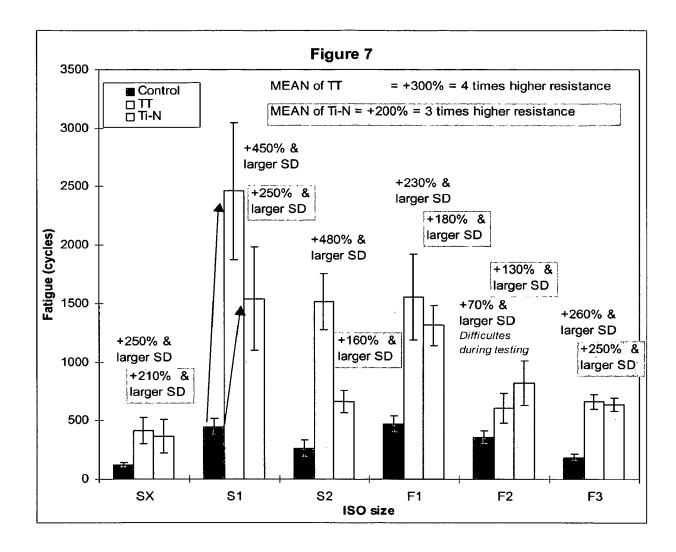
Fig. 1b











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						LUEBKE, NEIL			
				Examiner		Art Unit			
				MATTHEW	NELSON	3776			
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Examiner Signature						Date Considered			

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

<sup>\*</sup>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.

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.

Docket Number: 115207.00009

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke Filed:

Herewith

For: Dental and Medical Instruments Comprising Titanium

#### INFORMATION DISCLOSURE STATEMENT

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

Dear Sir:

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

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

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

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

Respectfully submitted,

/Richard T. Roche/ Date: April 25, 2012

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

Electronic Patent Application Fee Transmittal							
Application Number:							
Filing Date:							
Title of Invention:		Dental and Medical Instruments Comprising Titanium					
First Named Inventor/Applicant Name:	Neill H. Luebke						
Filer:	Richard T. Roche						
Attorney Docket Number:	115207.00009						
Filed as Small Entity							
Utility under 35 USC 111(a) Filing Fees							
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)		
Basic Filing:							
Utility filing Fee (Electronic filing)		4011	1	95	95		
Utility Search Fee		2111	1	310	310		
Utility Examination Fee		2311	1	125	125		
Pages:							
Claims:							
Miscellaneous-Filing:							
Petition:							
Patent-Appeals-and-Interference:							

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

Electronic Acl	knowledgement Receipt
EFS ID:	12629679
Application Number:	13455841
International Application Number:	
Confirmation Number:	5421
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill H. Luebke
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	115207.00009
Receipt Date:	25-APR-2012
Filing Date:	
Time Stamp:	16:55:40
Application Type:	Utility under 35 USC 111(a)
Payment information:	

# **Payment information:**

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$530
RAM confirmation Number	4246
Deposit Account	170055
Authorized User	

# File Listing:

	<b>3</b>				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages
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1	Transmittal of New Application	Transmittal.PDF	208732 9883415df1ed4b3af1d742348bab67f8196	no	1					
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	Abstrac	t	19		19					
Warnings:										
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3	Drawings-only black and white line	Luebke-00009-Drawings.PDF	137566	no	7					
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5	Information Disclosure Statement (IDS)	Luebke-00009-IDS.PDF	368473	na	5					
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6	Transmittal Letter	IDS-trans.pdf	d7d66b4cf1d824988cdf1cf075f2c7d2befd 1851	no	1					
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

## New Applications Under 35 U.S.C. 111

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

# National Stage of an International Application under 35 U.S.C. 371

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

### New International Application Filed with the USPTO as a Receiving Office

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



# United States Patent and Trademark Office

FILING OR 371(C) DATE

04/25/2012

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

ATTY. DOCKET NO./TITLE FIRST NAMED APPLICANT

Neill Hamilton Luebke 115207.00009

**CONFIRMATION NO. 5421** 

**FORMALITIES LETTER** 

Date Mailed: 05/09/2012

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

APPLICATION NUMBER

13/455,841

# NOTICE TO FILE CORRECTED APPLICATION PAPERS

# Filing Date Granted

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

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

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) 2-4, 6.
  - The drawings have a line quality that is too light to be reproduced (weight of all lines and letters must be heavy enough to permit adequate reproduction) or text that is illegible (reference characters, sheet numbers, and view numbers must be plain and legible) see 37 CFR 1.84(I) and (p)(1)); See Figure(s) 7.

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

# Replies should be mailed to:

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

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. <a href="https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html">https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html</a>

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

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

/tnguyen/					
Office of Data Management, Application Assistance Unit (571)	272-4000, o	r (571)	272-4200,	or 1-888	3-786-010

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FOR NUMBER FILED NUMBER EXTRA							RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
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	RCH FEE FR 1.16(k), (i), or (m))	N	/A	١	I/A		N/A	310		N/A	
	MINATION FEE FR 1.16(o), (p), or (q))	N	/A	١	I/A		N/A	125		N/A	
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	PENDENT CLAIM FR 1.16(h))	S 2	minus :	3 = *		×	125 =	0.00			
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(Column 1) (Column 2) (Column 3)    CLAIMS							SMALL RATE(\$)	ADDITIONAL FEE(\$)	OR	SMALL RATE(\$)	ADDITIONAL FEE(\$)
MEN	Total '	,	Minus	**	=	x	=		OR	x =	
AMENDMENT	Independent (37 CFR 1.16(h))	,	Minus	***	=	х	=		OR	x =	
AME	Application Size Fee	(37 CFR 1.16(s))	<u>                                       </u>						-		
	FIRST PRESENTAT	ION OF MULTIPI	E DEPEN	DENT CLAIM (37 C	CFR 1.16(j))				OR		
						_	TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
		(Column 1)		(Column 2)	(Column 3)	_					
NT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
ME	Total '		Minus	**	=	х	=		OR	x =	
AMENDMENT	Independent * (37 CFR 1.16(h))		Minus	***	=	х	=		OR	x =	
Application Size Fee (37 CFR 1.16(s))									]		
	FIRST PRESENTAT	ION OF MULTIPI	E DEPEN	DENT CLAIM (37 C	CFR 1.16(j))				OR		
							TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
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 <sup>\*\*\*</sup> If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
 \*\*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
 The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.



# UNITED STATES 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	FILING or	GRP ART				
	NUMBER	371(c) DATE	UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
•	13/455,841	04/25/2012	3732	530	115207.00009	18	2

**CONFIRMATION NO. 5421** 

FILING RECEIPT

\*0.00000054113990\*

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

Date Mailed: 05/09/2012

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

Applicant(s)

Neill Hamilton Luebke, Brookfield, WI;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 13/336,579 12/23/2011 which is a CON of 12/977,625 12/23/2010 PAT 8083873 which is a DIV of 11/628,933 12/07/2006 PAT 8062033 which is a 371 of PCT/US05/19947 06/07/2005 which claims benefit of 60/578,091 06/08/2004

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

If Required, Foreign Filing License Granted: 05/04/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/455,841** 

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

Non-Publication Request: No

Early Publication Request: No

\*\* SMALL ENTITY \*\*

page 1 of 3

**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 quidance 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

### **GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

page 2 of 3

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

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

### **NOT GRANTED**

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

# SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage, facilitate, and accelerate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit <u>SelectUSA.gov</u>.

# CERTIFICATION OF SUBMISSION

I hereby certify that, on the date shown below, this correspondence is being transmitted via the Patent Electronic Filing System (EFS).

Date: July 9, 2012

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

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Neill Hamilton Luebke

Application No.: 13/455,841 Filing Date: April 25, 2012

Confirmation No.: 5421

Docket No.: 115207.00009

Title: Dental and Medical Instruments Comprising Titanium

# RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Dear Sir:

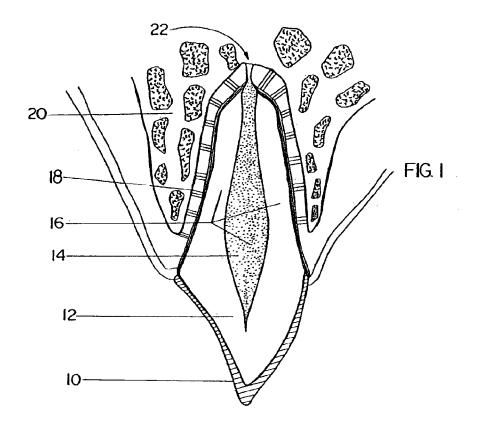
In response to the Notice To File Corrected Application Papers mailed on May 9, 2012, Applicant submits the replacement drawings in compliance with 37 CFR 1.84 and 1.121(d). No new matter has been added.

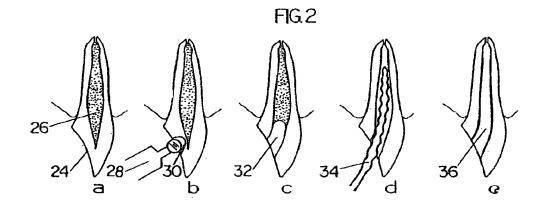
This response is being timely filed, therefore no fees are believed to be due. However, if any other fees are needed, please charge them to Deposit Account No. 170055.

Respectfully submitted,

Date: July 9, 2012 /Richard T. Roche/

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





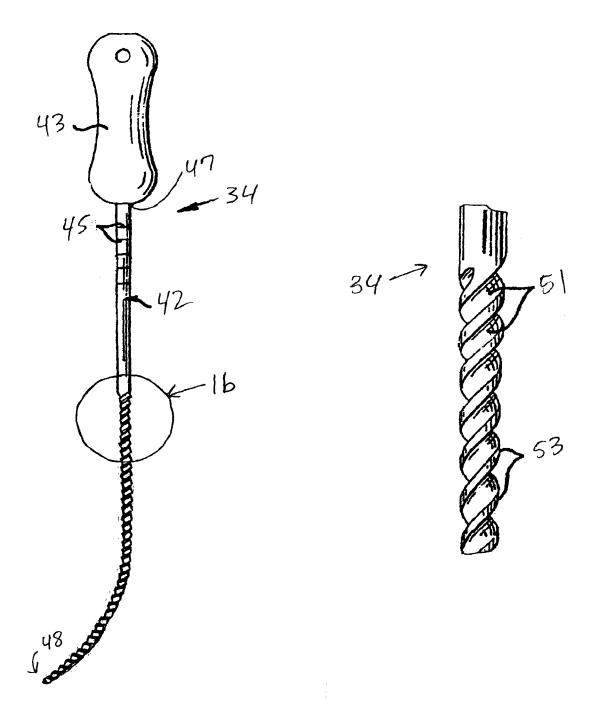
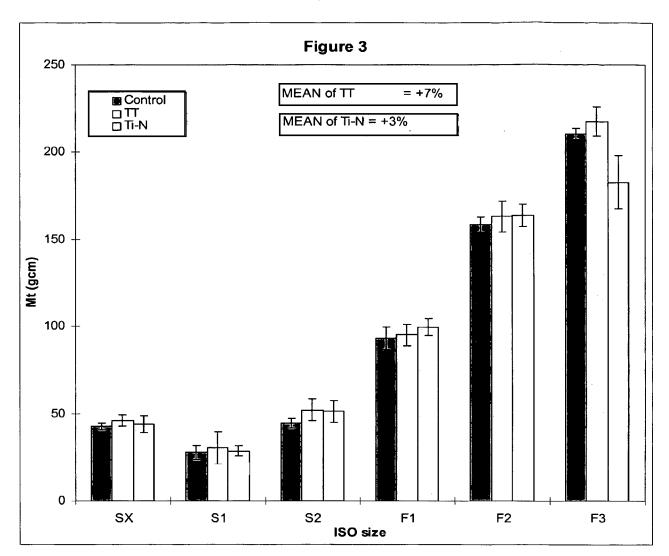
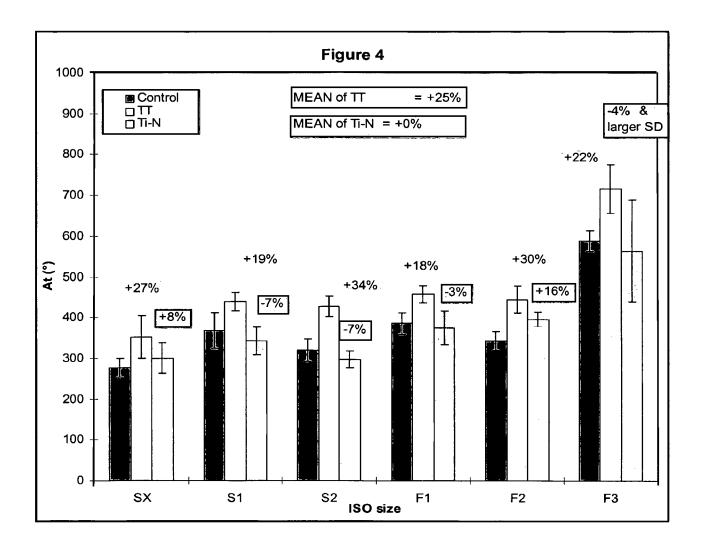
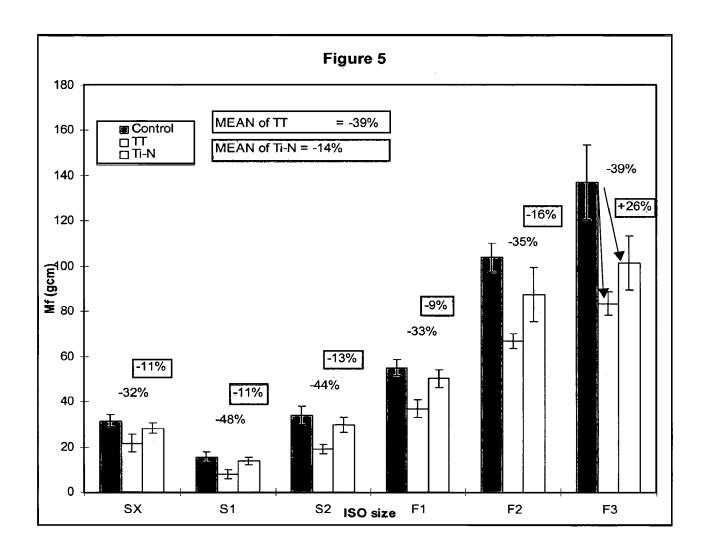


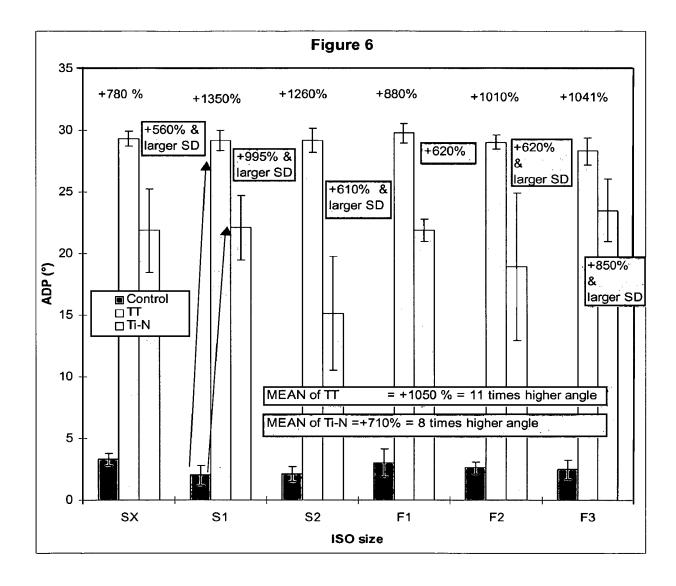
Fig. 1a

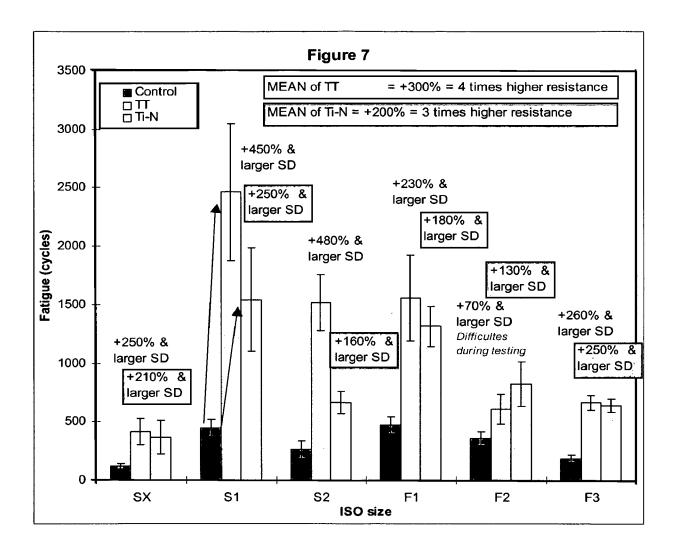
Fig. 1b











Electronic Ack	knowledgement Receipt
EFS ID:	13201769
Application Number:	13455841
International Application Number:	
Confirmation Number:	5421
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:	115207.00009
Receipt Date:	09-JUL-2012
Filing Date:	25-APR-2012
Time Stamp:	14:42:26
Application Type:	Utility under 35 USC 111(a)

# **Payment information:**

Submitted with Payment no

# File Listing:

1 Transmittal Letter transmittal.pdf 86177  1 9671fcba8e21096182241ce12baadda910 7b83e	Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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Warnings:

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2	Drawings-only black and white line drawings	Luebke-00009-Drawings- edited.PDF	335060 6af68639186cf36496c1382ead9fd6b7f3ae 304d	no	7
Warnings:					
Information					
		4.	21237		

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

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### 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.

	PATE	NT APPLI		ON FEE DE		TIOI	N RECORI	)	Applica 13/45	tion or Docket Num 5,841	ber
	APPL	ICATION A			umn 2)		SMALL	ENTITY	OR	OTHEF SMALL	
FOR NUMBER FILED NUMBER EXTRA							RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
	IC FEE FR 1.16(a), (b), or (c))	N	/A	١	J/A		N/A	95		N/A	
	RCH FEE FR 1.16(k), (i), or (m))	N	/A	١	I/A		N/A	310		N/A	
	MINATION FEE FR 1.16(o), (p), or (q))	N	/A	١	I/A		N/A	125		N/A	
	AL CLAIMS FR 1.16(i))	18	minus :	20= *		х	30 =	0.00	OR		
	PENDENT CLAIM FR 1.16(h))	S 2	minus :	3 = *		×	125 =	0.00			
FEE	PLICATION SIZE E CFR 1.16(s))	sheets of p \$310 (\$15 50 sheets	paper, the offor sma or fraction	and drawings e e application si. all entity) for ea n thereof. See CFR 1.16(s).	ze fee due is ch additional			0.00			
MUL	TIPLE DEPENDEN	IT CLAIM PRE	SENT (37	7 CFR 1.16(j))				0.00			
* If th	ne difference in colu	ımn 1 is less th	an zero,	enter "0" in colur	nn 2.	_	TOTAL	530		TOTAL	
(Column 1) (Column 2) (Column 3)    CLAIMS							SMALL RATE(\$)	ADDITIONAL FEE(\$)	OR	SMALL RATE(\$)	ADDITIONAL FEE(\$)
MEN	Total '	,	Minus	**	=	x	=		OR	x =	
AMENDMENT	Independent (37 CFR 1.16(h))	,	Minus	***	=	х	=		OR	x =	
AME	Application Size Fee	(37 CFR 1.16(s))	<u>                                       </u>						-		
	FIRST PRESENTAT	ION OF MULTIPI	E DEPEN	DENT CLAIM (37 C	CFR 1.16(j))				OR		
						_	TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
		(Column 1)		(Column 2)	(Column 3)	_					
NT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
ME	Total '		Minus	**	=	х	=		OR	x =	
AMENDMENT	Independent * (37 CFR 1.16(h))		Minus	***	=	х	=		OR	x =	
Application Size Fee (37 CFR 1.16(s))									]		
	FIRST PRESENTAT	ION OF MULTIPI	E DEPEN	DENT CLAIM (37 C	CFR 1.16(j))				OR		
							TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
	* If the entry in colu * If the "Highest Nu						١.		•	'	

 <sup>\*\*\*</sup> If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
 \*\*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
 The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.



# United States 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.18910.gov

APPLICATION	FILING or	GRP ART				
NUMBER	371(c) DATE	UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/455,841	04/25/2012	3732	530	115207.00009	18	2

CONFIRMATION NO. 5421
UPDATED FILING RECEIPT

\*0.00000055349213\*

26710 QUARLES & BRADY LLP Attn: IP Docket 411 E. WISCONSIN AVENUE SUITE 2350

MILWAUKEE, WI 53202-4426

Date Mailed: 07/16/2012

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

Applicant(s)

Neill Hamilton Luebke, Brookfield, WI;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 13/336,579 12/23/2011 which is a CON of 12/977,625 12/23/2010 PAT 8083873 which is a DIV of 11/628,933 12/07/2006 PAT 8062033 which is a 371 of PCT/US05/19947 06/07/2005 which claims benefit of 60/578,091 06/08/2004

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If Required, Foreign Filing License Granted: 05/04/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/455,841** 

Projected Publication Date: Perfected

Non-Publication Request: No

Early Publication Request: No

\*\* SMALL ENTITY \*\*

page 1 of 3

**Title** 

Dental and Medical Instruments Comprising Titanium

# **Preliminary Class**

433

### PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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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

# **GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

page 2 of 3

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

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

### **NOT GRANTED**

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

# SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage, facilitate, and accelerate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit <u>SelectUSA.gov</u>.

Doc code: PET.OP.AGE

Description: Petition to make special based on Age/Health

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

PETITION TO MAKE SPECIAL BASED ON AGE FOR ADVANCEMENT OF EXAMINATION UNDER 37 CFR 1.102(c)(1)										
Application Information										
Application Number Confirmation Number 5421 Filing Date 2012-04-25										
Attorney Docket Number (optional)	115207.00009	Art Unit	3732		Examin	er				
First Named Inventor	Neil H. Lijebke									
Title of Invention	Dental and Medical Inst	ruments Comprising T	itanium							
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).										
i .	BY PETITIONS TO MA 02(c)(1) and MPEP 70					TION IN THIS APPLICATION GE.				
(1) Statement by one (2) Certification by a	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 w	vho is 65 years of age	e, or older								
Given Name	Middle Na	me	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    Contact   Con						2012-07-16				

Name

38599

Richard T. Roche

Registration

Number

Doc code: PET.OP.AGE

Description: Petition to make special based on Age/Health

PTO/SB/130 (07-09)
Approved for use through 07/31/2012. OMB 0651-031
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.
- 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).
- 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.



# UNITED STATES PATENT AND TRADEMARK OFFICE

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. 13455841

Filed: April 25,2012

Attorney Docket No. 115207.00009

: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 16-JUL-2012 to make the above-identified application special based on applicant's age as set forth in MPEP § 708.02, Section IV.

#### The petition is **GRANTED**.

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

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

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

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

Electronic Acknowledgement Receipt							
EFS ID:	13256475						
Application Number:	13455841						
International Application Number:							
Confirmation Number:	5421						
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:	115207.00009						
Receipt Date:	16-JUL-2012						
Filing Date:	25-APR-2012						
Time Stamp:	11:43:35						
Application Type:	Utility under 35 USC 111(a)						

# **Payment information:**

Submitted with Payment no

# File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Petition automatically granted by EFS	Petition-Age.PDF	752342	no	2
	remonational early granted by Ers	retition Age. Di	3d009d37c2805166f9ffceefc3917b2d611e e261		
Wayninga				'	

# **Warnings:**

Information:

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

## New Applications Under 35 U.S.C. 111

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

# National Stage of an International Application under 35 U.S.C. 371

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

### New International Application Filed with the USPTO as a Receiving Office

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

	PATEN	IT APPLI		ON FEE DE titute for Form		ΓΙΟΝ	RECORI	)	Applica 13/45	tion or Docket Num 5,841	ber
	APPLIC	CATION AS		D - PART I	umn 2)		SMALL	ENTITY	OR	OTHEF SMALL	
FOR NUMBER FILED NUMBER EXTRA						R	ATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
	IC FEE FR 1.16(a), (b), or (c))	N.	/A	N	I/A		N/A	95	1	N/A	
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	MINATION FEE FR 1.16(o), (p), or (q))	N.	/ <b>A</b>	N	√A		N/A	125		N/A	
	AL CLAIMS FR 1.16(i))	18	minus	20= *		x	30 =	0.00	OR		
	PENDENT CLAIMS FR 1.16(h))	2	minus	3 = *		×	125 =	0.00	1		
FEE	PLICATION SIZE E CFR 1.16(s))	sheets of p \$310 (\$155 50 sheets of	aper, the for small fraction of the formal o	and drawings e le application si all entity) for ea on thereof. See ' CFR 1.16(s).	ze fee due is ch additional			0.00			
MUL	TIPLE DEPENDENT	CLAIM PRE	SENT (3	7 CFR 1.16(j))				0.00	]		
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A		(Column 1) CLAIMS REMAINING AFTER		(Column 2) HIGHEST NUMBER	(Column 3)	F	SMALL RATE(\$)	ADDITIONAL	OR	OTHEF SMALL RATE(\$)	ENTITY ADDITIONAL
	Total *	MENDMENT		PREVIOUSLY PAID FOR	EXTRA			FEE(\$)			FEE(\$)
AMENDMENT	(37 CFR 1.16(i))  Independent *		Minus	***	-	х	=		OR	X =	
MEN	(37 CFR 1.16(h))		Minus			х	=		OR	X =	
A	Application Size Fee (3					-					
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OTAL D'L FEE		OR OR	TOTAL ADD'L FEE	
		(Column 1)		(Column 2)	(Column 3)				•	'	
NT B		CLAIMS REMAINING AFTER MENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	F	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
ME	Total * (37 CFR 1.16(i))		Minus	**	=	×	=		OR	x =	
AMENDMENT	Independent * (37 CFR 1.16(h))		Minus	***	=	x	=		OR	x =	
Α	Application Size Fee (37 CFR 1.16(s))										
	FIRST PRESENTATIO	N OF MULTIPL	E DEPEN	IDENT CLAIM (37 C	DFR 1.16(j))				OR		
							OTAL		OR	TOTAL	

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APPLICATION	FILING or	GRP ART				
NUMBER	371(c) DATE	UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/455 841	04/25/2012	3732	530	115207 00009	18	2.

26710 QUARLES & BRADY LLP Attn: IP Docket 411 E. WISCONSIN AVENUE SUITE 2350 MILWAUKEE, WI 53202-4426 CONFIRMATION NO. 5421 UPDATED FILING RECEIPT



Date Mailed: 07/23/2012

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Neill Hamilton Luebke, Brookfield, WI;

Power of Attorney: None

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If Required, Foreign Filing License Granted: 05/04/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/455,841** 

**Projected Publication Date:** 11/01/2012

Non-Publication Request: No

Early Publication Request: No

\*\* SMALL ENTITY \*\*

page 1 of 3

**Title** 

Dental and Medical Instruments Comprising Titanium

# **Preliminary Class**

433

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

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

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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

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

### **NOT GRANTED**

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

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APPLICATION NUMBER

FILING OR 371(C) DATE

FIRST NAMED APPLICANT

ATTY. DOCKET NO./TITLE 115207.00009

13/455,841

04/25/2012

Neill Hamilton Luebke

**CONFIRMATION NO. 5421** 

**PUBLICATION NOTICE** 



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

Title: Dental and Medical Instruments Comprising Titanium

Publication No.US-2012-0272526-A1

Publication Date: 11/01/2012

### NOTICE OF PUBLICATION OF APPLICATION

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

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

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

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

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

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

page 1 of 1

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
13/455,841	13/455,841 04/25/2012 Neill Hamilton Luebke		115207.00009	5421	
26710 QUARLES & E	7590 01/18/201 BRADY LLP	EXAMINER			
Attn: IP Docket		NELSON, MATTHEW M			
SUITE 2350	NSIN AVENUE	ART UNIT	PAPER NUMBER		
MILWAUKEE,	, WI 53202-4426	3776			
			NOTIFICATION DATE	DELIVERY MODE	
			01/18/2013	ELECTRONIC	

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

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

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

pat-dept@quarles.com

		Application No.	Applicant(s)					
	Office Action Comment	13/455,841	LUEBKE, NEILL HAMILTON					
	Office Action Summary	Examiner	Art Unit					
		MATTHEW NELSON	3776					
Period fo	The MAILING DATE of this communication app r Reply	ears on the cover sheet with the co	orrespondence address					
WHIC - Exter after: - If NO - Failur Any r	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DAISIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  (6(a). In no event, however, may a reply be tim  ill apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONE	ely filed the mailing date of this communication. (35 U.S.C. § 133).					
Status								
1) 🖂	Responsive to communication(s) filed on 25 Ag	oril 2012.						
2a)	This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.						
3)	An election was made by the applicant in response	onse to a restriction requirement s	set forth during the interview on					
	; the restriction requirement and election	have been incorporated into this	action.					
4)	Since this application is in condition for allowan	ce except for formal matters, pro	secution as to the merits is					
	closed in accordance with the practice under $\boldsymbol{E}$	<i>x parte Quayle</i> , 1935 C.D. 11, 45	3 O.G. 213.					
Dispositi	on of Claims							
6)	Claim(s) 1-18 is/are pending in the application.  5a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed.  Claim(s) 1-18 is/are rejected.  Claim(s) is/are objected to.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or aims have been determined allowable, you may at a participating intellectual property office for the substantial property of subst	election requirement. The be eligible to benefit from the <b>Pa</b> ne corresponding application. For	more information, please see					
	on Papers	send an inquiry to intrinseduder	twasto.gov.					
11)	The specification is objected to by the Examiner The drawing(s) filed on 09 July 2012 is/are: a) Applicant may not request that any objection to the control of the control	☑ accepted or b) ☐ objected to b drawing(s) be held in abeyance. See	37 CFR 1.85(a).					
	Replacement drawing sheet(s) including the correcti	on is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).					
Priority u	ınder 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>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)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
Attachment	Ne)							
	e of References Cited (PTO-892)	3) Interview Summary	(PTO-413)					
Paper No(s)/Mail Date  2) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/25/2012</u> .								

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#### **DETAILED ACTION**

# Claim Rejections - 35 USC § 112

• The following is a quotation of 35 U.S.C. 112(a):

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

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

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

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(B) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claims 7-8 and 18 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.
- Regarding claims 7-8 and 18, the phrase "may be" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

# Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1-9, 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (US 2005/0090844) in view of Shiota (US 2004/0129352).
- Patel shows a method for manufacturing or modifying a dental instrument, the method comprising providing a dental elongate shank comprising a titanium alloy (10)

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and heat-treating the entire instrument or device at a temperature from 400 degrees Celsius up to but not equal to the melting point of the titanium alloy ([0041]-[0042]). wherein the heat-treated instrument or device has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion (this test would be entirely dependent on what degree the instrument was permanently deformed to before the test; for instance, Patel discusses orthodontic wires in [0004] which would have a predetermined deformation over 10 degrees, forming to the dental arch, to elicit desired tooth movements and this test on this embodiment of Patel would result in greater than 10 degrees). With respect to claim 2, the temperature is from 475 to 525 degrees Celsius ([0042]). With respect to claim 3, the instrument or device is heat-treated for 1 to 2 hours ([0041]). With respect to claim 4, the titanium alloy is slected from nickeltitnaium alloys ([0029]). With respect to claim 5, the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium ([0029]). With respect to claims 6 and 7, this is performed in any atmosphere acceptable for heat treatment (Patel is conducting heat treatment in an atmosphere). Claims 8-9 are rejected similarly to the above and below. With respect to claims 12-14, heat-treated at a single temperature ([0042]). However, Patel fails to show the dental instrument is specifically an endodontic instrument having a cutting edge extending from a distal end of the shank along an axial length of the shank with a diameter of 0.5 to 1.6 mm.

• Matsutani teaches a similar heat treatment process conducted on an endodontic instrument elongate shank (6 and 7 in Fig. 1) having a cutting edge (at 4 in Fig. 1) extending from a distal end of the shank along an axial length of the shank (Fig. 1) with

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a diameter of 0.5 to 1.6 mm (col. 7, lines 55-59 show overlapping ranges). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Patel's method by choosing an endodontic instrument as the dental instrument as taught by Matsutani since it is well known in the art to conduct heat treatments on endodontic instruments and this range of diameters is known for endodontic reamers. Additionally, in regards to the permanent deformation after torque at 45 degrees, Matsutani discusses in col. 4, lines 45-57 applying a pre-curve to the shape of the instrument.

- Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of Matsutani as applied to claim 1 above, and further in view of Heath et al. (US 5,380,200).
- Patel/Matsutani discloses the device as previously described above, but fails to show the instrument and the angle of permanent deformation is tested in accordance with ISO Standard 3630-1.
- Heath teaches titanium alloy dental devices whose physical properties after manufacture are tested by the standard of subjecting the shank to torque at 45 degrees of flexion and measuring the results (col. 5, lines 17-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Patel/Shiota's method by including the testing step of Heath in order to determine the end properties of the device and ensure they are as desired.

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Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Patel in view of Matsutani and further in view of Heath.

Patel/Matsutani/Heath discloses the device as previously described above and

additionally shows the shank having helical flutes (Matsutani: at 4 in Fig. 1).

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.

IPR2015-00632 - Ex. 1008 US ENDODONTICS, LLC., Petitioner

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/MMN/

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3776

# Notice of References Cited Application/Control No. 13/455,841 Examiner MATTHEW NELSON Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON Page 1 of 2

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

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U.S. Patent and Trademark Office PTO-892 (Rev. 01-2001)

**Notice of References Cited** 

Part of Paper No. 20130110

# Notice of References Cited Application/Control No. 13/455,841 Examiner MATTHEW NELSON Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON Art Unit Page 2 of 2

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*	В	US-7,137,815 B2	11-2006	Matsutani et al.	433/102
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**Notice of References Cited** 

Part of Paper No. 20130110

# Search Notes



Application/Control I	No.
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13455841

Applicant(s)/Patent Under Reexamination

LUEBKE, NEILL HAMILTON

Examiner

MATTHEW NELSON

Art Unit

**SEARCHED** 

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Class	Subclass	Date	Examiner		
29	896.1,896.11				
148	402, 421, 426				
433	102, 224				

SEARCH NOTES		
Search Notes	Date	Examiner
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	С	US-5,653,590 A	08-1997	Heath e	et al.			433/102
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	G	US-6,431,863 B1	08-2002	Sachde	eva et al.			433/102
	Н	US-6,428,634 B1	08-2002	Besseli	nk et al.			148/421
	I	US-2002/0191878 A1	12-2002	Ueda e	t al.			384/492
	J	US-2004/0121283 A1	06-2004	Mason,	Robert M.			433/102
	К	US-7,137,815 B2	11-2006	Matsuta	ani et al.			433/102
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Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (f known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				
		<sup>US-</sup> 6783438	10/23/2003	Aloise et al.					
		<sup>US-</sup> 20040171333	09/02/2004	Aloise et al.					
		<sup>US-</sup> 20060014480	01/13/2006	Aloise et al.					
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	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>			
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Examiner Signature	/Matthew Nelson/	Date Considered	01/10/2013

\*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. Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspic.gov">www.uspic.gov</a> 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. 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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Receipt date: 04/25/2012

13455841 - **GAJJ**: 3776

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 03/31/2009. 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.

	Application Number		
INFORMATION DIOCE COURT	Filing Date		
INFORMATION DISCLOSURE	First Named Inventor	Neill F	H. Luebke
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		3732
( Not for Submission under 67 of 17 1.55)	Examiner Name	Matth	ew M. Nelson
	Attorney Docket Number	er	

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue D	)ate	Name of Pate of cited Docu	entee or Applicant ment	Relev	es,Columns,Lines where vant Passages or Relev es Appear	
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If you wis	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 <sup>1</sup>	Publica Date	tion	Name of Pate of cited Docu	entee or Applicant ment	Relev	es,Columns,Lines where vant Passages or Relev es Appear	
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Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> i		Kind Code <sup>4</sup>	Publication Date	Name of Patented Applicant of cited Document	e or	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
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Receipt date: 04/25/2012

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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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Complete if Known

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First Named Inventor

Art Unit

(Use as many sheets as necessary)

Sheet

PTO/SB/08a (07-06)

Approved for use through 09/30/2006, OMB 0651-0031

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Complete if Known

Application Number

Filling Date

First Named Inventor

Art Unit

Examiner Name

Attorney Docket Number

U. S. PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Number-Kind Code <sup>2 (d known)</sup>		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
		<sup>∪S-</sup> 6,431,863	08-13-2002	Lal Sachdeva, et al.				
		<sup>US-</sup> 6,422,865	07-23-2002	Fischer				
		<sup>US-</sup> 6,428,634	08-06-2002	Besselink, et al.				
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Examiner Signature	/Matthew Nelson/	Date Considered	101/10/2013

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13455841 - GAU: 3776

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Application Number

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INFO	RMA	TION DI	SCLO	SURE	Filing Date		
STAT	EME	ENT BY A	<b>1</b> PPLI	CANT	First Named Inventor	LUEBKE, Neill Hamilton	
					Art Unit		
	(Use as	many sheets as	necessary	)	Examiner Name		
Sheet	<u> </u>		of		Attorney Docket Number		
				NON PATE	NT LITERATURE DOCUMENTS		
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	Copy of International Search Report corresponding to PCT/US2005/019947, under date of mailing of 10 November 2005.						
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Examiner Signature	/Matthew Nelson/	Date Considered	01/10/2013	

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# **EAST Search History**

# **EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2834	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/01/10 09:57
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
<b>S</b> 8	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 87 of	US-PGPUB; USPAT;	OR	ON	2008/04/29 15:16

IPR2015-00632 - Ex. 1008 US ENDODONTICS, LLC., Petitioner

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

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

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

IPR2015-00632 - Ex. 1008 US ENDODONTICS, LLC., Petitioner

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

(Nickel NEAR1 TAND (anneal\$3 treated OR heat NEAR1 gas))	ID ((Ni NEAR1 Ti) OR itanium) OR Nitinol) OR heat NEAR5 ) SAME ((unreactive 3".clas.) AND ((Ni	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2011/05/12
NEAR1 Ti) OR (I Titanium) OR Ni OR heat NEAR5 SAME ((unreacti NEAR1 Ti) OR (I Titanium) OR Ni OR heat NEAR5 SAME ((inert NE S59 S1 (endodontic "43 (anneal\$3 OR heat) SAME ((ur NEAR1 oxidizing NEAR1 oxidizing) OR heat NEAR5 SAME ((unreacti NEAR5 SAME) ((unreacti NEAR5 SAME) ((unreacti	3".clas.) AND ((Ni	DERWENT			2011/05/12 09:38
NEAR1 Ti) OR (I Titanium) OR Ni OR heat NEAR5 SAME ((inert NE  S59 51 (endodontic "43 (anneal\$3 OR heat) SAME ((ur NEAR1 oxidizing  S61 1346 ((Ni NEAR1 Ti) OTitanium) OR Ni OR heat NEAR5 SAME ((unreacti	Nickel NEAR1 itinol) AND (anneal\$3 treated OR heat)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
(anneal\$3 OR h heat) SAME ((ur NEAR1 oxidizing S61 1346 ((Ni NEAR1 Ti) ( Titanium) OR Ni OR heat NEAR5 SAME ((unreacti	tinol) AND (anneal\$3 treated OR heat)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
Titanium) OR N OR heat NEAR5 SAME ((unreacti	eat NEÁR5 treated OR nreactive inert (non	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:40
	OR (Nickel NEAR1 Itinol) AND (anneal\$3 treated OR heat) ve inert (non NEAR1 R1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:46
	tinol) SAME eat NEAR5 treated OR preactive inert (non	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:52
heat) SAME ((ur		US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:56
heat) SAME ((ur	eat NEAR5 treated OR nreactive inert (non )) NEAR1 gas) SAME	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S67 8 "433".clas. AND NEAR5 treated ( ((unreactive ine oxidizing)) NEAF oxidiz\$4	rt (non NEAR1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S68 2 Nitinol AND (ani		US-PGPUB;	OR	ON	2011/05/12

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

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

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

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

# **EAST Search History (Interference)**

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

#### 1/10/2013 10:28:47 AM



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

# **BIB DATA SHEET**

#### **CONFIRMATION NO. 5421**

SERIAL NUMBER	R FILING OF DAT			CLASS	GRO	UP ART	UNIT	ATTO	RNEY DOCKET NO.		
13/455,841	04/25/2			433		3776		1	15207.00009		
	RUL	E									
<b>APPLICANTS</b> Neill Hamiltor	n Luebke, Brookf	ield, WI;									
** CONTINUING DATA ********************************  This application is a CON of 13/336,579 12/23/2011     which is a CON of 12/977,625 12/23/2010 PAT 8,083,873     which is a DIV of 11/628,933 12/07/2006 PAT 8,062,033     which is a 371 of PCT/US05/19947 06/07/2005     which claims benefit of 60/578,091 06/08/2004  ** FOREIGN APPLICATIONS *********************************  ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** ** SMALL ENTITY **     05/04/2012  Foreign Priority claimed											
Foreign Priority claimed 35 USC 119(a-d) conditions Verified and /MATT NELS	☐ Met aft Allowa	ter nce	STATE OR COUNTRY WI	_	EETS WINGS	VINGS CLAIMS		INDEPENDENT CLAIMS 2			
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QUARLES & Attn: IP Dock 411 E. WISC SUITE 2350	et ONSIN AVENUE , WI 53202-4420										
TITLE											
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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	13455841	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

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	1	✓											
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U.S. Patent and Trademark Office Part of Paper No. : 20130110

Docket No.: 115207.00009

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

Date: May 20, 2013 /Richard T. Roche/

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

#### IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke

Application No.: 13/455,841

Filing Date: December 23, 2011

Title: Dental And Medical Instruments Comprising Titanium

Confirmation No.: 5421

Art Unit: 3776

Examiner: Matthew M. Nelson

### <u>AMENDMENT</u>

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 18, 2013.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 5 of this paper.

### Amendments To The Claims

- 1. (Currently Amended) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:
- (a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a titanium alloy, and
- (b) heat-treating the entire shank at a temperature from 400°C up to but not equal to the melting point of the titanium alloy,

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

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

- 2. (Original) The method of claim 1 wherein: the temperature is from 475°C to 525°C.
- 3. (Original) The method of claim 1 wherein: the shank is heat-treated for 1 to 2 hours.
- 4. (Cancelled)
- 5. (Cancelled)
- 6. (Original) The method of claim 1 wherein: step (b) is performed in any atmosphere.

7. (Currently Amended) The method of claim 6 wherein:

the atmosphere <u>may be is</u> unreactive, ambient or any other acceptable heat treatment process.

8. (Currently Amended) The method of claim 6 wherein:

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

the atmosphere may be is unreactive, ambient or any other acceptable heat treatment process,

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

9. (Original) The method of claim 6 wherein:

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

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

- 10. (Cancelled)
- 11. (Original) The method of claim 1 wherein: the instrument shank has a diameter of 0.5 to 1.6 millimeters.
- 12. (Original) The method of claim 1 wherein: the instrument shank is heat-treated in step (b) at a single temperature.
- 13. (Original) The method of claim 12 wherein: the single temperature is from 400°C to 525°C.

- 14. (Original) The method of claim 13 wherein: the single temperature is from 475°C to 525°C.
- 15. (Original) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:
- (a) providing an elongate shank having 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, the shank consisting essentially of a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium; and
- (b) heat-treating the entire instrument shank at a temperature from 475°C to 525°C.

wherein the heat-treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion tested in accordance with ISO Standard 3630-1.

- 16. (Original) The method of claim 15 wherein: the shank is heat-treated for 1 to 2 hours.
- 17. (Original) The method of claim 15 wherein: the instrument shank is heat-treated in step (b) at a single temperature.
- 18. (Currently Amended) The method of claim 15 wherein: step (b) is performed in an atmosphere may be that is unreactive, ambient or any other acceptable heat treatment process.

### **REMARKS**

#### Claim Amendments

Independent claim 1 has been amended to include the limitations of original claim 5. Independent claim 1 has also been amended to recite that the heat treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 as described at the first sentence of Example 4 of the application.

Claims 4 and 5 have been cancelled.

Claims 7 and 8 have been amended to replace the term "may be" with - - is - -.

Claim 8 has also been amended to remove the nickel and titanium percentages now recited in independent claim 1.

Claim 10 has been cancelled.

Claim 18 has been amended to replace the term "may be" with - - that is - -.

#### Claim Rejections - 35 USC § 112

The Office Action rejected claim 1 under 35 U.S.C. 112, first paragraph, stating "not all titanium alloys subjected to this treatment would result in that degree of deformation". Claim 1 has been amended to recite that the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium. This was an example alloy (54-57 weight percent nickel and 43-46 weight percent titanium) used in Example 4 of the application that provided the resulting deformation recited in Claim 1.

Claims 7-8 and 18 were rejected under 35 U.S.C. 112, second paragraph due to the term "may be". Claims 7-8 and 18 has been amended to remove this term.

It is submitted that these amendments overcome the 35 U.S.C. 112 rejections.

### Claim Rejection - 35 USC § 103

Claims 1-9 and 11-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2005/0090844 to Patel *et al.* ("Patel") in view of U.S. Patent No. 7,137,815 to Matsutani *et al.* ("Matsutani").

Claim 10 was rejected under 35 U.S.C. 103(a) as being unpatentable over Patel and Matsutani in view of U.S. Patent No. 5,380,200 to Heath *et al.* ("Heath").

Claims 15-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Patel and Matsutani and Heath.

Independent claim 1 has been amended to recite that the endodontic instrument has been treated in the method such that the heat-treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1. Original independent claim 15 also recites this feature of the invention. Patel does not teach a method that provides this property.

Attached for Office consideration is an Inventor's Declaration under 37 C.F.R. § 1.132. Patel is directed to a <u>superelastic</u> Nitinol wire, ribbon, sheet or tubing to fabricate a biomedical device. See, paragraphs [0022], [0024], and [0046], and claim 1, line 3, and claim 23, lines 1 and 5 of Patel. The Inventor's Declaration points out that this means that the Patel wire material will return to its original shape after deformation and that the Patel wire material would not undergo permanent deformation as recited in amended independent claim 1 and original claim 15. The Inventor's Declaration further notes that one skilled in the art when reviewing Patel would understand that the Patel superelastic material (Nitinol) would not undergo an angle greater than 10 degrees of

permanent deformation after torque at 45° of flexion as recited in amended independent claim 1 and original claim 15.

To the extent that Patel mentions orthodontic wire, the Inventor's Declaration explains that orthodontic wires are not bend tested for torque, i.e., Type 2 orthodontic wires are tested in three point bending for millimeters at 37 ± 1 °C. In contrast, endodontic instruments (as recited in independent claim 1) are tested with a torque measuring device at 23 ± 2 °C thereby making any comparison of test results of little value. Thus, one skilled in the art would not test orthodontic wires in accordance with ISO Standard 3630-1 as recited in amended independent claim 1 and original claim 15. In this regard, it is well settled that "a prima facie case of obviousness can be rebutted if the applicant ... can show 'that the art in any material respect taught away' from the claimed invention." *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997) *citing In re Malagari*, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974).

Thus, Patel does not teach a method that produces an endodontic instrument having a entire heat-treated shank that has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 as recited in amended independent claim 1 and original claim 15.

Looking now 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]Ithough 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 Office Action states that "Patel shows ... heat-treating the entire instrument or device at a temperature from 400 degrees Celsius up to but not equal to the melting point of the titanium alloy". In contrast, Matsutani heat treats only the tip of the instrument. Therefore, the principle of operation of Patel and Matsutani are completely different. It is well settled that if a proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). See M.P.E.P. § 2143.01 VI. Therefore, Matsutani does not make up for the deficiencies in Patel.

Heath was cited as teaching the torque testing of dental devices. However, as explained above, one skilled in the art would not test the orthodontic wires mentioned in Patel in accordance with ISO Standard 3630-1 as recited in amended independent claim 1 and original independent claim 15.

It is well settled that in order to establish a prima facie case of obviousness of a

claimed invention, all of the claim limitations must be taught or suggested by the prior

art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Taken together, Patel

and Matsutani and Heath fail to teach or suggest a method that produces an endodontic

instrument having a entire heat-treated shank that has an angle greater than 10

degrees of permanent deformation after torque at 45 degrees of flexion when tested in

accordance with ISO Standard 3630-1 as recited in amended independent claim 1 and

original independent claim 15. Accordingly, it is submitted that independent claim 1

(and claims 2-3 and 6-9 and 11-14 that depend thereon) and independent claim 15 (and

claims 6-18 that depend thereon) are patentable over Patel, Matsutani and Heath.

Conclusion

Claims 1-3, 6-9, and 11-18 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.

An extension fee has been submitted. If additional fees are needed, please

charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Neill H. Luebke

Dated: May 20, 2013 By: \_\_\_/Richard T. Roche/

Richard T. Roche

Registration No. 38,599

Quarles and Brady LLP

411 East Wisconsin Ave. Milwaukee, WI 53202

(414) 277-5805

21251593

Docket Number: 115207.00009

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke

Application No.: 13/455,841

Filing Date: December 23, 2011

Title: Dental And Medical Instruments Comprising Titanium

Art Unit: 3776

Examiner: Matthew M. Nelson

# DECLARATION UNDER 37 C.F.R. § 1.132

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

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

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

- 3. Another instrument in accordance with ISO Standard 3630-1 made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium and including an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank was heat-treated in a furnace at 500°C for 75 minutes. The heat-treated instrument had a natural straight orientation before pressure was applied. See the top photo in attached Applicant's Exhibit 2. Pressure was applied to the heat-treated instrument with cotton pliers until the heat-treated instrument had a bend of approximately 90 degrees. After the bending pressure was released, the heat-treated instrument did not return to its original natural straight orientation. See the bottom photo in Applicant's Exhibit 2.
- 4. It is believed that the control instrument detailed in Item 2 above exhibited superelastic behavior as described in U.S. Patent Application Publication No. 2005/0090844 to Patel *et al.* ("Patel") that was cited in the Office Action mailed on January 18, 2013.

- 5. In contrast, the heat-treated instrument detailed in Item 3 above underwent permanent deformation as in the claimed invention of my above-identified patent application.
- 6. It is noted that pending claim 1 of my above-identified patent application recites permanent deformation and not just deformation. The Office Action cites the mention of orthodontic wires in Patel as an example for deformation but the orthodontic wires in Patel are austenitic NiTi which means they will be superelastic and will deform under stress but will return to their original shape which is the precise mechanism that allows teeth to be orthodontically moved. This explains why an orthodontic wire may be deformed to fit the dental arch and still be superelastic (austenitic NiTi). Permanent deformation refers to martensitic NiTi and will remain permanently deformed (underlining added) which is recited in claim 1 in this application. Items 2-5 above and the attached photographs of Exhibits 1 & 2 demonstrate the differences between superelasticity and permanent deformation.
- 7. Further, Patel is attempting to make a high fatigue life Nitinol wire, ribbon, sheet, or tubing to be made into a device implanted in the body which has a long period of service. To accomplish this end, in paragraph [0011] Patel heat-treats the Nitinol wire, ribbon, sheet or tubing between 450°C and 500°C with no time stated. In paragraph [0012] Patel states, "In accordance with the present invention, the high fatigue metal wire (underlining added) in a heat-treated condition has a fatigue life greater than approximately 22,760 mean cycles to failure . . .". As one continues to

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

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

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

http://www.academia.edu/820015/Effect\_of\_Heat\_Treatment\_on\_the\_Superelasticity\_a nd Hardness of NiTi

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

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

- 9. With Patel the <u>final step</u> (underlining added) for this invention was cold working the Nitinol wire, ribbon, tubing or sheet to assure the Nitinol was in a <u>superelastic state</u> (underlining added). The fact that the Nitinol wire, ribbon, sheet, or tubing is superelastic means it remains in an austenitic state.
- 10. Amended independent claim 1 of my above-identified patent application now recites that "the heat treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1". Part 1 of ISO 3630 defines general requirements and test methods for endodontic instruments. The endodontic instruments are tested with a torque measuring device at a temperature range of  $23 \pm 2$  °C.
- 11. The specification used to test orthodontic wires is ANSI/ADA Specification 32: Orthodontic wires, which is a direct copy of ISO 15841:2006 Dentistry -- Wires for use in orthodontics without the Tables of documentation. Nickel-titanium alloy orthodontic wire in ANSI/ADA Specification 32: Orthodontic wires is considered Type 2

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

- 12. The Office Action of January 18, 2013 states that "Patel discusses orthodontic wires in [0004] which would have a predetermined deformation over 10 degrees, forming to the dental arch, to elicit desired tooth movements and this test on this embodiment of Patel would result in greater than 10 degrees)".
- 13. It is acknowledged that Patel mentions orthodontic wires at paragraph [0004]. However, I respectfully disagree with the statement that the Patel orthodontic wires "would have a predetermined deformation over 10 degrees ... and this test on this embodiment of Patel would result in greater than 10 degrees".
- 14. As noted above, Type 2 orthodontic wires are tested at oral temperature (37 ± 1) °C using a three-point, symmetric bending test. Simply put, orthodontic wires are not tested using ISO Standard 3630-1. More generally, Type 2 orthodontic wires are not tested using the bending test to measure torque in mN•m (or gm•cm) as in ISO Standard 3630-1, i.e., rather, ANSI/ADA Specification 32: Orthodontic wires describes a three-point, symmetric bending test that measures ". . . deflection measurements in millimeters . . . to be taken during unloading".

15. Thus, I believe that the Patent Office will not be able to provide factual

support for the statement that the Patel orthodontic wires "would have a predetermined

deformation over 10 degrees ... and this test on this embodiment of Patel would result

in greater than 10 degrees". In this regard, (i) orthodontic wires are bend tested for

deflection, i.e., Type 2 orthodontic wires are tested for bending in three point bending

and reported in millimeters versus endodontic instruments are tested in bending in a

torque measuring device and reported in mN·m (or gm·cm); and (ii) Type 2 (nickel

titanium) orthodontic wires are tested at 37 ± 1 °C versus endodontic instruments are

tested at 23 ± 2 °C thereby making any comparison of test results of little value.

16. I declare that all statements made herein of my own knowledge are true

and that all statements made on information and belief are believed to be true; and

further that these statements were made with the knowledge that willful false statements

and the like made are punishable by fine or imprisonment, or both, under Section 1001

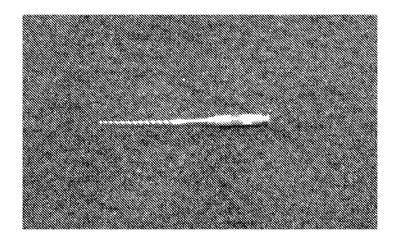
of Title 18 of the United States Code and that such willful false statements may

jeopardize the validity of the above-identified application or any patent issuing thereon.

Dated: May 20, 2013

Dr. Neill H. Luĕbke

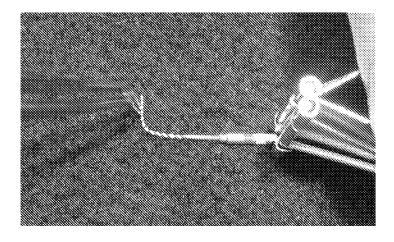
### <u>Applicant's Exhibit 1</u> Standard Nickel Titanium Endodontic File

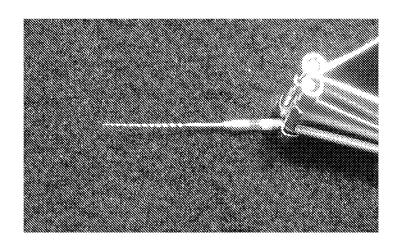


File Size 25 with 04 taper

Natural straight orientation before pressure is applied

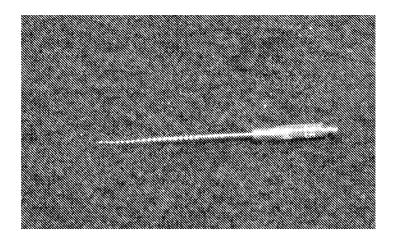
File Size 25 with 04 taper with pressure applied





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



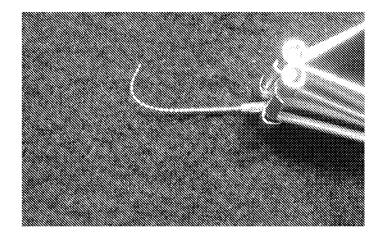
File Size 25 with 04 taper

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



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. Docket Number (Optional) PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) 115207.00009 Application Number April 25, 2012 13/455,841 Dental and Medical Instruments Comprising Titanium Art Unit 3732 Examiner Matthew M. Nelson This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below): Small Entity Fee Micro Entity Fee <u>Fee</u> <sub>\$</sub> 100 One month (37 CFR 1.17(a)(1)) \$200 \$100 \$50 Two months (37 CFR 1.17(a)(2)) \$600 \$300 \$150 Three months (37 CFR 1.17(a)(3)) \$1,400 \$700 \$350 Four months (37 CFR 1.17(a)(4)) \$2,200 \$1,100 \$550 Five months (37 CFR 1.17(a)(5)) \$3,000 \$1,500 \$750 Applicant asserts small entity status. See 37 CFR 1.27. Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously. A check in the amount of the fee is enclosed. Payment by credit card. Form PTO-2038 is attached. The Director has already been authorized to charge fees in this application to a Deposit Account. The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 170055 Payment made via EFS-Web. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. applicant. attorney or agent of record. Registration number 38,599 attorney or agent acting under 37 CFR 1.34. Registration number /Richard T. Roche/ May 20, 2013 Signature Richard T. Roche 414-277-5805 Typed or printed name Telephone Number NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below\*

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

forms are submitted

\* Total of 1

Electronic Patent Application Fee Transmittal						
Application Number:	13	455841				
Filing Date:	25-Apr-2012					
Title of Invention:	De	ntal and Medical In:	struments Con	nprising Titanium		
First Named Inventor/Applicant Name:	Ne	ill Hamilton Luebke				
Filer: Richard T. Roche						
Attorney Docket Number: 115207.00009						
Filed as Small Entity						
Utility under 35 USC 111(a) Filing Fees						
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)	
Basic Filing:						
Pages:						
Claims:						
Miscellaneous-Filing:						
Petition:						
Patent-Appeals-and-Interference:						
Post-Allowance-and-Post-Issuance:						
Extension-of-Time:						
Extension - 1 month with \$0 paid		2251	1	100	100	

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
	Total in USD (\$)			100

Electronic Acknowledgement Receipt				
EFS ID:	15820222			
Application Number:	13455841			
International Application Number:				
Confirmation Number:	5421			
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:	115207.00009			
Receipt Date:	20-MAY-2013			
Filing Date:	25-APR-2012			
Time Stamp:	16:04:36			
Application Type:	Utility under 35 USC 111(a)			

## **Payment information:**

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$100
RAM confirmation Number	3105
Deposit Account	170055
Authorized User	

## File Listing:

	<b>9</b> -				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest		
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Document Description   Start   E	1 4
Amendment/Req. Reconsideration-After Non-Final Reject 1  Claims 2  Applicant Arguments/Remarks Made in an Amendment 5  Warnings:  Information:  2  Affidavit-traversing rejectns or objectns rule 132  Affidavit-traversing rejectns or objectns rule 132  Luebke-00009- InventorsDeclaration.PDF  873316seb999b9b523cbccfeab 189a2bb13 6a28	1 4
Claims  Applicant Arguments/Remarks Made in an Amendment  Marnings: Information:  2  Affidavit-traversing rejectns or objectns rule 132  Affidavit-traversing rejectns or objectns rule 132	4
Applicant Arguments/Remarks Made in an Amendment 5  Warnings:  Information:  2 Affidavit-traversing rejectns or objectns rule 132 Luebke-0009- Inventors Declaration. PDF  R7331f3e5b99b9b523cbccfeab 189a2bb13 6a28 no	
Warnings:  Information:  2 Affidavit-traversing rejectns or objectns rule 132 Luebke-00009-InventorsDeclaration.PDF  R7331f3e5b99b9b523cbccfeab189a2bb13 6a28  no	9
Information:  2 Affidavit-traversing rejectns or objectns rule 132 Luebke-00009-InventorsDeclaration.PDF  R7331f3e5b99b9b523cbccfeab189a2bb13 6a28 no	
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3 Extension of Time Extension.PDF	1
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Information:	
4 Fee Worksheet (SB06) fee-info.pdf no	2
28d3d0f212eb1ab4e4c77ced0d9c66b9eee 52d45	
Warnings:	
Information:	
Total Files Size (in bytes): 1091233	

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.

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						on or Docket Number 3/455,841	Filing Date 04/25/2012	To be Mailed	
	ENTITY: LARGE SMALL MICRO								
					ATION AS FIL	.ED – PAF	RT I		
			(Column 1		(Column 2)				
Ļ	FOR	1	NUMBER FIL	.ED	NUMBER EXTRA		RATE (\$)	F	FEE (\$)
Ш	BASIC FEE (37 CFR 1.16(a), (b),	or (c))	N/A		N/A		N/A		
	SEARCH FEE (37 CFR 1.16(k), (i), o	or (m))	N/A		N/A		N/A		
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A		
	ΓAL CLAIMS CFR 1.16(i))		mir	nus 20 = *			X \$ =		
IND	EPENDENT CLAIM CFR 1.16(h))	S	m	inus 3 = *			X \$ =		
	APPLICATION SIZE (37 CFR 1.16(s))	of p for s frac	aper, the a	ation and drawing application size f y) for each additi of. See 35 U.S.C	ee due is \$310 ( onal 50 sheets o	\$155 or			
	MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))								
* If t	he difference in colu	umn 1 is less thai	n zero, ente	r "0" in column 2.			TOTAL		
		(Column 1)		APPLICAT (Column 2)	ION AS AMEN (Column 3		ART II		
TN:	05/20/2013	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	(TRA	RATE (\$)	ADDITIO	ONAL FEE (\$)
AMENDMENT	Total (37 CFR 1.16(i))	* 15	Minus	** 20	= 0		x \$40 =		0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0		× \$210 =		0
AME	Application Si	ize Fee (37 CFR	1.16(s))						
	FIRST PRESEN	NTATION OF MULT	IPLE DEPEN	DENT CLAIM (37 CFF	R 1.16(j))				
							TOTAL ADD'L FE	≣	0
		(Column 1)		(Column 2)	(Column 3	)			
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	(TRA	RATE (\$)	ADDITIO	ONAL FEE (\$)
ENT	Total (37 CFR 1.16(i))	*	Minus	**	=		X \$ =		
ENDM	Independent (37 CFR 1.16(h))	*	Minus	***	=		X \$ =		
1EN	Application Si	ize Fee (37 CFR	1.16(s))						
AM	FIRST PRESEN	NTATION OF MULT	IPLE DEPEN	DENT CLAIM (37 CFF	R 1.16(j))				
							TOTAL ADD'L FE		
** If ***	the entry in column of the "Highest Number f the "Highest Numb	er Previously Pai per Previously Pa	d For" IN Th id For" IN T	HIS SPACE is less HIS SPACE is less	than 20, enter "20' s than 3, enter "3".		LIE /MELINDA L.		

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

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.	CONFIRMATION NO.	
13/455,841	04/25/2012	Neill Hamilton Luebke	115207.00009	5421
26710 QUARLES & F	7590 06/24/201 BRADY LLP	3	EXAM	INER
Attn: IP Docket		NELSON, MATTHEW M		
SUITE 2350	NOIN A VENUE	ART UNIT	PAPER NUMBER	
MILWAUKEE,	, WI 53202-4426	3776		
			NOTIFICATION DATE	DELIVERY MODE
			06/24/2013	ELECTRONIC

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

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

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

pat-dept@quarles.com

	Application No.Applicant(s)13/455,841LUEBKE, NEILL HAMILTON					
Office Action Summary  Examiner MATTHEW NELSON  Art Unit Status No						
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondend	e address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period v  - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONEI	J. ely filed the mailing date of O (35 U.S.C. § 133	this communication.			
Status						
1) Responsive to communication(s) filed on <u>20 M</u> A declaration(s)/affidavit(s) under <b>37 CFR 1.1</b>	<del></del>					
	action is non-final.					
3) An election was made by the applicant in response		set forth durin	a the interview on			
the restriction requirement and election;	•		g and interview on			
4) Since this application is in condition for allowar	·		the merits is			
closed in accordance with the practice under E	·					
Disposition of Claims						
5) Claim(s) 1-3,6-9 and 11-18 is/are pending in the 5a) Of the above claim(s) is/are withdraw 6) Claim(s) is/are allowed.  7) Claim(s) 1-3,6-9 and 11-18 is/are rejected.  8) Claim(s) is/are objected to.  9) Claim(s) are subject to restriction and/o  * If any claims have been determined allowable, you may be el participating intellectual property office for the corresponding al <a href="http://www.uspto.gov/patents/init_events/pph/index.jsp">http://www.uspto.gov/patents/init_events/pph/index.jsp</a> or send  Application Papers  10) The specification is objected to by the Examine 11) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the sentence of the sentence	wn from consideration.  r election requirement.  igible to benefit from the <b>Patent Pros</b> pplication. For more information, plea  an inquiry to <u>PPHfeedback@uspto.c</u> ir.  epted or b) □ objected to by the E	se see ov. Examiner.				
Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign Certified copies:  a) All b) Some * c) None of the:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureau	priority under 35 U.S.C. § 119(a) ts have been received. ts have been received in Applicat brity documents have been receive	-(d) or (f).				
* See the attached detailed Office action for a list of Interim copies:  a) All b) Some c) None of the: Interior	the certified copies not received.	ts have been	received.			
Attachment(s)  1) Notice of References Cited (PTO-892)	3) Interview Summary	(PTO-413)				
ON THE CONTRACT OF THE CONTRAC	Paper No(s)/Mail Da					

Paper No(s)/Mail Date \_

2) Information Disclosure Statement(s) (PTO/SB/08)

4) Other: \_\_\_\_\_.

Art Unit: 3776

#### **DETAILED ACTION**

Amendment filed on 5/20/2013 is acknowledged.

#### Claim Rejections - 35 USC § 103

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

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

- Claims 1-3, 6-9, 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (US 2005/0090844) in view of Matsutani (US 7,137,815) and further in view of Heath et al. (US 5,380,200).
- Patel shows a method for manufacturing or modifying a dental instrument, the method comprising providing a dental elongate shank comprising a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium ([0029]; 10) and heat-treating the entire instrument or device at a temperature from 400 degrees Celsius up to but not equal to the melting point of the titanium alloy ([0041]-[0042]), wherein the heat-treated instrument or device has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion (this test would be entirely dependent on what degree the instrument was permanently deformed to before the test; for instance, Patel discusses orthodontic wires in [0004] which would have a predetermined deformation over 10 degrees, forming to the dental arch, to elicit desired tooth movements and this test on this embodiment of Patel would result in greater than

Art Unit: 3776

10 degrees). With respect to claim 2, the temperature is from 475 to 525 degrees Celsius ([0042]). With respect to claim 3, the instrument or device is heat-treated for 1 to 2 hours ([0041]). With respect to claims 6 and 7, this is performed in any atmosphere acceptable for heat treatment (Patel is conducting heat treatment in an atmosphere). Claims 8-9 are rejected similarly to the above and below. With respect to claims 12-14, heat-treated at a single temperature ([0042]). However, Patel fails to show the dental instrument is specifically an endodontic instrument having a cutting edge extending from a distal end of the shank along an axial length of the shank with a diameter of 0.5 to 1.6 mm.

• Matsutani teaches a similar heat treatment process conducted on an endodontic instrument elongate shank (6 and 7 in Fig. 1) having a cutting edge (at 4 in Fig. 1) extending from a distal end of the shank along an axial length of the shank (Fig. 1) with a diameter of 0.5 to 1.6 mm (col. 7, lines 55-59 show overlapping ranges). With respect to claim 15, the shank having helical flutes (at 4 in Fig. 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Patel's method by choosing an endodontic instrument as the dental instrument as taught by Matsutani since it is well known in the art to conduct heat treatments on endodontic instruments and this range of diameters is known for endodontic reamers. Additionally, in regards to the permanent deformation after torque at 45 degrees, Matsutani discusses in col. 4, lines 45-57 applying a pre-curve to the shape of the instrument. However, Patel/Matsutani fails to show that the instrument and the angle of permanent deformation is tested in accordance with ISO Standard 3630-1.

Art Unit: 3776

Heath teaches titanium alloy dental devices whose physical properties after

manufacture are tested by the standard of subjecting the shank to torque at 45 degrees

of flexion and measuring the results (col. 5, lines 17-25). Therefore, it would have been

obvious to one having ordinary skill in the art at the time of invention to modify

Patel/Matsutani's method by including the testing step of Heath in order to determine

the properties of the device and ensure they are as desired.

Response to Amendment

• The declaration under 37 CFR 1.132 filed 5/20/2013 is insufficient to overcome

the rejection of claims 1-3, 6-9, 11-18 based upon Patel/Matsutani/Heath as set forth in

the last Office action because:

The declaration only considers the Patel devices properties after cold working,

rather than after the heat treatment (annealing) which is when the claims suggest the

test. The Patel device is heat treated just as in the claims and would have the same

resultant properties before it is later cold worked.

• The declaration also brings up different tests for wires and endodontic files,

which appears to dismiss the combination with Matsutani having the heat treatment

done on an endodontic file. It is also noted that the wire of Patel would be capable of

undergoing the endodontic test and have similar resultant properties due to the same

materials/manufacturing steps.

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#### Response to Arguments

 Applicant's arguments filed 5/20/2013 have been fully considered but they are not persuasive.

- Applicant argues with respect to the flexion test and Patel having a final superelastic property. First, it is noted that the claims do not currently recite the flexion test actually being performed as part of the method. The test is only referred to inferentially to establish physical properties of the shank, so the prior art references do not currently need to show the conducting of this test (however, Heath has been included to show this being a standard test to make the rejection more complete). Secondly, the test is referred to as being conducted on the *heat treated* shank, which Patel's wire after annealing (heat treatment) would have the same properties as the claimed invention (same material/manufacture steps). It is only after Patel's wire is *cold worked* that it returns to the superelastic state. The flexion test is currently claimed specific to the heat treated shank rather than a cold worked shank.
- Applicant argues that different tests would be performed on a wire versus an endodontic file. First, this is attacking the references individually, since the combination of Patel/Matsutani has the heat treatment on an endodontic file. Secondly, the wire of Patel is capable of being tested in the same manner as a file.
- Applicant again argues the references individually, stating that Matsutani does not heat treat the entire shank, however Patel has already shown heat treating the entire instrument. Matsutani is simply being incorporated to show that it is known to perform similar heat treatment conditions on an endodontic file.

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Conclusion

 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to MATTHEW NELSON whose telephone number is

(571)270-5898. The examiner can normally be reached on Monday-Friday 7:30am-

5:00pm EDT.

If attempts to reach the examiner by telephone are unsuccessful, *please contact* 

the examiner's supervisor, Todd Manahan, at (571) 272-4713. The fax phone

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

273-8300.

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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

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robyn Doan/

Primary Examiner, Art Unit 3776

/MMN/

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## Search Notes



Application/Control No.	Applicant(s)/Patent Under Reexamination
13455841	LUEBKE, NEILL HAMILTON
Examiner	Art Unit
MATTHEW NELSON	3776

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED				
Symbol	Date	Examiner		

	US CLASSIFICATION SEARCHE	ED .	
Class	Subclass	Date	Examiner
29	896.1,896.11	1/10/2013	MN
148	402, 421, 426	1/10/2013	MN
433	102, 224	1/10/2013	MN
29, 148, 433	Updated	6/4/2013	MN

SEARCH NOTES		
Search Notes	Date	Examiner
See EAST search history	1/10/2013	MN
Updated EAST search	6/4/2013	MN

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

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	13455841	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

✓	Rejected	_	Cancelled		N	Non-Elected		A	Appeal
=	Allowed	÷	Restricted		_	Interference		0	Objected
			•				-		
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47								). 🗌 R.1.47	
	CLAIM								

Claims renumbered in the same order as presented by applicant							□ СРА	□ т.п	D. 🗆	R.1.47
CL	AIM		DATE							
Final	Original	01/10/2013	06/04/2013							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	-							
	5	✓	-							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	<b>√</b>	✓							
	10	<b>√</b>	-							
	11	✓	✓							
	12	✓	✓							
	13	✓	✓							
	14	✓	✓							
	15	✓	✓							
	16	✓	✓							
	17	✓	✓							
	18	✓	<b>√</b>							

U.S. Patent and Trademark Office Part of Paper No.: 20130604

#### **EAST Search History**

#### **EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	2876	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/06/04 10:10
S2	6	"6431863".pn. "6422865".pn. "6428634".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 07:56
S5	1068	Ni adj Ti AND anneal\$2 AND time	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S6	544	Ni adj Ti AND anneal\$2 AND time AND hour	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S7	16	Ni adj Ti AND anneal\$2 AND time AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:54
S8	876	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:54
S9	53	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:55
S10	183	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 15:12
S11	29	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND	US-PGPUB; USPAT;	OR	ON	2008/04/29 15:16

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

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

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

			USOCR; FPRS; EPO; JPO; DERWENT			
S45	226	S44 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S46	1	S45 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S47	11	S45 AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:07
S48	10	(US-20040121283-\$).did. or (US-6431863-\$ or US-6428634-\$ or US-6375458-\$ or US-4490112-\$ or US-5775902-\$ or US-5206695-\$ 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 138 of 2	<b>§</b>	OR	ON	2011/05/12 015-00632 - Ex. 10

		(Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			09:36
S56	2	(endodontic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S57	2	(endodontic "433".clas.) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S58	16	(endodontic "433".clas.) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S59	51	(endodontic "433".clas.) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:40
S61	1346	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:46
S64	126	((Ni ADJ Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) SAME (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:52
S65	10	((Ni ADJ Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) SAME (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:56
S66	8234	(anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S67	8	"433".clas. AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S68	2	Nitinol AND (anneal\$3 OR heat	US-PGPUB;	OR	ON	2011/05/12
:1	25	139 of 2	56	23	" IPR201	ម 5-00632 - Ex.

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

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

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

		memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated) SAME (inert gas) SAME temperature AND @ad<= "20040608"	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			13:32
S101	51	(medical dental) AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated) SAME (inert gas) SAME temperature AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:33
S102	3	"12977625"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:40
S103	2	"5380200".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/05 08:39
S104	2819	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/12/05 09:41
S105	2834	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/01/10 09:57
S106	2	"8048345".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/01/10 11:03

#### **EAST Search History (Interference)**

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

#### 6/4/2013 10:10:34 AM

Doc Code: M865 or FAI.REQ.INTV

PTOL-413A (08-10)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

	Applicant	Initiated Intervie	w Request 1	Form CENTR	ECEIVED			
Application No.: 13/4	55,841	First Named Applican	<sub>it:</sub> Neill H. Lueb	ke JUL	2 5 2013			
Examiner: Matthew M. Nels	on	Art Unit: 3776	Status of App	olication: Final Reje	ection			
Tentative Participant (1) Examiner Nelson		(2) Neill H. Luebke, Inven	ntor	<u> </u>	÷			
(3) Richard T. Roche	(38599)	(4)						
Proposed Date of Inte				ime: 1 PM	_(AM/PM)			
Type of Interview Re (1) [/] Telephonic		al (3)[] Video	Conference					
		ed: [ ] YES			_			
		Issues To Be Discu	ıssed					
Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed			
(1) 103 Rej.	1	US 2005/0090844 (Patel)	1 ]	[]	[]			
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(3)			[]	[]	U			
(4) [v] Continuation Sheet Brief Description of A	t Attached	[ ] Proposed Amenda	[ ] nent or Argume	 nts Attached	[ <b>]</b>			
An interview was con	ducted on the a	bove-identified applica	tion on					
NOTE: This form should be completed and filed by applicant in advance of the interview (see MPEP § 713.01). If this form is signed by a registered practitioner not of record, the Office will accept this as an indication that he or she is authorized to conduct an interview on behalf of the principal (37 CFR 1.32(a)(3)) pursuant to 37 CFR 1.34. This is not a power of attorney to any above named practitioner. See the Instruction Sheet for this form, which is incorporated by reference. By signing this form, applicant or practitioner is certifying that he or she has read the Instruction Sheet. After the interview is conducted, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible. This application will not be delayed from issue because of applicant's failure to submit a written record of this interview.								
	/Richard T. Roche/							
Applicant/Applicant Richard T. Roch	•	e Signature	Exam	iner/SPE Signa	ițure			
Typed/Printed Name of		Lepresentative						
38599	••	•						
Registration Number, if applicable								

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- (1) U.S. Patent Application Publication No. 2005/0090844 to Patel et al. ("Patel") has been cited against the claims. Page 5 of the Office Action of June 24, 2013 states: "Applicant argues with respect to the flexion test and Patel having a final superelastic property. ... The test is only referred to inferentially to establish physical properties of the shank". Applicant does not dispute this reasoning.
- (2) Page 5 of the Office Action of June 24, 2013 continues: "the test is referred to as being conducted on the heat treated shank, which Patel's wire after annealing (heat treatment) would have the same properties as the claimed invention (same material/manufacture steps). It is only after Patel's wire is cold worked that it returns to the superelastic state." Applicant agrees that the test is referred to in claim 1 as being conducted on the heat treated shank. However, Applicant disagrees with: (i) the conclusion that Patel's wire after annealing (heat treatment) would have the same properties as the claimed invention (same material/manufacture steps), and (ii) the conclusion that after Patel's wire is cold worked that it returns to the superelastic state.
- (3) Applicant understands that the U.S. Patent Office possesses the authority to require the Applicant to prove that the subject matter shown to be in the prior art does not possess a characteristic relied on in a patent claim to establish patentability. See, *In re Swinehart*, 439 F.2d 210, 212-213 (CCPA 1971). However, Applicant has provided evidence and can provide further evidence that the subject matter of Patel does not possess the flexion test properties recited in claim 1.
- (4) Patel is manufacturing a wire, ribbon, sheet, tubing, or the like for a medical device. The manufacture of medical devices is explained in the following excerpt from "Study of Mechanical, Fatigue and Corrosion Properties of the Superelastic NiTi Alloy" by D. Vojtěch in Metal 2011:

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

Thus, the medical devices, or its components, as in Patel are manufactured by a process including: cold drawing followed by straight annealing followed by shape setting. In a typical shape setting treatment, "[m]oderate temperatures and short times are used to prevent the

permanent deformation of implants and to maintain their superelastic behavior" (underlining added - see Vojtěch above).

- (5) Patel distinguishes between annealing and shape setting heat treatments. For example, paragraph [0027] states "[a] full anneal implies that the alloy has been completely stress relieved, typically at about 750°C for 5 to 10 minutes", and paragraphs [0041] and [0042] describe shape setting heat treatments. Regardless of these distinctions, the Vojtěch article above refutes the Office Action conclusion that Patel's wire after annealing would have the same properties as the claimed invention (same material/manufacture steps), and that after Patel's wire is cold worked it returns to the superelastic state. The Vojtěch article above points out that the shape setting heat treatment of straight annealed superelastic wire maintains the superelastic behavior. Thus, Patel's annealed wire would be superelastic, and Patel's shape set wire would be superelastic.
- (6) The Inventor's Declaration filed 5/20/2013 compared and distinguished a superelastic wire and the invention of claim 1. Throughout Patel, the term "superelastic" is used to describe the Patel device (see, e.g., Abstract and paragraphs [0022], [0032], [0046], and claim 1).
- (7) Thus, the Applicant has provided evidence that the Patel device is superelastic and that the subject matter of claim 1 does not have this property of Patel.

# Synopsis of Following Pages of Research and Analysis for Examiner Nelson

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

Clause [0035] The greatest difference between the standard wire versus the present invention wire is the amount of final cold work, where the amount of the final cold work step in the present invention wire is much lower. The expression "final cold work" as defined earlier is intended to mean the last cold work step bringing the part into its final dimensions, after a full anneal, and before the shape setting step where the shape memory is imparted into the alloy. (underline added) Further references to shape setting are in [0040, 0041, 0043]

One skilled in the art knows that <u>shape setting occurs in a fixture</u> whether it is straight or has a specific configuration. This is cited again in Claim 17. The use of a fixture is different from the Luebke application. See further explanation and five references to shape setting. (pages 6-8

References to Martensite-Austenite and Af Temperatures

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

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

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

B. Documentation of process for Patent Application 13455841. Two references to research on the martensitic phase of NiTi.

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

- A. Process that Patel employs in his Patent Application with supporting documentation, and
- B. Documentation of the process for the Patent Application 13455841.

## A. Process that Patel employs:

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

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

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

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

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

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

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

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

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

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

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

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

EFFECT OF ANNEALING PARAMETERS ON THE SHAPE MEMORY PROPERTIES OF NITI THIN FILMS, http://www.mrl.columbia.edu/Gen\_ICALEO08.pdf

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

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

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

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

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

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

# Technical Bulletin from Johnson Matthey Medical Components

"The DSC yields excellent, repeatable results on fully annealed samples (annealed at temperatures above 700 deg. C for sufficient time to achieve a full anneal, generally about 10 to 15 minutes for small samples)."

In the Patel application anneal (or heat treatment) are sometimes used synonymously except when Patel explains the full anneal and when Patel explains the percentage of cold work necessary to obtain a fatigue resistant wire for extended life.

The only other heat temperatures that are relevant are the shape setting temperature(s) [Patel refers to heat treatment as well]. These are found in the following citations.

**ABSTRACT** A high fatigue/life superelastic nickel-titanium (nitinol) wire, ribbon, sheet, tubing, or the like is disclosed. The nitinol has a 54.5 to 57.0 weight percent nickel with a balance of titanium composition and has less than 30 percent cold working final step after a full anneal and before **shape setting heat treatment**. Through a rotational beam fatigue test, fatigue life improvement of 37 percent has been observed.

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

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

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

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

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

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

Claim 17. The process of claim 15, wherein after the final cold working step the process includes mounting the wire, ribbon, sheet or tubing on a fixture (see (Note 3) explanation above) and shape setting the wire, ribbon, sheet or tubing at approximately 250-600° C. for 1 to 60 minutes.

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

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

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

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

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

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

#### Martensite-Austenite References

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

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

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

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

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

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

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

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

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

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

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

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

Page 9 of 16

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

## Af Finish Temperatures References

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

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

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

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

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

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

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

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

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

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

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

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

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

# Technical Bulletin from Johnson Matthey Medical Components

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

# Technical Bulletin from memry, a SAES Group company

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

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

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

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

Effect of Heat Treatment on the Superelasticity and Hardness of NiTi by O Mortagy and M Farag,

http://www.academia.edu/820015/Effect\_of\_Heat\_Treatment\_on\_the\_Superelasticity\_and\_Hard ness of NiTi

"At 500°C Till Nil4 precipitates had grown in size but were still coherent and the material also showed shape memory behavior. No precipitates were observed at 600°C, and, as a result the alloy did not exhibit the shape memory property."

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

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

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

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

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

"A single heat treatment at temperatures near 775 K [500°C] is usually applied in the production of the pre-expanded stents whereas the fabrication of pre-cut stents requires a succession of post-cutting expansion and heat treatment. The single heat treatment for the pre-expanded stents is a simple ageing process, whereas that of the pre-cut stents, on the other hand, is more complicated." "These stents are deployed in application in superelastic state, so to enable instantaneous self-restoration of the designed shape after each pulse contraction."

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

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

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

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

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

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

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

Af (°C)

As-received

18.9±1.6\*

Heat-treated

39.3±5.6\*

## B. Documentation of the process for the Patent Application 13455841

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

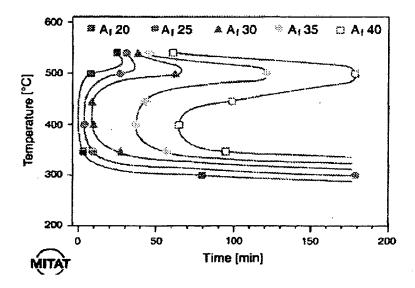
Annealing Temperature Effect on Superelastic and Cyclic Response of NiTi SMA by Li Lan et al., 2009, Advanced Materials Research, 79-82

"The SMA starts to transform into the low temperature martensite, when cooling down to the martensite start temperature (Ms). The transformation is complete after the temperature is cooled down past the Ms, down to the martensite finish temperature (Mf). When in this phase, the alloy can be easily manipulated in a very large strain range. "

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

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



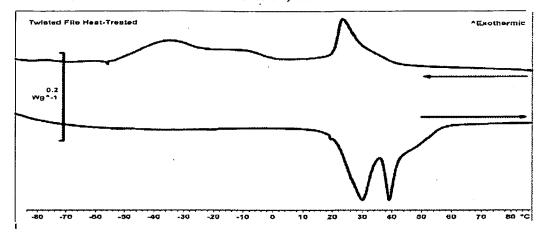


As seen by the graph above, obtaining an Af temperature of 39°C is accomplished with 500°C temperature and approximately two hours of heating. This is what this application accomplishes.

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

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

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



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



411 East Wisconsin Avenue Suite 2040 Milwaukee, Wisconsin 53202-4497

FAX: 414/277-3552 414/277-5591 Attorneys at Law in Milwaukee and Madison, Wisconsin Phoenix and Tucson, Arizona Chicago, Illinois Naples and Tampa, Florida Washington, D.C.

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Message:

Attn: Examiner Matthew Nelson

Re: Applicant Initiated Interview Request Form

Docket No. 115207.00009

THE INFORMATION CONTAINED IN THIS MESSAGE IS PERSONAL AND CONFIDENTIAL
FOR THE RECIPIENT(S) NAMED ABOVE.
IF YOU HAVE RECEIVED THIS MESSAGE IN ERROR,
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIG		
13/455,841	04/25/2012	Neill Hamilton Luebke	115207.00009	5421	
26710 <b>QUARLES &amp; F</b>	7590 08/01/201: BRADY LLP	EXAMINER			
Attn: IP Docket			NELSON, MATTHEW M		
411 E. WISCONSIN AVENUE SUITE 2350			ART UNIT PAPER NUMBE		
MILWAUKEE, WI 53202-4426			3776		
			NOTIFICATION DATE	DELIVERY MODE	
			08/01/2013	ELECTRONIC	

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

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

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

pat-dept@quarles.com

Applicant-Initiated Interview Summary	13/455,841 LUEBKE, NEILL HAMIL		HAMILTON			
Applicant-initiated linerview Summary	Examiner	Art Unit				
	MATTHEW NELSON	3776				
All participants (applicant, applicant's representative, PTO personnel):						
(1) <u>MATTHEW NELSON</u> .	(3) <u>Neill Luebke</u> .					
(2) <u>Richard Roche</u> .	(4) <i>Fran Luebke</i> .					
Date of Interview: 26 July 2013.						
Type: X Telephonic Video Conference Personal [copy given to: Applicant						
Exhibit shown or demonstration conducted:	⊠ No.					
Issues Discussed 101 112 102 103 0th (For each of the checked box(es) above, please describe below the issue and detail						
Claim(s) discussed: <u>1</u> .						
Identification of prior art discussed: Patel.						
Substance of Interview (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc)						
Discussed the differences between the present invention and the prior art, specifically that the prior art conducts the heat treatment described on a nickel-titanium alloy for annealing and shape setting purposes to arrive at a superelastic device, whereas the present invention is conducting the heat treatment on a superelastic device (rather than as part of the forming a superelastic device) resulting in non-superelastic properties that allow for some degree of permanent deformation. Suggested incorporating language into the claims to this effect in order to differentiate from the prior art of record. Further search and consideration will be required.						
Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview						
<b>Examiner recordation instructions</b> : Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.						
Attachment						
/Matthew M Nelson/ Examiner, Art Unit 3776	/Robyn Doan/ Primary Examiner					

Application No.

Applicant(s)

U.S. Patent and Trademark Office
PTOL-413 (Rev. 8/11/2010) Interview Summary Paper No. 20130727

# **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.

Doc code: RCEX

PTO/SB/30EFS (07-09)

Doc description: Request for Continued Examination (RCE)

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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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL (Submitted Only via EFS-Web)							
Application Number	13455841	Filing Date	2011-12-23	Docket Number (if applicable)	115207.00009	Art Unit	3776
First Named Inventor	Neill H. Luebke			Examiner Name	Matthew M. Nelson		
Request for C	ontinued Examina	ation (RCE)		R 1.114 does not a	above-identified application. pply to any utility or plant applic WWW.USPTO.GOV		prior to June 8
		s	SUBMISSION REQ	UIRED UNDER 37	7 CFR 1.114		
in which they	were filed unless	applicant in		applicant does not wi	nents enclosed with the RCE w sh to have any previously filed		
	y submitted. If a fi on even if this box			any amendments file	ed after the final Office action m	iay be con	sidered as a
☐ Co	nsider the argume	ents in the A	Appeal Brief or Reply	Brief previously filed	I on		
☐ Ott	ner 						
<b>X</b> Enclosed							
X An	nendment/Reply						
Information Disclosure Statement (IDS)							
☐ Aff	idavit(s)/ Declarat	ion(s)					
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			MIS	CELLANEOUS			
			entified application is and d 3 months; Fee und		CFR 1.103(c) for a period of m quired)	onths _	
Other —							
FEES							
X The Dire	ctor is hereby aut		is required by 37 CF charge any underpay		RCE is filed. it any overpayments, to		
		SIGNATUF	RE OF APPLICANT	T, ATTORNEY, OF	R AGENT REQUIRED		
_	Practitioner Signant Signature	ature					

Doc code: RCEX

PTO/SB/30EFS (07-09) Doc description: Request for Continued Examination (RCE) 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.

Signature of Registered U.S. Patent Practitioner				
Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2013-09-24	
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.: 115207.00009

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, 2013 /Richard T. Roche/

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

# IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke

Application No.: 13/455,841

Filing Date: December 23, 2011

Title: Dental And Medical Instruments Comprising Titanium

Confirmation No.: 5421

Art Unit: 3776

Examiner: Matthew M. Nelson

# <u>AMENDMENT</u>

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

Sir:

This is in response to the Final Office Action mailed on June 24, 2013.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 5 of this paper.

# Amendments To The Claims

- (Currently Amended) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:
- (a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic nickel titanium alloy, and
- (b) <u>after step (a)</u>, heat-treating the entire shank at a temperature from 400°C up to but not equal to the melting point of the <u>superelastic nickel</u> titanium alloy,

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

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

- 2. (Original) The method of claim 1 wherein: the temperature is from 475°C to 525°C.
- 3. (Original) The method of claim 1 wherein: the shank is heat-treated for 1 to 2 hours.
- 4. (Cancelled)
- 5. (Cancelled)
- 6. (Original) The method of claim 1 wherein: step (b) is performed in any atmosphere.

7. (Previously Presented) The method of claim 6 wherein:

the atmosphere is unreactive, ambient or any other acceptable heat treatment process.

8. (Previously Presented) The method of claim 6 wherein:

the atmosphere is unreactive, ambient or any other acceptable heat treatment process,

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

9. (Currently Amended) The method of claim 6 wherein:

the instrument shank consists essentially of a <u>superelastic nickel</u> titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium,

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

- 10. (Cancelled)
- 11. (Original) The method of claim 1 wherein: the instrument shank has a diameter of 0.5 to 1.6 millimeters.
- 12. (Original) The method of claim 1 wherein: the instrument shank is heat-treated in step (b) at a single temperature.
- 13. (Original) The method of claim 12 wherein: the single temperature is from 400°C to 525°C.
- 14. (Original) The method of claim 13 wherein: the single temperature is from 475°C to 525°C.

- 15. (Currently Amended) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:
- (a) providing an elongate shank having 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, the shank consisting essentially of a <u>superelastic nickel</u> titanium alloy <del>comprising 54-57 weight percent nickel</del> and 43-46 weight percent titanium; and
- (b) <u>after step (a)</u>, heat-treating the entire instrument shank at a temperature from 475°C to 525°C.

wherein the heat-treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion tested in accordance with ISO Standard 3630-1.

- 16. (Original) The method of claim 15 wherein: the shank is heat-treated for 1 to 2 hours.
- 17. (Original) The method of claim 15 wherein: the instrument shank is heat-treated in step (b) at a single temperature.
- 18. (Previously Presented) The method of claim 15 wherein: step (b) is performed in an atmosphere that is unreactive, ambient or any other acceptable heat treatment process.
- 19. (New) The method of claim 1 wherein: the superelastic nickel titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.
- 20. (New) The method of claim 15 wherein: the superelastic nickel titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.

# REMARKS

# Examiner Interview

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

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

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

# Claim Amendments

Independent claim 1 has been amended to recite providing a dental instrument including an elongated shank comprising a <u>superelastic nickel</u> titanium alloy as described at page 7, lines 2-8 of the specification and to make it clear that step (b) ("heat-treating the entire shank at a temperature from 400°C up to but not equal to the melting point of the <u>superelastic nickel</u> titanium alloy") is after step (a).

Dependent claim 9 has been amended to recite <u>superelastic nickel</u> titanium alloy in view of the amendment to independent claim 1. Also, "in" has been replaced with — to — in the last line of claim 9 (to read like claim 16).

The phrase "wherein the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium" in previous claim 1 has been moved to new claim 19 (which also has a basis at page 7, lines 2-8 of the specification).

Independent claim 15 has been amended to recite providing a dental instrument including an elongated shank comprising a <u>superelastic nickel</u> titanium alloy as described at page 7, lines 2-8 of the specification and make it clear that step (b) ("heat-treating the entire shank at a temperature from 400°C up to but not equal to the melting point of the <u>superelastic nickel</u> titanium alloy") is after step (a).

The phrase "wherein the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium" in previous claim 15 has been moved to new claim 20 (which also has a basis at page 7, lines 2-8 of the specification).

# Claim Rejection - 35 USC § 103

Claims 1-3, 6-9 and 11-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2005/0090844 to Patel *et al.* ("Patel") in view of U.S. Patent No. 7,137,815 to Matsutani *et al.* ("Matsutani") and U.S. Patent No. 5,380,200 to Heath *et al.* ("Heath").

As detailed in the Interview Summary dated August 1, 2013, Patel conducts the heat treatment described on a nickel-titanium alloy for annealing and shape setting purposes to arrive at a superelastic device, whereas the present invention is conducting the heat treatment on a superelastic instrument (rather than as part of the forming a

superelastic device) resulting in non-superelastic properties that allow for permanent deformation. Amended independent claims 1 and 15 recite these differences between Patel and the claimed invention. Specifically, amended independent claims 1 and 15: (i) recite in step (a), providing a dental instrument including an elongated shank comprising a <u>superelastic nickel</u> titanium alloy; (ii) recite in step (b), heat-treating the instrument including the elongated shank comprising the superelastic nickel titanium alloy after step (a); and (iii) recite the permanent deformation noted in the Interview Summary dated August 1, 2013.

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

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

As explained above in the excerpt from Exhibit A, in a typical shape setting treatment, 
"[m]oderate temperatures and short times are used to prevent the permanent

deformation of implants and to maintain their superelastic behavior" (underlining added).

Accordingly, after the shape setting treatment of Patel, one has a superelastic device.

Thus, the reasoning in the Interview Summary dated August 1, 2013 that "Patel conducts the heat treatment described on a nickel-titanium alloy for annealing and shape setting purposes to arrive at a superelastic device" is confirmed in the technical literature. In addition, amended independent claims 1 and 15 now make it clear that the present invention is conducting the heat treatment on a superelastic instrument rather than as part of the forming a superelastic device as noted in the Interview Summary dated August 1, 2013.

Looking at U.S. Patent No. 7,137,815 to Matsutani et al., there is described a root canal treatment tool that includes a work portion having a shape memory characteristic in the range of a predetermined length from the tip and a superelastic characteristic in a remaining portion (see column 2, lines 11-24 of Matsutani). In one manufacturing method for the Matsutani root canal treatment tool, "a raw material previously provided with a superelastic characteristic is subjected to a working of removing metal to form a work portion, and by which the tip side of the work portion is again subjected to a heat treatment to provide the tip side with a shape memory characteristic" (see column 6, lines 18-23 of Matsutani). Still referring to Matsutani, it is stated that "the length of the shape memory portion 6 in the work portion 4 needs to be at least 2 mm from the tip 3 [, and] [a]Ithough the maximum length is not limited to a special length, the maximum length is about 3/4 of the whole length of the work portion

4" (see column 5, lines 25-29 of Matsutani). Thus, Matsutani heat treats only the tip of the instrument to create a shape memory portion at the tip and a superelastic portion for the remainder of the instrument. In contrast, amended independent claims 1 and 15 require heat-treating the entire shank.

Regarding U.S. Patent No. 5,380,200 to Heath *et al.*, the Heath publication was cited as teaching the standard of subjecting the shank to torque at 45 degrees of flexion. Heath does not make up for the deficiencies in Patel detailed above.

Summarizing, Patel and Matsutani and Heath do not teach a method that heat treats an entire shank comprising a superelastic nickel titanium alloy to produce a dental instrument that has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 as recited in amended independent claims 1 and 15. It is well settled that in order to establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Accordingly, it is submitted that independent claim 1 (and claims 2-3, 6-9, 11-14 and 19 that depend thereon) and independent claim 15 (and claims 16-18 and 20 that depend thereon) are patentable over Patel and Matsutani and Heath.

# Conclusion

Claims 1-3, 6-9, and 11-20 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.

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

Respectfully submitted, Neill H. Luebke

Dated: September 24, 2013 By: \_\_\_/Richard T. Roche/\_

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

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### **Abstract**

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

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

## 1. INTRODUCTION

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

In general, nitinol shape memory alloys exhibit three phases, the high-temperature B2 austenite phase (structure of CsCl), low-temperature B19′ martensite phase (monoclinic structure) and intermediate-temperature R-phase (rhombohedral structure) [1-3]. Transformations of these phases are of a great importance, because they determine the superelastic and shape memory characteristics of nitinol, as well as its mechanical and functional properties and performance. These transformations can proceed by various ways, B2→B19′, B2→R, R→B19′, depending on thermal and mechanical history of alloys. The direct transformation of austenite B2 to martensite B19′upon cooling generally occurs when an alloy is in a solution annealed state, i.e. annealed at a high temperature and water quenched. Upon subsequent ageing, the solid solution decomposes to form Ti₃Ni₄ precipitates. All stages of precipitation strongly influence both phase transformations and mechanical characteristics of a material, mainly yield strength and tensile strength.



Strength may be increased by an elastic lattice stress introduced by coherent and semi-coherent Ti<sub>3</sub>Ni<sub>4</sub> precipitates.

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

Corrosion resistance of nitinol is mainly influenced by its surface chemistry and state. When even a weak oxidizing environment, such as water, air or humidity, is in contact with nitinol, a few nm thick native passive layer dominated by titanium dioxide forms on the nitinol surface. However, there may be defects in this passive layer acting as sites for pitting and accelerated corrosion. Therefore, any treatment leading to an improvement of the passive layer quality would reduce corrosion rate of nitinol. In addition, any heat-treatment induces surface oxidation which modifies the surface oxide layer and its protective effect. Taking into account thermodynamics of the Ni-Ti-O system, it is beneficial that titanium oxidizes preferentially in wide intervals of oxygen partial pressure and temperature. Therefore, thermodynamics says that, when oxidizing a nitinol, a protective TiO<sub>2</sub>-enriched and Ni-depleted oxide layer forms on the surface. Simultaneously, inward diffusion of nickel results in a Ni-enriched and Ti-depleted region beneath the external oxide [5, 6].

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

### 2. EXPERIMENT

A nitinol wire having a thickness of  $0.3 \, \text{mm}$  and a chemical composition of  $50.9 \, \%$  Ni was used in our experiment (hereafter, all concentrations are in at. % unless otherwise stated). The wire was produced by the standard procedure, including vacuum induction-melting, hot forging and repeated cold drawing with intermediate annealing. Final cold drawing reduced the wire diameter by 40 %, and this step was followed by the straight annealing of the wire. Surface finishing of the wire included chemical etching in an intensively stirred acid bath containing HF, HNO<sub>3</sub> and H<sub>2</sub>O (1:4:5 by volume) at room temperature for 4 min, followed by ultrasonic washing in distilled water for 5 min. Hereafter, the wire prepared by the procedure above will be referred to as "as-prepared" for simplicity.

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

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

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



Low-cycle fatigue behavior was studied in the bend-type loading mode. The wire was fixed to two arms of a cyclic bend-type loading machine. One arm was kept in a stable position, while the other periodically moved with simultaneous recording of the number of cycles. This cyclic motion enabled the wire to be periodically bent up to the fracture with a constant bending angle of 50°. The fatigue test was stopped automatically when wire fracture occurred. The cyclic loading frequency was 3 Hz, and the testing temperature was 23°C. Fatigue tests were performed ten times for each heat treatment regime.

Corrosion behavior was examined by immersion tests. The wires were immersed in a simulated physiological solution (9 g/l NaCl, pH=2 adjusted by the addition of HCl) for 168 hours at 23°C. Afterwards, the nickel and titanium released into the solution were determined by an inductively coupled plasma – mass spectrometer (ICP-MS).

### 3. RESULTS AND DISCUSSION

## 3.1 Structure and surface

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

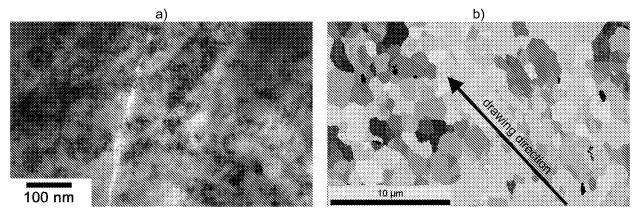


Fig. 1: Structures of the wire: a) as-prepared (TEM), b) heat-treated at 600°C/10 min (EBSD)

One can see that the structure of the as-prepared wire possesses typical features of the cold-worked and annealed state. Cold working induces the formation of a large concentration of lattice defects, mainly dislocations. Dislocations accumulate in clusters, which appear as dark areas in Fig. 1a. Dislocation clusters are mainly associated with the deformation texture, i.e., they mainly appear within B2 grains elongated in the drawing direction. These deformed grains are of about 50-100 nm in size. Regarding the mechanical properties, the large concentration of lattice defects and the extremely fine grains are strengthening factors contributing to the tensile strength of the as-prepared wire, as will be shown later.

It is expected that the heat treatments at  $450\text{-}600^\circ\text{C}$  will accelerate the recrystallization and grain growth. At  $450\text{-}500^\circ\text{C}/10$  min, however, the structural changes are relatively small, the structures are similar to those in Fig. 1a, and, as a result, the strength also remains similar to that of the as-prepared wire (heat-treatment at  $450^\circ\text{C}$ ) or slightly lower (heat-treatment at  $500^\circ\text{C}$ ) (see below). After heat treatment at  $600^\circ\text{C}/10$  min, the wire structure is significantly modified, as illustrated in Fig. 1b. This figure shows an EBSD map of the wire heat-treated at this temperature. One can observe that the deformation texture vanishes and that all grains have nearly equi-axed shapes. The grain size ranges between 500 nm and 5  $\mu$ m. It will be illustrated later that the structural changes induced by this short-time heat-treatment strongly influence the tensile mechanical properties of the wire.

Both fatigue and the corrosion behavior are influenced by the surface structure and chemistry of a wire. SEM images of the surface of as-prepared wire and the wire heat-treated at 600°C/10 min are shown in Fig. 2.



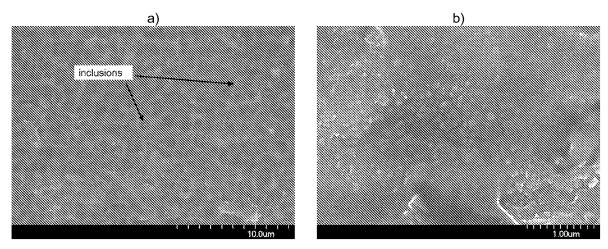


Fig. 2: Surface of the as-prepared wire (a) and the wire heat-treated at 600°C/10 min (b).

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

## 3.2 Mechanical and fatigue properties

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



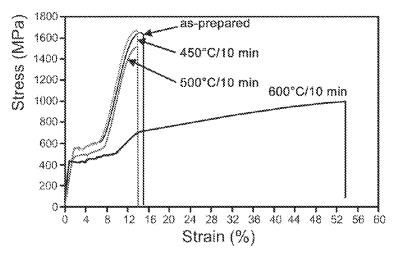
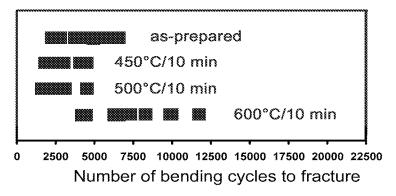


Fig. 3: Stress-strain curves of the wires treated by various regimes.

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



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



#### 3.3 Corrosion resistance

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

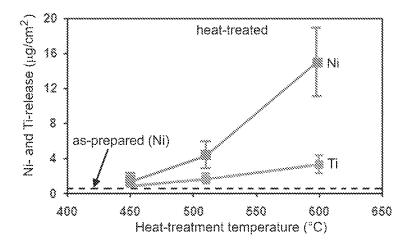


Fig.5: Ti and Ni release into the corrosive medium as a function of heat treatment temperature.

One can see that there is a clear relationship between the Ti and Ni amounts released into the corrosion media and the heat treatment temperature; the higher the temperature, the higher the element release. The best corrosion resistance is observed for the as-prepared wire whose surface was finished by chemical etching. From the biocompatibility point of view, nickel release is of primary importance. The difference in the total Ni release between the as-prepared wire and that treated at 600°C is more than 14 µg/cm2. It was shown before (Fig. 2) that the increase of heat treatment temperature results in the growth of thickness of Nidepleted surface titania. Therefore, one could postulate that the heat treatment at 600°C provides a good barrier against element release. However, the immersion tests presented in Fig. 5 reveal the totally opposite trend. This trend can be explained in terms of the internal defectiveness of the surface oxide layer. Figure 2b shows that there are many micro-cracks in the surface oxide formed by oxidation at 600°C. The origin of such defects was already explained before, and it is well known that their formation is supported by two factors, namely a large oxide thickness and an increase of the oxide grain size. Both these factors enhance the internal stress induced in the oxide, for example, that due to temperature variations. Once a micro-crack is created, it serves as a good path for nickel transport from the metallic substrate towards the corrosion medium. In contrast, the as-prepared wire is coated with a very thin and almost defect-free oxide (Fig. 2a) and, therefore, it exhibits the highest corrosion resistance (Fig. 5).

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

#### 4. CONCLUSIONS

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



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

#### **ACKNOWLEDGEMENTS**

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Electronic Patent /	App	olication Fee	Transmit	tal	
Application Number:	13	455841			
Filing Date:	25	-Apr-2012			
Title of Invention:	De	ntal and Medical In	struments Comp	orising Titanium	
First Named Inventor/Applicant Name:	Ne	ill Hamilton Luebke			
Filer:	Ric	hard T. Roche			
Attorney Docket Number:	11:	5207.00009			
Filed as Small Entity					
Utility under 35 USC 111(a) Filing Fees					
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:					
Pages:					
Claims:					
Miscellaneous-Filing:					
Petition:					
Patent-Appeals-and-Interference:					
Post-Allowance-and-Post-Issuance:					
Extension-of-Time:					

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

Electronic Acknowledgement Receipt							
EFS ID:	16933945						
Application Number:	13455841						
International Application Number:							
Confirmation Number:	5421						
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:	115207.00009						
Receipt Date:	24-SEP-2013						
Filing Date:	25-APR-2012						
Time Stamp:	10:15:37						
Application Type:	Utility under 35 USC 111(a)						

# **Payment information:**

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$600
RAM confirmation Number	10126
Deposit Account	170055
Authorized User	

## File Listing:

i lie Listili	9.				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

		1323511			
1	Request for Continued Examination	RCE.PDF	1323511	no	2
	(RCE)		6bff1cbd9ba83cf66ba2e8b65991ec6d6ae8 e2ae		End  1  4  17
Warnings:					
Information:					
2		response-9-24-13.pdf	11553756	yes	17
_			77b13cf3015e6a67b20cf22e49e0911aa373 9e31	,	
	Multip	part Description/PDF files in .	zip description		
	Document De	scription	Start	E	nd
	Response After F	inal Action	1		1
	Claims		2		4
	Applicant Arguments/Remarks	Made in an Amendment	5		17
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30236	no	2
_	,		29a3004ae1e0aa0c108c267a7a736c7301f8 7614		
Warnings:					
Information:					
		Total Files Size (in bytes)	129	907503	

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.

Index the Panerwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMR control number

PA	ATENT APPL				RECORD			Filing Date 04/25/2012	To be Mailed
							ENTITY: L	ARGE 🛛 SMA	LL MICRO
				APPLICA	ATION AS FIL	ED – PAF	RTI		
			(Column <sup>-</sup>	1)	(Column 2)				
	FOR	ı	NUMBER FIL	_ED	NUMBER EXTRA		RATE (\$)	F	FEE (\$)
	BASIC FEE (37 CFR 1.16(a), (b), (	or (c))	N/A		N/A		N/A		
	SEARCH FEE (37 CFR 1.16(k), (i), o	or (m))	N/A		N/A		N/A		
			N/A		N/A		N/A		
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IND	EPENDENT CLAIM	S	m	inus 3 = *			X \$ =		
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Substitute for Form PTO-875    13/455,841									
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				(Column 2)			ART II	_	
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AM	Application Si	ze Fee (37 CFR	1.16(s))						
	FIRST PRESEN	ITATION OF MULT	IPLE DEPEN	DENT CLAIM (37 CFF	R 1.16(j))				
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		(Column 1)		(Column 2)	(Column 3	)			
L		REMAINING AFTER		NUMBER PREVIOUSLY	PRESENT EX	TRA	RATE (\$)	ADDITIO	ONAL FEE (\$)
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JEN	Application Si	ze Fee (37 CFR	1.16(s))						<u> </u>
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PATENT APPLICATION FEE DETERMINATION RECORD   Application to Code Number   Slubstitute for Form PTO-875   To be Mail   Slubstitute for Form PTO-875   Small PTO-875   To be Mail   Slubstitute for Form PTO-875   To be Mail   Slubstitute for Form PTO-875   Small PTO									
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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 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.	
26710 7590 10/24/2013 QUARLES & BRADY LLP Attn: IP Docket		Neill Hamilton Luebke	115207.00009	5421	
		3	EXAM	INER	
Attn: IP Docket	İ	NELSON, MATTHEW M			
SUITE 2350	NSIN AVENUE		ART UNIT	PAPER NUMBER	
MILWAUKEE,	, WI 53202-4426		3776		
			NOTIFICATION DATE	DELIVERY MODE	
			10/24/2013	ELECTRONIC	

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

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

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

pat-dept@quarles.com

	13/455,841	LUEBKE, NE	ILL HAMILTON
Office Action Summary	Examiner MATTHEW NELSON	Art Unit 3776	AIA (First Inventor to File) Status No
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondend	e address
Period for Reply		•	
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period was realized to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	J. ely filed the mailing date of O (35 U.S.C. § 133	this communication.
Status			
1) Responsive to communication(s) filed on <u>9/24/2</u> A declaration(s)/affidavit(s) under <b>37 CFR 1.1</b>	<b>30(b)</b> was/were filed on		
<i>i</i>	action is non-final.		
3) An election was made by the applicant in response	•		g the interview on
<ul> <li>the restriction requirement and election</li> <li>Since this application is in condition for allowan closed in accordance with the practice under E</li> </ul>	ce except for formal matters, pro	secution as to	o the merits is
Disposition of Claims			
5) Claim(s) 1-3,6-9 and 11-20 is/are pending in the 5a) Of the above claim(s) is/are withdraw 6) Claim(s) is/are allowed.  7) Claim(s) 1-3,6-9 and 11-20 is/are rejected.  8) Claim(s) is/are objected to.  9) Claim(s) are subject to restriction and/or * If any claims have been determined allowable, you may be eliparticipating intellectual property office for the corresponding aphttp://www.uspto.gov/patents/init_events/pph/index.jsp or send  Application Papers  10) The specification is objected to by the Examiner 11) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the consequence of the correction of o	on from consideration.  The election requirement.  The gible to benefit from the Patent Prosecution. For more information, pleas an inquiry to PPHfeedback@uspto.com  The epted or b   □ objected to by the Edrawing(s) be held in abeyance. See	se see ov. Examiner. 37 CFR 1.85(	a).
Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign Certified copies:  a) All b) Some * c) None of the:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Applicat rity documents have been receive (PCT Rule 17.2(a)).	ion No	
Attachment(s)		, ·	
1) Notice of References Cited (PTO-892)	3) Interview Summary		
2) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da		

Application No.

Applicant(s)

Paper No(s)/Mail Date \_

4) Other: \_\_

Art Unit: 3776

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

#### **DETAILED ACTION**

Amendment filed on 9/24/2013 is acknowledged.

## Double Patenting

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

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

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activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

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

- Claims 1-3, 6-9, 11-20 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2, 4-16 of U.S. Patent No. 8,083,873. Although the claims at issue are not identical, they are not patentably distinct from each other because the difference between claims of the application and claims of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of the patent is in effect a "species" of the "generic" invention of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the claims are anticipated by the claims of the patent, it is not patentably distinct.
- Claims 1-3, 6-9, 11-20 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, 8-10, 12-14, 16 of U.S. Patent No. 8,562,341 (issued US App #13/336,579). Although the claims at issue are not identical, they are not patentably distinct from each other because the difference between claims

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of the application and claims of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of the patent is in effect a "species" of the "generic" invention of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the claims are anticipated by the claims of the patent, it is

not patentably distinct.

Response to Arguments

Applicant's arguments filed have been fully considered and are persuasive that
the prior art does not show heat treatment of entire instruments nor more importantly
perform these heat treatments on superelastic dental instruments and devices; however

the above Double Patenting rejections remain.

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.

273-8300.

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-

Art Unit: 3776

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

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robyn Doan/

Primary Examiner, Art Unit 3776

/MMN/

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	13455841	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

✓	Rejected	-	Cancelled		N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted		I	Interference	0	Objected
	Claims renumbered in the	same o	rder as presented by ap	plica	ant	□ СРА	] T.C	D R.1.47

Claims	renumbered	in the same	order as pr	esented by ap	plicant		☐ CPA	☐ T.E	D. 🗆	R.1.47
CL	AIM		DATE							
Final	Original	01/10/2013	06/04/2013	10/17/2013						
	1	<b>√</b>	✓	✓						
	2	<b>√</b>	✓	✓						
	3	<b>√</b>	✓	✓						
	4	✓	-	-						
	5	✓	-	-						
	6	✓	✓	✓						
	7	✓	✓	✓						
	8	✓	✓	✓						
	9	✓	✓	✓						
	10	✓	-	-						
	11	✓	✓	✓						
	12	✓	✓	✓						
	13	✓	✓	✓						
	14	✓	✓	✓						
	15	✓	✓	✓						
	16	✓	✓	✓						
	17	✓	✓	✓						
	18	✓	✓	✓						
	19			✓						
	20			<b>√</b>						

U.S. Patent and Trademark Office Part of Paper No.: 20131015

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## **EAST Search History**

## **EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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L2	0	"8562341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
L3	2	"13336579"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
L4	3097	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/10/17 09:51
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;	OR	ON	2008/04/29 10:54

			DERWENT			
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;	OR	ON	2009/02/23 14:48 015-00632 - Ex. 10

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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
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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	\$26 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;	OR	ON	2009/12/31 12:33 015-00632 - Ex. 10

		1	DERWENT			***************************************
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		OR	ON	2010/10/07 11:33
S40	1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2010/10/19 15:02

		1	DERWENT		***************************************	
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-5137815-\$ 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. 200 of 2	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2011/05/12 09:32

		JPO; DERWENT			
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
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
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
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
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
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
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
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
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
126	((Ni ADJ Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) SAME (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non 201 of 2	FPRS; EPO;	OR	ON	2011/05/12 09:52
	10068 1335 6 2 2 2 16 1346	NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) AND (gas atmosphere)  10068 ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME (gas atmosphere)  1335 ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))  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))  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))  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))  16 (endodontic "433".clas.) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 gas))  16 (endodontic "433".clas.) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 gas))  16 (endodontic "433".clas.) AND ((anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive NEAR1 gas))  17 (endodontic "433".clas.) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))  18 ((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)  18 ((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)	SS1 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) AND (gas atmosphere)	B	St AND ((Ni NEAR1 TI) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) AND (gas atmosphere)

Titanium) OR Nitinol) SAME (anneals3 OR heat NEAP5 treated OR NEAPH oxidizing)) NEAPt gas) SAME (DERWENT   Coxidizs4   Coxidizs5   Coxidizs5   Coxidizs6   Coxidix6		NEAR1 oxidizing)) NEAR1 gas)	JPO; DERWENT				
heat) SAME ((unreactive inert (non NeART; coxidizing)) NEAR1 gas) SAME	S65	10	Titanium) OR Nitinol) SAME (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME	USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2011/05/12 09:56
NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME   USPAT; USOOR; PFRS, EPO; JPO; DEFWENT   USPAT; USPAT	S66	8234	heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME	USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2011/05/12 10:00
NEARS treated OR heat) SAME	S67	8	NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME	USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2011/05/12 10:00
OR heat NEAR5 tréated OR heat)   SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME   SAME ((unreactive inert (non NEAR1 properties))   SAME ((unreactive inert (non NEAR1 properties))   SAME (unreactive inert (non NEAR1 properties))   SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME   SAME (Unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME   SAME (Unreactive inert (non NEAR1 properties))   SA	S68	2	NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME	USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2011/05/12 10:01
OR heat NEAR5 treated OR heat   SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME   USOCR;   PPRS; EPO;   DERWENT   USOCR;   PPRS; EPO;   PO;   DERWENT   USPAT;   USOCR;   PPRS; EPO;	S69	130	OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME	USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2011/05/12 10:02
USPAT; USOCR;   FPRS; EPO; UPO; DERWENT	S70	37	OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME	USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2011/05/12 10:02
USPAT;   USOCR;   FPRS; EPO;   JPO;   DERWENT   USPAT;   USOCR;   S73   54   29/896.11   US-PGPUB;   USPAT;   USOCR;   FPRS; EPO;   JPO;   DERWENT   USPAT;   USOCR;   FPRS; EPO;   JPO;   DERWENT   USPAT;   USOCR;   USOCR;   USPAT;   USOCR;   USOCR;   USPAT;   USOCR;   US	S71	2	"6783438".pn.	USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2011/05/12 10:33
USPAT;   USOCR;   FPRS; EPO;   JPO;   DERWENT   USPAT;   USPAT;   USOCR;   S74   985   433/102,224.ccls.   US-PGPUB;   USPAT;   USOCR;	S72	99	29/896.1	USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2011/05/23 14:27
USPAT; 14:27 USOCR;	S73	54	29/896.11	USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2011/05/23 14:27
	S74	985	433/102,224.ccls.	USPAT; USOCR;	OR	ON	2011/05/23 14:27

			JPO; DERWENT			
S75	41	(S72 S73 S74) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:28
S76	1411	148/402,421,426.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:17
S77	822	S76 AND titanium	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:18
S78	621	S76 AND titanium AND heat	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:18
S79	254	S76 AND titanium AND heat AND atmosphere	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:18
S80	159	S76 AND titanium AND heat AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S81	126	S76 AND titanium AND (heat WITH treat\$4) AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S82	121	S76 AND titanium AND (heat ADJ treat\$4) AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S83	3	S76 AND titanium AND (heat ADJ treat\$4) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:20
S84	3	148/402.ccls. AND (heat ADJ treat\$4) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2011/09/07 13:24
		203 of 2	:56		IPR2	015-00632 - Ex. 10

ė.			JPO; DERWENT			
S85	191	148/402.ccls. AND (heat ADJ treat\$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
S86	0	148/402.ccls. AND (heat ADJ treat\$4) SAME shank	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
\$87	19	148/402.ccls. AND (heat ADJ treat\$4) SAME (atmosphere argon helium neon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:25
S89	336	148/669.ccls. <b>AN</b> D titanium	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 15:03
S90	48	148/669.ccls. AND titanium AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 15:04
S92	20245	((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:36
S93	11539	((shape ADJ memory) superelastic) AND (medical dental) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:36
S94	7768	((shape ADJ memory) superelastic) AND (medical dental) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium)) AND temperature	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:37
S95	5395	((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/23 10:37
S96	282	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2012/08/28 13:06

		OR heat NEAR5 treated)	JPO; DERWENT		***************************************	
S97	184	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:07
S98	71	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated) AND (inert gas) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:25
S99	18	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated) SAME (inert gas) AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:26
S100	13	"148".clas. AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated) SAME (inert gas) SAME temperature AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:32
S101	51	(medical dental) AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated) SAME (inert gas) SAME temperature AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:33
S102	3	"12977625"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:40
S103	2	"5380200".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/05 08:39
S104	2819	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/12/05 09:41
S105	2834	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/01/10 09:57
S106	2	"8048345".pn.	US-PGPUB;	OR	ON	2013/01/10

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			11:03
S107	2876	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	:2	2013/06/04 10:10

#### **EAST Search History (Interference)**

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

#### 10/17/2013 9:52:05 AM

 $\textbf{C:} \ \textbf{Users} \ \textbf{mnelson3} \ \textbf{Documents} \ \textbf{EAST} \ \textbf{Workspaces} \ \textbf{13455841} \ \ \textbf{Dental and medical instruments comprising titanium.wsp}$ 

## Search Notes



Application/Control No.	Applicant(s)/Patent Under Reexamination
13455841	LUEBKE, NEILL HAMILTON
Examiner	Art Unit
MATTHEW NELSON	3776

CPC- SEARCHED				
Symbol	Date	Examiner		
		·		

CPC COMBINATION SETS - SEARCHED					
Symbol Date Examiner					

US CLASSIFICATION SEARCHED					
Class	Subclass	Date	Examiner		
29	896.1,896.11	1/10/2013	MN		
148	402, 421, 426	1/10/2013	MN		
433	102, 224	1/10/2013	MN		
29, 148, 433	Updated	6/4/2013	MN		
29, 148, 433	Updated	10/17/2013	MN		

SEARCH NOTES						
Search Notes	Date	Examiner				
See EAST search history	1/10/2013	MN				
Updated EAST search	6/4/2013	MN				
Updated EAST search	10/17/2013	MN				

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

-

Docket No.: 115207.00009

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

Date: January 23 ,2014 /Richard T. Roche/

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

#### IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke

Application No.: 13/455,841

Filing Date: December 23, 2011

Title: Dental And Medical Instruments Comprising Titanium

Confirmation No.: 5421

Art Unit: 3776

Examiner: Matthew M. Nelson

## <u>AMENDMENT</u>

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 24, 2013.

Please amend the above-identified patent application as follows:

A Listing of the Claims begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

## Amendments To The Claims

- 1. (Previously Presented) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:
- (a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic nickel titanium alloy, and
- (b) after step (a), heat-treating the entire shank at a temperature from 400°C up to but not equal to the melting point of the superelastic nickel titanium alloy,

wherein the heat treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1.

- 2. (Original) The method of claim 1 wherein: the temperature is from 475°C to 525°C.
- 3. (Original) The method of claim 1 wherein: the shank is heat-treated for 1 to 2 hours.
- 4. (Cancelled)
- 5. (Cancelled)
- 6. (Original) The method of claim 1 wherein: step (b) is performed in any atmosphere.
- 7. (Previously Presented) The method of claim 6 wherein: the atmosphere is unreactive, ambient or any other acceptable heat treatment process.

8. (Previously Presented) The method of claim 6 wherein:

the atmosphere is unreactive, ambient or any other acceptable heat treatment process,

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

9. (Previously Presented) The method of claim 6 wherein:

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

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

- 10. (Cancelled)
- 11. (Original) The method of claim 1 wherein: the instrument shank has a diameter of 0.5 to 1.6 millimeters.
- 12. (Original) The method of claim 1 wherein: the instrument shank is heat-treated in step (b) at a single temperature.
- 13. (Original) The method of claim 12 wherein: the single temperature is from 400°C to 525°C.
- 14. (Original) The method of claim 13 wherein: the single temperature is from 475°C to 525°C.

- 15. (Previously Presented) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:
- (a) providing an elongate shank having 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, the shank consisting essentially of a superelastic nickel titanium alloy; and
- (b) after step (a), heat-treating the entire instrument shank at a temperature from 475°C to 525°C,

wherein the heat-treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion tested in accordance with ISO Standard 3630-1.

- 16. (Original) The method of claim 15 wherein: the shank is heat-treated for 1 to 2 hours.
- 17. (Original) The method of claim 15 wherein: the instrument shank is heat-treated in step (b) at a single temperature.
- 18. (Previously Presented) The method of claim 15 wherein: step (b) is performed in an atmosphere that is unreactive, ambient or any other acceptable heat treatment process.
- 19. (Previously Presented) The method of claim 1 wherein: the superelastic nickel titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.
- 20. (Previously Presented) The method of claim 15 wherein: the superelastic nickel titanium alloy comprises 54-57 weight percent nickel and 43-46 weight percent titanium.

## **REMARKS**

## **Double Patenting Rejections**

Claims 1-3, 6-9, 11-20 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2, 4-16 of U.S. Patent No. 8,083,873.

Claims 1-3, 6-9, 11-20 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, 8-10, 12-14, 16 of U.S. Patent No. 8,562,341.

Terminal disclaimers for U.S. Patent Nos. 8,083,873 and 8,562,341 have been submitted in order to overcome the double patenting rejections.

#### Conclusion

Claims 1-3, 6-9, and 11-20 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.

Terminal disclaimer fees have been submitted. If any additional fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted, Neill H. Luebke

<u>Dated: January 23, 2014</u> By: <u>/Richard T. Roche/</u>

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

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STATEMEN	T UNDER 37 CFR 3.73(b)			
Applicant/Patent Owner: Neill H. Luebke				
Application No./Patent No.: 13/455,841	Filed/Issue Date: April 25, 2013			
Tifled: Dental and Medical Instruments Comprising	Titanium			
Gold Standard Instruments, LLC , a	Corporation			
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.				
states that it is:				
1. X the assignee of the entire right, title, and interest	in;			
an assignee of less than the entire right, title, and (The extent (by percentage) of its ownership interests)				
the assignee of an undivided interest in the entire	ety of (a complete assignment from one of the joint inventors was made)			
the patent application/patent identified above, by virtue of eit	ther:			
An assignment from the inventor(s) of the patent the United States Patent and Trademark Office a copy therefore is attached.  OR	application/patent identified above. The assignment was recorded in at Reel 031478 , Frame 0155 , or for which a			
B. A chain of title from the inventor(s), of the patent	application/patent identified above, to the current assignee as follows:			
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	ited States Patent and Trademark Office at  e, or for which a copy thereof is attached.			
2. From:	То:			
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Reel, Fram	e, or for which a copy thereof is attached.			
Additional documents in the chain of title are list	ed on a supplemental sheet(s).			
As required by 37 CFR 3.73(b)(1)(i), the documentar or concurrently is being, submitted for recordation pur	y evidence of the chain of title from the original owner to the assignee was, suant to 37 CFR 3.11.			
	inal assignment document(s)) must be submitted to Assignment Division in nent in the records of the USPTO. <u>See</u> MPEP 302.08]			
The undersigned (whose title is supplied below) is afuthorized the formation of the supplied below) is afuthorized to the supplied below in th				
V Stignature	Date			
Neili H. Luebke Printed or Typed Name	President  Title			

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Docket Number (Optional) TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING **REJECTION OVER A "PRIOR" PATENT** 115207.00009 In re Application of: Neill H, Luebke Application No.: 13/455.841 Filed: April 25, 2012 For Dental and Medical Instruments Comprising Titanium The owner\*, <u>Gold Standard Instruments LLC</u>, of <u>100</u> percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond percent interest in the instant application hereby disclaims. the expiration date of the full statutory term of prior patent No. 8083873 as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. in making the above disclaimer, the owner does not disctaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: expires for failure to pay a maintenance fee; is held unenforceable; is found invalid by a court of competent jurisdiction; is statutority disclaimed in whole or terminally disclaimed under 37 CFR 1.321; has all claims canceled by a reexamination certificate; is reissued: or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. Check either box 1 or 2 below, if appropriate. For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. The undersigned is an attorney or agent of record. Reg. Neill H. Luebke Typed or printed name 414-277-5805 Telephone Number Terminal disclaimer fee under 37 CFR 1.20(d) included. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. \*Statement\_under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).

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Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

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Electronic Patent Application Fee Transmittal					
Application Number:	13	455841			
Filing Date:	25-Apr-2012				
Title of Invention:	De	ntal and Medical In	struments Comp	rising Titanium	
First Named Inventor/Applicant Name:	Ne	Neill Hamilton Luebke			
Filer:	Ric	hard T. Roche			
Attorney Docket Number:	115207.00009				
Filed as Small Entity					
Utility under 35 USC 111(a) Filing Fees					
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:					
Pages:					
Claims:					
Miscellaneous-Filing:					
Petition:					
Patent-Appeals-and-Interference:					
Post-Allowance-and-Post-Issuance:	_				
Extension-of-Time:					

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Statutory or Terminal Disclaimer	1814	2	160	320
Total in USD (\$) 320				

Electronic Acknowledgement Receipt				
EFS ID:	18004236			
Application Number:	13455841			
International Application Number:				
Confirmation Number:	5421			
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:	115207.00009			
Receipt Date:	23-JAN-2014			
Filing Date:	25-APR-2012			
Time Stamp:	14:48:41			
Application Type:	Utility under 35 USC 111(a)			

## **Payment information:**

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$320
RAM confirmation Number	1080
Deposit Account	170055
Authorized User	

## File Listing:

File Listing	y.				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest		
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	Amendment/Req. Reconsiderat	ion-After Non-Final Reject	1		1
	Claims	;	2		4
	Applicant Arguments/Remarks	5	;	5	
	Assignee showing of owne	6		5	
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

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

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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 115207.00009
In re Application of: Neilt H. Luebke	
Application No.: 13/455,841	
Filed: April 25, 2012	
For: Dental and Medical Instruments Comprising Titanium	
except as provided below, the terminal part of the statutory term of any patent granted on the instant	said prior patent is presently shortened ation shall be enforceable only for and
In making the above disclaimer, the owner does not disclaim the terminal part of the term of any pate would extend to the expiration date of the full statutory term of the prior patent, "as the term of said programmer," in the event that said prior patent later:  expires for failure to pay a maintenance fee; is held unenforceable; is found invalid by a court of competent jurisdiction; is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; has all claims canceled by a reexamination certificate; is reissued; or is in any manner terminated prior to the expiration of its full statutory term as presently short	rior patent is presently shortened by any
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1. For submissions on behalf of a business/organization (e.g., corporation, partnership, universit etc.), the undersigned is empowered to act on behalf of the business/organization.	y, government agency,
I hereby declare that all statements made herein of my own knowledge are true and that all selief are believed to be true; and further that these statements were made with the knowledge that we made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United St statements may jeopardize the validity of the application or any patent issued thereon.	villful false statements and the like so
2. The undersigned is an attorney or agent of record. Reg. No	1(-7-(3 Date
Neill H. Luebke	
Typed or printed name	
	414-277-5805 Telephone Number
Terminal disclaimer fee under 37 CFR 1.20(d) included.	
WARNING: Information on this form may become public. Credit card information be included on this form. Provide credit card information and authorization	
*Statement_under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.	
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In is collection of information is required by 37 CFR 1.321. The information is required to oxigin or retain a benefit by the public which is to trice (and by the USP 10 to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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U.S. Patent AND TRADEMARK OFFICE 
P/	PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application	on or Docket Number 3/455,841	Filing Date 04/25/2012		
							ENTITY: L	ARGE SMALL MICRO	
					ATION AS FIL	ED – PAF	RTI		
			(Column 1	l) 	(Column 2)				
Ļ	FOR	٨	IUMBER FIL	_ED	NUMBER EXTRA		RATE (\$)	FEE (\$)	
Ш	BASIC FEE (37 CFR 1.16(a), (b),	or (c))	N/A		N/A		N/A		
	SEARCH FEE (37 CFR 1.16(k), (i), (	or (m))	N/A		N/A		N/A		
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A		
	OTAL CLAIMS CER 1.16(i)) minus 20 = *				X \$ =				
	NDEPENDENT CLAIMS (37 CFR 1.16(h)) minus 3 = *					X \$ =			
	APPLICATION SIZE FEE (37 CFR 1.16(s))  If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
	MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))								
* If t	* If the difference in column 1 is less than zero, enter "0" in column 2.								
		(Column 1)		(Column 2)	(Column 3		ART II		
LN∃	01/23/2014	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	TRA	RATE (\$)	ADDITIONAL FEE (\$)	
AMENDMENT	Total (37 CFR 1.16(i))	* 17	Minus	** 20	= 0		x \$40 =	0	
Z I	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0		x \$210 =	0	
AM	Application Si	ze Fee (37 CFR	1.16(s))						
	FIRST PRESEN	ITATION OF MULTI	PLE DEPEN	DENT CLAIM (37 CFF	R 1.16(j))				
							TOTAL ADD'L FE	<b>■</b> 0	
		(Column 1)		(Column 2)	(Column 3	)			
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	TRA	RATE (\$)	ADDITIONAL FEE (\$)	
ENT	Total (37 CFR 1.16(i))	*	Minus	**	=		X \$ =		
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Ę.	Application Si	ze Fee (37 CFR	1.16(s))						
AM	FIRST PRESEN	ITATION OF MULTI	PLE DEPEN	DENT CLAIM (37 CFF	R 1.16(j))				
							TOTAL ADD'L FE	<u> </u>	
** If *** I	the entry in column the "Highest Numbe f the "Highest Numb	er Previously Paid per Previously Pai	l For" IN Th d For" IN T	HIS SPACE is less HIS SPACE is less	than 20, enter "20' s than 3, enter "3".		LIE /DONNA PRIC		

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Disclaimer  This patent is subject to a Terminal Disclaimer  Approved/Disapproved by:	Application Number	R		Applicant(s)/Patent under Reexamination LUEBKE, NEILL HAMILTON	
TERMINAL DISCLAIMER					
Disclaimer  This patent is subject to a Terminal Disclaimer  Approved/Disapproved by:	Document Code - DISQ		Internal Do	cument - DO NOT MAIL	
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	Date Filed : 1/23/14	to a Terminal			
IDRE ROBINSON	Approved/Disapproved	d by:			
	ORE ROBINSON				
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UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

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26710 7590 03/03/2014 QUARLES & BRADY LLP

Attn: IP Docket

411 E. WISCONSIN AVENUE

**SUITE 2350** 

MILWAUKEE, WI 53202-4426

EXAMINER

NELSON, MATTHEW M

ART UNIT PAPER NUMBER

3776

DATE MAILED: 03/03/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/455,841	04/25/2012	Neill Hamilton Luebke	115207.00009	5421

TITLE OF INVENTION: Dental and Medical Instruments Comprising Titanium

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	06/03/2014

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.

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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. 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. CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Certificate of Mailing or Transmission 26710 7590 03/03/2014 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. **QUARLES & BRADY LLP** Attn: IP Docket 411 E. WISCONSIN AVENUE (Depositor's name **SUITE 2350** (Signature MILWAUKEE, WI 53202-4426 (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 13/455.841 04/25/2012 Neill Hamilton Luebke 115207.00009 5421 TITLE OF INVENTION: Dental and Medical Instruments Comprising Titanium PUBLICATION FEE DUE PREV. PAID ISSUE FEE APPLN. TYPE ENTITY STATUS ISSUE FEE DUE TOTAL FEE(S) DUE DATE DUE nonprovisional **SMALL** \$480 \$480 06/03/2014 **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). 2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. 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. ☐ "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. 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. (B) RESIDENCE: (CITY and STATE OR COUNTRY) (A) NAME OF ASSIGNEE 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: 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) ☐ Issue Fee A check is enclosed. ☐ Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any Advance Order - # of Copies overpayment, to Deposit Account Number 5. Change in Entity Status (from status indicated above) NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. Applicant certifying micro entity status. See 37 CFR 1.29 Applicant asserting small entity status. See 37 CFR 1.27  $\underline{NOTE}$ : If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status. ☐ Applicant changing to regular undiscounted fee status. NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable. NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications. Authorized Signature \_ Date Typed or printed name \_ Registration No. \_

> 223 of 256 Page 2 of 3

IPR2015-00632 - Ex. 1008 US ENDODONTICS, LLC., Petitioner



### UNITED STATES PATENT AND TRADEMARK OFFICE

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DATE MAILED: 03/03/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/455,841	13/455,841 04/25/2012 Neill Hamilton Luebke		115207.00009	5421
26710 75	90 03/03/2014		EXAM	INER
QUARLES & BF Attn: IP Docket	RADY LLP	NELSON, M	ATTHEW M	
411 E. WISCONSI	N AVENUE		ART UNIT	PAPER NUMBER
SUITE 2350			3776	
MILWAUKEE, W	I 53202-4426			

### **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.

#### OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

#### **Privacy Act Statement**

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.

	Applicat 13/455,8		Applicant(s)	LL HAMILTON
Notice of Allowability	Examine		Art Unit	AIA (First Inventor to
Notice of Anowability	MATTHE	EW NELSON	3776	File) Status No
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS (herewith (or previously mailed), a Notice of Allowance (PTOL-85) of NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIC of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMA or other ap <b>GHTS.</b> Th	AINS) CLOSED in this applopropriate communication visation is subject to	ication. If not i will be mailed ir	ncluded n due course. <b>THIS</b>
1. This communication is responsive to the Terminal Disclaimed  A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was/				
2. An election was made by the applicant in response to a restr requirement and election have been incorporated into this ac		uirement set forth during the	e interview on .	; the restriction
3. The allowed claim(s) is/are 1-3,6-9 and 11-20. As a result of Prosecution Highway program at a participating intellectual please see <a href="http://www.uspto.gov/patents/init_events/pph/indegetates-number-15">http://www.uspto.gov/patents/init_events/pph/indegetates-number-15</a> .	l property o	office for the corresponding	application. F	or more information,
4.  Acknowledgment is made of a claim for foreign priority under	r 35 U.S.C	s. § 119(a)-(d) or (f).		
Certified copies:				
<ul> <li>a) All b) Some *c) None of the:</li> <li>1. Certified copies of the priority documents have</li> <li>2. Certified copies of the priority documents have</li> <li>3. Copies of the certified copies of the priority documents have</li> <li>International Bureau (PCT Rule 17.2(a)).</li> </ul>	been rece	ived in Application No		oplication from the
* Certified copies not received:				
Applicant has THREE MONTHS FROM THE "MAILING DATE" of noted below. Failure to timely comply will result in ABANDONMITHIS THREE-MONTH PERIOD IS NOT EXTENDABLE.			omplying with t	he requirements
5. CORRECTED DRAWINGS ( as "replacement sheets") must	be submit	ted.		
including changes required by the attached Examiner's Paper No./Mail Date	: Amendme	ent / Comment or in the Off	fice action of	
Identifying indicia such as the application number (see 37 CFR 1.8 each sheet. Replacement sheet(s) should be labeled as such in th	84(c)) shou ne header a	ild be written on the drawing ccording to 37 CFR 1.121(d)	gs in the front (r	ot the back) of
<ol> <li>DEPOSIT OF and/or INFORMATION about the deposit of BI attached Examiner's comment regarding REQUIREMENT FO</li> </ol>				е
Attachment(s)				
1. Notice of References Cited (PTO-892)		5. Examiner's Amendm		
<ol> <li>Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date</li> </ol>		6. X Examiner's Statemen	nt of Reasons t	or Allowance
<ul> <li>3.  Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> <li>4.  Interview Summary (PTO-413), Paper No./Mail Date</li> </ul>		7.  Other		
/MATTHEW NELSON/		/TODD MANAHAN/		
Examiner, Art Unit 3776		Supervisory Patent Exa	miner, <b>A</b> rt Un	it 3776

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13)

**Notice of Allowability** 

Part of Paper No./Mail Date 20140208

Application/Control Number: 13/455,841 Page 2

Art Unit: 3776

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

#### **DETAILED ACTION**

#### Allowable Subject Matter

- Claims 1-3, 6-9, 11-20 are allowed.
- The following is an examiner's statement of reasons for allowance: A method of manufacturing or modifying a dental instrument/device where a dental instrument or device is provided having an elongated shank of superelastic nickel titanium alloy and then subsequently heat-treating the entire instrument or device at 400 C or above but not the melting temperature, resulting in a device with shape memory characteristics in that an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1 was neither taught nor suggested by the prior art as a whole, either alone or in combination, and in combination with the elements set forth in the claims. The closest prior art does not tend to heat treat entire instruments, nor does it more importantly perform these heat treatments on superelastic dental instruments or devices. Rather, the prior art is interested in heat-treating in order to arrive at a superelastic instrument. So what the present invention is essentially doing is taking a completed superelastic instrument (the prior art) and then conducting further heat-treatment in order to arrive at a shape memory alloy with the prescribed deformation characteristics. After discussion with class 148 regarding the properties of the alloys and heat-treatment, it was understood that while a titanium alloy will not always result in the above properties, a shape

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Art Unit: 3776

memory nickel-titanium alloy will result from the claimed method distinguished from the

superelastic properties of the prior art.

Any comments considered necessary by applicant must be submitted no later

than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on

Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to MATTHEW NELSON whose telephone number is

(571)270-5898. The examiner can normally be reached on Monday-Friday 7:30am-

5:00pm EDT.

If attempts to reach the examiner by telephone are unsuccessful, *please contact* 

the examiner's supervisor, Todd Manahan, at (571) 272-4713. The fax phone

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

273-8300.

If there are any inquiries that are not being addressed by first contacting

the Examiner or the Supervisor, you may send an email inquiry to

TC3700\_Workgroup\_D\_Inquiries@uspto.gov.

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Application/Control Number: 13/455,841 Page 4

Art Unit: 3776

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 MANAHAN/

Supervisory Patent Examiner, Art Unit 3776

### **EAST Search History**

### **EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3236	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2014/02/08 08:19
S2	6	"6431863".pn. "6422865".pn. "6428634".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 07:56
S5	1068	Ni adj Ti AND anneal\$2 AND time	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S6	544	Ni adj Ti AND anneal\$2 AND time AND hour	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S7	16	Ni adj Ti AND anneal\$2 AND time AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:54
S8	876	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:54
S9	53	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:55
S10	183	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 15:12
S11	29	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND	US-PGPUB; USPAT;	OR	ON	2008/04/29 15:16

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

	***************************************		USOCR; FPRS; EPO; JPO; DERWENT	***************************************		
S25	78	S24 AND (heat WITH treat\$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S26	917	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S27	32	\$26 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S28	917	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S29	192	S28 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S30	1099	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:33
S31	18	S30 AND microstructure	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:34
S32	200	S30 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/12/31 12:35
S33	2	("7175655").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/18 13:12
S34	1112	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT;	OR	ON	2010/03/22 09:45

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

			USOCR; FPRS; EPO; JPO; DERWENT			
S45	226	S44 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S46	1	S45 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S47	11	S45 AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:07
S48	10	(US-20040121283-\$).did. or (US-6431863-\$ or US-6428634-\$ or US-6375458-\$ or US-4490112-\$ or US-5775902-\$ or US-5206695-\$ or US-7137815-\$ or US-5653590-\$).did. or (US-6422865-B-\$).did.	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S49	0	S48 AND gas	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S50	2	S48 AND atmosphere	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S51	982	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:32
S52	8	S51 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) AND (gas atmosphere)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:32
S53	10068	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME (gas atmosphere)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:35
S54	1335	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:36
S55	6	(endodontic) AND ((Ni NEAR1 Ti) OR	US-PGPUB;	OR	ON	2011/05/12

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

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

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

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

		memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated) SAME (inert gas) SAME temperature AND @ad<= "20040608"	USPAT; USOCR; FPRS; EPO; JPO; DERWENT			13:32
S101	51	(medical dental) AND ((shape ADJ memory) superelastic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated) SAME (inert gas) SAME temperature AND @ad<="20040608"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:33
S102	3	"12977625"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/08/28 13:40
S103	2	"5380200".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/05 08:39
S104	2819	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/12/05 09:41
S105	2834	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/01/10 09:57
S106	2	"8048345".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/01/10 11:03
S107	2876	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/06/04 10:10
S108	2	"8083873".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S109	0	"8562341".pn.	US-PGPUB; USPAT; USOCR;	OR	ON IPP201	2013/10/17 09:38 5-00632 - Ex. 10

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S110	2	"13336579"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/17 09:38
S111	3097	148/402,421,426.ccls. 433/102,224.ccls. 29/896.1,896.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/10/17 09:51

#### **EAST Search History (Interference)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	1	(433/102).OCLS.	UPAD	OR	OFF	2014/02/08 08:20
S88	0	(29/896.1,896.11).CCLS.	UP <b>A</b> D	OR	OFF	2011/09/07 14:33
S91	0	(148/669).CCLS.	UPAD	OR	OFF	2011/09/07 15:04

2/8/2014 8:22:33 AM

C:\ Users\ mnelson3\ Documents\ EAST\ EAST Workspaces\ 13455841 Dental and medical instruments comprising titanium.wsp



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### **BIB DATA SHEET**

#### **CONFIRMATION NO. 5421**

<b>SERIAL NUMBER</b> 13/455,841	FILING or 371(c) DATE 04/25/2012		CLASS 433	GROUP AR			ORNEY DOCKET NO. 15207.00009			
	RULE									
APPLICANTS										
<b>INVENTORS</b> Neill Hamilton L	uebke, Brookfield, WI;									
** <b>CONTINUING DATA</b> ***********************************										
** FOREIGN APPLICATIONS ************************************										
Foreign Priority claimed  35 USC 119(a-d) conditions m  Verified and /MATTHE  NELSON  Acknowledged Fyaming	W M	after wance	STATE OR COUNTRY WI	SHEETS DRAWINGS	TOT CLAI	MS	INDEPENDENT CLAIMS 2			
ADDRESS  QUARLES & BI Attn: IP Docket 411 E. WISCON SUITE 2350	QUARLES & BRADY LLP Attn: IP Docket 411 E. WISCONSIN AVENUE SUITE 2350 MILWAUKEE, WI 53202-4426									
TITLE  Dental and Med	lical Instruments Comp	risina Tit	tanium							
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### Search Notes



Application/Control No.	Applicant(s)/Patent Under Reexamination
13455841	LUEBKE, NEILL HAMILTON
Examiner	Art Unit
MATTHEW NELSON	3776

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARC	CHED	
Symbol	Date	Examiner

	US CLASSIFICATION SEARCHED					
Class	Subclass	Date	Examiner			
29	896.1,896.11	1/10/2013	MN			
148	402, 421, 426	1/10/2013	MN			
433	102, 224	1/10/2013	MN			
29, 148, 433	Updated	6/4/2013	MN			
29, 148, 433	Updated	10/17/2013	MN			
29, 148, 433	Updated	2/8/2014	MN			

SEARCH NOTES		
Search Notes	Date	Examiner
See EAST search history	1/10/2013	MN
Updated EAST search	6/4/2013	MN
Updated EAST search	10/17/2013	MN
Updated EAST search	2/8/2014	MN

	INTERFERENCE SEARCH				
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner		
433	102	2/8/2014	MN		

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	13455841	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

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Application/Control No.	Applicant(s)/Patent Under Reexamination
13455841	IIIERKE NEUI HAMUTON

Examiner Art Unit

MATTHEW NELSON 3776

CPC	PC						
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CPC Combination Sets								
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/MATTHEW NELSON/ Examiner.Art Unit 3776	2/8/2014	Total Clain	ns Allowed:
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/TODD MANAHAN/ Supervisory Patent Examiner.Art Unit 3776	02/21/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A



Application/Control No.	Applicant(s)/Patent Under Reexamination
13455841	LUEBKE, NEILL HAMILTON
Examiner	Art Unit
MATTHEW NELSON	3776

	US ORIGINAL CLASSIFICATION									INTERNATIONAL	CLA	SS	IFIC	ATI	ON
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CROSS REFERENCE(S)															
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/MATTHEW NELSON/ Examiner.Art Unit 3776	2/8/2014	Total Clain	ns Allowed:
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/TODD MANAHAN/ Supervisory Patent Examiner.Art Unit 3776	02/21/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A



Application/Control No.	Applicant(s)/Patent Under Reexamination
13455841	LUEBKE, NEILL HAMILTON
Examiner	Art Unit
MATTHEW NELSON	3776

☐ Claims renumbered in the same order as presented by applicant							СР	A [	] T.D.		R.1.4	47			
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/TODD MANAHAN/ Supervisory Patent Examiner.Art Unit 3776	02/21/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A

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				Ap	ril 4, 2014			(Date)
APPLICATION NO.	FILING DATE		FIRST NA	MED INVENTOR		ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
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FITLE OF INVENTION	: DENTAL AND N	MEDICAL INST	RUMENTS	COMPRISI	NG TITANILIN	Л		
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Non-Prov.	Small	\$480	\$0		\$0		\$480.00	06/03/2014
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Matthew M. Nelso	on	3776	433-1	02000	J			
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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.

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Electronic Patent Application Fee Transmittal								
Application Number:	13455841							
Filing Date:	25-Apr-2012							
Title of Invention:	Dental and Medical Instruments Comprising Titanium							
First Named Inventor/Applicant Name: Neill Hamilton Luebke								
Filer:	Richard T. Roche/Sandra Szablewski							
Attorney Docket Number:	rney Docket Number: 115207.00009							
Filed as Small Entity								
Utility under 35 USC 111(a) Filing Fees								
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)			
Basic Filing:								
Pages:								
Claims:								
Miscellaneous-Filing:								
Petition:								
Patent-Appeals-and-Interference:								
Post-Allowance-and-Post-Issuance:								
Utility Appl Issue Fee	_	2501	1	480	480			
Extension-of-Time:								

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
	Tot	al in USD	(\$)	480

Electronic Ac	knowledgement Receipt
EFS ID:	18679466
Application Number:	13455841
International Application Number:	
Confirmation Number:	5421
Title of Invention:	Dental and Medical Instruments Comprising Titanium
First Named Inventor/Applicant Name:	Neill Hamilton Luebke
Customer Number:	26710
Filer:	Richard T. Roche/Sandra Szablewski
Filer Authorized By:	Richard T. Roche
Attorney Docket Number:	115207.00009
Receipt Date:	04-APR-2014
Filing Date:	25-APR-2012
Time Stamp:	16:14:24
Application Type:	Utility under 35 USC 111(a)

## **Payment information:**

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$480
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#### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	luebke_issue_fee_transmittal_	178955	no	1
.	issue ree rayment (r 10 03b)	Part_B.PDF	c83b44396d1f1de3fd7c3bcfb0f1e91e136c 5703		•
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30226	no	2
-			4c9a961d2623c3903c57d387e51a9d4aded 72ce0		
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		Total Files Size (in bytes)	20	9181	

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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.

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App	licatio	n/Co	ntrol	No
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13455841

LUEBKE, NEILL HAMILTON

Applicant(s)/Patent Under Reexamination

Examiner

MATTHEW NELSON

Art Unit

3776

CPC		
Symbol	Туре	Version

CPC Combination Sets									
Symbol	Туре	Set	Ranking	Version					

/MATTHEW NELSON/ Examiner.Art Unit 3776	2/8/2014	Total Claims Allowed:			
(Assistant Examiner)	(Date)				
/TODD MANAHAN/ Supervisory Patent Examiner.Art Unit 3776	02/21/2014	O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1	1A		



Application/Control No.	Applicant(s)/Patent Under Reexamination
13455841	LUEBKE, NEILL HAMILTON
Examiner	Art Unit
MATTHEW NELSON	3776

US ORIGINAL CLASSIFICATION										INTERNATIONAL	CLA	SSI	FIC	ATIC	ON
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133			102			Α	6	1	С	5 / 02 (2006.01.01)					
	CR	OSS REF	ERENCE(	S)											
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				CK)										

/MATTHEW NELSON/ Examiner.Art Unit 3776	2/8/2014	Total Claims Allowed:			
(Assistant Examiner)	(Date)				
/TODD MANAHAN/ Supervisory Patent Examiner.Art Unit 3776	02/21/2014	O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1	1A		



Application/Control No.	Applicant(s)/Patent Under Reexamination
13455841	LUEBKE, NEILL HAMILTON
Examiner	Art Unit
MATTHEW NELSON	3776

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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16	18														

/MATTHEW NELSON/ Examiner.Art Unit 3776 (Assistant Examiner)	2/8/2014 (Date)	Total Claims Allowed:			
/TODD MANAHAN/ Supervisory Patent Examiner.Art Unit 3776	02/21/2014	O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1	1A		

Receipt date: 04/25/2012

Sheet

13455841 - GAU: 3776

PTO/SB/08a (04-07)

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

Attorney Docket Number

	U. S. PATENT DOCUMENTS					
	Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
Change( to docun	1.	1	<sup>US-</sup> 6783438	10/23/2003	Aloise et al.	August 31, 2004
		g	<sup>US-</sup> 20040171333	09/02/2004	Aloise et al.	
	ient,		<sup>US-</sup> 20060014480	01/13/2006	Aloise et al.	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
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Examiner Signature	/Matthew Nelson/	Date Considered	01/10/2013

\*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 <a href="https://www.uspie.gov">www.uspie.gov</a> 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.

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 APPLICATION NO.
 ISSUE DATE
 PATENT NO.
 ATTORNEY DOCKET NO.
 CONFIRMATION NO.

 13/455,841
 05/20/2014
 8727773
 115207.00009
 5421

26710 7590

QUARLES & BRADY LLP Attn: IP Docket 411 E. WISCONSIN AVENUE SUITE 2350

MILWAUKEE, WI 53202-4426

### **ISSUE NOTIFICATION**

The projected patent number and issue date are specified above.

04/30/2014

#### 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;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit <u>SelectUSA.gov</u>.