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Dental and Medical Instruments Comprising Titanium

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a divisional application of U.S. Patent Application No. 11/628,933 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.

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STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable.

BACKGROUND OF THE INVENTION

1. Field of the Invention

10 [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.

Description of the Related Art

15 Endodontics or root canal therapy is the branch of dentistry that deals with [0004] 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.

Figure 1 shows a representation of a tooth to provide background. Root [0005] 20 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 25 substitute. Figure 1 also shows the apical foramen 22 through which blood and nerves pass to support the pulp tissues.

One method for the preparation of a root canal for filling is represented by [0006] Figures 2a-2e. A tooth having a basically sound outer structure 24 but diseased pulp

- 1 -

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.

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[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
20 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.

- 2 -

[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.

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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.

- 3 -

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.

- 5 **[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
- 10 avoids the use of complex two material systems that are expensive to produce and are prone to delamination of the materials. This version of the invention also solves the problems encountered when cleaning and enlarging a curved root canal.

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

[0019] Figure 3 is a graph showing the results of a study of torsion (M_t) reported in 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_t) reported in degrees of deflection performed in accordance with "ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification

- 4 -

No. 28, Endodontic files and reamers" for untreated (Control) files, heat-treated files (TT), and titanium nitride coated files (Ti-N).

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

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[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.

- 5 -

[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.

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The titanium alloy may be selected from alpha-titanium alloys, beta-[0026] titanium alloys, alpha-beta-titanium alloys, and nickel-titanium alloys. Non-limiting examples of alpha-titanium alloys, beta-titanium alloys, alpha-beta-titanium alloys for use in this embodiment of the invention are: Ti-5AI-2.5Sn alpha alloy; Ti-5AI-2.5Sn-15 ELI (low O₂) 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-20 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-2AI-1Mo alpha-beta alloy; Ti-6AI-4V alpha-beta alloy; Ti-6AI-4V-ELI (low O₂) alphabeta alloy; Ti-6AI-6V-2Sn-0.75Cu alpha-beta alloy; Ti-7AI-4Mo alpha-beta alloy; Ti-25 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 30 for the shank includes 54-57 weight percent nickel and 43-46 weight percent titanium

- 6 -

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.

5 [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 10 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 15 fabricated solely from an alpha-titanium alloy, a beta-titanium alloy, or an alpha-betatitanium alloy to avoid the problems associated with multiple alloy systems. Non-limiting examples of alpha-titanium alloys, beta-titanium alloys, alpha-[0028] beta-titanium alloys for use in this embodiment of the invention are: Ti-5AI-2.5Sn alpha alloy; Ti-5AI-2.5Sn-ELI (low O₂) alpha alloy; Ti-3AI-2.5V alpha alloy; Ti-5AI-5Zr-20 5Sn alpha alloy; Ti-6Al-2Cb-1Ta-0.8Mo alpha alloy; Ti-5Al-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-25 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-2AI-1Mo alpha-beta alloy; Ti-6AI-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-3AI beta alloy; Ti-

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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 15 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 nickeltitanium 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-20 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 25 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

- 8 -

visually exhibit a near failure of the instrument. This aspect of the invention relates to all drills, burs, files, and instruments used in medicine and dentistry.

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

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[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

- 9 -

applications. This aspect of the present invention pertains to the application of coatings and optionally heat-treatment to cutting instruments such as drills and files to produce a sharper cutting edge and a higher resistance to heat degradation that should provide for better cutting, a smooth surface and/or different metallurgical

properties than the material from which it was manufactured. This includes instrumentation that will facilitate the cleaning and sealing of the root canal system. In addition, a heat-treatment separately applied or as utilized in the coating process may relieve stress in the instrument which should allow for more instrument longevity by the ability to withstand more torque, rotate through a larger angle of deflection,
change the handling properties, remove shape memory or visually exhibit a near failure of the instrument. This aspect of the invention relates to all drills, burs, files,

and instruments used in medicine and dentistry.

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

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

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- 10 -

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

5 [0036] Thirty ISO size SX files, thirty ISO size S1 files, thirty ISO size S2 files, thirty ISO size F1 files, thirty ISO size F2 files and thirty ISO size F3 files were used in a study of torsion (Mt) reported in 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 10 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 15 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 20 furnace in an argon atmosphere at 500°C for 75 minutes showed the best result with the highest M_t.

Example 2

[0037] Thirty ISO size SX files, thirty ISO size S1 files, thirty ISO size S2 files, thirty ISO size F1 files, thirty ISO size F2 files and thirty ISO size F3 files were used in a study of torsion (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

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- 11 -

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.

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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- 12 -

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 5 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 10 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 15 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 20 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

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- 13 -

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

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

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

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- 14 -

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 shank at a temperature above 25°C in an atmosphere consisting essentially of a gas unreactive with the shank.

2. The method of claim 1 wherein:

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

3. The method of claim 1 wherein:

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

4. The method of claim 1 wherein: the temperature is from 475°C to 525°C.

5. The method of claim 1 wherein: the shank is heat-treated for 1 to 2 hours.

6. The method of claim 1 wherein:

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

- 15 -

7. The method of claim 1 wherein:

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

8. The method of claim 1 wherein:

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

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

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

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

9. The method of claim 1 wherein:

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

the gas is argon,

the temperature is 500°C, and

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

10. The method of claim 1 wherein: the instrument shank is in accordance with ISO Standard 3630-1.

11. The method of claim 1 wherein:

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

12. The method of claim 1 wherein:the instrument shank has a diameter of 0.5 to 1.6 millimeters.

- 16 -

13. The method of claim 1 wherein:

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

14. The method of claim 1 wherein:

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

15. The method of claim 14 wherein: the single temperature is from 400°C to 525°C.

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

17. 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 instrument shank at a temperature from 475°C to 525°C in an atmosphere consisting essentially of a gas unreactive with the shank.

18. The method of claim 17 wherein:

the shank is heat- treated in step (b) at a single temperature from 475°C to 525°C.

19. The method of claim 17 wherein:

the entire shank is heat-treated in step (b) at a single temperature from 475°C to 525°C.

20. The method of claim 17 wherein:

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

- 18 -

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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Under the Paperwork Reduction	Act of 1995, no per	sons are required to respond	and to a collection of infor	mation unless i	t contains a valid (OMB control number.		
			Attorney Docket	1152	07.00002			
DECLARATION			First Named Invento			amiltan		
	-R 1.03)		Application Number					
Declaration	Declara	tion	Filing Date					
With Initial	Filing (s	surcharge	Art Unit					
r inng	require	d)	Examiner Name					
I hereby declare that: Each inventor's residence, mailing address, and citizenship are as stated below next to their name. I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:								
DENTAL A	ND MEDIC	CAL INSTRUME	ENTS COMPR	SING TI	ΓΑΝΙUΜ			
L		(Title of the I	nvention)					
the specification of which		·						
is attached hereto								
			-					
was filed on (MM/DD/Y	YYY) [07 Ji	un 05 (07.06.05)	as United States	Application	Number or PO	CT International		
Application Number PCT/L	JS05/019947	and was amended	on (MM/DD/YYYY)			(if applicable).		
I horoby state that I have revis		stand the contents	f the above identify	L		the claime as		
amended by any amendment	specifically refe	erred to above.		eu specificat	ion, including	the claims, as		
I acknowledge the duty to di continuation-in-part applicatio and the national or PCT intern	sclose informa ns, material inf ational filing da	tion which is mater ormation which beca te of the continuatio	al to patentability a ame available betw n-in-part application	as defined i een the filin	n 37 CFR 1.5 g date of the	56, including for prior application		
I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.								
Prior Foreign Application	Country	Foreign Filing	Date Pr	iority	Certified C	opy Attached?		
Number(s)			T) Not C					
Additional foreign ap	plication numbe	ers are listed on a su	pplemental priority	data sheet F	PTO/SB/02B a	ttached hereto.		

[Page 1 of 2] This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance completing the form, call 1-800-PTO-9199 and select option 2. 5883562

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(09-04) Approved for use through 07/31/2006. OMB 0651-0032 Frademark Office: U.S. DEPARTMENT OF COMMERCE U.S. Detect and T

Under the Paperwork Reduction	Act of 1995, no perso	ns are requi	red to	respon	d to a co	lectio	on of informati	on unle	ss it conta	ains a valid OMB control number.
DECLARATION — Utility or Design Patent Application										
Direct all correspondence to:	he address ssociated with ustomer Number		26	710				OR		Correspondence address below
Name	<u> </u>									
Address	<u></u>									
City					State	;				ZIP
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I hereby declare that all states and belief are believed to b statements and the like so ma false statements may jeopardi	ments made here e true; and furt ade are punishab ze the validity of	ein of my her that ble by fine the applic	own these or in atior	know e stat mprise n or ar	ledge ement onmen ny pate	are sw t, or ent is	true and th ere made both, unde ssued there	at all with er 18 l eon.	stateme the kno J.S.C.	ents made on information owledge that willful false 1001 and that such willful
NAME OF SOLE OR FIRST I	NVENTOR:		Г		etition	has	been filed	for thi	s unsiai	ned inventor
Given Name (first and middle	[if any])				Family Name or Surname			ame		
Neill Hamilton	0				LUEBKE					
Inventor \$Signature	Fuelth	/ e ,					<u>.</u>			Date 9-29-06
Residence: City V	State				Cour	ntry			Citize	nship
Brookfield	WI				US				US	
Mailing Address										
18010 Continental Driv	ve									
City	State					Zip)			Country
Brookfield	WI					5	3045-12	.04		US
NAME OF SECOND INVENT							petition ha	as bee	n filed f	for this unsigned inventor
Given Name (first and middle	[if any])						Family Na	me or	Surnar	me
Inventor's Signature	<u></u>									Date
Residence: City	State				Cour	ntry			Citize	nship
Mailing Address	_l				L,					
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Additional inventors or a legal r	epresentative are beir	ng named or	n the		upplem	ental s	sheet(s) PTO/	SB/02A	or 02LR	attached hereto.

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[Page 2 of 2]

5883562

Electronic Patent Application Fee Transmittal								
Application Number:								
Filing Date:								
Title of Invention:	Dental and Medical Instruments Comprising Titanium							
First Named Inventor/Applicant Name:	Neill Hamilton Luebke							
Filer:	Richard T. Roche							
Attorney Docket Number:	115207.00005							
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	82	82			
Utility Search Fee		2111 1		270	270			
Utility Examination Fee		2311	1	110	110			
Pages:								
Claims:								
Miscellaneous-Filing:								
Petition:								
Patent-Appeals-and-Interference:								

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
) (\$)	462		

Electronic Acl	Electronic Acknowledgement Receipt						
EFS ID:	9107609						
Application Number:	12977625						
International Application Number:							
Confirmation Number:	9691						
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:	115207.00005						
Receipt Date:	23-DEC-2010						
Filing Date:							
Time Stamp:	14:24:42						
Application Type:	Utility under 35 USC 111(a)						

Payment information:

Submitted wi	th Payment	yes							
Payment Type	5	Deposit Account	Deposit Account						
Payment was	successfully received in RAM	\$462	\$462						
RAM confirma	ation Number	1335							
Deposit Account 170055									
Authorized U	ser								
File Listin	g:								
Document Number	Document Description	File Name	File Name File Size(Bytes)/ Multi Page Message Digest Part /.zip (if ap						
		IPR2015-00632 - Ex. 1013 31 of 163 US ENDODONTICS, LLC., Petitioner							

1	Drawings-only black and white line	drawings.pdf	591821	no	7
	drawings		4e2e10cd71a74ab435a8921d08fc5b01615 091f		
Warnings:					
Information:					
2	Specification	specification.pdf	106272	no	10
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Information:					
3	Oath or Declaration filed	declaration pdf	117429	no	2
5	Oath of Declaration filed declaration.pdf		a0ca3296846293f3010e4b26c2e9c3b5841 88316		
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Information:					
		Total Files Size (in bytes)	8	48256	
This Acknowl characterized Post Card, as <u>New Applicat</u> If a new appli 1.53(b)-(d) ar Acknowledge <u>National Stag</u> If a timely sul U.S.C. 371 an national stag <u>New Internat</u> If a new inter	ledgement Receipt evidences receip d by the applicant, and including pag described in MPEP 503. <u>tions Under 35 U.S.C. 111</u> ication is being filed and the applica nd MPEP 506), a Filing Receipt (37 CF ement Receipt will establish the filin ge of an International Application ur bmission to enter the national stage of other applicable requirements a F ge submission under 35 U.S.C. 371 wi tional Application Filed with the USF mational application is being filed a	ot on the noted date by the U ge counts, where applicable. FR 1.54) will be issued in due og date of the application. <u>Inder 35 U.S.C. 371</u> of an international application form PCT/DO/EO/903 indication ill be issued in addition to th <u>PTO as a Receiving Office</u> and the international applicat	SPTO of the indicated It serves as evidence components for a filir course and the date s ion is compliant with ing acceptance of the e Filing Receipt, in du tion includes the nece of the International	document of receipt : ng date (see shown on th the condition application te course.	s, similar to a 37 CFR his ons of 35 h as a
and of the Int national secu the application	ternational Filing date (see PCT Article 11 an ternational Filing Date (Form PCT/R(irity, and the date shown on this Ack on.	Id MPEP 1810), a Notification O/105) will be issued in due c knowledgement Receipt will	course, subject to pre- establish the interna	scriptions c tional filing	Number oncerning date of

PETITION TO MAKE SPECIAL BASED ON AGE FOR ADVANCEMENT OF EXAMINATION UNDER 37 CFR 1.102(c)(1)									
			Application I	nforma	ation				
Application Number	12977625	5	Confirmation Number	9691		Filing Date	2010-12-23		
Attorney Docket Number (optional)	115207.00	005	Art Unit	Examiner					
First Named Inventor	Neill H. L	Neill H. Luebke							
Title of Invention	DENTAL	AND MEDIC	AL INSTRUMENTS C	ompri	SING TITANIUM				
Attention: Office of Petitions An application may be made special for advancement of examination upon filing of a petition showing that the applicant is 65 years of age, or more. No fee is required with such a petition. See <u>37 CFR 1.102(c)(1)</u> and MPEP 708.02 (IV). APPLICANT HEREBY PETITIONS TO MAKE SPECIAL FOR ADVANCEMENT OF EXAMINATION IN THIS APPLICATION UNDER 37 CFR 1.102(c)(1) and MPEP 708.02 (IV) ON THE BASIS OF THE APPLICANT'S AGE. A grantable petition requires one of the following items: (1) Statement by one named inventor in the application that he/she is 65 years of age, or more; or (2) Certification by a registered attorney/agent having evidence such as a birth certificate, passport, driver's license, etc. showing one named inventor in the application is 65 years of age, or more.									
Given Name		Middle Na	ne	Family	Name	S	uffix		
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 re	etain such ir	n the applicati	on file record, showing	; that th	e inventor listed al	bove is 65 ye	ars of age, or more.		
Signature		/Richard T.	Roche/		Date (YYYY-MM-DD)		10-12-23		
Name		Richard T. R	oche		Registration Number	38	599		

EFSWeb 1.0.18

Privacy Act Statement

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

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

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



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. 12977625 Filed: : DECISION ON PETITION TO MAKE SPECIAL :UNDER 37 CFR 1.102(c)(1)

Attorney Docket No. 115207.00005

This is a decision on the electronic petition under 37 CFR 1.102 (c)(1), filed 23-DEC-2010 application special based on applicant's age as set forth in MPEP § 708.02, Section IV.

to make the above-identified

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 Acl	Electronic Acknowledgement Receipt						
EFS ID:	9109586						
Application Number:	12977625						
International Application Number:							
Confirmation Number:	9691						
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:	115207.00005						
Receipt Date:	23-DEC-2010						
Filing Date:							
Time Stamp:	14:44:09						
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		petitionagesb00005 pdf	823066	no	2		
			petitionagesbooods.par	5a165d75602ec2e9eb0f0c4c09a08aa82eac 74e1	110			
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.



	United State	<u>es Patent</u>	and Tradema	ARK OFFICE United States Address: COMMISS PC. Bax 14 Alexandia, www.uspto.	ES DEPARTMENT OF COMMERCE Patent and Trademark Office SIONER FOR PATENTS S0 Vignina 22313-1450
APPLICATION	FILING or	GRP ART			
NUMBER	371(c) DATE	UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS IND CLAIMS
12/977,625	12/23/2010	3732	462	115207.00005	20 2
					CONFIRMATION NO. 9691
26710				FILING RI	ECEIPT
QUARLES & E	BRADY LLP				
411 F WISCO	NSIN AVENUE	=			
SUITE 2040		_			DC00000045390120*
00112 2040		_			
MILWAUKEE,	WI 53202-449	7			

Date Mailed: 01/12/2011

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 DIV of 11/628,933 12/07/2006 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: 01/07/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/977,625**

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

Non-Publication Request: No

Early Publication Request: No ** SMALL ENTITY **

Title

Dental and Medical Instruments Comprising Titanium

Preliminary Class

433

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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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).

UNITED ST	ates Patent and Tradema	ARK OFFICE UNITED STA United State: Address: COMMI PO Box Alexandri www.uspt	TES DEPARTMENT OF COMMERCE 5 Patent and Trademark Office SSIONER FOR PATENTS 1450 a, Virginia 22313-1450 o.gov
APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/977,625	12/23/2010	Neill Hamilton Luebke	115207.00005
			CONFIRMATION NO. 9691
26710		FORMALI	TIES LETTER
QUARLES & BRADY LLP 411 E. WISCONSIN AVEN	NUE		0C000000045390121*
MILWAUKEE, WI 53202-4	497		

Date Mailed: 01/12/2011

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) 2e, 3, 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) 3-7.

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.

page 1 of 2

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. <u>https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html</u>

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

/hchin/

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

page 2 of 2

I hereby certify that this correspondence is being electronically transmitted to the United States Patent and Trademark Office on the date set forth below.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill Hamilton Luebke
Application No.:	12/977,625
Filed:	December 23, 2010
For:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Art Unit:	3732
Confirmation:	9691
Docket No.:	115207.00005

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

In response to the Notice to File Corrected Application Papers mailed on January 12,

2011, Applicants submit replacement drawings in compliance with 37 CFR 1.84 and 37 CFR

1.121(d) as required.

No fees are believed to be needed for this amendment. If additional fees are needed, please charge them to Deposit Account No. 17 0055.

Respectfully submitted,

Neill Hamilton Luebke

Dated: February 3, 2011

/Richard T. Roche/

Richard T. Roche, Reg. No. 38,599 Quarles and Brady LLP 411 East Wisconsin Ave. Milwaukee, WI 53202 (414) 277-5805 I hereby certify that this correspondence is being electronically transmitted to the United States Patent and Trademark Office on the date set forth below.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Neill Hamilton Luebke
Application No.:	12/977,625
Filed:	December 23, 2010
For:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM
Art Unit:	3732
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Respectfully submitted,

Neill Hamilton Luebke

Dated: February 3, 2011

/Richard T. Roche/

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

Electronic Acknowledgement Receipt				
EFS ID:	9373153			
Application Number:	12977625			
International Application Number:				
Confirmation Number:	9691			
Title of Invention:	Dental and Medical Instruments Comprising Titanium			
First Named Inventor/Applicant Name:	Neill Hamilton Luebke			
Customer Number:	26710			
Filer:	Richard T. Roche/sara kerstein			
Filer Authorized By:	Richard T. Roche			
Attorney Docket Number:	115207.00005			
Receipt Date:	03-FEB-2011			
Filing Date:	23-DEC-2010			
Time Stamp:	18:16:07			
Application Type:	Utility under 35 USC 111(a)			

Payment information:

Submitted wi	th Payment	no	no			
File Listing:						
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)	
1	Drawings-only black and white line	luebke figures odf	597234	no	7	
	drawings		29175f88ef6246b40a180e21e7ea5b651b3 038fe		,	
Warnings:						
Information:						

2	Applicant Response to Pre-Exam	luebke_response.pdf	977435	no	1
	Formalities Notice		75cd7855838cb7d83d293ae9bca390e3b67 adc79		
Warnings:			· · ·		
Information:					
		Total Files Size (in bytes)	: 157	4669	
<u>New Applica</u> If a new appl 1 53(b)-(d) av	tions Under 35 U.S.C. 111 lication is being filed and the applicat	tion includes the necessary o	components for a filing	g date (see	e 37 CFR
<u>New Applica</u> If a new appl 1.53(b)-(d) a Acknowledg	tions Under 35 U.S.C. 111 lication is being filed and the applicat nd MPEP 506), a Filing Receipt (37 CF ement Receipt will establish the filing	tion includes the necessary c R 1.54) will be issued in due g date of the application.	components for a filing course and the date sh	g date (see nown on th	e 37 CFR nis
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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.











Fig. 1b

49 of 163

2/7

Replacement Sheets



50 of 163







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IPR2015-00632 - Ex. 1013 US ENDODONTICS, LLC., Petitioner

53 of 163



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	Jnited State	<u>s Patent</u>	AND TRADEMA	NRK OFFICE UNITED STA United State Address: COMM P.O. Box Alexand www.usp	TES DEPARTMENT OF COMMERCE s Patent and Trademark Office ISSIONER FOR PATENTS 1450 is, Virginia 22313-1450 to gov	
APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS IND CLAIMS	
12/977,625	12/23/2010	3732	462	115207.00005	20 2	
					CONFIRMATION NO. 9691	
26710				UPDATE	ED FILING RECEIPT	
QUARLES & E	BRADY LLP					
411 E. WISCO	411 E. WISCONSIN AVENUE					
SUITE 2040					*OC00000045941097*	
MILWAUKEE.	WI 53202-449	7				

Date Mailed: 02/15/2011

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 DIV of 11/628,933 12/07/2006 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 <u>http://www.uspto.gov</u> for more information.)

If Required, Foreign Filing License Granted: 01/07/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/977,625**

Projected Publication Date: 05/26/2011

Non-Publication Request: No

Early Publication Request: No ** SMALL ENTITY **

Title

Dental and Medical Instruments Comprising Titanium

Preliminary Class

433

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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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.

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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).



UNITED STA	ates Patent and Trademai	RK OFFICE UNITED STA United States Address COMMU PO: Bax Alexandri www.uspt	TES DEPARTMENT OF COMMERCE 5 Patent and Trademark Office SSIONER FOR PATENTS 450 a, Virginia 22313-1450 ogov
APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/977,625	12/23/2010	Neill Hamilton Luebke	115207.00005
			CONFIRMATION NO. 9691
26710		PUBLICA	FION NOTICE
QUARLES & BRADY LLP			
411 E. WISCONSIN AVE	NUE		
SUITE 2040			000000047895785"
MILWAUKEE, WI 53202-4	497		

Title:Dental and Medical Instruments Comprising Titanium

Publication No.US-2011-0120601-A1 Publication Date:05/26/2011

NOTICE OF PUBLICATION OF APPLICATION

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

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

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

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

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

page 1 of 1



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)				
	12/977,625	LUEBKE, NEILL HAMILTON				
Office Action Summary	Examiner	Art Unit				
	MATTHEW NELSON	3776				
The MAILING DATE of this communication app Period for Reply	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
 A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 						
Status						
1) Responsive to communication(s) filed on $23 L$	December 2010.					
2a) This action is FINAL . $2b$ This	s action is non-final.					
3) Since this application is in condition for allowa	nce except for formal matters, pro	secution as to the merits is				
closed in accordance with the practice under <i>l</i>	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.				
Disposition of Claims						
4 Claim(s) 1-20 is/are pending in the application						
 4) X Claim(s) <u>1-20</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) X Claim(s) <u>1-20</u> is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 						
Application Papers						
9) The specification is objected to by the Examine	er.					
10) The drawing(s) filed on <u>23 December 2010</u> is/a	are: a)🛛 accepted or b)🗌 object	ed to by the Examiner.				
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correc	tion is required if the drawing(s) is ob	jected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Ex	xaminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:					
1. Certified copies of the priority document	ts have been received.					
2. Certified copies of the priority document	ts have been received in Applicati	on No				
3. Copies of the certified copies of the prio	rity documents have been receive	ed in this National Stage				
application from the International Burea	u (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) X Notice of References Cited (PTO-892)	4) 🔲 Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D	ate				
 Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 	5) I INDICE of Informal F 6) Other:	atent Application				
L J.S. Patent and Trademark Office PTOL -326 (Rev. 08-06) Office A	ction Summary Pa	art of Paper No /Mail Date 20110523				

Office	Action	Summary
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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

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

2. Claims 1-4, 6-7, 11, 13-16 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Sachdeva (US 6,431,863) in view of Ueda (US 2002/0191878).

3. Sachdeva shows a method for manufacturing/modifying an endodontic

instrument comprising providing an elongate shank (working shaft 12) having a cutting

edge (Fig. 2b) extending from a distal end of the shank along an axial length of the

shank (Fig. 1), the shank comprising a titanium alloy (col. 3, lines 30-33); and heat-

treating the shank at a temperature above 25 degrees Celsius (col. 4, lines 59-65; Fig.

4, 5). With respect to claims 3-4, 15-16, the temperature is from 400 degrees Celsius

up to but not equal to the melting point of the titanium alloy or 475 to 525 degrees

Celsius (col. 4, line 59-65; Fig. 4-5 show anneal temperatures at 350, 400, 450, 500).

With respect to claim 6, the titanium alloy is selected from alpha-titanium, beta-titanium,

alpha-beta-titanium, and nickel-titanium alloys (col. 3, lines 30-33). With respect to

claim 7, the titanium alloy comprises 54-57 weight percent nickel and 43-46 weight

percent titanium (col. 3, lines 30-32; Table 1). With respect to claim 11, the heat-treated

shank has an angle greater than 10 degrees of permanent deformation after torque at

45 degrees of flexion (Sachdeva has the same process of making as described above

and therefore exhibits similar shape memory characteristics such as permanent deformation after a degree of flexion). With respect to claims 13-14, the entire instrument shank is heat-treated at a single temperature (col. 2, lines 38-46). However, Sachdeva fails to show heat-treating the shank in an atmosphere consisting essentially of a gas unreactive with the shank.

4. Ueda teaches heat treating a titanium alloy wherein the heat treatment being conducted in an atmosphere consisting essentially of a gas unreactive with the shank such as argon ([0039] for instance). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva's instrument by including the heat treating in an atmosphere consisting essentially of a gas unreactive with the shank as taught by Ueda in order to prevent the titanium alloy from oxidizing as is known in the art.

5. Claims 5, 8-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Ueda as applied to claim 1 above and further in view of Besselink et al. (US 6,428,634).

6. Sachdeva/Ueda discloses the device as previously described above, but fails to show the shank is heat-treated for 1 to 2 hours.

7. Besselink teaches heat treating titanium alloys wherein the shank is heat-treated for a period of time that depends on the temperature that is chosen (col. 4, line 38-40). It would have been obvious to one having ordinary skill in the art at the time of invention to have modified the heat-treatment time based on the temperature and material

chosen, since it has been held that discovering an optimum value of a result effect variable (as established by Besselink) involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205, USPQ 215 (CCPA 1980).

8. Claims 10, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Ueda as applied to claim 1 above and further in view of Wong (US 6,206,695).

9. Sachdeva/Ueda discloses the device as previously described above, but fails to show the endodontic instrument being in accordance with ISO Standard 3630-1 and therefore having a diameter within the range of 0.5 to 1.6 mm.

10. Wong teaches in the background of the invention endodontic tools manufactured pursuant to ISO Standard 3630 and having diameters of 0.5-1.6 mm (col. 2, lines 5-30; Table I). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva/Ueda's instrument by utilizing the ISO Standard as taught by Wong in order to provide sizes and an internationally recognized standard that is recognizable by and commonly used by dentists.

11. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Ueda and Wong.

12. Sachdeva discloses the device as previously described above, but fails to show heat-treating the shank in an atmosphere consisting essentially of a gas unreactive with the shank.

13. Ueda teaches heat treating a titanium alloy wherein the heat treatment being conducted in an atmosphere consisting essentially of a gas unreactive with the shank such as argon ([0039] for instance). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva's instrument by including the heat treating in an atmosphere consisting essentially of a gas unreactive with the shank as taught by Ueda in order to prevent the titanium alloy from oxidizing as is known in the art. However, Sachdeva/Ueda fails to show the endodontic instrument being in accordance with ISO Standard 3630-1.

14. Wong teaches in the background of the invention endodontic tools manufactured pursuant to ISO Standard 3630 and having diameters of 0.5-1.6 mm (col. 2, lines 5-30; Table I). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Sachdeva/Ueda's instrument by utilizing the ISO Standard as taught by Wong in order to provide sizes and an internationally recognized standard that is recognizable by and commonly used by dentists.

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.

65 of 163

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

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

/MMN/

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

Notice of Beferences Cited	Application/Control No. 12/977,625	Applicant(s)/Patent Under Reexamination LUEBKE, NEILL HAMILTON		
Notice of References Cited	Examiner	Art Unit		
	MATTHEW NELSON	3776	Page 1 of 1	

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	А	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
*	С	US-5,653,590 A	08-1997	Heath et al.	433/102
*	D	US-5,775,902 A	07-1998	Matsutani et al.	433/102
*	Е	US-6,206,695 B1	03-2001	Wong et al.	433/102
*	F	US-6,375,458 B1	04-2002	Moorleghem et al.	433/2
*	G	US-6,431,863 B1	08-2002	Sachdeva et al.	433/102
*	Н	US-6,428,634 B1	08-2002	Besselink et al.	148/421
*	-	US-2002/0191878 A1	12-2002	Ueda et al.	384/492
*	ſ	US-2004/0121283 A1	06-2004	Mason, Robert M.	433/102
*	к	US-7,137,815 B2	11-2006	Matsutani et al.	433/102
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NON-PATENT DOCUMENTS

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Part of Paper No. 20110523

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	12977625	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

SEARCHED									
Class	Subclass	Date	Examiner						
433	102, 224	5/23/2011	MN						
29	896.1, 896.11	5/23/2011	MN						

SEARCH NOTES								
Search Notes	Date	Examiner						
See EAST search history	5/23/2011	MN						
Search request from Jermie Cozart	5/23/2011	MN						

Class	Subclass	Date	Examiner



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BIB DATA SHEET

CONFIRMATION NO. 9691

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APPLICANTS Neill Hamilton Luebke, Brookfield, WI;												
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	99	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:27
L4	54	29/896.11	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:27
L5	985	433/102,224.œls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/23 14:27
L6	41	(L3 L4 L5) 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
82	6	"6431863".pn. "6422865".pn. "6428634".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 07:56
S 5	1068	Ni adj Ti AND anneal \$2 AND time	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S 6	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

S 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 (anneal\$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 15:16
S12	891	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S13	67	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S14	16	Ni adj Ti AND anneal \$2 AND time AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S15	30	S12 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:58
S19	11	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((flexib\$5) SAME ("400" "425" "450" "475" "500" "525")) AND "433". clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 14:47
S20	34	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((temperature) SAME ("400" "425" "450" "475" "500" "525")) AND "433". clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 14:48
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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
S24	1092	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:13
S 25	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
S 32	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
S 33	2	("7175655").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/18 13:12
S 34	1112	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:45
S 35	1	(ISO WITH 3630-1) AND S34	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:45
S 36	8	(ISO WITH "3630") AND S34	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:46
S 37	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
\$38	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

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
1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:02
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
52	S41 AND ((shape NEAR1 memory) (permanent NEAR1 deformation))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:34
2	"5843244".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:56
1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
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
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
11	S45 AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:07
	83 11139 226 52 11139 226 11 11	83 ("433".clas. 29/896.1) AND ((Ni WI TH Ti) (Nickel WI TH Titanium)) AND endodontic AND deformation 1139 433/102,224.ccls. 29/896.1.ccls. 226 S40 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) 52 S41 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) 2 "5843244".pn. 1139 433/102,224.ccls. 29/896.1.ccls. 210 "5843244".pn. 1139 433/102,224.ccls. 29/896.1.ccls. 21139 433/102,224.ccls. 29/896.1.ccls. 226 S44 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) 1 S45 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) AND (("54" "55" "56" "57") WITH nickel) 11 S45 AND (("54" "55" "56" "57") WITH nickel)	83 ("433".clas. 29/896.1) AND ((Ni WI TH Ti) (Nickel WI TH Titanium)) AND endodontic AND deformation USPAT; USOCR; FPRS; EPO; JPO; DERWENT 1139 433/102,224.ccls. 29/896.1.ccls. US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT 226 S40 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT 52 S41 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT 2 "5843244".pn. US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT 1139 433/102,224.ccls. 29/896.1.ccls. US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT 226 S44 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT 226 S44 AND ((Ni NEAR1 Titanium) OR Nitinol) US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT 1 S45 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) AND (("54" "55" "55") US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT 11 S45 AND (("54" "55") "56" "57") WITH nickel) US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT 11 S45 AND (("54" "55") "56" "57") WITH nickel) US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	83("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel USCR; FPRS; EPO; JPO; DERWENTOR1139433/102,224.ccls. 29/896.1.ccls.US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR226S40 AND ((Ni NEAR1 Titanium) OR Nitinol) (permanent NEAR1 deformation))US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR52S41 AND ((shape NEAR1 memory) (permanent NEAR1 deformation))US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR2"5843244".pn.US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR2S43/102,224.ccls. 29/896.1.ccls.US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR1139433/102,224.ccls. 29/896.1.ccls.US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR226S44 AND ((Ni NEAR1 Titanium) OR Nitinol) ID OR (Nickel NEAR1 Titanium) OR Nitinol)US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR226S44 AND ((Shape NEAR1 memory) (permanent NEAR1 deformation)) AND (r54" "55" "56"" S7") WITH nickel)US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR1S45 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) AND (r54" "55" "56" "57") WITH nickel)US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR11S45 AND (("54" "55" US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR11S45 AND (("54" "55" US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR11S45 AND (("54" "55" US-PGPUB; USCR; FPRS; EPO; JPO; DERWENTOR	83 ("433" cdas. 29/896.1) AND ((Ni WTH Ti) (Nickel WTH Ti) (Nickel S29/896.1.ccls. US-RGPUB; USPAT; USOCR; FPRS; EPC, JPC; DEFWENT OR ON 226 S40 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) US-RGPUB; USOCR; FPRS; EPC, JPC; DEFWENT OR ON 52 S41 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) US-RGPUB; USOCR; FPRS; EPC, JPC; DEFWENT OR ON 2 "5843244".pn. US-RGPUB; USOCR; FPRS; EPC, JPC; DEFWENT OR ON 1139 433/102,224.ccls. US-RGPUB; USOCR; FPRS; EPC, JPC; DEFWENT OR ON 2 "5843244".pn. US-RGPUB; USOCR; FPRS; EPC, JPC; DEFWENT OR ON 1139 433/102,224.ccls. US-RGPUB; USOCR; FPRS; EPC, JPC; DEFWENT OR ON 226 S44 AND ((Ni NEAR1 Titanium) OR Nitinol) US-RGPUB; USOCR; FPRS; EPC, JPC; DEFWENT OR ON 1 S45 AND ((Shape NEAR1 memory) (permanent NEAR1 Hefor, JPC; DEFWENT US-RGPUB; USOCR; FPRS; EPC, JPC; DEFWENT OR ON 11 S45 AND ((Shape NEAR1 memory) (permanent NEAR1 Hefor, JPC; DEFWENT

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
S 54	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

S 55	6	(endodontic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:36
S56	2	((inert NEAR1 gas)) (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
S 57	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
S 59	51	(endodontic "433". clas.) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:40

S61	1346	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:46
S64	126	((Ni ADJ Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) SAME (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:52
S65	10	((Ni ADJ Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) SAME (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:56
S66	8234	(anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S67	8	"433".clas. AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S68	2	Nitinol AND (anneal \$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:01

S69	130	(titanium ADJ alloy) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:02
S70	37	(titanium ADJ alloy) SAME (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:02
S71	2	"6783438".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:33

EAST Search History (Interference)

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 $5/23/2011\ 2:28:51\ PM$ C:\ Documents and Settings\ mnelson3\ My Documents\ EAST\ Workspaces\ 12977625 Dental Instruments Comprising Titanium.wsp

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

Date: August 26, 2011

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

IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant: Neill H. Luebke

Application No.: 12/977,625

Filing Date: December 23, 2010

Title: Dental And Medical Instruments Comprising Titanium

Confirmation No.: 9691

Art Unit: 3776

Examiner: Matthew M. Nelson

AMENDMENT

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

Sir:

This is in response to the Non-Final Office Action mailed on June 7, 2011.

Please amend the above-identified patent application as follows:

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

Remarks begin on page 6 of this paper.

Amendments To The Claims

1. (Currently Amended) A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

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

(b) heat-treating the <u>entire</u> shank at a temperature above 25°C from 400°C up to but not equal to the melting point of the titanium alloy in an atmosphere consisting essentially of a gas unreactive with the shank.

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

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

3. (Cancelled)

4. (Original) The method of claim 1 wherein: the temperature is from 475°C to 525°C.

5. (Original) The method of claim 1 wherein: the shank is heat-treated for 1 to 2 hours.

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

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

- 2 -

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

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

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

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

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

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

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

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

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

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

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

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

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

12. (Original) The method of claim 1 wherein: the instrument shank has a diameter of 0.5 to 1.6 millimeters.

- 3 -

13. (Currently Amended) The method of claim 1 wherein:

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

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

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

15. (Original) The method of claim 14 wherein: the single temperature is from 400°C to 525°C.

16. (Original) The method of claim 14 wherein: the single temperature is from 475°C to 525°C.

17. (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 titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium; and

(b) heat-treating the instrument <u>entire</u> shank at a temperature from 475°C to 525°C in an atmosphere consisting essentially of a gas unreactive with the shank.

18. (Original) The method of claim 17 wherein:

the shank is heat-treated in step (b) at a single temperature from 475°C to 525°C.

19. (Cancelled)

20. (Original) The method of claim 17 wherein:

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

- 5 -

REMARKS

Examiner Interview

Applicant and Applicant's representative wish to express appreciation to Examiner Nelson for the courtesy of a telephone interview on August 4, 2011 in the parent application no. 11/628,933. In that interview, Examiner Nelson suggested the submittal of a Declaration under 37 C.F.R. 1.132 directed to: (i) the issues of the support in the Examples for a claim limitation regarding heat treatment of the entire shank, and (ii) the criticality of the temperatures in the claims. This is a divisional application of parent application no. 11/628,933 so Applicant wishes to also address those issues in this application.

Claim Amendments

Independent claims 1 and 17 have been amended to recite that the "entire shank" is heat treated. Claim 3 has been incorporated into claim 1. Claims 3 and 19 have been cancelled. The word "heat-treated" in claim 13 has been amended to be consistent with the other claims.

The basis for this claim limitation "entire shank" in amended claims 1 and 17 can be found in Example 4 of the present application where each ISO size file was heattreated in a furnace having an argon atmosphere. The Court of Appeals for the Federal Circuit outlined the written description requirement in *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (2000), as follows:

"In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir.1996). Nonetheless, the disclosure must ... convey with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-

64, 19 USPQ2d 1111, 1117 (Fed.Cir.1991). Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. Waldemar Link GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558, 31 UPSQ2d 1855, 1857 (Fed.Cir.1994)."

Attached is a Declaration under 37 C.F.R. 1.132 for Office consideration. The Declaration notes that argon (which was used in Example 4 of the present application) is considered to be hazardous by OSHA. Therefore, when using argon gas in a heat treating process as in Example 4 of the present application, a metal heat treating company will use the argon gas in a sealed closed system to provide containment of the argon gas. Item 6 of the Declaration states "[t]he use of an argon atmosphere as described in Example 4 requires that the entire file be heat-treated in the furnace in order to keep the argon contained in a closed system".

Stated a different way, one skilled in the art, when reading the original disclosure of Example 4 of the present application, would immediately discern that the entire shank has to be heat-treated in the furnace using a closed system due to the use of argon (which "can cause rapid suffocation" according to the MSDS attached to the Declaration). Therefore, Example 4 of the present application "convey[s] with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention" of amended independent claims 1 and 17 (see *Purdue Pharma L.P.* above). In other words, one skilled in the art would discern that the "entire shank" as recited in amended independent claims 1 and 17 is being heat-treated in Example 4.

Claim Rejections - 35 USC § 103

Claims 1-4, 6-7, 11, 13-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva (US 6,431,863) in view of Ueda (US 2002/0191878). Claims 5 and 8-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over

- 7 -

Sachdeva in view of Ueda and further in view of Besselink et al. (US 6,428,634). Claims 10 and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Ueda and further in view of Wong (US 6,206,695). Claims 17-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Ueda and Wong.

Independent claims 1 and 17 have been amended as shown above to recite that the "entire shank" is heat-treated. The attached Declaration under 37 C.F.R. 1.132 from one skilled in the metal heat treating art provides evidence that Example 4 of the present application "convey[s] with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention" of amended independent claims 1 and 17 in which the entire shank is heat-treated. In this regard, it is noted that not heat treating the entire shank in a closed furnace as in Example 4 could lead to operator suffocation.

In view of these amendments to independent claims 1 and 17, Applicant wishes to address Sachdeva. Looking at Sachdeva, column 4, lines 31-36, state that "it is believed that the desired flexibility/stiffness and hardness properties, as discussed below, can be achieved ... by performing selective heat treatments of the working shaft portion", and column 4, lines 59-63 of Sachdeva state that "FIG. 6 represents, in a graphic manner, the effect of selective heat treatment. The FIG. 6 data is for a Ni--Ti wire (50.6% Ni) of 0.018" diameter wherein a first section was heat treated (annealed) at 450°C., and a second portion was heat treated at 350°C". Thus, Sachdeva is heat treating different portions of a <u>wire</u> at different temperatures. In contrast, the invention of amended independent claims 1 and 17 requires that the entire shank of an

- 8 -

instrument be heat-treated. The limitations of amended independent claims 1 and 17, in which the entire shank of an instrument is heat-treated, can provide that instrument with uniform mechanical properties. In contrast, Sachdeva is heat treating different portions of a <u>wire</u> at different temperatures. As a result, the Sachdeva wire has different mechanical properties at different regions.

Ueda was cited as teaching the use of a gas unreactive with the shank. Ueda does not teach heat treating an entire shank comprising a titanium alloy. Thus, Ueda does not make up for the deficiencies of Sachdeva with respect to amended independent claims 1 and 17.

Besselink was cited as teaching heat treating for certain time periods. However, the Example at column 5 of Besselink shows that the heat treatment in Besselink was undertaken on a wire, not an elongate shank having a cutting edge as in independent claims 1 and 17. Thus, Besselink does not make up for the deficiencies of Sachdeva with respect to amended independent claims 1 and 17.

Wong was cited as mentioning ISO Standard 3630. Wong does not teach heat treating an entire shank comprising a titanium alloy. Thus, Wong does not make up for the deficiencies of Sachdeva with respect to amended independent claims 1 and 17.

It is well settled that in order to establish a prima facie case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Taken together, Sachdeva and Wong and Ueda and Besselink fail to teach or suggest heat treating an entire shank as recited in amended independent claims 1 and 17. Accordingly, it is respectfully submitted that independent claim 1 (and claims 2 and 4-16 that dependent

- 9 -

thereon) and independent claim 17 (and claims 18 and 20 that depend thereon) are patentable over Sachdeva and Wong and Ueda and Besselink.

In addition, claims 7-9 (which depend from claim 1) each require a nickel-titanium alloy and the use of an unreactive gas. Ueda is particular to the heat treatment of alpha/beta titanium in argon, and not nickel titanium. Therefore, nothing in Ueda would suggest the use of argon for the treatment of a nickel-titanium alloy. For these additional reasons, claims 7-9 (which depend from claim 1) are patentable over Sachdeva and Wong and Ueda and Besselink.

As suggested in the Examiner interview on August 4, 2011 in the parent application, Applicant provides Declaration evidence of the criticality of the process temperatures in independent claims 1 and 17. M.P.E.P. § 2144.05 III. notes that "Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range." *See, In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) ("The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. ... [and] in such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." (citations omitted)).

Attached as Exhibit A is a copy of the Inventor's Declaration that was submitted August 29, 2008 in the parent application U.S. 11/628,933. Looking at independent claim 1, the claimed invention requires that the entire shank be heat-treated at a temperature from 400°C up to but not equal to the melting point of the titanium alloy.

- 10 -

Independent claim 17 requires heat-treating the entire shank at a temperature from 475°C to 525°C.

The Inventor's Declaration describes comparative tests of two groups of heat-treated files, that is, a first group of files heat-treated at 375°C for 1¼ hours and a second group of files heat-treated at 500°C for 1¼ hours. The first group was heat-treated at a temperature (375°C) outside of the claimed temperature range in independent claims 1 and 17, and the second group was heat-treated at a temperature (500°C) within the claimed range in independent claims 1 and 17.

The Inventor's Declaration explains that the angular deflection was significantly larger for the files heat-treated at 500°C, that the cyclic fatigue data demonstrate the remarkable property of passive flexibility in the files heat-treated at 500°C compared to the files heat-treated at 375°C, that the torque data indicates that the heat did not degrade the metal in the files heat-treated at 500°C, and that the bend test data shows that the files heat-treated at 500°C have improved flexibility compared to the files heat-treated at 375°C. Thus, heat treatment within the claimed range was critical to improving the beneficial properties of the endodontic instruments.

Looking at Sachdeva, the heat treatment was not undertaken on the entire shank as recited in independent claims 1 and 17. Nothing in Sachdeva suggests the criticality of the temperature range of independent claims 1 and 17 or that the claimed temperature range is critical when heat-treating an entire shank of an instrument.

Attached as Exhibit B is Zinelis *et al.*, "The effect of thermal treatment on the resistance of nickel-titanium rotary files in cyclic fatigue", Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, Endodontology, 2007;103:843-847. This article

provides further evidence that the claimed range is critical. The later independent work of Zinelis *et al.* shows in Figure 3 at page 845 that there is a critical temperature range for the thermal treatment of nickel-titanium files in order to improve cyclic fatigue. Therefore, others in the Inventor's field, working after the effective filing date of the present application, have confirmed that there is a critical range for heat treatment.

Another citation is Phukaoluan, A. *et al.*, entitled "Effect of Ni-content on mechanical and transformation behavior of NiTi shape memory alloys for orthodontics applications" a paper presented at the first TSME international conference on mechanical engineering, 20-22 October, 2010 (Exhibit C). Phukaoluan, A. *et al.* states that "[f]or the alloy heat treat at 600 degrees C, influences of reduction ratio can not be observed, since this temperature (600° C) is higher than the alloy recrystallization temperature which is about 500-600° C." The Zinelis and Phukaoluan references were all published after the effective filing date of the present application by authors that the present inventor does not know.

Therefore, evidence in Inventor's Declaration, and the Zinelis and Phukaoluan references (which were all published after the effective filing date of the present application) confirm that the particular temperature range of independent claims 1 and 17 is critical. The Applicant respectfully submits that any *prima facie* case of obviousness based on Sachdeva has been rebutted by the above showing of the criticality of the claimed temperature range of amended independent claims 1 and 17.

Conclusion

Claims 1-2, 4-18 and 20 are believed to be in condition for allowance. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the

- 12 -

telephone number appearing below if such would advance the prosecution of this application.

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

Respectfully submitted,

Neill H. Luebke

Dated: August 26, 2011

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

14194288

EXHIBIT A

Docket Number: 115207.00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

DECLARATION UNDER 37 C.F.R. § 1.132

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

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

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

3. Others working according to my directions heat treated a first group of

these files at 375°C for 1¼ hours and heat treated a second group of these files at 500°C for 1¼ hours.

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

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

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

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



Illustration 1

Illustration 2



Illustration 3



Illustration 4



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

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

Dated: August 29, 2008

Neill A. Faille.

Dr.' Neill H. Luebke

EXHIBIT B

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

ENDODONTOLOGY

Editor: Larz S. W. Spångberg

The effect of thermal treatment on the resistance of nickeltitanium rotary files in cyclic fatigue

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

Objective. The purpose of this study was to determine the effect of various thermal treatments on the fatigue resistance of a nickel-titanium (NITi) engine-driven endodontic file.

Study design. Fifteen groups of 5 files each of ISO 30 and taper .04 were tested in this study. The cutting tip (5 mm from the end) of files from 14 groups were heat treated for 30 minutes in temperatures 250°C, 300°C, 350°C, 375°C, 400°C, 410°C, 420°C, 425°C, 430°C, 440°C, 450°C, 475°C, 500°C, and 550°C, respectively, while 1 group was used as reference. The files were placed in a device that allowed the instruments to be tested for rotating bending fatigue inside an artificial root canal. The number of rotations to breakage was recorded for each file. The mean values of all groups were statistically analyzed using 1-way analysis of variance and Student Newman Keuls multiple comparison test at $\alpha = .05$.

Results. The 430°C and 440°C groups showed the highest values, with fatigue resistance decreasing for thermal treatment at lower and higher temperatures. This may be the result of metallurgical changes during annealing. **Conclusion.** Within the limitations of the low sample size and the specific instrument size tested, it appears that the appropriate thermal treatment may significantly increase the fatigue resistance of the NiTi file tested. **(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2007;103:843-7**)

Nickel-titanium (NiTi) alloy has been used in endodontics for about 2 decades. It was introduced to facilitate instrumentation of curved root canals. Although NiTi files showed increased flexibility compared with stainless steel counterparts, the unexpected fracture during mechanical preparation of root canals still remains a problem.¹⁻³ It has been reported that rotary NiTi instruments are more prone to intracanal fracture compared

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"Dental R&D section, MANI, Inc, Tochigi, Japan.

Received for publication Jun 2, 2006; returned for revision Nov 27, 2006; accepted for publication Dec 21, 2006.

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with stainless steel hand instruments.³ These unexpected fractures occur without any visible changes to the instruments, such as permanent defect or deformation.^{1,2}

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

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

^dProfessor and Director, Laboratory of Physical Metallurgy, School of Mining and Metallurgical Engineering, National Technical University of Athens.



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

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

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

Previous studies¹⁰⁻¹⁴ have already proved that additional thermal treatments significantly modify the mechanical and superelastic properties of NiTi files, implying that the assumption that NiTi files are manufactured by fully cold-worked alloys is right. In



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

this perspective, the aim of this study was to evaluate the effect of thermal treatment on the fatigue resistance of a commercially available engine-driven NiTi file.

MATERIAL AND METHODS

Fifteen sets of 5 endodontic NiTi files each (NRT, Mani Inc., Tochigi-Ken, Japan) of ISO 30 and taper .04 (Lot number 5040677600) were selected for this study. The tips (5 mm from the cutting tip) of files from 14 sets were heat treated for 30 minutes in temperatures 250°C, 300°C, 350°C, 375°C, 400°C, 410°C, 420°C, 425°C, 430°C, 440°C, 450°C, 475°C, 500°C, and 550°C, respectively. One set was used as a reference. The tip of each file was heat treated by a hot air device (Weldy hot air tool, Malcom Hot Air Systems, Andover, MA), whereas the rest of the file remained immersed in water as illustrated in Fig. 1. The processed pieces were cooled to room temperature. Then, the files were placed in a specific device that allowed the instruments to be tested in rotating-bending position inside a guide that had the form of an artificial root canal engraved on the surface of 2 hard-steels pins (Fig. 2). The instruments were rotated inside the artificial canal with a 5-mm bending arc of curvature at a constant speed of 200 rpm. The number of rotations to breakage was recorded for each file and the mean Volume 103, Number 6

Tab	le		Mean	val	lues	and	stan	dard	devia	ations	of	nu	m-
ber	of	ro	tations	to	brea	akag	e of	nick	el-tita	nium	file	es	for
all į	gro	up	s teste	d									

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

*Results are sorted in decreasing order of mean values.

†Means with same SNK (Student Newman Keuls) grouping letter are not significantly different (P > .05).

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

RESULTS

Table 1 shows the results of number of rotations to breakage for each group, sorted in decreasing order. According to the statistical analysis, the group at 430°C showed the highest number of rotations to breakage, with statistical significance differences with all groups except that of 440°C. Fractures of all specimens occurred within the deflected part of the file. Fig. 3 illustrates the alteration of rotation to breakage in relation to the annealing temperature. The reference group was set at room temperature. The number of rotations to breakage was found to increase from the reference group to the group of 430°C and 440°C and then to decrease again until the group of 550°C.

DISCUSSION

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

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



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

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

The maximum fatigue resistance for the 440°C group might be explained by the fact that recovery of NiTi cold-worked alloys is commonly taking place⁷ within the range of 450°C to 550°C. The progressive attenuation of dislocation density from the as received state to the 440°C annealing temperature state significantly decreases the brittleness,⁷ enhancing the resistance to the crack propagation mechanism and thus the fatigue strength. However, the aforementioned approach cannot explain the decrease of fatigue resistance beyond 450°C, as the dislocation's density is steadily decreased through annealing at higher temperatures. A significant insight in the metallurgical alterations of cold-worked NiTi alloys is given by the work of Frick et al., 2005.¹⁴

The microstructure of cold-worked NiTi alloys consists of a large dislocation density as well as residual martensite in an austenitic matrix. During heat treating, the microstructure is changed by 2 antagonistic mechanisms: precipitate growth of Ni₃Ti₄ and dislocation annihilation. Precipitate growth of Ni₃Ti₄ is also effective at stopping dislocation sliding, as does a large dislocation density in cold-worked structures. Although ductility is progressively increased through attenuation of dislocation density, the precipitation process during annealing has the inverse effect by hindering dislocation motion. According to the results of this study, the temperature range of 430°C to 440°C is the optimum for the specific alloy, and for its thermomechanical treatment, in obtaining the maximum fatigue resistance. Of course, thermal treatment definitely has an effect on characteristic transformation temperatures (Af, As, Ms and Mf)⁷ of this alloy, but the evaluation of this phenomenon is beyond the aim of this study.

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

Of course, the results of this study are appended only to the tested files. However, previous studies¹⁸ showed that commercially available endodontic files have hardness values (HV₂₀₀: ProFile = 450, Ergoflex K = 410, Hero642 = 376, Hyflex X-File = 371) close to the tested files in the as received condition (465 VHN), and much higher than those of the fully annealed state (200 VHN),¹⁷ denoting that endodontic files are manufactured from cold-worked NiTi wires. This is also advocated by the fact that ProFile instruments of the same size and taper (number 30, taper .04) demonstrate comparable cycles to failure $(812 \pm 52)^{19}$ when tested with the tested files in the reference group (rotations to breakage 936 \pm 136). Of course, differences in hardness among the aforementioned materials are appended to variations to their thermomechanical history-which

of course remains unknown for each product—whereas variations in cycles to failure may also be attributed to the geometric differences between ProFile and Mani NRT instruments. This means that heat treatment can be applied to all endodontic files to modify their mechanical properties.

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

Recent studies3,5-6 based on clinically fractured NiTi instruments reported that fracture occurs due to a single overloading under torsion, tensile, or bending-loading conditions (the combination of all the aforementioned loading is also very possible), rather than a fatigue mechanism. Given that the fracture strength is significantly decreased after thermal treatment (from 1723 to 1378 MPa),⁷ it is expected that the instrument will be more susceptible to fracture. However, the decrease in fracture strength is followed by an increase in ductility (from 7%-15%), enhancing the fracture toughness of the alloy. Generally, this means that the alloy might be more susceptible to the initiation of plastic deformation but more resistant to separation. In any case, this is only a speculation, and thus the behavior of thermal-treated NiTi instruments in this failure mechanism, together with the possible adverse effect on the cutting ability of endodontic instruments, requires further analysis to optimize the effect of thermal treatment on the efficacy of engine-driven NiTi instruments. Although the current results definitely show a trend for fatigue resistance, manufacturers should modify the parameters of the thermal treatment (i.e., temperature, time portion of instrument subjected to heat treatment) according to the thermomechanical history of NiTi alloy used, as well as the clinical demands to optimize the effect of thermal treatment on NiTi instruments.

Although the thermomechanical history of NiTi instruments still remains unknown, the results of this study show that the mechanical properties of such instruments can be effectively modified by thermal treatment. However, the application of heat treatment can significantly vary for different commercial products due to differences in their thermomechanical history. Therefore, thermal treatment can be used to increase the in vivo performance of NiTi instruments, modifying the mechanical properties that have crucial implication Volume 103, Number б

on the cutting and failure mechanisms encountered under clinical conditions.

CONCLUSIONS

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

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Exhibit C



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Effect of Ni-Content on Mechanical and Transformation Behavior of NiTi Shape Memory Alloys for Orthodontics Applications

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Abstract

This study aims to investigate the effect of Ni-content on mechanical properties and transformation behavior of NiTi shape memory alloys for utilizing as orthodontic wires. NiTi binary alloys with Ni-content ranging from 50 to 51 at% were prepared. The specimens were cold-rolled with percentage reduction of 10, 20 and 30%, respectively. Then they were heat treated at 400°C and 600°C for 3,600s, respectively. The results show that transformation temperatures strongly depend on Ni-content, i.e., transformation temperatures rapidly decrease with the increase of Ni-content. Moreover transformation temperature decreases with the increase of cold-rolling reduction ratio. However, the higher is the reduction ratio, the superelastic properties become more evidently. Further heat treatment temperature 400°C provides specimens with better properties compared to those of 600°C. The results obtained can be use to determine optimum alloy composition of NiTi alloy to be used as orthodontic wires.

Keywords: orthodontic wires, Ni-content, Reduction ratio

1. Introduction

NITI was introduced to be used in clinical orthodontic for leveling phase in 1971[1]. The physical properties of nickel-titanium alloy have several advantages over precious metals and stainless steel. NITI alloys have extraordinary properties: shape memory effect and superelasticity with excellent corrosion resistance, as well as good mechanical properties and biocompatibility. NITi alloy are wildly used in clinical orthodontics since their superelasticity property gives continuous and light forces transmitted to the dentition over a long activation period, resulting in a desirable biological response [2-4]. The relative alloy composition of martensite and austenite is a



function of mechanical stress and ambient temperature. Some key characteristics of superelastic nickel-titanium may show exceptional temperature sensitivity [5-7]. Small chemical composition variations can produce significant modifications of such behavior, which can be analyzed considering variation of the transformation start of martensitic (Ms) temperature [8-9]. The properties of NITi can be modified to a great extent by judicious choice of composition, cold work and heat treatment. This study will be a preliminary work to fabricate of NiTi alloy samples.

The purpose of this study is to evaluate the chemical composition, mechanical properties and phase transformation behavior of the fabricated near equiatomic NITI alloy samples. The influence of degrees of cold-rolling and heat treatment temperatures will be discussed in order to further develop NiTi alloy used in orthodontics.

2. Experimental procedure

2.1 Materials

The raw materials used commercial grade with high purity; nickel 99.9% and titanium 99.8%. The targeted composition for each sample is equiatomic NiTi alloy (50-51 at.% Ni). Firstly, nickel and titanium were cleaned in the acid (HF:HNO₃:H₂O, 5:4:1) and then rinsed by acetone to remove surface grease and oxide before melting.

2.2 Melting method

A conventional Vacuum Arc Re-melting technique in argon atmosphere was employed. After charging the constituent element in crucible Fig.1(a), the furnace was purged with argon at pressure of 0.3-0.5 bar. Melting of the raw elements was performed with arc rotation torch created by tungsten electrode Fig.1(b). The ingot was turned over and re-melted five times to ensure chemical homogeneity. The examples of melted ingot is show in Fig.1(c). All melted ingots were then homogenized at 800°C for 3600s Fig.1(d).



Fig. 1 Sequence of the VAR process: (a) pilling up raw materials, (b) rotating torch, (c) melted ingot on a copper crucible, (d) melted ingot after homogenized.

2.3 Characterization

Ingots were sliced into small plates (1.5 mm. in thickness) using a CNC wire cutting machine and then cold-rolled at determined reduction ratio, i.e., 10%, 20% and 30 %, respectively. The lubricant used for the rolling is ISO cut 570A in combination with sodium strearate scap. After removing oxide layers and surface contaminants on the specimen surfaces by mechanical polishing, they were annealed at 400°C and 600°C in heat treatment furnace for 3,600s. The specimens were then cut into specific by а CNC wire cutting machine. Specimens used for investigation phasetransformation behavior were test by using. Differential Scanning Calorimeter (DSC). During

the test temperature was varied in the range of -50°C to 100°C with cooling and heating rate of 10°C/min. The hardness of the specimens was determined by Vickers Microhardness tester with a Vickers diamond tip at room temperature under a maximum load of 500 g_f. To examine load-deflection characteristics of melted NiTi specimens, a three-point bending tests using the Instron Universal Testing Machine (load cell 100N) were performed. The span for bending test was 10 mm. Specimens were loaded to till a maximum deflection of 1.5 mm and deflection rate is 5 mm/min. The influences of Ni-content for NITI on the mechanical properties and transformation behavior of the alloys were then discussed.

3. Results and Discussion

3.1 Transformation temperature behavior

The transformation temperatures of NiTi. Austenetic finish (Af) and Martensitic start (Ms) are critical factors of their transformation behavior. The results of Af and Ms values obtained are shown in Table 1. Actually, we intended to make a superelastic NiTi alloy having transitional temperature lower than oral temperature. It is generally known this can be achieved by increasing Ni content over 50 at.%. From Table 1, the NiTi having nominal composition of Ni_{50.4}Ti_{49.6} at.% and Ni_{50.6}Ti_{49.4} at.% provides Austenite finished temperature (A_f) set as 42.5°C and 32°C, which are closed to oral temperature.

Table 1 Transformation temperature of the specimens obtained by DSC

Nominal	al Transformation						
Composition	te	temperature (°C)					
(at.%)	Ms	Mf	As	Af			
NI ₅₀ TI ₅₀	51.5	20	50.5	79			
Ni _{50 2} Ti _{49 8}	27	7	42	62.5			
Ni _{50.4} Ti _{49.6}	12	-12	16.5	42.5			
Ni _{50.6} Ti _{49.4}	4.5	-31	-8	32			
Ni ₅₁ Ti ₄₉	-37	-	-41	-4			



Fig. 2 Thermographs of $Ni_{50.4}Ti_{49.6}$ at.% with 10%, 20% and 30% reductions followed by heat-treatment at 400°C for 3,600s

Fig. 2 shows the results of DSC for Ni_{50.4}Ti_{49.6} at.% with 10, 20 and 30% reductions followed by 400°C heat treatment for 3,600s. It can be found from the result that the peak on cooling curve reveals the R-phase transformation or the intermediate phase occurs. This R-phase transformation often occurs when the alloys are work-hardened, which also can occur in nickel-rich NITi alloys. Further Ni_{50.4}Ti_{49.6} at.% does not reveals superelasticity properties at the oral temperature because its A_f is higher than 37°C.



Fig. 3 Thermographs of $Ni_{50.6}Ti_{49.4}$ at.% with 10%, 20% and 30% reductions followed by heat-treatment at 400°C for 3,600s

Fig. 3 shows the DSC result for Ni_{50.6}Ti_{49.4} at.% with 10, 20 and 30% reductions followed by 400°C heat treatment for 3,600s. The alloy has Af temperature very closed to oral temperature as shown previously. From Fig. 2, the higher of the percent reduction is the lower and shorter of transformation temperature of both heating and cooling paths are obtained. This can be implied that percent reduction has an impact on phase transformation, and can be explained that transformation was suppressed by internal stress due to cold work. In other words, the internal structure of the work-hardened material is composed of multiple dislocations that hinder the phase transformation. Some works reported that cold-worked NiTi alloys had wide transformation temperature range and the peak height was small. The broadening of the peak was enhanced by increasing the amount of cold-working reduction percent [10].

For the alloy heat treated at 600°C, influence of reduction ratio can not be observed, since this temperature (600°C) is higher than the alloy recrystalization temperature which is about 500-600°C [11]. This result confirms that the dislocation obstructing the phase transformation.

Moreover, the Af temperature of the alloys obtained from all conditions are summarized and shown in Table 2.

Table 2Transformation temperature of thespecimens with heat-treatment at 400°C for3,600s obtained by DSC

Nominal Composition	% Reduction	Transformation temperature (°C)		
(at. 70)		Af	Rs	
	10	49.8	48.8	
TI _{49.6} NI _{50.4}	20	47	41.3	
	30	45.7	39.1	
	10	47	40	
TI _{49.4} NI _{50.6}	20	40	39	
	30	37	39	

3.2 Vickers hardness test.

The micro-indentation hardness is measured at the cross-sectional areas of each alloy specimen. Fig. 4 and Fig. 5 shows the relation between the hardness value (HV) and the cold-rolled reduction ratio, for heat treatment temperature of 400 and 600°C, respectively.



Fig. 4 Hardness values of NiTi with 10%, 20% and 30% reductions followed by heat-treatment at 400° C for 3,600s





Fig. 5 Hardness values of NiTi with 10%, 20% and 30% reductions followed by heat-treatment at 600° C for 3,600s

From Fig. 5, at 600°C heat treatment temperature, which is higher than alloy recrystalization temperature, dislocations are eliminated, hence there is no difference between the hardness value of the specimens undergone rolling at different reduction ratio.

3.3 Three-point bending test.

Three-point bending tests of the specimens are conducted at oral temperature or at 37° C. The results are shown in Fig. 5 and Fig. 6 for the specimen with different. Composition for the Ni_{50.6}Ti_{49.4} at.% with 10%, 20% and 30% reductions followed by heat treatment at 400°C for 3600s (Fig. 6), the completely reverse stress-strain curve is obtained only for the reduction ratio of 30%. From Fig. 7 for Ni_{50.4}Ti_{49.6} at.% alloy, the completely reverse transformation cannot be obtained from any conditions.

This can be explained by the transformation temperature (Af) of the alloy. Since there is only $NI_{50.6}TI_{49.4}$ at.% undergone rolling 30% having Af lower than $37^{\circ}C$, it becomes only one condition that gives superior

superelastic behavior without permanent strain left after unloading.



Fig. 6 Stress-strain curves for $Ni_{50.6}Ti_{49.4}$ at.% with 10%, 20% and 30% reductions follow by heat-treatment at 400°C for 3,600s (tested at 37°C)



Fig. 7 Stress-strain curves for $Ni_{50,4}Ti_{49,6}$ at.% with 10%, 20% and 30% reductions follow by heat-treatment at 400°C for 3,600s (tested at 37°C)

4. Conclusions

In order to fabricate the NiTi shape memory alloy used in orthodontics, three principle factors, i.e., alloy composition, work hardening and heat treatment temperature, affecting the transformation behavior and mechanical properties of NiTi should be effectively determined. The cold work reduction higher than 30% tends to improve the superelastic property of the alloys. The heat treatment temperature higher than 600°C



remove all dislocation resulted in unsatisfied properties of the alloys. The fraction of Ni at 50.6% in the alloy provides the best mechanical properties as well as superelastic behavior to be used as orthodontic wires.

5. Acknowledgement

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Filing Date: December 23, 2010

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Examiner: Matthew M. Nelson.

DECLARATION UNDER 37 C.F.R. 1.132

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

Sir

I, Robert Struebing, hereby declare as follows:

1. I am a production manager at the Sturtevant Plant of Bodycole Thermal Processing, Inc., ("Bodycole"). Bodycole is one of the world's largest providers of thermal processing services, with over 170 facilities in 27 countries. Further information on Bodycole is available at www.bodycole.com. Lam experienced in the vacuum heat treating of metals, including the use of argon gas in heat treating.

3. I have reviewed the attached "Praxair Material Safety Data Sheet" and confirm that OSHA regulations require special procedures when using argon gas in a heat treating process as argon "is considered hazardous" as stated on the MSDS.

4. When using argon gas in a heat treating process, a heat treating company will use the argon gas in a sealed closed system to provide containment of the argon gas.

5. I have read attached Example 4 from U.S. Patent Application No. 11/628,933, and I have noted the language "Ten of each ISO size were heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes."

6. The use of an argon atmosphere as described in Example 4 requires that the entire file be heat treated in the furnace in order to keep the argon contained in a closed system.

7. I declare that all statements are made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like made are punishable by fine or imprisonment, or both, under Section 1001

- 2 -

of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Respectfully submitted,

Bodycote Thermal Processing, Inc.

By: Robert Struebing

Dated, August 23, 2011

Production Manager

- 3 -

Example 4 from U.S. Patent Application No. 11/628,933

Example 4

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

- 4 -

Praxair Material Safety Data Sheet

1. Chemical Product and Company Identification								
Product Name: Argon, compressed (MSDS No. P-4563-I)			Trade Names	Trade Names: Argon				
Chemical Na	me: Argon	***************************************	Synonyms: S	hielding gas, argon 40				
Chemical Family: Rare gas			Product Grad Zero, 4.8 Indu Trace Analytic Gas	Product Grades: 4.8 Oxygen Free, 4.8 Zero, 4.8 Inductively Coupled Plasma, 5.5 Trace Analytical, 6.0 Research, Industrial Gas				
Telephone: *Call eme involving represer	Emergencies: CHEMTREC: Routine: ergency numbers 2 this product. For ntative, or call 1-80	1-800-645-4633* 1-800-424-9300* 1-800-PRAXAIR 24 hours a day only routine information 00-PRAXAIR (1-800	Company Name: for spills, leaks, fire , contact your supp -772-9247).	Praxair, Inc. 39 Old Ridgebury Road Danbury, CT 06810-5113 e, exposure, or accidents lier, Praxair sales				
2. Hazards Identification								
		EMERGENCY	OVERVIEW					
	CAUTIONI High-proceurs ase							

CAUTION! High-pressure gas. Can cause rapid suffocation. May cause dizziness and drowsiness. Self-contained breathing apparatus and protective clothing may be required by rescue workers. Under ambient conditions, this is a colorless, odorless, tasteless gas with no odor.

OSHA REGULATORY STATUS: This material is considered hazardous by the OSHA Hazard Communications Standard (29 CFR 1910.1200).

POTENTIAL HEALTH EFFECTS:

Effects of a Single (Acute) Overexposure

Inhalation. Asphyxiant. Effects are due to lack of oxygen. Moderate concentrations may cause headache, drowsiness, dizziness, excitation, excess salivation, vomiting, and unconsciousness. Lack of oxygen can kill.

Skin Contact. No harm expected.

Swallowing. An unlikely route of exposure. This product is a gas at normal temperature and pressure.

Eye Contact. No harm expected.

Effects of Repeated (Chronic) Overexposure. No harm expected.

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A vertical line in the left margin indicates revised or new material.

Electronic Acknowledgement Receipt						
EFS ID:	10824065					
Application Number:	12977625					
International Application Number:						
Confirmation Number:	9691					
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:	115207.00005					
Receipt Date:	26-AUG-2011					
Filing Date:	23-DEC-2010					
Time Stamp:	15:15:58					
Application Type:	Utility under 35 USC 111(a)					

Payment information:

Submitted wi	th Payment	no			
File Listin	g:				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		115207_00005_Amd.pdf	4141384 8fd9bc85ebd083ed7f13f27020a295d9a715 a5be	yes	29

	Multi	part Description/PDF files in .	zip description		
	Document Do	Start	Er	nd	
	Amendment/Req. Reconsidera	tion-After Non-Final Reject	1		1
	Claim	IS	2	<u>.</u>	5
	Applicant Arguments/Remark	s Made in an Amendment	6	2	29
Warnings:			L L		
Information	1				
2	Pula 120, 121 or 122 Affidavite	115207 00005 Declaration add	2298161	20	5
2			ff30f45cb91c1d065355b79c46e7db0f5a15 5c1f	no	
Warnings:					
Information					
		Total Files Size (in bytes)	: 643	39545	
This Acknow characterize Post Card, as <u>New Applica</u> If a new appl 1.53(b)-(d) a Acknowledg <u>National Sta</u> If a timely su U.S.C. 371 ar	vledgement Receipt evidences recei d by the applicant, and including pa s described in MPEP 503. <u>tions Under 35 U.S.C. 111</u> lication is being filed and the applic nd MPEP 506), a Filing Receipt (37 C ement Receipt will establish the fili ge of an International Application u ibmission to enter the national stag nd other applicable requirements a	pt on the noted date by the Us age counts, where applicable. FR 1.54) will be issued in due ng date of the application. Inder 35 U.S.C. 371 e of an international applicati Form PCT/DO/EO/903 indicati	SPTO of the indicated It serves as evidence components for a filin course and the date si on is compliant with t ing acceptance of the s	documents of receipt s g date (see hown on thi the conditic application	;, .imilar to a 37 CFR is ons of 35 a as a
national stag <u>New Interna</u> If a new inter an internation and of the In national sect the application	ge submission under 35 U.S.C. 371 v tional Application Filed with the US rnational application is being filed a onal filing date (see PCT Article 11 a ternational Filing Date (Form PCT/F urity, and the date shown on this Ac on.	vill be issued in addition to the <u>PTO as a Receiving Office</u> and the international applicat nd MPEP 1810), a Notification RO/105) will be issued in due c knowledgement Receipt will d	e Filing Receipt, in due ion includes the neces of the International A ourse, subject to pres establish the internat	ssary compo ssary compo Application criptions co ional filing	onents for Number oncerning date of

PTO/SB/06 (07-06)

Approved for use through 1/31/2007. OMB 0651-0032 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

AF	Under the Paperwork Reduction Act of 1995, no persons are required to response PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875							ing Date 23/2010	To be Mailed
	D – PART I	SMALL	entity 🛛	OR	OTH SMA	HER THAN ILL ENTITY			
FOR	NU	NUMBER FILED NUMBER EXTRA				FEE (\$)		RATE (\$)	FEE (\$)
BASIC FEE (37 CFR 1.16(a), (b), c	or (c))	N/A		N/A	N/A			N/A	
SEARCH FEE (37 CFR 1.16(k), (i), c	or (m))	N/A		N/A	N/A			N/A	
EXAMINATION FE (37 CFR 1.16(o), (p), c	E pr (q))	N/A		N/A	N/A			N/A	
AL CLAIMS FR 1.16(i))		min	us 20 = *		X \$ =		OR	X \$ =	
PENDENT CLAIM FR 1.16(h))	S	mi	nus 3 = *		X \$ =			X \$ =	
PPLICATION SIZE 77 CFR 1.16(s))	ICATION SIZE FEE FR 1.16(s)) If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
	DENT CLAIM PRE	ESENT (3	7 CFR 1.16(j))					TOTAL	
* If the difference in column 1 is less than zero, enter "0" in column 2. TOTAL TOTAL									
APPLICATION AS AMENDED – PART II						OTHER THAN SMALL ENTITY OR SMALL ENTITY			ER THAN LL ENTITY
08/26/2011	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
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FIRST PRESEN	ITATION OF MULTIP	LE DEPENI	DENT CLAIM (37 CFF	R 1.16(j))			OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	
	(Column 1)		(Column 2)	(Column 3)		-			
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =		OR	X \$ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =		OR	X \$ =	
Application Siz	ze Fee (37 CFR 1.	16(s))							
	TATION OF MULTIP		DENT CLAIM (37 CFF	R 1.16(j))			OR		
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he "Highest Numbe the "Highest Numb 'Highest Number Pi	er Previously Paid er Previously Paid reviously Paid For'	For" IN TH For" IN T ' (Total or	IIS SPACE is less HIS SPACE is less Independent) is the	than 20, enter "20" s than 3, enter "3". e highest number fo	/ERIC [DANTZLER/	mn 1.	01.	
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UULTIPLE DEPENDENT CLAIM PRE e difference in column 1 is less than : APPLICATION SIZE FEE (Column 1) CLAIMS REMAINING AFTER AMENDMENT Total (37 CFR 1.16(n)) CLAIMS REMAINING CLAIMS REMAINING AFTER AMENDMENT TOTAL (37 CFR 1.16(n)) CLAIMS REMAINING CLAIMS REMAINING AFTER AMENDMENT TOTAL (37 CFR 1.16(n)) CLAIMS REMAINING AFTER AMENDMENT TOTAL (37 CFR 1.16(n)) CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLAIMS CLA	BASIC FEE (37 CFR 1.16(a), (b), or (c)) SEARCH FEE (37 CFR 1.16(b), (c), or (m)) EXAMINATION FEE (37 CFR 1.16(c), (p), or (q)) AL CLAIMS FR 1.16(f) PENDENT CLAIMS FR 1.16(h) If the specifical sheets of paperis \$250 (\$125 additional 50 stress of paperis \$250 (\$125 additional 50 stress sheets of paperis \$250 (\$125 additional 50 stress s	BASIC FEE N/A (37 CFR 1.16(k), (l), or (m)) N/A SEARCH FEE N/A (37 CFR 1.16(k), (l), or (m)) N/A EXAMINATION FEE N/A (37 CFR 1.16(k), (l), or (g)) minus 20 = AL CLAIMS minus 3 = PENDENT CLAIMS minus 3 = PPLICATION SIZE FEE If the specification and drawing sheets of paper, the applicatio is \$250 (\$125 for small entity) additional 50 sheets or fractior 35 U.S.C. 41(a)(1)(G) and 37 MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) e difference in column 1 is less than zero, enter *0° in column 2. APPLICATION AS AMENDED – PART II (Column 1) (Column 2) (Column 1) (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR Total (37 CFR 1.16(j)) * 18 Minus *** 20 Independent (37 CFR 1.16(j)) * 2 Minus *** 3 Independent (37 CFR 1.16(j)) * 2 Minus *** 20 Independent (37 CFR 1.16(j)) * 2 Minus *** 3 Independent (37 CFR 1.16(j)) * 2 Minus *** 3 Independent (37 CFR 1.16(j)) * 2 Minus *** 4 (Column 1) (Column 2)	ASIC FEE (37 CFR 1.16(a), (b), or (c) SEARCH FEE (37 CFR 1.16(b), (b), or (c) N/A N/A N/A N/A N/A N/A N/A N/A	ASIC FEE (37 CFR 1.16(b), (b), or (c)) N/A N/A N/A SEARCH FEE (37 CFR 1.16(b), (b), or (c)) N/A N/A N/A SEARCH FEE (37 CFR 1.16(b), (b), or (c)) N/A N/A N/A EXAMINATION FEE FR 1.16(b) N/A N/A N/A AL CLAIMS FFR 1.16(b) minus 3 = * * * PENDENT CLAIMS FR 1.16(b) minus 3 = * * * PULCATION SIZE FEE (7 CFR 1.16(s)) If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$12 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). TOTAL MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) TOTAL TOTAL APPLICATION AS AMENDED – PART II (Column 1) (Column 2) (Column 3) (Column 1) (Column 2) (Column 3) SMAL Mart Er * 18 Minus *** 20 = 0 x sze = Total (37 CFR 1.16(s)) * NUMBER PAID FOR X sze = x sitilo = ClaimS (3 CFR 1.16(s)) * 18 Minus *** = x sitilo = ClaimS (3 CFR 1.16(s)) * Minus *** = x s = <td>ASIC FEE (37 CFR.116(a), (b), or (c)) N/A N/A N/A SARACH FEE (37 CFR.116(b), (b), or (m)) N/A N/A N/A SAMUATION FEE (37 CFR.116(b), (b), or (m)) N/A N/A N/A AL CLAIMS minus 20 = 1 N/A N/A TOTAL LOUND SIZE FEE (1.16(h)) minus 3 = 1 T PPLICATION SIZE FEE (1.16(h)) If the specification and drawings exceed 100 is \$250 (\$125 for small entity) for each additional 50 sheets of radict thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). TOTAL WUTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(g)) TOTAL TOTAL BPLICATION AS AMENDED – PART II Column 1) (Column 2) (Column 3) (Column 1) (Column 2) Column 3) SMALL ENTITY B8/26/2011 CLAIMS AFTER AMENDMENT HIGHEST PAUP COR PRESENT PREVIOUSLY PREVIOUSLY PREVIOUSLY RATE (\$) ADDITIONAL FEE (\$). Total (07 CFR 1.16(s)) Independent AMENDMENT HIGHEST NUMBER PAUP COR X Stop = 0 X Stop = 0 Independent (2 CCAIMS AFTER AMENDMENT HIGHEST NUMBER PREVIOUSLY PREVIOUSLY PREVIOUSLY PRESENT PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOU</td> <td>SASIC FEE N/A N/A N/A N/A N/A SASIC FEE N/A N/A N/A N/A N/A SARCH FEE N/A N/A N/A N/A N/A STER 116(0), (0, or (m) N/A N/A N/A N/A N/A CLAMS minus 30 = : . 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TOTAL WUTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(g)) TOTAL TOTAL BPLICATION AS AMENDED – PART II Column 1) (Column 2) (Column 3) (Column 1) (Column 2) Column 3) SMALL ENTITY B8/26/2011 CLAIMS AFTER AMENDMENT HIGHEST PAUP COR PRESENT PREVIOUSLY PREVIOUSLY PREVIOUSLY RATE (\$) ADDITIONAL FEE (\$). Total (07 CFR 1.16(s)) Independent AMENDMENT HIGHEST NUMBER PAUP COR X Stop = 0 X Stop = 0 Independent (2 CCAIMS AFTER AMENDMENT HIGHEST NUMBER PREVIOUSLY PREVIOUSLY PREVIOUSLY PRESENT PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOUSLY PREVIOU	SASIC FEE N/A N/A N/A N/A N/A SASIC FEE N/A N/A N/A N/A N/A SARCH FEE N/A N/A N/A N/A N/A STER 116(0), (0, or (m) N/A N/A N/A N/A N/A CLAMS minus 30 = : . 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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.**

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number		12977625		
Filing Date		2010-12-23		
First Named Inventor	Neill F	ł. Luebke		
Art Unit		3776		
Examiner Name Matth		ew M. Nelson		
Attorney Docket Number		115207.00005		

		-			U.S.I	PATENTS			
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue C)ate	Name of Pate of cited Docu	entee or Applicant ment	Page Relev Figur	s,Columns,Lines where /ant Passages or Relevant es Appear
	1	6783438		2004-08	J-31	Aloise et al.			
	2	6422865		2002-07	7-23	Fischer			
	3	7175655		2007-02	2-13	Molaci			
If you wish to add additional U.S. Patent citation information please click the Add button.									
			U.S.P	ATENT	APPLI	CATION PUBL	ICATIONS		
Examiner Initial*	er Cite No Publication Number Kind Code ¹ Publication Name of Patentee or Applicant of cited Document				entee or Applicant ment	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear			
	1	20040171333		2004-09	9-02	Aloise et al.			
	2	20060014480		2006-01	-19	Aloise et al.			
If you wish to add additional U.S. Published Application citation information please click the Add button.									
	FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code²í	y Kind í Code4		Publication Date Name of Patentee Applicant of cited Document		e or	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

	Application Number		12977625	
	Filing Date		2010-12-23	
INFORMATION DISCLOSURE	First Named Inventor Neill I		ill H. Luebke	
Not for submission under 37 CFR 1 99)	Art Unit		3776	
	Examiner Name	Matth	ew M. Nelson	
	Attorney Docket Number		115207.00005	

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If you wis	h to ac	dd add	litional Foreign P	atent Document	citation	information pl	ease click the Add butto	n	
	NON-PATENT LITERATURE DOCUMENTS								
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Examiner	Signa	iture					Date Considered		
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.									
¹ See Kind C Standard ST ⁴ Kind of doo English lang	Codes o 1.3). ³ F cument uage tri	f USPT for Jap by the anslatic	O Patent Documents anese patent docume appropriate symbols a n is attached.	at <u>www.USPTO.GC</u> nts, the indication of as indicated on the d	<u>∖V</u> or MPE the year locument	EP 901.04. ² Ente of the reign of the under WIPO Stan	r office that issued the docume Emperor must precede the se dard ST.16 if possible. ⁵ Appli	ent, by the two-letter code (W rial number of the patent doc cant is to place a check mark	IPO ument. there if

	Application Number		12977625	
	Filing Date		2010-12-23	
	First Named Inventor Neill F		IH. Luebke	
OTATEMENT DT APPLICANT	Art Unit		3776	
	Examiner Name Matth		hew M. Nelson	
	Attorney Docket Numb	er	115207.00005	

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

None

SIGNATURE

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

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2011-09-12
Name/Print	Richard T. Roche	Registration Number	38599

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

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:

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

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

Date: September 12, 2011

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

IN THE UNITED PATENT AND TRADEMARK OFFICE

Applicant:	Neill H. Luebke
Application No.:	12/977,625
Filing Date:	December 23, 2010
Title:	Dental And Medical Instruments Comprising Titanium
Confirmation No.:	9691
Art Unit:	3776
Examiner:	Matthew M. Nelson

INFORMATION DISCLOSURE STATEMENT

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

Dear Sir:

M.P.E.P. § 609.02 notes that "The examiner will consider information which has been considered by the Office in a parent application when examining: ... (B) a divisional application filed under 37 CFR 1.53(b)... A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent."

Applicant has reviewed the "Notice of References Cited" in the present application. The references cited on the attached Information Disclosure Statement were cited and submitted by the Applicants or Examiner in U.S. Patent Application No. 11/628,933 (from which the present divisional application claims priority), but did not show up on the list of "Notice of References Cited" in 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.

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

Respectfully submitted, Neill H. Luebke

Dated: September 12, 2011

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

14470638

Electronic Acknowledgement Receipt		
EFS ID:	10922711	
Application Number:	12977625	
International Application Number:		
Confirmation Number:	9691	
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:	115207.00005	
Receipt Date:	12-SEP-2011	
Filing Date:	23-DEC-2010	
Time Stamp:	12:24:44	
Application Type:	Utility under 35 USC 111(a)	

Payment information:

Submitted with Payment		no				
File Listin	g:					
Document Number	Document Description		File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS)		Luebke_00005_IDS.pdf	66207	no	4
	10111(3000)			14e8621aa89dde013b4f88d552f05aa77ab 26c16		
Warnings:						
Information:						

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2 Transmittal Lottor	Luebke_00005_IDS_transmittal	63718		2	
2		.pdf	f1044110901ea3701e285f4c30e6ec7ff8fea 0ec	no	2
Warnings:		·			
Information					
		Total Files Size (in bytes):	: 129	9925	
characterize Post Card, as <u>New Applica</u> If a new app 1.53(b)-(d) a Acknowledg <u>National Sta</u> If a timely su U.S.C. 371 an national stag <u>New Interna</u> If a new inte an international sec the applicat	d by the applicant, and including parts described in MPEP 503. <u>tions Under 35 U.S.C. 111</u> lication is being filed and the applicand MPEP 506), a Filing Receipt (37 C ement Receipt will establish the filing <u>ge of an International Application under 35 U.S.C. 371 will applicable requirements and the applicable requirements and the applicable requirements and the application rise submission under 35 U.S.C. 371 with the US to a submission under 35 U.S.C. 371 with the US to a submission of the submission to enter the state of the submission under 35 U.S.C. 371 with the US to a submission of the submission of the submission to submiss being filed at the submission on this Actional filing date (see PCT Article 11 and the date shown on this Actional Submission the submission of </u>	ation includes the necessary of FR 1.54) will be issued in due of ng date of the application. <u>Inder 35 U.S.C. 371</u> e of an international applicati Form PCT/DO/EO/903 indicati vill be issued in addition to the <u>PTO as a Receiving Office</u> and the international applicati nd MPEP 1810), a Notification (O/105) will be issued in due co	It serves as evidence of components for a filing course and the date sh ng acceptance of the a e Filing Receipt, in due ion includes the neces of the International A ourse, subject to prese establish the internati	document of receipt s date (see hown on th he condition course. sary comp pplication criptions co onal filing	s, similar to a 37 CFR is ons of 35 n as a onents for Number oncerning date of

UNITED STATES PATENT AND TRADEMARK OFFICE



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

NOTICE OF ALLOWANCE AND FEE(S) DUE

26710 7590 09/21/2011 QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE SUITE 2040 MILWAUKEE, WI 53202-4497 EXAMINER

NELSON, MATTHEW M

ART UNIT PAPER NUMBER
3776

DATE MAILED: 09/21/2011

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/977,625	12/23/2010	Neill Hamilton Luebke	115207.00005	9691

TITLE OF INVENTION: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	12/21/2011

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

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED</u>. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:	If the SMALL ENTITY is shown as NO:
A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.	A. Pay TOTAL FEE(S) DUE shown above, or
B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or	B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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

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

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

125 of 163

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: <u>Mail</u> Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. 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 CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) have its own certificate of mailing or transmission. 26710 7590 09/21/2011 **Certificate of Mailing or Transmission QUARLES & BRADY LLP** 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. **411 E. WISCONSIN AVENUE SUITE 2040** MILWAUKEE, WI 53202-4497 (Depositor's name (Signature Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 12/977.625 12/23/2010 Neill Hamilton Luebke 115207.00005 9691 TITLE OF INVENTION: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM DATE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE APPLN, TYPE SMALL ENTITY ISSUE FEE DUE YES \$755 \$300 \$0 \$1055 12/21/2011 nonprovisional CLASS-SUBCLASS EXAMINER ART UNIT NELSON, MATTHEW M 433-102000 3776 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 or agents OR, alternatively, Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 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) LISSUE Fee A check is enclosed. Dublication 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 credit any overpayment, to Deposit Account Number ______ (enclose an extra copy of this fo Advance Order - # of Copies _ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) □ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature	Date
Typed or printed name	Registration No

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

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

OMB 0651-0033 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE 126 of 163 US ENDODONTICS, LLC., Petitioner

	ted States Pate	NT AND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 223 www.uspto.gov	TMENT OF COMMERCE Trademark Office OR PATENTS 313-1450
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/977,625	12/23/2010	Neill Hamilton Luebke	115207.00005	9691
26710 75	90 09/21/2011		EXAM	IINER
QUARLES & BF 411 E WISCONSI	RADY LLP N AVENUE		NELSON, M	ATTHEW M
SUITE 2040			ART UNIT	PAPER NUMBER
MILWAUKEE, W	I 53202-4497		3776	
			DATE MAILED: 09/21/201	1

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

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

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

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

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

Privacy Act Statement

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

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

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- 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.

	Application No.	Applicant(s)		
	10/077 605			
Notice of Allowability	Examiner	Art Unit		
	MATTHEW NELSON	3776		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.				
1. \square This communication is responsive to <u>8/26/2011</u> .				
 An election was made by the applicant in response to a rest requirement and election have been incorporated into this a 	riction requirement set forth during th action.	ne interview on; the restriction		
3. 🔲 The allowed claim(s) is/are				
 3. ☐ The allowed claim(s) is/are 4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some* c) ☐ None of the: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) ☐ hereto or 2) ☐ to Paper No./Mail Date				
Attachment(s) 5. Notice of Informal Patent Application 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) 6. Interview Summary (PTO-413), Paper No./Mail Date 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 7. Examiner's Amendment/Comment 4. Examiner's Comment Regarding Requirement for Deposit of Biological Material 8. Examiner's Statement of Reasons for Allowance 9. Other /TODD E. MANAHAN/ Supervisory Patent Examiner, Art Unit 3776				
U.S. Patent and Trademark Office	I			

Application/Control Number: 12/977,625 Art Unit: 3776

DETAILED ACTION

1. Amendment filed on 8/26/2011 is acknowledged.

Response to Amendment

2. The declaration under 37 CFR 1.132 filed 8/26/2011 in addition to the amendment to claim 1 is sufficient to overcome the previous rejections.

Allowable Subject Matter

3. Claims 1-2, 4-18, 20 allowed.

The following is an examiner's statement of reasons for allowance: a method for manufacturing a titanium alloy endodontic instrument having a shank with cutting edges by heat treating the entire shank at a temperature from 400 degrees Celsius up to but not equal to the melting point of the titanium alloy in an atmosphere consisting essentially of a gas unreactive with the shank (this temperature range and environment has been shown to be critical in providing distinguishing shape memory qualities along the entire length of the shank from the prior art, which teaches heat treatment at temperatures outside this range, treatment only to the tips of devices, and without the described atmosphere) was neither taught nor suggested by the prior art as a whole, either alone or in combination, and in combination with the elements set forth in the claims..

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

130 of 163

Application/Control Number: 12/977,625 Art Unit: 3776 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.

Application/Control Number: 12/977,625 Art Unit: 3776 Page 4

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

/MMN/

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

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	12977625	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776

Class	Subclass	Date	Examiner
433	102, 224	5/23/2011	MN
29	896.1, 896.11	5/23/2011	MN
433, 29	Updated	9/7/2011	MN
148	402,421,426,669	9/7/2011	MN

SEARCH NOTES

Search Notes	Date	Examiner
See EAST search history	5/23/2011	MN
Search request from Jermie Cozart	5/23/2011	MN
Updated EAST search	9/7/2011	MN
Search request from Jermie Cozart for 29 and 148 and George	9/7/2011	MN
Wyszomierski for 148		

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
29	896.1,896.11	9/7/2011	MN
148	669	9/7/2011	MN

U.S. Patent and Trademark Office	Part of Paper No. : 20110907

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	336	148/669.ccls. AND titanium	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 15:03
L2	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
82	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
S 6	544	Ni adj Ti AND anneal\$2 AND time AND hour	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:53
S7	16	Ni adj Ti AND anneal\$2 AND time AND "433". clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 10:54
S8	876	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:54
S9	53	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 14:55

S10	183	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 15:12
S11	29	S8 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/04/29 15:16
S12	891	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S13	67	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S14	16	Ni adj Ti AND anneal\$2 AND time AND "433". clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:57
S15	30	S12 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2008/10/21 12:58
S19	11	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((flexib \$5) SAME ("400" "425" "450" "475" "500" "525")) AND "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 14:47
S20	34	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((temperature) SAME ("400" "425" "450" "475" "500" "525")) AND "433". clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 14:48
S21	62	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND ((temperature) SAME (degree)) AND "433". clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/23 15:17

S22	903	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/24 12:26
S23	71	29/896.1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/02/24 12:26
S24	1092	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:13
S25	78	S24 AND (heat WITH treat\$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S26	917	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S27	32	S26 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S28	917	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S29	192	S28 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2009/08/03 13:14
S 30	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

<u>532</u>	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
S 35	1	(ISO WITH 3630-1) AND S34	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:45
S36	8	(ISO WITH "3630") AND S34	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/03/22 09:46
S37	989	("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel WITH Titanium))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/07 11:31
S38	258	("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel WITH Titanium)) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/07 11:32
S39	83	("433".clas. 29/896.1) AND ((Ni WITH Ti) (Nickel WITH Titanium)) AND endodontic AND deformation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/07 11:33
S40	1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:02
S41	226	S40 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:02

S42	52	S41 AND ((shape NEAR1 memory) (permanent NEAR1 deformation))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:34
S43	2	"5843244".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 15:56
S44	1139	433/102,224.ccls. 29/896.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S45	226	S44 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S46	1	S45 AND ((shape NEAR1 memory) (permanent NEAR1 deformation)) AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:06
S47	11	S45 AND (("54" "55" "56" "57") WITH nickel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/10/19 18:07
S48	10	(US-20040121283-\$).did. or (US-6431863-\$ or US- 6428634-\$ or US- 6375458-\$ or US- 4490112-\$ or US- 5775902-\$ or US- 5080584-\$ or US- 6206695-\$ or US- 7137815-\$ or US- 5653590-\$).did. or (US- 6422865-B-\$).did.	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S49	0	S48 AND gas	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S50	2	S48 AND atmosphere	US-PGPUB; USPAT; DERWENT	OR	ON	2011/05/12 09:28
S51	982	433/102,224.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:32

S52	8	S51 AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) AND (gas atmosphere)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:32
S53	10068	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal \$3 OR heat NEAR5 treated OR heat) SAME (gas atmosphere)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:35
S54	1335	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal \$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:36
S55	6	(endodontic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:36
S56	2	(endodontic) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S57	2	(endodontic "433".clas.) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal \$3 OR heat NEAR5 treated OR heat) SAME ((unreactive NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38
S58	16	(endodontic "433".clas.) AND ((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal \$3 OR heat NEAR5 treated OR heat) SAME ((inert NEAR1 gas))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:38

S59	51	(endodontic "433".clas.) AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:40
S61	1346	((Ni NEAR1 Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) AND (anneal \$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:46
S64	126	((Ni ADJ Ti) OR (Nickel NEAR1 Titanium) OR Nitinol) SAME (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 09:52
S 65	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
S 66	8234	(anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz \$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S67	8	"433".clas. AND (anneal \$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz \$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:00
S68	2	Nitinol AND (anneal\$3 OR heat NEAR5 treated OR heat) SAME ((unreactive inert (non NEAR1 oxidizing)) NEAR1 gas) SAME oxidiz \$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/05/12 10:01

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

S78	621	S76 AND titanium AND heat	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:18
S79	254	S76 AND titanium AND heat AND atmosphere	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:18
S80	159	S76 AND titanium AND heat AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S81	126	S76 AND titanium AND (heat WITH treat\$4) AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S82	121	S76 AND titanium AND (heat ADJ treat\$4) AND atmosphere AND (helium neon argon krypton xenon radon)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:19
S83	3	S76 AND titanium AND (heat ADJ treat\$4) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:20
S84	3	148/402.ccls. AND (heat ADJ treat\$4) AND endodontic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
S85	191	148/402.ccls. AND (heat ADJ treat\$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
S86	0	148/402.ccls. AND (heat ADJ treat\$4) SAME shank	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2011/09/07 13:24
S 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

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	0	(148/669).CCLS.	UPAD	OR	OFF	2011/09/07 15:04
S88	0	(29/896.1,896.11).CCLS.	UPAD	OR	OFF	2011/09/07 14:33

9/7/2011 3:10:58 PM

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BIB DATA SHEET

CONFIRMATION NO. 9691

SERIAL NUMBER FILING O			_ 371(c)	371(c) CLASS GF			GROUP ART UNIT			ATTORNEY DOCKET	
12/977,62	12/23/2010			433	3776		115207.00005				
RUL			E								
APPLICANTS Neill Hamilton Luebke, Brookfield, WI;											
** CONTINUING DATA ******************											
This application is a DIV of 11/628,933 12/07/2006 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 ** 01/07/2011											
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ADDRESS	ADDRESS										
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE SUITE 2040 MILWAUKEE, WI 53202-4497 UNITED STATES											
TITLE											
Dental and Medical Instruments Comprising Titanium											
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	FEES: Authority has been given in Paper No to charge/credit DEPOSIT ACCOUNT No for following:				1.16 Fees (Filing)						
					NT	□ 1.17 Fees (Processing Ext. of time)					
462					1.18 Fees (Issue)						
							• Other				
							Credit				
	Application/Control No.	Applicant(s)/Patent Under Reexamination									
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Issue Classification	12977625	LUEBKE, NEILL HAMILTON									
	Examiner	Art Unit									
	MATTHEW NELSON	3776									

ORIGINAL							INTERNATIONAL CLASSIFICATION								
	CLASS			SUBCLASS					С	LAIMED		NON-CLAIMED			
148			669			А	6	1	С	5 / 10 (2006.0)					
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CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					С	2	2	F	1 / 18 (2006.0)					
29	896.1	896.11													

	Claims re	numbere	d in the s	ame orde	er as prese	ented by a	applicant		СР	A [] 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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/MATTHEW NELSON/ Examiner.Art Unit 3776	9/7/2011	Total Claims Allowed:			
(Assistant Examiner)	(Date)	18			
/TODD MANAHAN/ Supervisory Patent Examiner.Art Unit 3776	09/09/2011	O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1	1a		

U.S. Patent and Trademark Office

Part of Paper No. 20110907

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	Claims r	enumbered	in the s	ame	order as	as presented by applicant CPA									T.D R.1.47				
	CLA	IM								DATE									
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Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-09) Approved for use through 03/31/2009. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number		12977625
Filing Date		2010-12-23
First Named Inventor	Neill I	ł. Luebke
Art Unit		3776
Examiner Name	Matth	ew M. Nelson
Attorney Docket Numb	er	115207.00005

U.S.PATENTS											
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue D)ate	Name of Pate of cited Docu	entee or Applicant ment	Page Relev Figur	s,Columns,Lines where /ant Passages or Relevant es Appear		
	1	6783438		2004-08	-31	Aloise et al.					
	2	6422865		2002-07	-23	Fischer					
	3	7175655		2007-02	-13	Molaci					
If you wish to add additional U.S. Patent citation information please click the Add button.											
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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publica Date	tion	Name of Pate of cited Docu	entee or Applicant ment	Pages,Columns,Lines where Relevant Passages or Relev Figures Appear			
	1	20040171333		2004-09	-02	Aloise et al.					
	2	20060014480		2006-01	-19	Aloise et al.					
If you wisl	If you wish to add additional U.S. Published Application citation information please click the Add button.										
				FOREI	SN PAT	ENT DOCUM	ENTS				
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code²í	y Kind i Code4		Publication Date Name of Patentee Applicant of cited Document		ə or	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear		

EFS Web 2.1.11 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.N./

Receipt date: 09/12/2011

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number		12977625
Filing Date		2010-12-23
First Named Inventor	Neill I	1. Luebke
Art Unit		3776
Examiner Name	Matth	ew M. Nelson
Attorney Docket Numb	er	115207.00005

	1											
If you wis	If you wish to add additional Foreign Patent Document citation information please click the Add button											
NON-PATENT LITERATURE DOCUMENTS												
Examiner Initials*	Cite No	Include (book, publish	name of th magazine, j er, city and/	e author ournal, s or coun	r (in CAPIT serial, sym try where ۱	AL LET posium, publishe	TERS), title c catalog, etc) d.	of t , da	he article (when approp ate, pages(s), volume-is	riate), title of the item ssue number(s),	T 5	
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If you wis	h to ac	d additi	onal non-pa	tent liter	rature doci	ument ci	tation informa	atic	on please click the Add	button	i	
						XAMINE	R SIGNATU	RE			******	
Examiner	Signa	iture	/Matthey	v Nelso	n/				Date Considered	10/17/2011		
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.												
¹ See Kind 0 Standard S ⁻¹ ⁴ Kind of do English lang	Codes o T.3). ³ F cument juage tr	f USPTO I for Japane by the app anslation is	Patent Docume se patent docu iropriate symbo s attached.	ents at <u>ww</u> uments, th ols as indi	w.USPTO.G e indication (cated on the	<u>QV</u> or MPI of the year document	EP 901.04. ² Er of the reign of t under WIPO St	iter he l and	office that issued the docume Emperor must precede the se lard ST.16 if possible. ⁵ Appli	ent, by the two-letter code (W rial number of the patent doc cant is to place a check mark	1PO :ument. < here if	

US ENDODONTICS, LLC., Petitioner

Receipt date: 09/12/2011	Application Number		12977625			
	Filing Date		2010-12-23			
	First Named Inventor	Neill I	H. Luebke			
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1 99)	Art Unit	-	3776			
	Examiner Name	Matth	ew M. Nelson			
	Attorney Docket Numb	er	115207.00005			

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

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

OR

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

See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

None

SIGNATURE

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

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2011-09-12
Name/Print	Richard T. Roche	Registration Number	38599

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

US ENDODONTICS, LLC., Petitioner

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:

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

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

IPR2015-00632 - Ex. 1013 US ENDODONTICS, LLC., Petitioner



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

Notice of Allowability	Application No.	Applicant(s)
	12/977,625	LUEBKE, NEILL HAMILTON
	Examiner	Art Unit
	MATTHEW NELSON	3776
	•	· · ·

The MAILING DATE of this communication appears on the All claims being allowable, PROSECUTION ON THE MERITS IS (OR REM herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other a NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. T of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPE	All cover sheet with the correspondence address AINS) CLOSED in this application. If not included appropriate communication will be mailed in due course. THIS his application is subject to withdrawal from issue at the initiative EP 1308.
1. X This communication is responsive to <i>the IDS filed on 9/12/2011</i> .	
2. An election was made by the applicant in response to a restriction requirement and election have been incorporated into this action.	quirement set forth during the interview on; the restriction
3. ⊠ The allowed claim(s) is/are <u>1,2,4-18 and 20</u> .	
 4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S. a) ☐ All b) ☐ Some* c) ☐ None of the: 	C. § 119(a)-(d) or (f).
1. 🔲 Certified copies of the priority documents have been rec	ceived.
2. 🗌 Certified copies of the priority documents have been rec	ceived in Application No
3. Copies of the certified copies of the priority documents	nave been received in this national stage application from the
International Bureau (PCT Rule 17.2(a)).	
* Certified copies not received:	
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this co noted below. Failure to timely comply will result in ABANDONMENT of th THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	mmunication to file a reply complying with the requirements nis application.
5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note INFORMAL PATENT APPLICATION (PTO-152) which gives reason	the attached EXAMINER'S AMENDMENT or NOTICE OF (s) why the oath or declaration is deficient.
6. CORRECTED DRAWINGS (as "replacement sheets") must be subm	litted.
(a)	ent Drawing Review (PTO-948) attached
1) hereto or 2) to Paper No./Mail Date	
(b) ☐ including changes required by the attached Examiner's Amendr Paper No /Mail Date	nent / Comment or in the Office action of
Identifying indicia such as the application number (see 37 CFR 1.84(c)) sho each sheet. Replacement sheet(s) should be labeled as such in the header	ould be written on the drawings in the front (not the back) of according to 37 CFR 1.121(d).
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGIC attached Examiner's comment regarding REQUIREMENT FOR THE D	CAL MATERIAL must be submitted. Note the DEPOSIT OF BIOLOGICAL MATERIAL.
Attachment(s)	
1. Notice of References Cited (PTO-892)	5. Notice of Informal Patent Application
2. 🔲 Notice of Draftperson's Patent Drawing Review (PTO-948)	6. Interview Summary (PTO-413),
 Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>9/12/2011</u> 	7. Examiner's Amendment/Comment
4. Examiner's Comment Regarding Requirement for Deposit	8. Examiner's Statement of Reasons for Allowance
of Biological Material	9. 🔲 Other
/Matthew M Nelson/	/TODD E. MANAHAN/
Examiner, Art Unit 3776	Supervisory Patent Examiner, Art Unit 3776
U.S. Patent and Trademark Office	

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: <u>Mail</u> Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This appropriate. All further indicated unless correcte maintenance fee notificat	form should be used f correspondence includir ed below or directed oth tions.	or transmitting the lag the Patent, advance of the Patent, advance of the patent of th	SSUE FEE and PU te orders and notification oy (a) specifying a ne	BLICATIO ation of m ew corresp	ON FEE (if required aintenance fees will pondence address; an	d). Blocks 1 through 5 s be mailed to the current nd/or (b) indicating a sep	should be completed where t correspondence address as arate "FEE ADDRESS" for
26710 QUARLES & 1 411 E. WISCON	ENCE ADDRESS (Note: Use BI 7590 09/21 BRADY LLP ISIN AVENUE	ock 1 for any change of addi /2011	ess)	Note Fee(s paper have I here State	: A certificate of ma s) Transmittal. This c rs. Each additional p its own certificate of Certifi eby certify that this 3 s Postal Service with	illing can only be used for certificate cannot be used aper, such as an assignme mailing or transmission. icate of Mailing or Tram Fee(s) Transmittal is bein a sufficient postage for fir	or domestic mailings of the for any other accompanying ent or formal drawing, must smission g deposited with the United st class mail in an envelope
SUITE 2040 MILWALIKEE	WI 53202 4407			addre trans	essed to the Mail S mitted to the USPTC	top ISSUE FEE address (571) 273-2885, on the d	above, or being facsimile ate indicated below.
WILL WAUKEE,	W1 55202-4497						(Depositor's name)
							(Signature)
							(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED IN	IVENTOR	А	TTORNEY DOCKET NO.	CONFIRMATION NO.
12/977,625	12/23/2010		Neill Hamilton	Luebke		115207.00005	9691
TITLE OF INVENTION	: DENTAL AND MEDI	CAL INSTRUMENT	'S COMPRISING TI	TANIUM			
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION H	FEE DUE	PREV. PAID ISSUE F	EE TOTAL FEE(S) DUE	E DATE DUE
nonprovisional	YES	\$755	\$300		\$0	\$1055	12/21/2011
EXAM	INER	ART UNIT	CLASS-SUBC	LASS			
NELSON, MA	ATTHEW M	3776	433-1020	000			
 Change of corresponded CFR 1.363). Change of corresponded Address form PTO/SE "Fee Address" indi PTO/SB/47; Rev 03-0 Number is required. 	ence address or indication ondence address (or Cha 3/122) attached. ication (or "Fee Address' 12 or more recent) attache	n of "Fee Address" (3 nge of Corresponden " Indication form ed. Use of a Custome	7 2. For printing (1) the names or agents OR, (2) the name registered attr 2 registered p listed, no nam	g on the pa s of up to , alternative of a single orney or ag patent attor- ne will be r	ttent front page, list 3 registered patent a ely, firm (having as a m gent) and the names neys or agents. If no rinted.	ttorneys 1_Quarles ember a 2 of up to name is 3	& Brady LLP
3. ASSIGNEE NAME A PLEASE NOTE: Unl recordation as set forth (A) NAME OF ASSIG Gold Standa	ND RESIDENCE DATA ess an assignee is identi h in 37 CFR 3.11. Comp GNEE ard Instruments, LI	A TO BE PRINTED (ified below, no assig oletion of this form is	DN THE PATENT (p nee data will appear NOT a substitute for (B) RESIDENC Brookfi	orint or type on the pa filing an a Œ: (CITY ield, WI	e) tent. If an assignee ssignment. and STATE OR CO	is identified below, the c UNTRY)	locument has been filed for
Please check the appropri	iate assignee category or	categories (will not b	be printed on the pate	nt): 🗖	Individual 🖾 Corp	oration or other private gr	oup entity 🖵 Government
 4a. The following fee(s) a Issue Fee Publication Fee (N Advance Order - # 	are submitted: To small entity discount p t of Copies	permitted)	4b. Payment of Fee A check is e Payment by The Director overpayment	e(s): (Pleas nclosed. credit card is hereby t, to Depos	e first reapply any I. Form PTO-2038 is authorized to charge it Account Number	previously paid issue fee attached. the required fee(s), any de 170055 (enclose a	shown above) eficiency, or credit any un extra copy of this form).
5. Change in Entity Stat	tus (from status indicated	d above)					
■ a. Applicant claims NOTE: The Issue Fee and interest as shown by the r	s SMALL ENTITY statu d Publication Fee (if requerecords of the United Sta	uired) will not be acc tes Patent and Trader	b. Applicant epted from anyone of nark Office.	is no long	er claiming SMALL e applicant; a registe	ENTITY status. See 37 C red attorney or agent; or t	FR 1.27(g)(2). he assignee or other party in
Authorized Signature	/Richard T. Roch	ie/			Date _ Novem	ber 23, 2011	
Typed or printed name	e <u>Richard T. Roc</u> ł	10			Registration No.	38,599	
This collection of inform an application. Confident submitting the completee this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	ation is required by 37 C tiality is governed by 35 4 application form to the ons for reducing this bur firginia 22313-1450. DO 13-1450.	FR 1.311. The inform U.S.C. 122 and 37 C USPTO. Time will rden, should be sent t NOT SEND FEES C	nation is required to c FR 1.14. This collec vary depending upon o the Chief Informati DR COMPLETED FO	obtain or re tion is esti the indivi ion Officer ORMS TO	tain a benefit by the mated to take 12 min dual case. Any comu , U.S. Patent and Tr. THIS ADDRESS. S	public which is to file (an nutes to complete, includi ments on the amount of ti ademark Office, U.S. Dep END TO: Commissioner	d by the USPTO to process) ng gathering, preparing, and me you require to complete partment of Commerce, P.O. for Patents, P.O. Box 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.

OMB 0651-0033U.S. Patent and Trademark Office: LLS DEPARTMENT OF COMMERCE153 of 163US ENDODONTICS, LLC., Petitioner

Electronic Patent Application Fee Transmittal						
Application Number:	12	12977625				
Filing Date:	23-	-Dec-2010				
Title of Invention:	DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM					
First Named Inventor/Applicant Name:	Neill Hamilton Luebke					
Filer:	Ric	hard T. Roche				
Attorney Docket Number:	11:	5207.00005				
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	870	870	
Publ. Fee- early, voluntary, or normal		1504	1	300	300	

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1170

Electronic Acknowledgement Receipt				
EFS ID:	11473684			
Application Number:	12977625			
International Application Number:				
Confirmation Number:	9691			
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:	115207.00005			
Receipt Date:	23-NOV-2011			
Filing Date:	23-DEC-2010			
Time Stamp:	12:15:39			
Application Type:	Utility under 35 USC 111(a)			

Payment information:

Submitted wi	th Payment	yes	yes			
Payment Type	2 2	Deposit Account	Deposit Account			
Payment was	successfully received in RAM	\$1170				
RAM confirma	ition Number	10243				
Deposit Acco	unt	170055				
Authorized U	ser					
File Listin	g:					
Document	Document Description	File Name	File Size(Bytes)/	Multi	Pages	
Number			Message Digest	Part /.zip	(if appl.)	
		156 of 163 US ENDODONTICS, LLC., Petitioner				

		Total Files Size (in bytes):	10)38678	
Information	:		1		
Warnings:					
2	Fee Worksheet (SB06)	fee-info.pdf	31702 e170c038daf9b65c83203d67180fa970f015 2203	no	2
Information	:				
Warnings:					
i issue ree rayment (i ro osb)			36218e82818a2ad279d67995faa6bd81481 a7ab8	10	
1	Issue Fee Payment (PTO-85B)	lssueFee PDF	1006976	no	1

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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





APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/977,625	12/27/2011	8083873	115207.00005	9691
26710 7	590 12/07/2011			

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

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

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

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

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

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

Neill Hamilton Luebke, Brookfield, WI;

I hereby certify that, on the date shown below, this correspondence is being transmitted via the U.S. Patent and Trademark Office's Patent Electronic Filing System (EFS). Date of Signature And Deposit: <u>November 20, 2013</u> /Richard T. Roche/

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

US Patent No.: 8,083,873 Issued: December 27, 2011 Title: Dental and Medical Instruments Comprising Titanium Applicants: Neill H. Luebke Serial No.: 12/977,625 Filed: December 23, 2010 Docket: 115207.00005

Request for Certificate of Correction

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

Dear Sir:

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

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

Respectfully submitted,

Neill H. Luebke

Date: November 20, 2013

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

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page <u>1</u> of <u>1</u>

PATENT NO. : 8/083,873

APPLICATION NO.: 12/977,625

ISSUE DATE : December 27, 2011

INVENTOR(S) : Neill H. Luebke

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

Column 10, line 17 "1 in 2" should read --1 to 2--

Column 10, line 27 "of c aim" should read --of claim--

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

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, 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.

16708612

IPR2015-00632 - Ex. 1013 US ENDODONTICS, LLC., Petitioner

Electronic Acknowledgement Receipt				
EFS ID:	17450443			
Application Number:	12977625			
International Application Number:				
Confirmation Number:	9691			
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:	115207.00005			
Receipt Date:	20-NOV-2013			
Filing Date:	23-DEC-2010			
Time Stamp:	10:25:30			
Application Type:	Utility under 35 USC 111(a)			

Payment information:

Submitted with Payment no						
File Listin	g:					
Document Number	Document Description		File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Paquat for Cartificate of Correction	Luebke-00005-Certificate-	211508	no	2	
			Correction.PDF	d1cc786a2f2ead6794d5af4514439500c7c0 fbba	110	2
Warnings:						
Information:						

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

 PATENT NO.
 : 8,083,873 B2

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 : 12/977625

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 INVENTOR(S)
 : Luebke

Page 1 of 1

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

In the Claims

Column 10, line 17 claim 8 "1 in 2" should read --1 to 2--

Column 10, line 27 claim 12 "of c aim" should read -- of claim--

Signed and Sealed this Twenty-eighth Day of January, 2014

Michelle K. Lee

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