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UTILITY PATENT APPLICATION TRANSMITTAL (Only for new nonprovisional applications under 37 CFR 1.53(b))	Attorney Docket No.	115207.00009
	First Inventor	Neill H. Luebke
	Title	Dental and Medical Instruments Comprising Titanium
	Express Mail Label No.	

APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents.	ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450
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18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:

 Continuation Divisional Continuation-in-part (CIP) of prior application No.: 13/336,579
Prior application information: Examiner _____ Art Unit: 3732**19. CORRESPONDENCE ADDRESS**
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This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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16020500

Dental and Medical Instruments Comprising Titanium

CROSS-REFERENCES TO RELATED APPLICATIONS

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

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

10 **[0002]** Not Applicable.

BACKGROUND OF THE INVENTION

1. Field of the Invention

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

2. Description of the Related Art

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

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

substitute. Figure 1 also shows the apical foramen 22 through which blood and nerves pass to support the pulp tissues.

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

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

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

[0009] While file 34 can easily bend to fit the curved shape of a canal due to the flexibility of the small diameter shank 42, with increasingly larger sizes of files, the file becomes significantly less flexible and becomes more and more difficult to insert through the curved portion of the canal. In some cases, the relatively inflexible file

will cut only on the inside of the curve and will not cut on the outside of the curvature of the root canal. Thus, the problems, which occur during the therapy of a root canal, are often the result of the basic stiffness of the files, particularly with the respect to the instruments of larger diameter.

5 **[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; 10 5,264,055; 5,358,586; 5,947,723; 6,132,209; and 6,258,182.) U.S. Patent No. 5,464,362 describes an endodontic instrument of a titanium alloy that is machined under certain specific operating parameters to produce an instrument having high flexibility, high resistance to torsion breakage, and sharp cutting edges. U.S. Patent 15 No. 6,315,558 proposes the use of superelastic alloys such as nickel-titanium that can withstand several times more strain than conventional materials without becoming plastically deformed. This property is termed shape memory, which allows the superelastic alloy to revert back to a straight configuration even after clinical use, 20 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 25 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 30

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.

5 The shank has high flexibility, high resistance to torsion breakage, maintains shape upon fracture, can withstand increased strain, and can hold sharp cutting edges. Thus, it solves the problems encountered when cleaning and enlarging a curved root canal.

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

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

20 BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

25 **[0018]** Figures 2a-2e represent a prior art procedure for preparing a tooth for endodontic restoration.

[0019] Figure 3 is a graph showing the results of a study of torsion (M_t) reported in g·cm performed in accordance with “ISO Standard 3630-1 Dentistry - Root-canal instruments - Part 1: General requirements and ANSI/ADA Specification No. 28,

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