


21861 U.S. PTO  
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**PROVISIONAL APPLICATION FOR PATENT COVER SHEET**  
 This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)				
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)		
Neill H.	Luebke	Brookfield, Wisconsin		
Additional inventors are being named on the ___ separately numbered sheets attached hereto				
TITLE OF THE INVENTION (500 characters max)				
Dental and Medical Instruments Comprising Titanium and Dental and Medical Instruments Having a Coating				
Direct all correspondence to: <b>CORRESPONDENCE ADDRESS</b>				
<input checked="" type="checkbox"/> Customer Number	000043629			
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ENCLOSED APPLICATION PARTS (check all that apply)				
<input checked="" type="checkbox"/> Specification	Number of Pages	12	<input type="checkbox"/> CD(s), Number	
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	1	<input checked="" type="checkbox"/> Other (specify)	Return Postcard
<input type="checkbox"/> Application Data Sheet.	See 37 CFR 1.76			
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT				
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE AMOUNT (\$)
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees				
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:	17-0055			\$80.00
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.				
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.				
<input checked="" type="checkbox"/> No.				
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are:	_____			

17548 U.S. PTO  
 60/578091

060804

Respectfully submitted,  
  
 SIGNATURE \_\_\_\_\_  
 TYPED or PRINTED NAME Richard T. Roche  
 TELEPHONE 414-277-5805

Date 6, 8, 04  
 REGISTRATION NO. 38,599  
 (if appropriate)  
 Docket Number: 115207.00002

**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending on the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Patent Application, Commissioner for Patents, Alexandria, VA 22313-1450.

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PTO/SB/17 (10-03)  
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<b>FEE TRANSMITTAL</b>		<b>Complete if Known</b>	
<b>for FY 2004</b>		Application Number	
<i>Effective 10/01/2003. Patent fees are subject to annual revision.</i>		Filing Date	Filed Herewith
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		First Named Inventor	Neill H. Luebke
<b>TOTAL AMOUNT OF PAYMENT</b> (\$ ) 80.00		Examiner Name	
		Art Unit	
		Attorney Docket No.	115207.00002

<b>METHOD OF PAYMENT (check all that apply)</b>		<b>FEE CALCULATION (continued)</b>																																																																																																																																																																																					
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ADDITIONAL FEES</b> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Large Entity</th> <th colspan="2">Small Entity</th> <th rowspan="2">Fee Description</th> <th rowspan="2">Fee Paid</th> </tr> <tr> <th>Fee Code</th> <th>Fee (\$)</th> <th>Fee Code</th> <th>Fee (\$)</th> </tr> </thead> <tbody> <tr><td>1051</td><td>130</td><td>2051</td><td>65</td><td>Surcharge - late filing fee or oath</td><td></td></tr> <tr><td>1052</td><td>50</td><td>2052</td><td>25</td><td>Surcharge - late provisional filing fee or cover sheet</td><td></td></tr> <tr><td>1053</td><td>130</td><td>1053</td><td>130</td><td>Non-English specification</td><td></td></tr> <tr><td>1812</td><td>2,520</td><td>1812</td><td>2,520</td><td>For filing a request for <i>ex parte</i> reexamination</td><td></td></tr> <tr><td>1804</td><td>920*</td><td>1804</td><td>920*</td><td>Requesting publication of SIR prior to Examiner action</td><td></td></tr> <tr><td>1805</td><td>1,840*</td><td>1805</td><td>1,840*</td><td>Requesting publication of SIR after Examiner action</td><td></td></tr> <tr><td>1251</td><td>110</td><td>2251</td><td>55</td><td>Extension for reply within first month</td><td></td></tr> <tr><td>1252</td><td>420</td><td>2252</td><td>210</td><td>Extension for reply within second month</td><td></td></tr> <tr><td>1253</td><td>950</td><td>2253</td><td>475</td><td>Extension for reply within third month</td><td></td></tr> <tr><td>1254</td><td>1,480</td><td>2254</td><td>740</td><td>Extension for reply within fourth month</td><td></td></tr> <tr><td>1255</td><td>2,010</td><td>2255</td><td>1,005</td><td>Extension for reply within fifth month</td><td></td></tr> <tr><td>1401</td><td>330</td><td>2401</td><td>165</td><td>Notice of Appeal</td><td></td></tr> <tr><td>1402</td><td>330</td><td>2402</td><td>165</td><td>Filing a brief in support of an appeal</td><td></td></tr> <tr><td>1403</td><td>290</td><td>2403</td><td>145</td><td>Request for oral hearing</td><td></td></tr> <tr><td>1451</td><td>1,510</td><td>1451</td><td>1,510</td><td>Petition to institute a public use proceeding</td><td></td></tr> <tr><td>1452</td><td>110</td><td>2452</td><td>55</td><td>Petition to revive - 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<b>SUBMITTED BY</b>		<i>(Complete (if applicable))</i>	
Name (Print/Type)	Richard T. Roche	Registration No. (Attorney/Agent)	38,599
Signature	<i>Richard T. Roche</i>	Telephone	414-277-5805
		Date	6-8-2004

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

CROSS-REFERENCES TO RELATED APPLICATIONS

**[0001]** Not Applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

**[0002]** Not Applicable.

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BACKGROUND OF THE INVENTION

1. Field of the Invention

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

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2. Description of the Related Art

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

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**[0005]** Figure 1 shows a representation of a tooth to provide background. Root canal therapy is generally indicated for teeth having sound external structures but having diseased, dead or dying pulp tissues. Such teeth will generally possess intact enamel 10 and dentin 12, and will be satisfactorily engaged with the bony tissue 20, by among other things, healthy periodontal ligaments 18. In such teeth, the pulp tissue 14, and excised portions of the root 16, should be replaced by a biocompatible substitute. Figure 1 also shows the apical foramen 22 through which blood and nerves pass to support the pulp tissues.

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**[0006]** One method for the preparation of a root canal for filling is represented by Figures 2a-2e. A tooth having a basically sound outer structure 24 but diseased pulp 26, is cut with conventional or coated dental drill 28 creating a coronal access opening 30. A broach is used for gross removal of pulp material 26 from the root canal through the coronal access opening 30. The void 32 formed is enlarged as in Figure 2d with reamers and/or files 34, to result in a fully

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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.

5 **[0007]** During this procedure, small endodontic instruments (e.g., files) are utilized to clean and enlarge the long narrow tapered root canals. While most files perform entirely satisfactorily when cleaning and enlarging a straight root canal, problems have been encountered when using certain files to clean and enlarge a curved root canal. As will be understood by those skilled in the art, a very large portion of the root canals encountered by a practicing dentist and/or endodontist  
10 are of the curved variety, and thus this problem is a significant one for the profession.

15 **[0008]** When performing an operation on a curved root canal with a smaller diameter file, the file can easily be inserted into the curved canal and will easily bend to fit the curved shape of the canal due to the flexibility of the small diameter file. However, with increasingly larger sizes of files, the file becomes significantly less flexible and becomes more and more difficult to insert through the curved portion of the canal. In some cases, the relatively inflexible file will cut only on the outside of the curve and will not cut on the inside of the curvature of the root canal. Thus, the problems which occur during the therapy of a root canal are  
20 often the result of the basic stiffness of the files, particularly with the respect to the instruments of larger diameter.

25 **[0009]** Various solutions have been proposed to limit the problems encountered when cleaning and enlarging a curved root canal with a file. For example, U.S. Patent No. 4,443,193 describes a shaped endodontic instrument that is said to solve this problem. U.S. Patent No. 5,464,362 describes an endodontic instrument of a titanium alloy that is machined under certain specific operating parameters to produce an instrument having high flexibility, high resistance to torsion breakage, and sharp cutting edges. U.S. Patent No.  
30 6,315,558 proposes the use of superelastic alloys such as nickel titanium that can withstand several times more strain than conventional materials without becoming plastically deformed.

**[0010]** It has also been proposed to manufacture orthodontic appliances from beta-titanium. However, it is believed that this material has not been proposed for endodontic instruments. For background on beta-titanium, see U.S. Patent Nos. 4,197,643; 4,892,479; 4,952,236; 5,156,807; 5,232,361; 5,264,055; 5,358,586; 5,947,723; 6,132,209; and 6,258,182.

**[0011]** In spite of the aforementioned advances, there remains a need for medical and dental instruments, and particularly endodontic instruments, such as drills, burs and files, that have high flexibility, have high resistance to torsion breakage, maintain shape upon fracture, can withstand increased strain, and can hold sharp cutting edges.

#### SUMMARY OF THE INVENTION

**[0012]** The present invention overcomes the problems encountered when cleaning and enlarging a curved root canal. In one aspect, the invention provides endodontic instruments fabricated from beta-titanium. These instruments have improved sharpness, cutting ability, and instrument longevity compared to instruments fabricated from nickel-titanium. Also, beta-titanium is superior because it is harder and hence will hold an edge better and still maintains near the flexibility of nickel-titanium to negotiate curved canals. Thus, endodontic instruments fabricated from beta-titanium according to the invention limit the problems encountered when cleaning and enlarging a curved root canal.

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



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