



American National Standard/
American Dental Association
Specification No. 28

Root Canal Files and Reamers, Type K

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**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 28
FOR ROOT CANAL FILES AND REAMERS, TYPE K**

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 28 for Root Canal Files and Reamers, Type K. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. The American National Standards Institute granted approval of ADA Specification No. 28 as an American National Standard on January 15, 2008.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: Frank Lentine (chairman), Lentine Enterprises, Ltd., Taylor, MI; Timothy Svec (secretary), Tigard, OR; Dave Clement, Oklahoma University, Oklahoma City; Gerald Glickman, Baylor College of Dentistry, Dallas, TX; Lonnie Graybill, Miltex Corp., York, PA; Jeff Hutter, Boston University School of Dentistry, Boston, MA; John Ingle, San Diego, CA; Nick Lenz, Endodent, Inc., Duarte, CA; Neill H. Luebke, Brookfield, WI; Randall Maxwell, Dentsply Endodontics, Tulsa, OK; Spiro Megremis, American Dental Association, Chicago, IL; Erin Riley, FDA Office of Device Evaluation, Rockville, MD; Michael Sobotka, Charles B. Schwed Co., Kew Gardens, NY; and Lars Spangberg, University of Connecticut Health Center, Farmington.

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FOREWORD

(This foreword does not form a part of ANSI/ADA Specification No. 28 Root Canal Files and Reamers, Type K).

This revision takes into consideration various portions of ISO 3630 Dental Root Canal Instruments.

The working group WG 4.27 has updated information and adjusted clause numbers to accommodate the revisions. A new section, Definitions, has been added using definitions common the ISO 3630.

The Title of clause 3.2 (now 4.2) has been changed from Sterilization to Heat effects of sterilization.

The entire section under Corrosion dealing with the Boiling test has been removed. The working group decided that the effects of the steam autoclave were sufficient to test for corrosion cause by water.

Figure 5, Handle pull strength fixture has been removed. The test procedure text is sufficient to identify the test equipment.

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1 SCOPE AND CLASSIFICATION

1.1 Scope

This specification is for endodontic files and reamers having a working part taper of 2% (0.02 millimeter per millimeter of length) and standard sizes for use in endodontic preparation or shaping operations.

1.2 Types

The instruments covered by this specification shall be of the following types.

I. Reamers, type K

II. Files, type K

2 APPLICABLE SPECIFICATIONS AND REGULATIONS

The following standards contain provisions, which, through reference in this text, constitute provisions of this specification. At the time of publication, the editions indicated were valid. Since all standards are subject to revision, parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent edition of the specification or standard listed.

2.1 Specifications

ANS Metric Practice, 2210.1-1976

(American National Standards are available from the American National Standards Institute, 25 West 43rd St., New York, NY 10036 or www.ansi.org).

ASTM B16 for free-cutting brass

(ASTM standards are available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428 or www.astm.org).

ANSI/ADA Specification No. 101 for Root canal instruments: General requirements

(ANSI/ADA specifications are available from the American Dental Association, 211 East Chicago Ave., Chicago, IL 60611 or www.ada.org).

2.2 Regulations

FDA Quality System Requirements, in CFR Title 21, Subchapter H-Medical Devices, Part 820, Quality System Regulation. Subpart B-Quality System Requirements

(Available from the U.S. Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857-0001 or www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1&subpartNode=21:8.0.1.1.12.2)

3 Definitions

3.1 Operative part

Portion of the instrument from the tip to the handle or shank.