



American National Standard/
American Dental Association
Specification No. 28

Root Canal Files and Reamers, Type K for Hand Use

This is a preview of "ANSI/ADA Specificati...". [Click here to purchase the full version from the ANSI store.](#)

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

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 28 for Root Canal File and Reamers, Type K for Hand Use. 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 March 3, 2002. This standard becomes effective March 3, 2003.

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; Preston Blain, Defense Personnel Support Center, Philadelphia, PA; William Frezel, Premier Dental, Norristown, PA; Richard Geary, American Dental Association, Chicago, IL; Max Gibbs, Austin, TX; Gerald Glickman, University of Texas, Houston, TX; Lonnie Graybill, Union Broach, York, PA; John L. Ingle, San Diego, CA; Max Lenz, Endodent Inc., Monrovia, CA; Neill H. Luebke, Brookfield, WI; Paul Murphy, Syntex Dental Products Inc., Valley Forge, PA; Herbert Schilder, Boston University Medical Center, Boston, MA; Michael Sobotka, Charles B. Schwed, Kew Gardens, NY; Lars Spangberg, University of Connecticut, Farmington, CT; Timothy Svec, University of Texas, Houston, TX; Harmeet Walia, University of Florida, Gainesville, FL; Jean Zuiker, Hu-Friedy, Chicago, IL.

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

FOREWORD

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

Revision of Specification No. 28-1988 includes adoption of Specification No. 28a, Root Canal Files and Reamers, Type K Addendum published in 1996. The ADA Standards Committee on Dental Products (SCDP) Working Group 4.27 incorporated a number of editorial changes based on commonly accepted documents updates and clarification of the previous edition. Listed below is a summary of the technical changes or additions in the revised document.

Title "FOR HAND USE" added reflecting the restriction identified in the Scope.

4.2 Inspection

Replaced "2X magnification" with "without magnification" was determined by the working group, WG 4.27, to be sufficient to identify metal corrosion.

5.2.2.1 Diameters

Requirement for measurement of diameter D0 was removed. The working group added the procedure for calculation of the tip diameter.

5.2.2.2 Taper

Procedure for determination of the taper value was improved using wording from ISO 3630.

5.2.2.3 Tip

Procedure was expanded to define the proper visual orientation of the tip for reproducible measurement.

5.2.2.4 Length

Definition of instrument length was added to the measurement procedure.

6 Preparation for delivery

Entire section replaced by duplication of sections for Designation, marking and identification. Packaging, and Marking from ISO 3630.

7 Notes

Section deleted since information is no longer required.

The provisions of this new document are harmony with ISO 3630, Part 1, 1992 except for the method to identify the location for the diameter measurement points. The subcommittee maintains that due to the nature of diameter dimensions along a taper, it is useful for proper understanding by testers and users, to designate the location with a descriptive subscript which informs. For instance, the location of the diameter along the taper is specified at 3 mm and 16 mm from the tip. We designate these diameters as D3 and D16 while ISO 3630 designates these same diameters as d 2 and d3.

Table 1

Size 006 added and tip dimension listed as referenced. Tolerance for sizes 070-140 changed to ± 0.04 . Contents (color code) moved from Table 4 to Table 1. Table 4 deleted.

Tables 2 and 3

Size 006 added and values converted to SI units.

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

1 SCOPE AND CLASSIFICATION

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

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

A Reamers, type K

B Files, type K

2 APPLICABLE SPECIFICATIONS AND REGULATIONS

The following documents form a part of this specification.

2.1 Specifications

ANS Metric Practice, 2210.1-1976.

ASTM B16 for free-cutting brass.

2.2 Regulations

Quality System Requirements (QSR) issued by the Food and Drug Administration.

3 REQUIREMENTS

3.1 Dimension

3.1.1 Diameters

The diameters designated as D0, D3, and D16 for all sizes of files and reamers with an allowable tolerance shall be as shown in Table 1 and Figure 1 when tested as specified in 5.2.2.1.

3.1.2 Taper

The taper of the cutting portion of the file or reamer shall be 0.02 mm per millimeter of cutting length when tested as specified in 5.2.2.2.

3.1.3 Tip

The tip length of the instrument shall be measured by the development of an included angle of 75° with an allowable tolerance of $\pm 15^\circ$ for all instruments as shown in Figure 1 when tested as specified in 5.2.2.3. Shape of tip is optional.

3.1.4 Lengths

The length of the cutting portion of the instrument shall not be less than 16 mm. The length of the instrument shall be the nominal length with a tolerance of ± 0.5 mm when tested as specified in 5.2.2.4.

3.2 Sterilization

Following one cycle of sterilization by autoclave and dry heat, the instruments shall still comply with requirements specified in 3.2, 3.3 and 3.5 when treated as specified in 5.3.2.1.

3.3 Resistance to fracture by twisting

The maximum torsion strength before failure and the angular deflection at failure of each