



American National Standard/
American Dental Association
Specification No. 63

Root Canal Barbed Broaches and Rasps



American Dental Association
Council on Scientific Affairs 2006



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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 63 FOR ROOT CANAL BARBED BROACHES AND RASPS

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 63 for Root Canal Barbed Broaches and Rasps. 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. 63 as an American National Standard on November 29, 2006.

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; Gerald Glickman, Baylor College of Dentistry, Dallas, TX; Lonnie Graybill, Miltex Instrument Co., York, PA; John Ingle, American Association of Endodontists, San Diego, CA; Nick Lenz, Endodent, Inc., Duarte, CA; Neill Luebke, Brookfield, WI; Spiro Megremis, American Dental Association, Chicago, IL; Robert Postal, Medidentia, Woodside, NY; Michael Sobotka, Charles B. Schwed Co., Key Gardens, NY; and Timothy Svec, The University of Texas, Houston, TX.

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FOREWORD

(This foreword does not form a part of ANSI/ADA Specification No. 63 for Root Canal Barbed Broaches and Rasps).

This revision to ANSI /ADA Specification No. 63 eliminates the referencing of specific materials for compliance with the requirement that the selected material allow the instruments to meet the requirements of this specification. The revision requires that an appropriate material be utilized that allows for adherence to the requirements of this specification.

The other significant change was removal of the Boiling Water test for corrosion. The Autoclave test was determined to be sufficient to test the effects of water. Minor editorial corrections are included.

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1 SCOPE AND CLASSIFICATION

1.1 Scope

This specification is for root canal instruments for hand use utilized in endodontic preparation.

1.2 Type

The instruments covered by this specification shall be of the following types and shall be made from an appropriate material which allows for adherence to the requirements of this specification.

I. Barbed Broach;

II. Rasp.

2 APPLICABLE SPECIFICATIONS AND REGULATIONS

2.1 Specifications

ANSI/ADA Specification No. 28-2002 for Root Canal Files and Reamers Type K for Hand Use & Addendum.

(ANSI/ADA standards may be purchased from the American Dental Association, Dept. of Standards Administration, 211 E. Chicago Ave., Chicago, IL 60611).

IEEE/ASTM SI 10-2002 for Use of the International System of Units (SI): The Modern Metric System.

(IEEE Standards are available from IEEE, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855).

ASTM B16/B16M-05 Standard Specification for Free-Cutting Brass Rod, Bar and Shapes for Use in Screw Machines.

(ASTM Standards are available from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428).

ISO 3630-1:1992, Dental root canal instruments-Part 1: Files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches.

(ISO dentistry standards may be purchased from the American Dental Association, Dept. of Standards Administration, 211 E. Chicago Ave., Chicago, IL 60611).

2.2 Regulations

Quality Systems requirements (QSR) issued by the Food and Drug Administration.

(Available from <http://www.fda.gov/cdrh/qsr/contnt.html>).

3 REQUIREMENTS

3.1 Dimensions

3.1.1 Length

The length of the instrument, as measured from the tip to the junction with the handle, shall be nominal length with a

tolerance of ± 0.5 mm when tested as specified in 5.2.2.1.

3.1.2 Core Diameter

The diameters and tolerances for the tapered core section of the instrument designated as C₃ and C_{10.5} for all sizes and types shall be as shown in Table 1, Table 2 and Figure 1, when tested as specified in 5.2.2.2.

3.1.3 Barbed Dimensions

3.1.3.1 Barb location

The barb locations are such that the first barb shall be no greater than 1.0 mm from the tip and the last barb shall be no less than 9.0 mm from the tip when tested as specified in 5.2.2.3.

3.1.3.2 Barb height

The barb height is referenced for information and is tested as specified in 5.2.2.4.

3.1.3.3 Number of Barbs

The minimum number of barbs in the working length shall be 36 for Type I and 50 for Type II when tested as specified in 5.2.2.5.

3.1.4 Tip

The tip length of the instrument shall be no greater than the distance to the first barb when tested as specified in 5.2.2.6. Shape of the tip is optional.

3.2 Handles

Handle, when affixed to the shaft, shall be fabricated of material of a quality suitable to withstand normal operative procedures. Operative end shall be securely and permanently affixed in the handle when tested as specified in 5.3.2.2 and 5.3.2.3. Handles shall be able to be autoclaved and dry heat sterilized without losing the shape of the handle or without bleaching out the color when tested 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 size Type I shall not be less than that given in Table 3 and of each size Type II shall not be less than that given in Table 4 when tested as specified in 5.4.

3.4 Stiffness

The stiffness of all instruments shall not be greater than that given in Table 5 for each size of Type I and in Table 6 for each size of rasp when tested as specified in 5.5.

3.5 Resistance to Corrosion

The stainless steel instruments shall not show evidence of corrosion of their surface when subjected to the corrosion test as described in 5.6.

3.6 Color Coding

When individual instruments or instrument packages are color-coded, the color coding for the respective nominal sizes shall be as shown in Table 7.