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

ANSI/ADA Specification No. 63 Approval date: March 3,1999



American National Standard/ American Dental Association Specification No. 63

Root Canal Barbed Broaches and Rasps



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. 63 FOR ROOT CANAL BARBED BROACHES AND RASPS

American Dental Association Specification No. 63 for Root Canal Barbed Broaches and Rasps has been approved by the Council on Scientific of the American Dental Association. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment. The Council acts as administrative sponsor of that committee, which 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. Approval of ADA specification No. 63 as an American National Standard was granted by the American National Standards Institute on March 3, 1999. This standard becomes effective March 3, 2000.

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 Blann, Defense Personnel Support Center, Philadelphia, PA; Richard Geary, American Dental Association, Chicago, IL; Lonnie Graybell, Union Broach/Moyco, York, PA; Michael Heuer, Northwestern University, Chicago, IL; John Ingle, San Diego, CA; Neill Luebke, Brookfield, WI; Trenholm Meyer, T.N. Meyer & Associates, Stow, OH; Leo Miserendino, Waukegan, IL; Paul Murphy, Syntex Dental Products, Inc., Valley Forge, PA; Herbert Schilder, Boston University, Boston, MA and Timothy Svec, University of Texas, Houston, TX.

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

FOREWORD

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

Combined efforts with the International Organization for Standardization (ISO) working group on root canal instruments, TC 106/SC4/WG9, resulted in development of a size designation system that can be universally applied. The older systems relied on words that provided little disclosure of size (4 Extra-Fine, Extra-Fine, Medium, etc.) or sequential numbers 1-6 which only provided some help in determination of increase or decrease of size.

The size designation system for barbed broaches and rasps was first published in ISO 3630 in February 1984. However, there was lack of agreement of the designations based on the charted dimensions provided. These issues were resolved for the 1992 publication of ISO 3630, Part 1. The new designation utilizes a combination of the diameter of the core tip and twice the nominal height of the barb. This represents the major change found in the revision to the Specification No. 63.

During work on this revision, the subcommittee identified a number of editorial changes that clarify requirements and procedures without affecting the technical results. One noticeable change was revision of the title of 3.7 (and 5.3.3.1) from *Sterilization to Heat Effects of Sterilization*.

The provisions of this new document are in 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 that informs. For instance, the location of the core diameter beyond the barbs is specified at 10.5 mm. We designate this as $C_{10.5}$ whereas ISO 3630 uses d_2 .

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

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 stainless type steel.

1.2.1 Type. I. Barbed Broach II. Rasp

2 APPLICABLE SPECIFICATIONS AND REGULATIONS

2.1 Specifications:

ANSI/ADA Specification No. 28 Endodontic Files and Reamers

ANSI/ADA Specification No. 29 for Hand Instruments

ANSI Metric Practice, Z210.1-1976

ISO 3630, Dental Root Canal Instruments

(Copies of ANSI and ISO specifications may be obtained from the American National Standards Institute, 11 West 42nd St., New York, N.Y. 10036).

2.2 Regulations

Good Manufacturing Practice Regulations (GMP) issued by the U.S. Food and Drug Administration.

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 C_3 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.