



American National Standard/
American Dental Association
Specification No. 95

Root Canal Enlargers

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. 95 FOR ROOT CANAL ENLARGERS

American National Standard/American Dental Association Specification No. 95 for Root Canal Enlargers has been approved by the Council on Scientific Affairs of the American Dental Association. 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. Approval of ADA Specification No. 95 as an American National Standard was granted by the American National Standards Institute on February 5, 2003. This standard becomes effective February 5, 2004. It was reaffirmed by ANSI on January 13, 2009.

The Council acknowledges, with thanks, the working group members who formulated the revision: Frank Lentine (chairman), Lentine Enterprises Ltd., Taylor, MI; Richard Geary, American Dental Association, Chicago, IL; Gerald Glickman, University of Texas - Houston Dental Branch, Houston, TX; John Ingle, American Association of Endodontists, San Diego, CA; Siegfried Kiesewetter, Miltex Instrument Co., Bethpage, NY; Neill Luebke, Brookfield, WI; Michael Sobotka, Charles B. Schwed Co., Key Gardens, NY; Lars Spangberg, University of Connecticut, Farmington, CT; Timothy Svec, University of Texas - Houston Dental Branch, Houston, TX.

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 95 FOR
ROOT CANAL ENLARGERS**

FOREWORD

(This foreword does not form a part of ANSI/ADA Specification No. 95 for Root Canal Enlargers.)

Combined efforts with the International Organization for Standardization (ISO) working group on Root Canal Instruments: Enlargers, TC 106/SC4/WG9, and research published in the Journal of Endodontics by Drs. Neill H. Luebke, DDS, MS and William A. Brantley, PhD, resulted in development of physical property requirements and criteria which influenced the working group to prepare this document. The first ISO publication, ISO 3630 - Part 2 provided only dimension and sizing requirements.

This new specification builds on the 1986 issue of ISO 3630 Part 2 by including the previously omitted Enlarger, Type M which has also been added in the pending version of the ISO document. A major addition is the requirement, testing procedure, and test device for Resistance to Fatigue. The provisions of this new document are harmony with ISO 3630, Part 2, pending publication at this writing.

Reference to the FDA's Good Manufacturing Practice Regulations is omitted from this specificiton since the GMP must be considered as a standard requirement for all product manufactures.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 95 FOR ROOT CANAL ENLARGERS

1 SCOPE AND CLASSIFICATION

1.1 Scope

This specification is for root canal instruments used mechanically to access and enlarge canals.

1.2 Type

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

- A Enlarger, Type B1;
- B Enlarger, Type B2;
- C Enlarger, Type G;
- D Enlarger, Type M;
- E Enlarger, Type P .

2 APPLICABLE SPECIFICATIONS

The following documents form a part of this specification.

2.1 SPECIFICATIONS

ANSI/ADA Specification No. 28 for Root Canal Files and Reamers, Type K. ANSI Metric Practice, Z210.1-1976.

ISO 1797, Dental Rotary Instruments, Shanks.

ISO 3630, Parts 1 and 2, Dental Root Canal Instruments.

ISO 8601, Data elements and interchange formats-Information interchange Representation of dates and times.

(Copies of ADA and ISO specifications may be obtained from the American Dental Association, Department of Standards Administration, 211 E. Chicago Ave., Chicago, IL).

3 SYMBOLS

For the purposes of this specification, the following symbols apply:

D₁ diameter of working part; head diameter;

D₂ neck diameter, measured at the end of the working part;

D₃ neck diameter, measured at the end of the operative end;

D₄ tip diameter;