



Revised American National Standard/
American Dental Association
Standard No. 63

Barbed Broaches and Rasps

ADA American
Dental
Association®
Council on
Scientific Affairs

**REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD
NO. 63 FOR BARBED BROACHES AND RASPS**

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Standard No. 63 for Barbed Broaches and Rasps. This and other standards 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 standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of revised ADA Standard No. 63 as an American National Standard on August 12, 2013.

The ADA Standards Committee on Dental Products thanks the members of Working Group 4.27 on Endodontic Instruments and the organizations with which they were affiliated at the time the standard was developed:

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REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 63 FOR BARBED BROACHES AND RASPS

FOREWORD

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

This revision of ANSI/ADA Standard No. 63 cancels and replaces ANSI/ADA Standard No. 63-2006.

For this edition of ANSI/ADA Standard No. 63, Working Group 4.27 agreed to excerpt portions of ISO 3630-4:2009, Dental root canal instruments, Part 4: Auxiliary Instruments, to provide for clarification and to be more closely aligned with the relevant portions of the ISO standard. The working group will address formal adoption of the ISO document upon publication of the full set of ISO 3630 -1 to 5 documents.

Changes made for this edition of ANSI/ADA Standard No. 63 consist of the following:

2 - Applicable standards and regulations: added relevant ISO Standards and replaced ISO 3630;

3 – Definitions: added from ISO 3630-4 to provide definitions not otherwise available;

4.1.1 – Length: provided proper nomenclature for the part and clarified the manufacturer's role;

5.1 – Sampling: provided greater detail and eliminated Table 8.

The ADA SCDP agreed that the term Standard should replace the term Specification as the designation of ADA standards, thus, the term specification has been replaced by the term standard throughout this document.

REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 63 FOR BARBED BROACHES AND RASPS

1.1 SCOPE AND CLASSIFICATION

1.1 Scope

This standard specifies requirements and test methods for root canal instruments for hand use utilized in endodontic preparation.

1.2 Type

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

- I. Barbed Broach;
- II. Rasp.

2 APPLICABLE STANDARDS AND REGULATIONS

2.1 Standards

ANSI/ADA Standard No. 28 for Endodontic Files and Reamers.

(ANSI/ADA standards may be purchased from the American Dental Association, Dept. of Standards Administration, 211 E. Chicago Ave., Chicago, IL 60611 or <http://catalog.ada.org>).

ANSI Metric Practice, Z210.1-1976.

(ANSI 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, P.O. Box C700, West Conshohocken, PA 19428 or www.astm.org).

ISO 1797-1, *Dental rotary instruments — Shanks — Part 1: Shanks made of metals*

ISO 1797-2 *Dental rotary instruments — Shanks — Part 2: Shanks made of plastics*

ISO 1942, *Dentistry — Vocabulary*

ISO 3630-1:2008, *Dentistry — Root-canal instruments — Part 1: General requirements and test methods*

ISO 3630-2:2000, *Dental root-canal instruments — Part 2: Enlargers*

(ISO dentistry standards may be purchased from the American Dental Association, Dept. of Standards Administration, 211 E. Chicago Ave., Chicago, IL 60611, or <http://catalog.ada.org>).

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 DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 3630-1 and the following apply.